Emergency Medical Services/Trauma Committee Meeting

Wednesday, August 30, 2017

California Hospital Association - Boardroom

1215 K Street, Suite 800

Sacramento, CA, 95814

Conference Call Option:

(800) 882-3610 Access Code: 1953936#

Meeting Book - Emergency Medical Services/Trauma Committee Meeting

AGENDA

IV. NEW BUSINESS

12:00 - 12:30	A. Whole Person Care Pilot Program Guest Speaker: Susan Bower	Page 471
	B. Cardiac Arrest Study Guest Speaker: Bryn E. Mumma, MD, MAS	Page 485
	C. Inpatient Discharge Delay Blaisdell	Page 486
	D. NQF Draft and Other ED Outcome Measures Bartleson	Page 489
	E. Unintentional Injury Prevention Strategic Plan Project Guest Speaker: Steve Barrow	Page 566

1:45 V. INFORMATION ONLY
Schneider

	A. Recommendations for First Responders Against Exposure	Page 575
	B. California ER Use Jumps Despite Medicaid Expansion	Page 589
	C. Homeless People Overuse ERs	Page 591
	D. Pain Management and the Opioid Epidemic	Page 593
	E. Meeting Our Patients Where They Are	Page 986
	F. Academic Emergency Medicine and the "Tragedy of the Commons"	Page 988

2:00 VI. ADJOURNMENT
Schneider

A. Next Meeting - Wednesday December 13, 2017 - 10 AM - 2 PM

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

August 30, 2017

TO: EMS/T Committee

FROM: BJ Bartleson, VP Nursing and Clinical Services

SUBJECT: Guests

Dr. Karl Sporer
Physician Director
Alameda LEMSA

Marguerite Paradis, RN, BSN, MHA
Director Emergency Services and Critical Care
Sharp Grossmont Hospital

CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

EMS/TRAUMA COMMITTEE
2017 MEMBER ROSTER

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Last revised: 8/23/2017

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EMS/T Committee Hospital Representation

BY COUNTY and HOSPITAL TYPE

As of February 10, 2017

HOSPITAL/HEALTH SYSTEM TYPES	
Free-Standing Facility	3
Hospital System	7
Small/Rural Facility	1
University/Teaching Facility	3
TOTAL COMMITTEE REPRESENTATION	14

Denotes number of hospitals/health systems represented within that county.

CHA Member/ED Breakdown

July, 2017

HOSPITAL COMMITTEE

MEMBER:

Carla Schneider		Hoag Memorial Presbyterian Hospital
Pam Allen		Redlands Community Hospital
Neal Cline		Enloe Medical Center
Rose Colangelo		Scripps Memorial Hospital La Jolla
Connie Cunningham		Loma Linda University Med Center
Karla Earnest		Lucile Packard Children's Hospital
Fred Hawkins		Ridgecrest Regional Hospital
Cheryl Heaney-Ordez		St. Joseph's Medical Center
Laurie McCully		Cedars-Sinai Medical Center
Marlena Montgomery		Sharp Memorial Hospital
Karen Murrell		Kaiser Permanente South Sacramento
Rupy Sandhu		UC Davis Medical Center
Jason Zepeda		Hoag Memorial Presbyterian Hospital

ED TYPE BY MEMBER:

Carla Schneider	Hoag Memorial Presbyterian Hospital	Emergency Services
Pam Allen	Redlands Community Hospital	Emergency Services
Neal Cline	Enloe Medical Center	Flight Nurse/Pre-Hospital/STEMI
Rose Colangelo	Scripps Memorial Hospital La Jolla	Emergency Services
Connie Cunningham	Loma Linda University Med Center	Emergency/Trauma
Karla Earnest	Lucile Packard Children's Hospital	Pediatric/Trauma
Fred Hawkins	Ridgecrest Regional Hospital	Emergency Services
Cheryl Heaney-Ordez	St. Joseph's Medical Center	Emergency Services
Laurie McCully	Cedars-Sinai Medical Center	General
Marlena Montgomery	Sharp Memorial Hospital	Emergency Services
Karen Murrell	Kaiser Permanente South Sacramento	Emergency Services
Rupy Sandhu	UC Davis Medical Center	Emergency Services
Jason Zepeda	Hoag Memorial Presbyterian Hospital	Trauma/General

EX-OFFICIO COMMITTEE MEMBER:

Heather Venezio		TMAC
Eric Morikawa		California Department of Public Health
Farid Nasr		California EMS Authority
Ross Fay		CALSTAR
Jim Pierson		Medic Ambulance
Ron Smith		California Department of Public Health
Lawrence Stock		Antelope Valley Hospital
Chi Perlroth		CAL ACEP
Bruce Barton		Riverside County EMS Agency

CHA/REGIONAL STAFF

BJ Bartleson	California Hospital Association
Judith Yates	HASD&IC
David Serrano Sewell	Hospital Council
Keven Porter	HASC

STATE REPRESENTATION

Northern California	**5**
Southern California	**9**

GUIDELINES FOR THE CALIFORNIA HOSPITAL ASSOCIATION'S EMS/TRAUMA COMMITTEE

Updated 09/23/15

I. NAME

The name of this committee shall be the CHA EMS/Trauma Committee.

II. MISSION

The EMS/Trauma Committee represents CHA members that provide emergency medical and/or trauma services in the State of California, and serves in an advisory capacity to the CHA Board of Trustees regarding EMS/Trauma member needs, policies and legislation.

Recognizing the diverse organizations and providers that work in emergency systems across the state, the mission of the committee also includes representation from diverse multidisciplinary health care organizations and associations that include professional associations, regulatory agencies, emergency services organizations, prehospital providers and others, that promote quality emergency services in the state of California. This multidisciplinary group will act as a collaborative source of emergency services expertise, providing a venue for the coordination of emergency and trauma services to advocate for the highest standards of emergency trauma care services across the state.

The purposes of the Committee shall be:

- to serve as a forum for all CHA members and associated groups interested in EMS/Trauma to receive and exchange information, adopt policies and positions, guide management, adopt strategies and serve as the primary public policy arm of CHA for emergency medical services and trauma issues;

- to provide CHA member EMS/Trauma providers with a statewide structure dealing with the issues important to their interests;

- to create a representative form of leadership which is based on participation of all its members;

- to provide direct input to the CHA Board of Trustees; and

- to provide a unified voice on behalf of CHA members, taking into account the multiple diverse organizations that interact with hospital emergency/trauma services

III. COMMITTEE

The committee shall consist of a maximum of 22 representatives from California hospital /health system organizations, and organizations with related interests.

A. MEMBERSHIP

1. Membership on the CHA EMS/Trauma Committee shall be based upon membership in CHA, and reserved for those members.

2. The Committee shall consist of various representatives from large hospital systems, public institutions, private facilities, free-standing facilities, small and rural facilities, university/teaching facilities, specialty facilities and a representative from a professional group specializing in EMS/Trauma issues.

3. Membership by EMS related organizations will be considered Ex-officio members. Ex-officio members will be determined by committee input and CHA determination.

4. Appointment of members to the Committee will follow the CHA Guidelines for Committee Membership.

B. TERMS OF THE COMMITTEE MEMBERS

1. As members leave the Committee, vacancies shall be filled. It is understood that a member forfeits his/her seat if they no longer serve in the capacity, or represent a facility that is not a CHA member.

2. Committee members with specialized skills, knowledge, or professional associations may serve on the committee as ex-officio members. Ex-officio members are not subject to the above terms. These determinations shall be made by CHA.

3. Provider representatives who transition from one position to another are welcome to attend committee meetings during their transition; however, this should not exceed two consecutive meetings.

4. Provider representatives who misrepresent their organization's position are subject to review and dismissal from the committee.

C. COMMITTEE MEETINGS

1. Meetings of the Committee shall be held quarterly.

2. Provider representatives may send an appropriate substitute to the meetings when they are unable to attend. To maintain continuity for Committee meetings, this should be used sparingly, not to exceed two consecutive meetings.

3. Three consecutive unexcused absences by a Committee member may initiate a review by the Chair and CHA staff for determination of the Committee member's continued service on the Committee.

4. Special meetings may be scheduled by the Chair, majority vote or CHA staff.

5. Membership is based on one's ability to be physically present at quarterly meetings and conference call only as needed for emergency situations.

D. VOTING

1. Voting rights shall be limited to members of the Committee, and each member present shall have one vote. Voting by proxy is not acceptable.

2. All matters requiring a vote of the Committee must be passed by a majority of a quorum of the Committee members only at a duly called meeting or telephone conference call.

E. QUORUM

Except as set forth herein, a quorum shall consist of the majority of the Committee membership in attendance.

F. MINUTES

Minutes of the Committee shall be recorded at each meeting, disseminated to the membership, and approved as disseminated or as corrected at the next meeting of the Committee.

IV. OFFICERS

The officers of the Committee shall be the committee chair, co-chair, and CHA staff.

Except as provided herein, the chair and co-chair shall be elected by the Committee for a two-year term.

The chair officers vacate their Committee positions upon election, and their seats shall be filled through the nominating and election process. The past-chairs will be invited by the Committee to serve as ex-officio members.

Should a chair or co-chair vacate his/her position prior to the end of the term, a nominating committee will convene to select a replacement, and assume a two-year term of office.

V. COMMITTEES

For special and specific purposes, the chair or CHA staff may appoint a committee or ad hoc on task force. Membership may be expanded to non-members of the Committee.

VI. GENERAL PROVISIONS

The strategic plan defining the goals, objectives, and work plans shall be developed annually by the CHA staff and approved by the Committee. Quarterly updates and progress reports shall be completed by the Committee and CHA staff.

Staff leadership at the state level shall be provided by CHA with local staff leadership provided by HCNCC, HASD&IC, and HASC. The primary office and public policy development and advocacy staff of the Committee shall be located within the CHA office.

The Committee staff shall be an employee of CHA.

VII. AMENDMENTS

These Guidelines may be amended by a majority vote of the members of the Committee at any regular meeting of the Committee.

VIII. LEGAL LIMITATIONS

Any portion of these Guidelines which may be in conflict with any state or federal statutes or regulations shall be declared null and void as of the date of such determination.

Any portion of these Guidelines which are in conflict with the Bylaws and policies of CHA shall be considered null and void as of the date of the determination.

Information provided in meetings is not to be sold or misused.

IX. CONFIDENTIALITY FOR MEMBERS

Many items discussed are confidential in nature, and confidentiality must be maintained. All Committee communications are considered privileged and confidential, except as noted.

X. CONFLICT OF INTEREST

Any member of the Committee who shall address the Committee in other than a volunteer relationship excluding CHA staff and who shall engage with the Committee in a business activity of any nature, as a result of which such party shall profit pecuniarily either directly or indirectly, shall fully disclose any such financial benefit expected to CHA staff for approval prior to contracting with the Committee and shall further refrain, if a member of the Committee, from any vote in which such issue is involved.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

CHA Emergency Services/Trauma Committee Goals and Objectives, 2017-2019

CHA EMS/T Committee Mission

The mission of the CHA EMS/Trauma Committee is to represent CHA members that provide emergency medical and or trauma services in the state of California, and serve in an advisory capacity to CHA Board of Trustees regarding EMS/Trauma member needs, policy and advocacy to promote an optimally health society.

Goals and Objectives 2017- 2019

1. Develop guidance, tools, information and strategies to support emergency department and trauma services of the future that enhance quality patient care.
   a. Connect local and regional best practices with toolkits or web connections.
   b. Explore new technologies and applications to streamline and improve emergency and trauma care practices.
   c. Continue to monitor APOT and work collaboratively with prehospital providers on performance improvement and reengineering efforts.

2. Successfully launch the Emergency Care Systems Initiative to resolve California's overburdened emergency care system with a roadmap for change.
   a. Use performance measures, technology and new modalities to assess ED crowding and strategize solutions across systems of care.
   b. Develop both provider and consumer education vehicles to improve ED crowding.
   c. Develop public policy and advocacy strategies to address ED crowding, particularly alternate destination policies for behavioral health patients.

3. Implement a successful annual ED Forum that assists members to become agents of change during health care reform.
   a. Use state and national experts that emphasize a collaborative, multi-stakeholder level of involvement.
   b. Focus on member evidence based practices that are affecting change.

4. Represent Trauma issues on the EMSA trauma regulatory review task force.
   a. Appoint CHA EMS/T member to head the trauma subcommittee workgroup and present issues at the EMSA trauma task force.
   b. Assist with funding and solutions to maximize trauma care and provisions across the state.
   c. Select CHA EMS/T member to represent EMSC issues and report to the committee

5. Understand HIE systems and how they will benefit transitions of care for patients between systems of care.
   a. Work closely with HIE networks to understand connections and linkages to improved care transitions.
   b. Work with EMSA on HIE prehospital pilot work.

6. Closely monitor federal and state health care reform changes and their effect on emergency services and systems of care.

a. Continue to monitor changes in the financial landscape that have a direct effect on emergency department visits.
b. Monitor statutory and regulatory changes affecting hospital emergency /trauma services.

CHA EMS/TRAUMA COMMITTEE
MEETING MINUTES
June 7, 2017 / 10:00 a.m. – 2:00 p.m.

1215 K Street, Suite 800
Sacramento, CA

Members Present: Pamela Allen, Fred Hawkins, Rose Colangelo, Laurie McCully, Cheryl Heaney-Ordez, Neal Cline, Carla Schneider, Jason Zepeda, Bruce Barton, Ron Smith, Chi Perlroth

Members Attending by Call: Karla Earnest, Ross Fay, Connie Cunningham, Nancy Blake

Guests: Bonnie Sinz (for Farid Nasr)**,** Judy Cline, Dan Smiley, Ken Meehan

CHA Staff: BJ Bartleson, Barb Roth

RVP Staff: Judith Yates

I. CALL TO ORDER/INTRODUCTIONS

Ms. Schneider called the meeting to order at 9:57 a.m. Introductions and member updates were made. No roster updates were requested.

Ex Officio member update:

- *ACTION: Heather Venezio – TMAC*
- *ACTION: Need a CALENA member*

Goals and Objectives:

- *ACTION: Suggested additions:*
  - *ECSI*
  - *HIE – EDIE*
  - *Healthcare Reform*
  - *Implementation of statewide recommendations regarding Trauma*

II. REVIEW OF PREVIOUS MEETING MINUTES

The minutes of the March 1, 2017, EMS/Trauma Committee meeting were reviewed.

IT WAS MOVED, SECONDED AND CARRIED:

- *Approved as submitted with no corrections.*

III. OLD BUSINESS

A. Trauma

1. Trauma Plan and ACS Consultation – Smiley
There were gaps in service with the current trauma plan along with fiscal implications for the implementation of the plan. Concern that the financial responsibility could filter down to Medi-Cal, which is a problem for the state when balancing the budget. Therefore, the plan was released as a state advisory committee document so it could be commented on and financial issues could be addressed on an individual basis.

No fiscal funding exists for the plan. Perhaps with a new administration in the future funding can be requested. Source funding is an issue, it puts pressures on the state general fund. If there were an alternate funding source, it would be looked at differently. Funding cannot be done in totality, but case-by-case individual items can possibly be funded.

LEMSAs and stakeholders can start implementing some of the easier objectives. Many people spent a lot of time and effort working on this document. EMSA, LEMSAs and stakeholders need to work together to achieve state, local and regional objectives. They need to be looking at this plan to identify deliverables that can be started now.

The TQUIP data system is flourishing. All but two hospitals are participating in the data system and the two are interested but meeting some barriers.

There are two new trauma centers for a total of 82 trauma centers across the state.

EMSA has a small workgroup (Dr. Mackersie, Dr. Gil Crier, Cathy Chidester, Linda Diaz, Tom McGinniss and Bonnie Sinz) working on trauma regulations – Title 22. The present regulations are applicable to present practice. Heather Venezio is our committee representative to be added to the EMSA task force once it opens up for broader representation and input.

Funding has been available but has been pulled. We need to craft whatever we decide to do carefully so that it does not allow for approved funding to be pulled. EMSA has provided a Maddy report of Maddy funding allocations broken down by county. Trauma funding needs to be prioritized and reviewed based on outcomes, deliverables and impact.
The California Office of Traffic Safety (OTS) may fund some of the TQIP needs. Stakeholders need to follow it up with outcomes and measurable analytics to recognize the return on investment from funding opportunities.

The coordination between EMSA, LEMSA and STAC is critical for future success.

- *Address trauma funding issues in future meetings to influence trauma plan execution that prioritize objectives in incremental steps.*

2. Annual Trauma Conference Meeting
Meeting is scheduled for June 29, 2017. The agenda and announcement are included in the committee meeting book. EMSA reported that the next trauma summit will be in San Diego in May, 2018.

3. TQIP Update – non at this time

4. TMAC Update – non at this time

➢ *ACTION: information only*

B. Stroke/STEMI
Stroke and STEMI regulations are almost finalized.

1. JC Thrombectomy Ready Hospital – Mr. Smiley
The JC comment period is closed, however hospitals need to be aware of the standards. EMSA put in a phrase under the primary stroke center classification regarding hospitals that are Thrombectomy capable.

The latest draft version of the Stroke and STEMI regulations will be taken to the EMS commission for approval on June 2, 2017.

LEMSAs are not sure what to do with the Thrombectomy Ready Hospital status yet, advising that it will be handled on a case-by-case basis.

A question was posed about when new paramedic education regulations would be released. Mr. Barton advised that the LEMSAs will look through the new regulations and create/vet/finalize policies to update. Then they will budget for education.

➢ *ACTION: information only*

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C. ECSI
1. Status Update – Ms. Bartleson
CHA is currently in a call to action mode; speaking to external stakeholders and going to meetings. CHA is approaching stakeholders for letters of support. The hospitals are already supporting this effort, so at this time CHA is requesting support from all ex officio members and their organizations. The stakeholder list is available in the meeting packet.

ECSI deliverables necessitating funding:
- White paper to define emergency services for the future
- Data analytics
- Consensus document
- Statewide report card

2. Currently learning more about community services such as Whole Person Care and No Place Like Home initiatives. The two ECSI like pilots in San Francisco and San Diego are providing excellent examples of care transitions between ED and the community public and private care resources.

3. Updates from San Francisco
   David Serrano Sewell provided information on the pilot project in San Francisco. Data from this project is currently showing what is known anecdotally.

4. Update from San Diego
   Update from Judith Yates on the project(s) in San Diego

   The HIE landscape is complex as there are many and they are decentralized. There is competition; EDIE is competing with HIE networks and much is still being learned about interoperability, etc. This presents a challenge for EMSA – how to bridge the competition and provide information/data when delivering care is critical. Hospitals *could* share, but *will* they share. How do we lead conversations to lead to a trusting relationship?

➢ *ACTION: Send ECSI Mission information to the committee (DONE - ECSI New Brochure sent to committee immediately following the meeting.)*

D. EMS/C Update
   ➢ *ACTION: No - information*

E. Community Paramedicine Update - Cline
   The project is extended until November 2017. We are using this time to retool and make their program more effective and negotiating for performance improvements. Most other programs will probably extend for a year.

   The Anaheim project is using family nurse practitioners to triage calls and, if they can, will send a nurse to provide care. This is a model outside of the community paramedicine model.

   Mr. Smiley reported that one program in LA area (Santa Monica) will drop out of the project. If additional programs wish to enter the pilot project, information is available indicating that OSHPD might be amenable.

   ➢ *ACTION: Information only*

F. APOT – Barton
   The commission approved the methodology. Statewide methodology has changed. They came up with a spreadsheet for APOT1 (90th percentile by hospital) and APOT2. EMSA is getting information out to all LEMSAs. This will probably be a short-term solution and more sophisticated systems will develop over time. We are waiting for input and approval from EMSA. The final information and direction will come from EMSA.

Judith emphasized the need for accurate data with everyone (field and hospital) for improved outcomes and accuracy of information.

- *ACTION: Information only*

G. Clostridium Difficele (C. diff)- Schneider
C. diff is a significant issue as many patients who have C. diff can spread the illness even when not symptomatic. No EMS statewide policy or oversight currently exists regarding the cleaning methods to use with patients who have diarrhea, particularly regarding EMS transport. If a model infection control policy were to be developed, Mr. Smiley indicated that EMSA may distribute it. Mr. Barton agreed that it can also be taken to the LEMSAs. The model must have a procedure that is quick and easy. Also, need to find an appropriate solution for the ambulance and other first responders to use.

- *ACTION: Locate a model policy – Ms. Bartleson will check with Jim. Mr. Barton will also check into this.*

H. Reducing Readmissions and ED Overcrowding - Zepeda
Review of Hoag's research and data in efforts to reduce readmissions and ED overcrowding.

- *ACTION: information only*

IV. NEW BUSINESS

A. Legislation
List of high priority bills are in the meeting book. Please contact Ms. Bartleson if anyone has questions or concerns.

Medi-Cal proposition passed in November, which addressed physician's compensation for Medi-Cal. Dr. Perlroth advised that legislators understand the issue however it's complex and they want to bargain. CMA is pursuing. CALACEP has discussed this issue and proposed some ideas to use funds that they have.
Ms. Yates advised that CHA is in support of money going where it's supposed to per the proposition and that CHA has partnered with CMA on this issue.

- *ACTION: information only*

B. Enloe Post Debrief on Spillway Evacuation – Judy Cline
A summary of the Oroville evacuation was provided. There were two hospitals affected by the evacuation and many ancillary health facilities.
All evacuees were directed to go to Chico – an influx of 180,000 people. Many people left their medications at home, which caused some problems.

A command center at the hospital in Chico was set up.
- Sent a hospitalist and ER nurse to the fairgrounds to create a clinic type setting.
- Many pharmacies would not renew prescriptions, even though they could have. Need to work on this for future disaster preparedness.

- Oroville hospital had census of 150 patients and they decided to stay in place – they were on higher ground and thought they would be safe.
- Gridley hospital had to evacuate – 29 patients in all: 9 were acute care, 20 SNF patients went to a rehab hospital. The hospital brought their staff. As the HR department was researching to ensure proper licensing requirements were met, it was found that some of the Gridley hospital staff had lapsed licenses.
- Several families came to the ER who needed dependents that needed equipment, ventilators, feeding tubes, etc.
- Lots of special needs and equipment had not been tested before.
- They have drawn up the plans for the clinic they set up at the fairground and have submitted it to the state agency for public/future use.

➢ *ACTION: Information only.*

C. CARESTAR – Ken Meehan

Mr. Meehan and 4 previous colleagues are working to create CARESTAR Foundation to invest in improving emergency and trauma care, injury, disability and death. They are using the proceeds from the sale of CALSTAR to create the foundation. They have submitted documents to get the foundation started - 501C3 documents were submitted yesterday. They still need approval from state attorney general to transfer the funds from one entity to the other - anticipate that happening by the end of January 2018. CARESTAR wants to make a difference and they are talking to various organizations to see what their grant needs might be. Mr. Smiley called him to talk about the HIE initiative. Mr. Meehan expressed interest in our innovative ideas. Their goal is to give away 2-2.5 million per year in grants.

➢ *ACTION: information (provide his contact information to the committee)*

D. ED Forum

Suggestion made to have Judy Cline share the information regarding the emergency plans that took place during the Oroville evacuation at the ED Forum.

➢ *ACTION: Informational, BJ will work with education on potential planning*

E. HIE – Dan Smiley

The SAFER (Search, Alert, File and Reconcile) model allows paramedics to search, file and reconcile health information and transfer information electronically to hospitals. The information is filed in the patient record, which allows for easier retrieval of information

There are opportunities to leverage Medi-Cal dollars for this program. A couple of pilot programs have already been created. Agencies (CMS) are allowing for a Medicaid match of 9:1 . This gives them an opportunity to leverage Medicaid dollars until august 2021. They are revising the state plan this summer to allow them to pull in funds to get the 9:1 match.

This will allow for electronic communication hospital/field. EMSA is seeking non-federal contributions and donations. This perhaps could be an opportunity of Maddy funds or foundation funds. It must be local/county money, not federal in nature.

Ms. Schneider confirmed that the physicians in her hospital are happy to be a part of this pilot.

- *ACTION: Information only.*

V. NEXT MEETING

August 30, 2017

- *ACTION: Informational Only.*

VI. ADJOURNMENT

Having no further business, the meeting adjourned at 2:11 p.m.

Emergency Care Systems Initiative

A partnership to shape the future of emergency care services

CALIFORNIA HOSPITAL ASSOCIATION

Hospital Council of Northern & Central California

HOSPITAL ASSOCIATION OF SOUTHERN CALIFORNIA

HOSPITAL ASSOCIATION of San Diego & Imperial Counties

Emergency Care Systems Initiative

Californians are turning to hospital emergency departments in record numbers, often because they cannot get the care or assistance they need elsewhere. How do we get people to appropriate care in the right place and at the right time?

The Emergency Care Services Initiative was formed to address this question head-on. ECSI stakeholders — leadership from California's hospitals, government agencies, local and state emergency medical services, first responders and trade associations — are committed to creating a roadmap for change that will transform delivery of emergency care services.

The time for action is now.

15 million

California ED visits were made in 2015

Source: Office of Statewide Health Planning and Development, Hospital Annual Financial Data, 2015

What will the Emergency Care Systems Initiative do?

1. **Convene a Consortium**
   All stakeholders must come together, including LEMSAs, hospitals, doctors, ambulance companies, mental health providers, police and fire services, community partners, post-acute care providers and others.

2. **Gather Data and Information**
   Who is coming to the emergency departments and why? Where are there gaps in services in our communities? By gathering objective data we can get to the root of the problem.

3. **Analyze Findings and Provide Solutions**
   Examining the findings and having input from all stakeholders will lead us to solutions. A consensus document will be prepared to explain what was learned and provide a roadmap for the future of emergency care services.

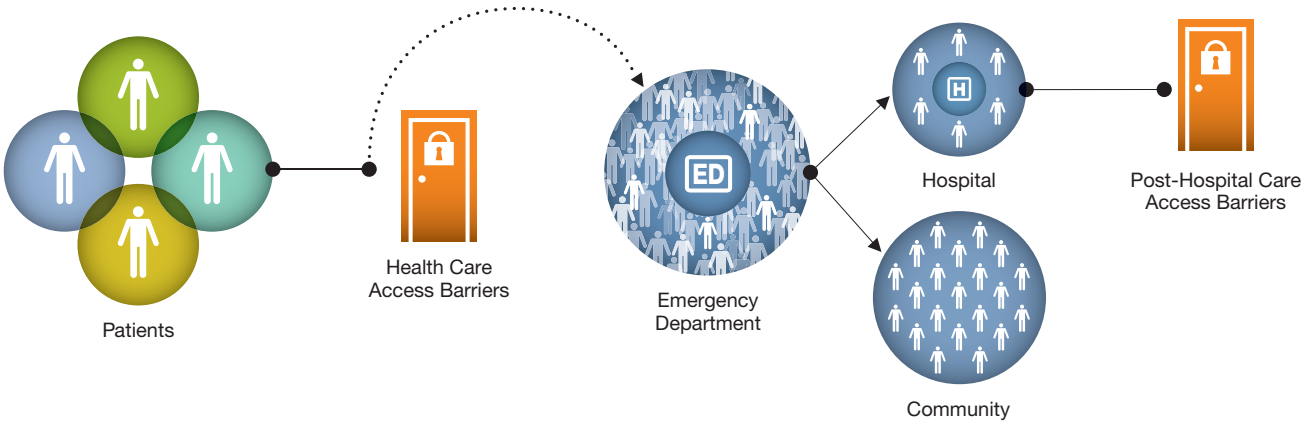
4. **Establish Emergency Services Metrics**
   The objective data gathered will inform development of clear metrics that will be used to measure progress or areas for improvement in emergency care services.

5. **Create Tools and Best Practices**
   Working with stakeholders, ECSI will develop processes and procedures to improve emergency services operations and programs.

6. **Promote Advocacy Action Plan**
   What we learn will help us drive policy. A strategic advocacy plan will be rolled out at local, regional and statewide levels to promote change and provide recommendations to policymakers.

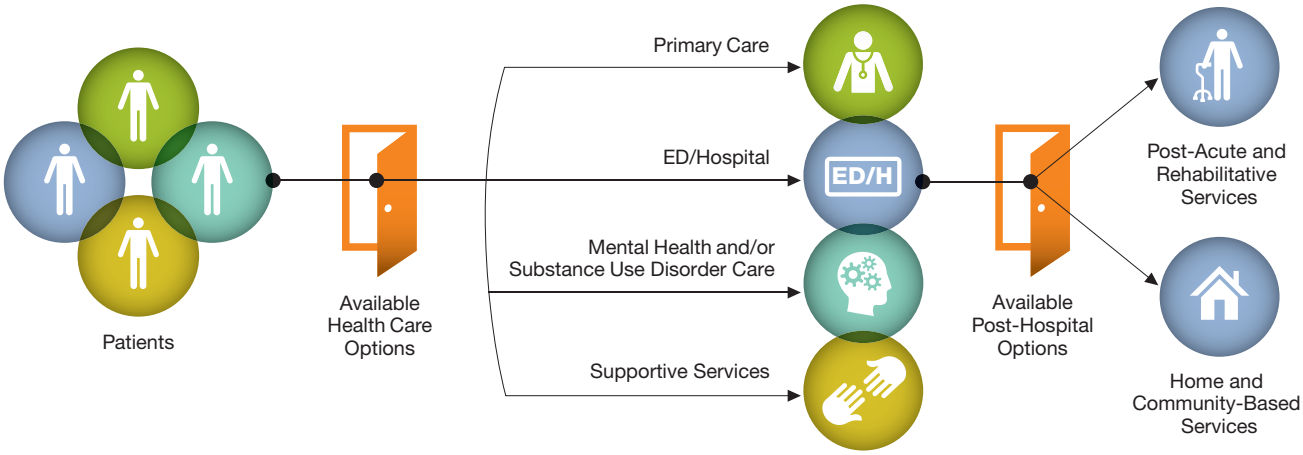
The Problem: Poor access, impacted Emergency Departments

When patients can't get the care they need, they often turn to hospital emergency departments (EDs) as a last resort. Alternative care settings should be available to patients, particularly those in need of mental health care or substance use disorder treatment. In addition, some patients stay in hospitals longer than necessary due to the lack of available post-acute care and supportive services in the community.



The Solution: Open the door to access

Caring for patients in the appropriate setting can lower costs and improve patients' well-being.



How can you support this important work?

Funders require support letters from stakeholders who will benefit from ECSI activities. Please send CHA a brief letter on your organization's letterhead to express support for ECSI's efforts and explain how ECSI could benefit your organization. We are happy to provide a letter template to help you get started. Email bjbartleson@calhospital.org for sample language. When your letter is complete, send it to:

California Hospital Association
Attn: BJ Bartleson, RN, MS, NEA-BC, 1215 K Street, Suite 800, Sacramento, CA 95814

Emergency Care Systems Initiative

What is ECSI?

The Emergency Care Systems Initiative is a bold approach to transform emergency care services by bringing stakeholders together to develop a roadmap for change through a culture of respect and professionalism.

Vision

California will lead the nation in emergency care, demonstrated by unsurpassed emergency care services, injury prevention and disaster response, to optimize the health of our communities.

Mission

To advance and accelerate California's emergency care services through a coordinated statewide approach as a roadmap for change.

CALIFORNIA HOSPITAL ASSOCIATION

Hospital Council of Northern & Central California

HOSPITAL ASSOCIATION OF SOUTHERN CALIFORNIA®

HOSPITAL ASSOCIATION of San Diego & Imperial Counties

For more information contact:

California Hospital Association
Attn: BJ Bartleson, RN, MS, NEA-BC
1215 K Street, Suite 800
Sacramento, CA 95814
bjbartleson@calhospital.org

STAKEHOLDERS

A. Healthcare
   1. Federal
      a. American Hospital Association (AHA)
      b. US Department of Health and Human Services (HHS)
      c. Centers for Medicare and Medicaid (CMS)
      d. American Medical Association (AMA)
      e. American Dental Association (ADA)
   2. State
      a. California Department of Health Care Services (DHCS)
      b. California Hospital Association (CHA)
      c. CHA Emergency Services/Trauma Committee
      d. CHA Center for Behavioral Health
      e. CHA Rural Healthcare Center
      f. CHA Center for Post-Acute Care
      g. California Association of Health Plans (CAPH)
      h. California Emergency Nurses Association (ENA)
      i. Association of California Nurse Leaders (ACNL)
      j. California American College of Emergency Physicians (California ACEP)
      k. California Trauma Managers (TMAC)
      l. California Association of Public Hospitals (CAPH)
      m. California Association of Health Facilities (CAHF)
      n. California Children's Hospital Association (CCHA)
      o. State Community Health Center Consortia
      p. California Health Clinics (CPCA)
      q. California Medical Association (CMA)
      r. Health Officers Association of California
   3. Regional/Local
      a. Hospital Council of Northern and Central California (HC)
      b. Hospital Association of Southern California (HASC)
      c. Hospital Association of San Diego and Imperial Counties (HASDIC)
      d. Trauma Hospital(s) Representation

e. Community Hospital(s) Representation
f. Rural Hospital(s) Representation
g. Critical Access Hospital(s) Representation
h. Psychiatric Hospitals
i. Local Community Health Center Consortia
j. County Clinic Consortia
k. Local EMS groups
l. Local Medical Societies

4. Local LEMSA Directors, Medical Directors

B. Public Health

1. Federal
2. State
   a. California Department of Public Health (CDPH)
   b. California Behavioral Healthcare Directors Association (CBHDA)
   c. California Public Health Association (CPHA)
   d. California State Association of Counties (CSAC)
   e. California Welfare Directors Association (CWDA)
3. Regional/Local
   a. County Director of Public Health
   b. County Director of Behavioral Health
   c. County Director of Social Services

C. Public Safety

1. Federal
2. State
   a. Emergency Services Authority (EMSA)
   b. Emergency Medical Services Administrator Association (EMSAAC)
   c. Emergency Medical Directors Association (EMDAC)
   d. State Law Enforcement, Police and Sheriff
   e. California Professional Firefighters
   f. California Association of Firefighters
   g. California Fire Chiefs
   h. California Ambulance Association

3. Regional/Local
    a. Local EMS Agency Directors
    b. City and County Fire Chiefs
    c. City and County Law Enforcement, Police and Sheriff
    d. Local Ambulance providers

D. Health Care Consumers
    1. Federal
        a. AARP
        b. NAMI
        c. Veterans Associations
    2. State
        a. NAMI State Chapters
        b. AARP – California
    3. Local
        a. County/Region based chapters of consumer advocate organizations

E. Health Care Payers
    1. Federal
    2. State
        a. California Association of Health Plans
        b. California Behavioral Health Directors Association (CBHDA)
        c. California Department of Health Care Services (DHCS)
        d. Local Health Plans of California (LHPC)
    3. Local
        a. CEOs of local initiative Medi-Cal managed care plans

<< Place on organization letterhead>>

<<Date>>

California Hospital Association
Attn: BJ Bartleson, RN, MS, NEA-BC
1215 K Street, Suite 800
Sacramento, CA 95814

Dear BJ:

<<Insert name of organization>>would like to express our support for the Emergency Care Systems Initiative (ECSI). Through this initiative — sponsored by the California Hospital Association, the Hospital Council of Northern and Central California, the Hospital Association of Southern California and the Hospital Association of San Diego and Imperial Counties — California hospital leaders will develop an effective roadmap for addressing the state's stressed emergency care system. Supporting ECSI is an important step toward decreasing emergency department crowding and improving patient outcomes.

Californians are turning to hospital emergency departments in record numbers, often because they cannot get the primary care or social assistance they need elsewhere. Studying emergency department utilization data will help determine the drivers of high utilization and inform the development of patient care delivery models across the care continuum. ECSI will engage stakeholders, identify barriers and issue a comprehensive set of policy recommendations to improve the quality of patient care and protect California's emergency care system as the state's safety net.

We support CHA and the Regional Associations in implementing this initiative to improve California's overburdened emergency care system and optimize care for all Californians.

Sincerely,

Behavioral Health Care Symposium—Day 1
Monday, December 4

8:30 – 9:00 a.m. | Registration/Check-in

9:00 – 9:15 a.m. | Opening Comments

9:15 – 10:45 a.m. | Keynote Session

Clinical Virtual Reality: A Brief Review of the Future
Albert "Skip" Rizzo, Director, Medical Virtual Reality Research & Research Professor, Department of Psychiatry & School of Gerontology

11:00 a.m. – 12:00 p.m. | General Session

Shifting the Paradigm to Prevention and Early Intervention
Maggie Merritt, Executive Director, Steinberg Institute
Adrienne Shilton, Government Affairs Director, Steinberg Institute

12:00 – 1:15 p.m. | Luncheon

Announce Board & Chair
Šimanek Distinguished Service Award

1:15 – 2:15 p.m. | General Session

Grievance Boot Camp
Mary Watanab, Director of Health Policy and Stakeholder Relations at the Department of Managed Health Care

2:30 – 3:30 p.m. | General Session

Technology Innovations
Danielle Schlosser, Principal Research Scientist, Verily Life Sciences

4:00 – 5:00 p.m. | Closing Session

A Family's Experience
Moryt Milo, Managing Partner at Tectonics Venture / Internbound CEO

5:00 – 6:00 p.m. | Reception

Behavioral Health Care Symposium—Day 2
Tuesday, December 5

7:00 – 8:00 a.m. | Continental Breakfast

8:00 – 8:15 a.m.| Opening Comments

8:15 – 9:30 a.m.| Keynote Session

Who Do We Choose to Be?
Margaret Wheatley, American writer and leadership management consultant

9:30 – 10:30 a.m.| General Session

Past, Present and Future of Behavioral Health Care
To be announced

11:00 a.m. – 12:00 p.m. | General Session

Innovations in Delivery Systems
Ron Boatman, Associate Hospital Administrator Professional Services, Arrowhead Regional Center

12:00 – 1:15 p.m. | Luncheon

The "S" Word video trailer

1:30 – 2:45 p.m. | General Session

Panel – Workplace Violence Prevention | General Session
Gail Blanchard-Saiger, Vice President, Labor and Employment, California Hospital Association (moderator),

3:15 – 4:15 p.m. | Closing Session

Managing Agitation from A to Zeller
Scott Zeller, Vice President, Acute Psychiatric Medicine, CEP America

Emergency Services Forum—Day 3
Wednesday, December 6

7:00 – 8:00 a.m. | Continental Breakfast

8:00 – 9:00 a.m. | Brief Intro and Keynote Session

Emergency Department Inform Exchange And High ED Utilizers
Maria Raven, Emergency Medicine Physician and Health Services Researcher, UCSF

9:00 – 10:00 a.m. | General Session
Whole Person Care
To be announced

10:00 – 1030 Break

10:30- 11:30 | Breakout Sessions

SF Pilot Program – Behavioral Focus
David Serrano Sewell, Regional Vice President, Hospital Council of Northern & Central California

SD Pilot Program – Care Coordination Focus
Roneet Lev, Director of Operations, Scripps Mercy Emergency Department, San Diego

12:00 – 1:15 p.m. | Luncheon Session

1:15 – 2:15 p.m. | General Session

National Quality Forum -- ED Care Transitions/Performance Metric
Dr. Steve Cantrill

2:30 – 3:30 p.m. | breakout Session
Clinical Decision Area in the ED
Rose Colangelo, Manager, Emergency Department, Scripps Memorial Hospital La Jolla

APOD 3.0 Using Technology to Improve Offload Delay
Pamela Allen, Director, Emergency Department, Redlands Hospital

3:30 – 4:30 p.m. | Closing Session
Provider Wellness in the ED
To be announced

Save the Date 2017

12th Annual

Behavioral Health Care Symposium

December 4 & 5

Emergency Services Forum

December 6

THE MISSION INN &
RIVERSIDE CONVENTION CENTER
RIVERSIDE, CA

Register at www.calhospital.org/behavioral-symposium

CALIFORNIA HOSPITAL ASSOCIATION

Contacts:

Sheree Lowe, VP Behavioral Health
slowe@calhospital.org

BJ Bartleson, VP Nursing & Clinical Services
bjbartleson@calhospital.org

CHA is now accepting submissions for presentations and best practices posters for the 2017 CHA Emergency Services Forum (ESF). The forum is a unique opportunity for your organization to showcase and share its emergency preparedness knowledge and expertise with a cross-section of peers. Submissions must be received by **July 26, 2017.**

The ESF is expected to draw more than 250 hospital emergency department leaders including ED physicians, CNOs, ED supervisors, hospital administrators, EMS personnel and public health officials. Mark your calendar — the ESF will be held December 6 in Riverside. We hope you'll plan to join us!

Presentations

Presenters who wish to be considered for both general and breakout sessions should submit an abstract for review. Presentations must be emergency department-focused. Suggested topics include, but are not limited to:

- Care Coordination for ED super users
- Health care collaboration to improve community care access
- Whole Person Care pilots and their impact on ED's-HIE use to improve ED care
- Innovations in ED practice and treatment
- Responding to crisis events
- Managing violence in ED environments
- Law enforcement partnerships that work
- Developing transitional/bridge services for homeless
- ED practices to spot and manage opioid addicted patients

Click here **to submit your presentation entry form**.

Best Practices Poster Showcase

The Best Practices Poster Showcase is a way for members to share innovative ideas and model programs that can be replicated by other hospitals. Poster displays will be showcased at the event. Hospital representatives should be available during exhibit and poster viewing sessions to discuss their best practices with attendees.

Click here **to submit your best practices poster entry form**.

Need More Information?

Call the CHA Education Department at (916) 552-7637.

CALIFORNIA HOSPITAL ASSOCIATION

Promotional Opportunities

Emergency Services Forum
December 6, 2017, Riverside Convention Center

Why exhibit? In the exhibit area, participants will be able to interact with decision makers of hospital emergency departments.

What's the display space like? Exhibitors will have a tabletop display in the exhibit area.

Who are our attendees? Emergency department leaders including emergency department physicians, chief nursing officers, emergency department supervisors, hospital administrators, EMS personnel and public health officials.

How many attend? Approximately 200+ participants each year.

Select Your Level of Participation

Benefits	Platinum Exhibitor $3,500	Gold Exhibitor $2,500	Silver Exhibitor $1,500
Exhibit table with electricity in Exhibit area	√	√	√
Complimentary registrations to the educational program	2	1	1
Company logo on CHA website	√	√	√
Color ad in rotating PowerPoint slides and signage shown in the Exhibit area	1	1	1
Acknowledgement at the beginning of the program	√	√	√

Additional Fees

$335 (Wed. only) Registration for *each additional* representative

Where and When

December 6, 2017
Riverside Convention Center
3637 Fifth Street
Riverside, CA 92501

Contact

Lisa Hartzell
Director, Education Operations
(916) 552-7502
lhartzell@calhospital.org
www.calhospital.org/promotional-opportunities

CHA reserves the right to decline exhibitor applications.

Exhibit Rules

Emergency Services Forum
December 6, 2017, Riverside Convention Center

Space Assignments
Assignment of tables will be made by the California Hospital Association (CHA) based on the following criteria: exhibitor level, order in which reservations are received, number of tables purchased, suitability and availability of locations.

Space and Services Included in Fee
Space charge is included in exhibitor fee. Items provided are: draped 6-foot table, 2 chairs, table-tent card with company name. Exhibitors are also listed in the conference program with a description of up to 75 words.

Exhibit Refund Policy
Exhibit fees are NON-REFUNDABLE.

Preliminary Exhibit Dates and Hours
(Date/Times are approximate and subject to change)

Location: Riverside Convention Center

Wednesday, December 6
Set-up: 6:00 a.m. – 7:00 a.m.
Viewing: 7:00 a.m. – 4:30 p.m.
Dismantling: 4:30 p.m.

Exhibit Set-up and Clean-up
Set-up of exhibits must be completed and ready for inspection by **7:00 a.m. on Wednesday, December 6**. No set-up work will be permitted after this time without specific permission from CHA. Exhibitors are prohibited from dismantling their exhibits until the designated tear-down time of **4:30 p.m. on Wednesday, December 6**. It is the responsibility of the exhibitor to remove all materials from the exhibit area on Tuesday.

Admittance to the Forum
Exhibit hall admittance is limited to symposium attendees and company representatives who have contracted and paid for exhibit space.

Eligible Exhibits
CHA reserves the right to refuse rental of display space, exhibit, or any part of an exhibit to any company.

Exhibitor Raffle
Exhibitors will have an opportunity to give prizes to the attendees. Each exhibitor is limited to two raffle prizes minimum value of $100 is recommended.

How the Prize Drawing Works!
Each attendee will be given an exhibit tour card with a list of each participating vendor. To enter and win a prize, the attendee must receive a sticker (CHA will provide stickers) from all vendors. Once they have visited each vendor they can enter the completed card in the raffle prize basket. The raffle will take place at the last break. A CHA representative will ask you to come up and draw the winner of your prize. The attendee must be present to win and CHA will provide the winner's contact information to the donating exhibitor.

Fire and Safety
All flammable materials must be flame proofed before being placed in the exhibit area. All materials and installations are subject to the fire and safety regulations in force by state and/or city fire authorities. Exhibitors must provide certification of flame proofing if requested by show management or the fire department. Volatile or flammable fluids, substances or materials of any nature are prohibited in any booth.

Social Functions
Social functions sponsored by exhibitors must not be scheduled during exhibit hours or during the CHA education program. Any function not approved by CHA that would compete for attendees' time, either during the hours of the exhibition or hours of educational sessions, general sessions or programs is prohibited.

Security
Exhibitors are responsible for any valuables at their booth. Security guards will be present at all times.

CALIFORNIA HOSPITAL ASSOCIATION

Emergency Services Forum

DECEMBER 6, 2017 • RIVERSIDE, CA

PLEASE PROVIDE THE FOLLOWING BY November 3, 2017

- ❑ Exhibit fees—make checks payable to CHA/CAHHS or provide Visa, MasterCard or American Express number with expiration date.
- ❑ Company logo in high resolution .jpeg file format.
- ❑ Artwork for a full color advertisement rotating in exhibit area.
  Dimension of ad: 13"w x 10"h. Ad submitted as a .jpeg file.
- ❑ A short description of your organization (75 words or less) for inclusion in the conference program.
- ❑ A description of your tabletop, dimensions, and product(s) being displayed.
- ❑ A description of items you may wish to contribute for the Exhibit show raffle prize drawing.
  **minimum value of $100 is recommended*

All materials can be submitted via email: lhartzell@calhospital.org • Fax: 916-552-7506 •
Mail: CHA, Education Department, 1215 K Street, Suite 800, Sacramento, CA 95814

HOTEL & EXHIBIT INFORMATION

- ❑ The **Mission Inn Hotel & Spa** has discounted sleeping rooms available starting at $179 for single or double occupancy. For reservations, call (800) 843-7755 and mention the *California Hospital Association* to receive the discounted rate. Discount deadline is **November 3**.
- ❑ Exhibit area includes one draped, 6-foot table, (2) chairs and a name tent listing your company's name. Please contact Lisa Hartzell at (916) 552-7502 or lhartzell@calhospital.org if you would like electricity at your tabletop and have not already signed up for it.

  NOTE: This is a table top exhibit. Each exhibitor will have roughly 9ft of space to display (this includes the 6ft table), so please plan accordingly.
- ❑ Shipping information: Packages must arrive **no sooner than Thursday, November 30, 2017**.

  Ship to: **Riverside Convention Center**
  Event Name/Date: Emergency Services Forum; Dec. 6, 2017
  ATTN: Pamela Sturrock
  3637 Fifth Street,
  Riverside, CA 92501

  *Please include your company name on the shipping label so the Convention Center knows to look out for your package.

EXHIBIT SCHEDULE

Wednesday, December 6

Set-up:	6:00 a.m. – 7:00 a.m.
Viewing:	7:00 a.m. – 4:30 p.m.
Dismantling:	4:30 p.m.

Application

Emergency Services Forum
December 6, 2017, Riverside Convention Center

Submit Completed Application

Fax: (916) 552-7506
E-mail: lhartzell@calhospital.org
Mail: California Hospital Association
Education Department
1215 K Street, Suite 800, Sacramento, CA 95814
Questions: Lisa Hartzell, (916) 552-7502

Select Your Level

☐ Platinum Exhibitor ($3,500)
☐ Silver Exhibitor ($1,500)
☐ Gold Exhibitor ($2,500)
☐ Additional Registration ($335) *(Wed. only)*

Amount to be Billed: $ _____

Billing Information

☐ VISA ☐ MC ☐ AMEX

Name on Card: _____

Card Number: _____

Expiration Date: _____ Security Code: _____

Billing Address: _____

City: _____ State: _____ Zip: _____

Authorizing Signature: _____

**Make checks payable to "CAHHS/CHA"*

Company Information

Please list your company name as you wish it to appear in marketing materials.

Company: _____

Contact Name/Title: _____

Address: _____

_____

Telephone: _____

E-mail: _____

Company web address: _____

Please provide a brief description about your company. This description will be used in marketing materials. Please adhere to 75 words. CHA reserves the right to alter your description for marketing purposes.

_____

_____

_____

_____

Please list special request consideration in table assignments (e.g., companies you do not wish to be located next to). List specific company names, not products or services. CHA cannot guarantee requests will be met but will make every effort to accommodate them.

_____

_____

Attending Representatives

Please list exactly as you wish it to appear in conference program.

Representative #1: _____
Title: _____
Telephone: _____
E-mail *(required)*: _____

Representative #2: _____
Title: _____
Telephone: _____
E-mail *(required)*: _____

Representative #3: _____
Title: _____
Telephone: _____
E-mail *(required)*: _____

Representative #4: _____
Title: _____
Telephone: _____
E-mail *(required)*: _____

Authorization

Exhibitor assumes responsibility and agrees to indemnify and defend the California Hospital Association and the Riverside Convention Center and their respective employees and agents against any claims or expenses arising out of the use of the exhibition premises. The Exhibitor understands that neither the California Hospital Association nor the Riverside Convention Center maintains insurance covering the Exhibitor's property, and it is the sole responsibility of the exhibitor to obtain such insurance. Our company shall be bound by the terms and conditions in the Exhibitor Rules information material.

Authorized Signature: _____ Date _____

Leading the Way
Addressing California's Growing Behavioral Health Crisis

Significant studies of California's behavioral health system have concluded that it is fragmented, unresponsive to consumers' needs, does not emphasize recovery and serves only a fraction of those suffering from mental illness.

To address the many complex health challenges and issues faced by our communities, President/CEO C. Duane Dauner of the California Hospital Association and Jessica Cruz, Executive Director of the National Alliance on Mental Illness, California, organized a landmark coalition meeting of statewide leaders. The meetings are facilitated by Darrell Steinberg, author of Proposition 63, the Mental Health Services Act, and included representatives from corrections agencies, first responders, faith-based groups, emergency services, law enforcement agencies, patients' rights organizations, courts, schools, community services providers, health care providers, medical professionals, counties, cities and behavioral advocacy and patient rights organizations.

To date, the Coalition has met three times, in February, May, and August 2017. The next meeting will tentatively be in November 2017.

At the Coalition's first meeting, four committees were established:

- Barriers – Legal and Regulatory
- Delivery System/Continuum of Care/Crisis Services
- Finance
- Workforce

Each of these groups was tasked with assembling a list of objectives, including recommendations for the current and upcoming legislative sessions. Listed below are the current recommendations for each committee.

<u>Barriers – Legal and Regulatory</u>

Recommendations for the current legislative session:

1. Support AB 501, which would create a new licensing category for children's crisis residential programs.

Recommendations for the next legislative session:

1. Pursue legislation to repeal the Medi-Cal prohibition on paying for two visits on the same day.
2. Pursue legislation regarding local zoning decisions. The legislation might raise the threshold before a conditional use permit would be required (perhaps to 15 patients);

streamline zoning requirements in underserved areas of the state; prohibit discrimination against entities providing services to behavioral health patients; and/or require each community to make provision for housing for individuals with behavioral health conditions. The committee will need expert help in land use and zoning laws to guide development of the legislation.

3. Explore pursuing legislation to clarify the Lanterman-Petris-Short Act. The committee is collecting LPS questions that need answering, and will meet again to discuss resolutions.
4. After outcomes data is published, explore legislation that extends the Stanislaus pilot project regarding alternate destinations for mental health patients.

Delivery System/Continuum of Care/Crisis Services

Recommendations:

1. Committee members assessed that it was not achievable to develop a new legislative proposal for this year, but would want all Coalition members to be aware of the behavioral health related bills already moving through the legislative process that they may wish to support.
2. The Committee identified topic areas for potential future legislation. If the intention of the Coalition is to advance legislative proposals, it would be helpful if Leading the Way leaders/conveners CHA and NAMI would collect ideas from all committees and propose potential options for the Coalition to prioritize and further develop in anticipation of next year's legislative session.
3. In exploring the concept of a CA Model, the Committee would recommend learning what we can from a similar effort from the late 1970s/early 1980s. The Coalition should consider whether it makes sense to invest in doing a similar exercise today.
4. In order to influence political leaders, government officials and cultivate champions for behavioral health needs in California, the Committee identified several ways that the Coalition could be helpful. We recommend a combination of activities sponsored by the Coalition and implemented in a collaborative manner, as well as the sharing of ideas for individual organizations within the Coalition to implement as they see fit.

Finance

To address the complex challenges that will help us collectively work to improve behavioral health care delivery in California, the *Leading the Way* Coalition (Coalition) should invite funders and researchers to explore with us an effort to conduct an in-depth policy analysis to examine the following:

- California's behavioral healthcare delivery system as a whole and how systems work together to create improved care coordination from crisis, to stabilization, maintenance and housing;
- Current behavioral health funding, including opportunities to leverage other sources of funding, and/or develop alternative funding opportunities;
- Capacity, training and opportunities to expand the behavioral health workforce;
- Various legal and regulatory barriers for behavioral health care access; and

- Create enhanced and improved methods and strategies to promote mental health and prevent mental illness.

Workforce

Short-Term Legislative Solutions (2017)

1. Support AB 1340 (Maienschein): Requires the Medical Board of California, in determining its continuing education requirements for licensed physicians and surgeons, to consider including a course in integrating mental and physical health care in primary care settings, especially as it pertains to early identification of mental health issues in children and young adults and their appropriate care and treatment.

Long-Term Legislative Solutions (2018 and beyond)

1. The LTW workforce committee recommends a legislative proposal that would be the equivalent of AB 1340 but specific to continuing education requirements for allied health professionals, who often are on the front lines of encountering patients who may be experiencing a mental or behavioral health condition.
2. The LTW workforce committee also recommends that the LTW Coalition consider sponsoring legislation to create peer counselor certification in California.
3. The LTW workforce committee recommends that the LTW Coalition consider sponsoring legislation to establish Psych Rehabilitation Practitioner certification.

Recommendation for opportunities for the LTW Coalition to influence new, government officials and decision makers:

1. The LTW workforce committee recommends that the LTW Coalition leverage the efforts of the newly established California's Future Health Workforce Commission, which will have as members CEOs of the prominent health foundations, California lawmakers, as well as the University of California President, and Chancellors for the California State University and the California Community Colleges. This commission has been established to create a master plan for health workforce in California. A priority of the commission will be to educate candidates and incumbent lawmakers, as well as the incoming administration, about the need to address health workforce shortages and disparities in California. While primary care workforce will be top tier, behavioral health workforce will be included as a priority.

Community Paramedicine Pilot Project – Letters of Interest

As of July 10, 2017

Agency	Concepts	Notes
Santa Clara County	Alternate Destination - Behavioral Health Alternate Destination – Sobering Center	
Dignity Health – North State	Post Discharge	
Cal Tahoe JPA	Alternate Destination - Behavioral Health Post Discharge	
El Dorado EMS Authority	Frequent 911 User	
Los Angeles County	Alternate Destination - Behavioral Health Alternate Destination – Sobering Center	
Central Valley EMS Agency Fresno, Kings, Madera & Tulare Counties	Alternate Destination - Behavioral Health Alternate Destination – Sobering Center	
Napa County EMS Agency	Directly Observed Therapy Tuberculosis Patients	
Marin County EMS Agency	Post Discharge	
City of San Francisco Fire	Frequent 911 User Alternate Destination – Behavioral Health Post Discharge	
Mountain Valley EMS	Post Discharge	
Downieville Fire District	Frequent 911 User Post Discharge Hospice Alternate Destination – Urgent Care	

AMENDED IN ASSEMBLY MARCH 23, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL No. 820

Introduced by Assembly Member Gipson

February 15, 2017

An act *to add Section 1797.119 to the Health and Safety Code,* relating to emergency medical services.

LEGISLATIVE COUNSEL'S DIGEST

AB 820, as amended, Gipson. ~~Community paramedicine program.~~ *Emergency Medical Services Authority: task force: transportation alternatives.*

Existing law, the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, governs local emergency medical services (EMS) systems. The act establishes the Emergency Medical Services Authority, which is responsible for the coordination and integration of all state agencies concerning emergency medical services.

This bill would authorize the authority to establish a task force, as provided, to develop a report evaluating alternative destinations to a general acute care hospital for first responders to transport a patient who may be a danger to himself, herself, or others or gravely disabled as a result of a mental health disorder. The bill would require the report to be published on the authority's Internet Web site.

~~This bill would declare the intent of the Legislature to enact legislation establishing a community paramedicine program in California.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1797.119 is added to the Health and Safety Code, to read:

1797.119. (a) The authority may establish a task force to develop a report evaluating alternative destinations to a general acute care hospital for first responders to transport a patient who may be a danger to himself, herself, or others or gravely disabled as a result of a mental health disorder.

(b) If the authority establishes a task force, the task force shall include representatives from statewide trade associations that represent consumers, physicians, hospitals, law enforcement officers, and public and private first responders.

(c) If the authority establishes a task force, the report shall be published on the authority's Internet Web site.

~~SECTION 1. It is the intent of the Legislature to enact legislation establishing a community paramedicine program in California.~~

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AMENDED IN ASSEMBLY APRIL 20, 2017

AMENDED IN ASSEMBLY APRIL 6, 2017

AMENDED IN ASSEMBLY MARCH 29, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL No. 1650

Introduced by Assembly Member Maienschein
(Coauthors: Assembly Members Chávez and Mathis)
(Coauthor: Senator Wilk)

February 17, 2017

An act to add *and repeal* Chapter 13 (commencing with Section 1800) ~~to~~ *of* Division 2.5 of the Health and Safety Code, relating to emergency medical services.

LEGISLATIVE COUNSEL'S DIGEST

AB 1650, as amended, Maienschein. Emergency medical services: community paramedicine.

Existing law, the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, governs local emergency medical services (EMS) systems. The act establishes the Emergency Medical Services Authority, which is responsible for the coordination and integration of all state agencies concerning emergency medical services. Among other duties, the authority is required to develop planning and implementation guidelines for emergency medical services systems, provide technical assistance to existing agencies, counties, and cities for the purpose of developing the components of emergency medical services systems, and receive plans for the implementation of emergency medical services and trauma care systems from local EMS agencies.

This bill ~~would~~ *would, until January 1, 2022,* create the Community Paramedic Program in the authority. The bill would authorize the authority to authorize a local EMS agency that opts to participate in the program to provide specified services, such as case management services and linkage to nonemergency services for frequent EMS system users, through a local community paramedic program. The bill would require the authority, in consultation with the Office of Statewide Health Planning and Development, to develop criteria to qualify services for participation in the program, develop an application and application process for local EMS agencies seeking to participate in the program, and to review and approve applications for participation in the program as a component of the local EMS agency's EMS plan. The bill would authorize a local EMS agency to opt to participate in the program if it meets the criteria established by the authority and completes the application process developed by the criteria. The bill would specify the necessary components of a community paramedic service plan to be included in the local EMS agency's application. The bill would require the medical director of the local EMS agency to oversee the local community paramedic program. *The bill would require the authority to annually report specified information related to local community paramedic programs to the office, and require the office to publish the report on its Internet Web site.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Chapter 13 (commencing with Section 1800) is added to Division 2.5 of the Health and Safety Code, to read:

Chapter 13. Community Paramedic Program

Article 1. General Provisions

1800. This chapter shall be known, and may be cited, as the Community Paramedic Program Act.

1802. Unless the context requires otherwise, the following definitions shall apply to this chapter:

(a) "Community paramedic" means an individual who is educated and trained in community paramedicine, whose scope of

practice is in accordance with standards established by the authority, who holds a current certification as a mobile integrated health community paramedic by the International Board of Specialty Certification or equivalent, who has a valid license issued pursuant to this chapter, and who is accredited by a local EMS agency.

(b) "Program" means the Community Paramedic Program established by this chapter.

1804. Within the authority there is the statewide Community Paramedic Program. The program may authorize a local EMS agency that opts to participate in the program to provide, through a local community paramedic program, *and notwithstanding Sections 1797.52 and 1797.218,* any of the following services:

(a) (1) Postdischarge followup services for targeted and eligible patients recently discharged from a hospital participating in the program.

(2) A postdischarge service authorized pursuant to this subdivision is intended to provide short-term assistance in order to reduce hospital admissions and shall not replace home health care or any other services available to patients.

(b) (1) Directly observed therapy for eligible patients undergoing tuberculosis treatment in partnership with a county public health department.

(2) A directly observed therapy service authorized pursuant to this subdivision is intended as a supplement to provide for after-hours availability or to reach patients who are difficult to serve, and shall not replace home community health workers or public health nurses.

(c) Hospice rapid response service for eligible and enrolled patients to administer comfort care, coordinate services with the hospice nurse, and, as appropriate, avoid patient transport to an acute care hospital emergency department.

(d) Case management services and linkage to nonemergency services for frequent EMS system users, for the purpose of reducing dependence of those users on the EMS system and acute care hospital emergency departments to provide primary medical care.

Article 2. Duties and Powers of the Authority

1810. (a) To implement the program, the authority shall do all of the following:

(1) Develop criteria that qualify local community paramedic services to participate in the program.

(2) Develop an application and application process to be used by a local EMS agency that seeks to participate in the program. The application process shall provide for the submission of a local community paramedic service plan described in Section 1820 that shall be a component of the local EMS agency's local EMS plan.

(3) Review and approve applications for the implementation of local community paramedic services as a component of the local EMS agency's EMS plan in accordance with Section 1797.105.

(b) Criteria described in paragraph (1) of subdivision (a) shall include, but not be limited to, the following:

(1) ~~Training~~ *Minimum training* and certification requirements for a community ~~paramedic.~~ *paramedic, including, but not limited to, the following:*

(A) Four years of job experience as an EMT-P.

(B) At least 48 hours of classroom-based instruction.

(C) At least four hours of clinical, hands-on training.

(D) At least 56 hours of study outside of the classroom.

(2) Regulations for the initiation, operation, and evaluation of a local community paramedic program.

1812. *(a)* The authority shall consult with the Office of Statewide Health Planning and Development in performing its duties required by this chapter.

(b) The authority shall provide the Office of Statewide Health Planning and Development with an annual report regarding all local community paramedic programs that shall include, but not be limited to, information regarding program effectiveness, cost-savings, and patient safety, including details regarding any adverse patient outcomes. The Office of Statewide Health Planning and Development shall publish the report on its Internet Web site.

Article 3. Local EMS Agency Participation

1820. (a) A local EMS agency may opt to participate in the program by meeting the criteria and completing the application

and application process established by the authority pursuant to Section 1810.

(b) A community paramedic service plan developed by a local EMS agency that seeks to participate in the program shall demonstrate that the local EMS agency will be able to meet the requirements of the program and shall include, but not be limited to, all of the following:

(1) Agreements between local agencies and service providers participating or partnering in the local community paramedic program.

(2) A description of the local community paramedic program.

(3) A description of existing problems that the local community paramedic program is intended to address.

(4) Criteria for the enrollment or inclusion of patients in the local community paramedic program.

(5) Goals and intended results of the local community paramedic program.

(6) Criteria for patient and provider safety.

(7) Estimated costs and savings attributable to the local community paramedic program.

(8) Data to be collected for the purpose of evaluating the effectiveness of the local community paramedic program.

(9) Criteria and processes for evaluating the effectiveness of the local community paramedic program.

(10) Protocols, policies, and procedures for the implementation and operation of local community paramedic program services by a community paramedic.

(11) Protocols for the assessment of patients served by the local community paramedic program.

(12) Any other information or plan component required by the authority pursuant to Section 1810.

1822. The local EMS agency medical director shall oversee a local community paramedic program participating in the program.

1823. This chapter shall remain in effect only until January 1, 2022, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2022, deletes or extends that date.

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Expanding the Roles of Emergency Medical Services Providers: A Legal Analysis

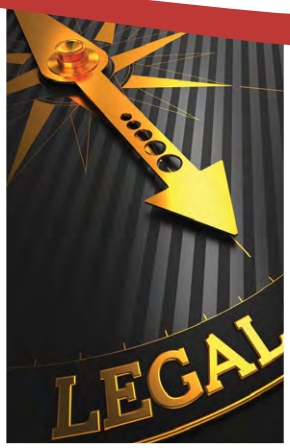

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Table of Abbreviations

ACA	Patient Protection and Affordable Care Act	EMTALA	Emergency Medical Treatment and Active Labor Act
ACO	Accountable Care Organization	HIPAA	Health Insurance Portability and Accountability Act
ASPR	Assistant Secretary for Preparedness and Response, HHS	HWPP	Health Workforce Pilot Project
ASTHO	Association of State and Territorial Health Officials	LPN	Licensed Practical Nurse
CDC	Centers for Disease Control and Prevention	MIH	Mobile Integrated Healthcare
CMS	Centers for Medicare and Medicaid Services	NACCHO	National Association of County and City Health Officials
CP	Community Paramedicine	NAEMT	National Association of Emergency Medical Technicians
HHS	Department of Health and Human Services	NHTSA	National Highway Traffic Safety Administration
ED	Emergency Department	NP	Nurse Practitioner
EHBs	Essential Health Benefits	OSHPD	Office of Statewide Health Planning and Development
EKG	Electrocardiogram	PA	Physician Assistant
EMS	Emergency Medical Services	RN	Registered Nurse
EMSA	Emergency Medical Services Authority	SDMAC	State Disaster Medical Advisory Committee
EMT	Emergency Medical Technician	TOPS	Top Options, Practices, or Solutions

Acknowledgments

This report was developed by James G. Hodge, Jr., JD, LLM, Lincoln Professor of Health Law and Ethics and director of the Public Health Law and Policy Program at the Arizona State University (ASU) Sandra Day O'Connor College of Law; Daniel G. Orenstein, JD, adjunct professor and fellow, Public Health Law and Policy Program at the ASU Sandra Day O'Connor College of Law; and Kim Weidenaar, JD, fellow, Public Health Law and Policy Program at the ASU Sandra Day O'Connor College of Law. Additional individuals who contributed to the research, drafting, or editing of this document include ASU students: Kellie Nelson, JD candidate; Susan Russo, JD candidate; Vince Miner, JD candidate; Asha Agrawal, JD candidate; and Rose Meltzer, BA candidate. We acknowledge colleagues at the Association of State and Territorial Health Officials (ASTHO) and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), members of ASTHO's advisory committee, and others who reviewed and commented on initial outlines and drafts of this report.

Disclaimer: Funding for this report is provided by ASTHO through ASPR. Information provided herein does not constitute legal advice. Please consult your legal counsel for specific legal guidance.

Executive Summary/Introduction

With support and guidance from the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Association of State and Territorial Health Officials (ASTHO) seeks to identify feasible approaches to increasing the opportunities to engage emergency medical services (EMS) providers for day-to-day activities in communities across the United States. A primary component of this project is an exploration of state legal and policy issues as described by ASTHO as "Activity 1.3" of the larger proposal, summarized below:

ACTIVITY 1.3: ASTHO, in collaboration with the National Association of County and City Health Officials (NACCHO) and other partner organizations such as the National Association of State EMS Officials (NASEMSO) (an ASTHO affiliate), will conduct a review and analysis of the existing statutory and regulatory provisions that either facilitate, or impose barriers to, expanded roles of EMS. These include community paramedicine (CP) and mobile health services in daily operations and during disasters/public health emergencies. This review will also identify and catalogue promising strategies, tactics, practices and supporting resources to further integrate public health and EMS in building community resilience. This includes assessments of the roles of different types of consultative entities found in various state and local communities, such as State Disaster Medical Advisory Committees (SDMACs).

This project's primary objective is to conduct innovative and relevant legal and policy research to ascertain core issues that may impede activities of health professionals in routine community paramedicine (CP)[1] or mobile integrated healthcare (MIH) activities. In addition to identifying issues, this report examines potential law and policy best practices, options, or solutions, based in part on research of specific jurisdictions selected in collaboration with ASTHO and its advisory group. As per **Figure 1**, these jurisdictions include Arizona, California, Delaware, Florida, Georgia, Idaho, Illinois, Massachusetts, Mississippi, Montana, North Dakota, Oregon, and Utah.

Project Limits. Although the scope of this project is extensive, there are several limits:

1. Although there are many issues related to the roles of EMS professionals during declared emergencies, this project is focused on routine, day-to-day activities consistent with discussions with ASTHO and ASPR.
2. For the purposes of this report, licensing, certification, or scope of practice laws or policies related to EMS professionals are considered "fixed," and thus not subject to state-based amendments or alterations.
3. Primary legal themes entail potential issues and corresponding options, practices, or solutions regarding the extent of activities that EMS professionals, supervisors, and their entities conduct related to:
    a. Triggers for deploying providers (e.g., via request through 9-1-1 calls or other mechanisms).
    b. Assessing patients on site, in transport, or after arrival at the healthcare facility.
    c. Altering patients' treatment destinations (other than hospital emergency departments [EDs]), when applicable.

Within these limitations, multiple legal and policy issues and approaches are ripe for exploration. Identifying and addressing these issues involve examining interrelated constitutional provisions, statutes, regulations, judicial cases, and policies within and across states. The project goal is to unravel and simplify these key legal issues, suggesting options, best practices, or solutions for practitioners and law and policymakers to effectuate continued expansion of the use of EMS providers nationally. Current and potential law and policy strategies are identified throughout the report in text boxes titled "Top Options, Practices, or Solutions" (TOPS), which are reproduced in **Table 1**, below, for ease of reference.

Project Organization. The report is divided into four major parts. **Part I** provides brief foundational information on core elements of existing projects and emerging approaches that may be adapted to expand EMS usage in new jurisdictions. **Part II** evaluates underlying legal "triggers" that authorize deployment of EMS personnel, and identifies new protocols, modifications, or waivers that may be necessary to authorize CP or similar initiatives in some jurisdictions. It also addresses coordinating limited resources, including contractual elements that support efficiency and avoid conflict, as well as initial liability concerns. **Part III** focuses on potential legal challenges and opportunities concerning expanding patient assessment. This section analyzes concerns related to scope of practice, standard of care, venue restrictions, and medical supervision requirements, as well as potential liability of EMS practitioners and organizations. It presents a series of options to enable EMS professionals to expand their roles while adhering to existing scope of practice limitations and health information privacy laws. **Part IV** explores legal and policy issues that may hinder or support the alteration of patient destinations through these initiatives, other than to hospital EDs. Key themes include the role of patient choice, potential for patient "dumping" or abandonment, reimbursement for services, impact of the Patient Protection and Affordable Care Act (ACA), and continued concerns over liability of practitioners, medical directors, and service providers.

Report Format: The format of this report, including citations and references, is consistent with the *Bluebook: A Uniform System of Citation*, the standard approach for legal reports.

Table 1. "Top Options, Practices, or Solutions" (TOPS) in Law or Policy Concerning Expanded EMS

"Top Options, Practices, or Solutions" (TOPS)
Ready, Set, Go: Legal Issues Underlying the Triggers for Expanded EMS Activities
TOPS # 1. Because existing trigger protocols in some states only address 9-1-1 EMS situations, state or local development of enhanced, flexible protocols under existing legal authority can provide oversight and address procedures such as clinic or health department referrals and home visits.
TOPS # 2. To support efficient use of CP, MIH, or similar programs, public and private sector entities must equitably share costs for essential resources and benefits of core services through contractual terms that seek advance agreements on issues of allocation.
TOPS # 3. In localities that are limited in their ability to contract with ambulance or other providers because of strict state or local bidding requirements, exceptions for localities to enter into new or expanded contracts for these programs may be considered.
TOPS # 4. To avoid potential liability for failures to properly operate or follow known triggers for EMS personnel, state and local government must avoid creating a special duty to provide care for specific individuals. Programs seeking to reduce their potential liability may frame implementation in broad terms related to communal health benefits rather than specific health services for identified persons.
On Closer Inspection: The Changing Nature of Patient Assessment and Corresponding Legal Challenges
TOPS # 5. Legal authority for EMS professionals to fully engage in activities like CP may be constrained by existing scope of practice limitations. Provisions authorizing ranges of activities, rather than specific and enumerated tasks, may facilitate expanding the traditional EMS role without altering legal scopes of practices.
TOPS # 6. Adherence to appropriate decision making tools (e.g., protocols and standing orders), medical supervision, and consultation requirements mitigates the risk of overstepping clinical decision making authority. Viewing follow-up care and similar actions as a continuation of, or prelude to, care by other medical professionals reflects key legal distinctions between medical and field diagnoses.
TOPS # 7. Nonemergency care may exceed lawful scopes of practice for EMS professionals. However, broadly defined scope of practice provisions may readily allow such care. Even narrower constructions may permit such care consistent with additional statutory authorizations or favorable interpretations of laws defining "emergency condition" or similar terms.
TOPS # 8. Medical professional oversight and supervision are required for EMS activities, but may be limited by physician availability. Expanded use of appropriate decision support tools and centralized on-line supervision models can increase the supervision potential of existing, available personnel, including non-physicians.
TOPS # 9. In the face of potential escalating liability claims, protections from ordinary negligence claims available to EMS personnel responding to an emergency may apply to other activities in select contexts. However, proper training, medical consultation, and observance of protocols and standing orders are essential to ensure that EMS practitioners with expanded roles comply with established standards of care.
TOPS # 10. To deter potential health information privacy violations or infringements, CP, MIH, or similar programs may require training for key personnel on privacy protections and develop of formal, HIPAA-compliant written policies addressing permissible uses and disclosures of identifiable health data.

Down the Road: Altering Patient Destinations
TOPS # 11. CP, MIH, or similar programs that do not explicitly authorize alternative destinations for patients may rely on broad and flexible statutes and regulations with protocols and supporting flowcharts that allow sufficient discretion to alter destinations. Waivers may also permit pilot programs to transport patients to alternative destinations.
TOPS # 12. EMS licensing requirements based on necessity can limit opportunities to alter destination for patients in CP or similar programs. State and local officials with discretionary authority to approve ambulance licensure may interpret these regulations to include such programs, particularly those including nonemergency transport.
TOPS # 13. To address budget crisis limiting the expanded use of EMS providers, states may consider authorizing reimbursement for patient transport and EMS services through Medicaid programs for cases involving transportation to EDs or acute care centers.
TOPS # 14. To expand funding of CP, MIH, and similar projects through private health insurance, states may amend their benchmark plans to cover services including home health services, preventative care, and emergency services.
TOPS # 15. To avoid potential Emergency Medical Treatment and Labor Act (EMTALA) infractions, protocols determining patient destinations should clearly designate hospital EDs as the primary destination for any patient with a known or suspected emergency condition. Procedures should also require a patient's written informed consent, where possible, if the patient refuses emergency transport.
TOPS # 16. To avoid liability for patient abandonment, CP, MIH, and similar programs should ensure adequate patient monitoring and communication with appropriate healthcare facilities during medical care and transfer. These programs may also establish written policies regarding patient refusal and accompanying patient rights, as well as patient consent procedures for enrollment and mutually agreed upon outcomes.
TOPS # 17. False imprisonment and related claims can arise if patients are forcibly held or transported to locations without the patients' valid consent. Programs that use EMS providers in expanded roles should abide by patient choice regarding destination whenever possible. State emergency hold procedures for appropriate mental health patients should be relied on where applicable.
TOPS # 18. Liability protections stemming from vehicular transport of patients outside of an emergency setting are limited. States seeking to increase the use of EMS providers in expanded roles may consider extending immunity laws to nonemergency care consistent with a careful balancing of patient and community safety.
TOPS # 19. Medical directors should adequately supervise EMS practitioners operating in CP, MIH, or similar programs and set protocols that properly direct patients to appropriate medical facilities. Use of approved, vetted flowcharts or other tools may help protect against claims of negligence in the transportation of emergency patients, while still allowing flexibility to alter destinations as needed.

I. Setting the Stage: Brief Primer on Expanded EMS Practices

The National Highway Traffic Safety Administration (NHTSA) predicts that "EMS of the future will be community-based health management that is fully integrated with the overall health care system."[2] Expanded EMS roles and programs are increasingly bringing medical care to people and places in need across the United States.[3]

These programs offer tangible benefits for patients and communities to bridge gaps between emergency services and primary care.[4] For example, community paramedics may (1) provide in-home preventive services to patients who might otherwise go to the ED for primary care treatment, obviating unnecessary emergency visits, or administer influenza or other vaccines; (2) conduct home health visits for households with children younger than age 5 to assess potential risks of injuries; or (3) assess special public health needs. In turn, emergency physicians, nurses, and other medical personnel can focus on patients with urgent needs, leading to decreases in patient and provider costs for healthcare services across communities. [5]

CP services may especially benefit rural populations. One quarter of Americans live in rural areas,[6] but only 10 percent of physicians practice in these locales.[7] Other healthcare practitioners may provide essential care and improve healthcare access in these areas (e.g., NPs operating with full practice authority, as currently permitted in 20 jurisdictions),[8] but significant gaps in access remain. Accordingly, nearly 40 percent of existing CP programs serve rural areas.[9] Patients in these settings may be aging or elderly, impoverished, and in poor health due to a lack of preventive care and follow-up treatment.[10] Through CP, they may receive treatment for essential health services for which they otherwise may lack access.

STATE AND LOCAL PROGRAMS

State and local governments are in various stages of considering and implementing programs using EMS providers in expanded roles. Taos County, New Mexico, implemented one of the first CP programs in the United States in 1995. Local paramedics received enhanced training to provide the town of Red River's rural population with primary care and treatment. The program ended five years later when additional physicians established practices in the community, but it inspired the creation of other programs nationally.[11] In 1997, the University of Pittsburgh Medical Center established another early CP program known as Emed Health. Emed Health later became part of the larger Center for Emergency Medicine of Western Pennsylvania.[12]

States have approached program implementation in various ways. California authorized paramedics to perform specific activities outside their usual roles via regulation.[13] EMS personnel are statutorily required to transport patients to a hospital with at least a basic ED.[14] However, the state has provisionally accepted 12 CP pilot projects, which are awaiting final approval.[15] These pilot programs, if approved, will be authorized through a legislatively-enacted program called the Health Workforce Pilot Project (HWPP). HWPP calls for innovative projects to improve the effectiveness of healthcare delivery in a wide range of fields and permits limited waivers of restrictive state laws.[16]

Nebraska implemented a CP program legislatively with support from its state EMS Office program and Office of Rural Health, which sought statewide CP standards.[17] Minnesota initially offered a training program to interested paramedics, which later developed into a full CP program due in part to legislation establishing CP certification for EMTs in 2011.[18] Minnesota also authorized medical assistance reimbursement to cover CP services to high-risk individuals in 2012.[19] Colorado's program began through grassroots efforts.[20] Maine amended its statutes in 2012 to allow the state EMS Board to establish 12 pilot CP programs, which may last up to three years.[21] North Dakota's state

legislature appropriated $276,000 in 2013 to research the potential for CP programs within the state.[22] Florida and Kentucky are developing new programs in 2014.[23] As noted by the Flex Monitoring Team—a collaborative effort between the Universities of Minnesota, North Carolina at Chapel Hill, and Southern Maine—in its February 2014 report, determining which types of state-led programs are most effective is difficult given insufficient research and studies on CP nationally.[24]

In addition to state-based programs, local governments in San Francisco and Wake County, North Carolina, have run their own CP programs.[25] In Texas, Fort Worth's MedStar program directs advanced practice paramedics to patients who frequently call 9-1-1 for primary care. The program is credited with saving hospitals and state governments millions of dollars through more efficient use of local ambulances.[26] The CP program in rural Eagle County, Colorado,[27] links current EMS personnel to existing public health services. Under physicians' direction, paramedics obtain extra training to perform services like blood draws and wound care.[28]

The use and development of CP, MIH, and similar programs are increasing. Based on its survey of EMS personnel in October 2013, the National Association of Emergency Medical Technicians (NAEMT) found 232 unique CP programs and MIH programs in existence nationally, which represented 6 percent of the respondents.[29] Another 15 percent of the respondents indicated that their EMS systems were developing or considering similar programs.[30]

FEDERAL SUPPORT FOR PUBLIC/PRIVATE COLLABORATIONS

CP and MIH programs involve significant collaborations among federal, state, and local governments and private sector entities. Delivery models may include partnerships between municipalities, public hospitals, fire departments, EMS systems, home health organizations (also known as patient navigation organizations), nonprofits, and for-profit entities.[31] Federal agencies including ASPR, Centers for Medicare and Medicaid (CMS), and the Office of Rural Health Policy may help fund state and local programs demonstrated to be effective in terms of cost and quality.[32]

The Patient Protection and Affordable Care Act (ACA) offers potential opportunities to support an expanded role for EMS as an integral part of the healthcare system.[33] First, ACA is projected to significantly increase the number of insured Americans through expanded employer coverage, insurance subsidies, and expansion of Medicaid programs in 27 states (as of March 26, 2014).[34] HHS' list of 10 Essential Health Benefits (EHBs), which most health insurance plans must cover, includes ambulatory and emergency services, chronic disease management, and possibly preventive and wellness care, each of which may be provided via CP or similar programs. ACA also promotes accountable care organizations (ACOs), defined generally as a "group of healthcare providers who give coordinated care [and] chronic disease management…tied to achieving healthcare quality goals and outcomes that result in cost savings."[35] The flat rate, quality-driven reimbursement model for ACOs may further promote integration of CP or similar programs within hospitals and other providers given its cost-efficient medical care.[36] Finally, ACA funds community health centers and development of innovative primary care models, which may afford new resources for these programs.

FUTURE OF COMMUNITY PARAMEDICINE AND MOBILE INTEGRATED HEALTHCARE

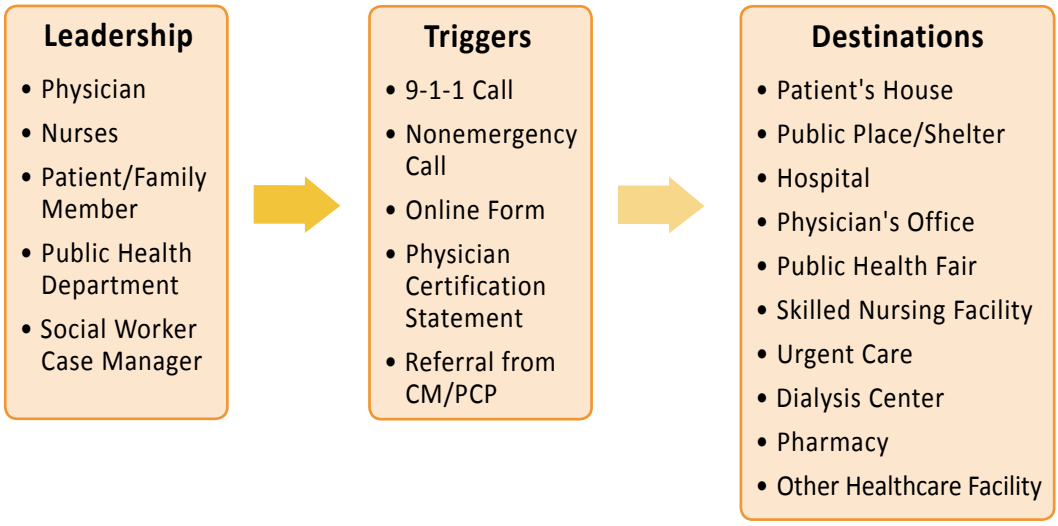
CP and MIH have the potential to revolutionize how patients receive healthcare services, especially among rural, elderly, and economically disadvantaged communities. Although they vary, these programs are on the rise in conjunction with a national shift to MIH.[37] At a 2012 conference focused on CP, attendees suggested several goals related to its growth, including: (a) expanding health practitioners' roles beyond their basic EMT or paramedic qualifications;[38] (b) integrating CP with other health service providers; (c) designing CP services to fill major gaps in healthcare; (d) sharing information for effective, coordinated patient care; and (e) utilizing enhanced technology.[39]

The MIH's potential for expanded access to essential health services and increased cost savings suggests that it may be a viable future for EMS personnel.[40] However, realizing this goal will mean overcoming some significant challenges, including perceived or actual issues of law and policy that may impinge the expansion of EMS into CP, MIH, and similar services. These issues and related options, practices, or solutions are the foci of this Report, beginning with the potential legal and policy concerns related to the triggers for the deployment and expanded use of EMS personnel discussed next in Part II.

II. Ready, Set, Go: Legal Issues Underlying Expanded EMS Activity Triggers

EMS personnel seeking to address specific health needs of patients and communities must be empowered to provide care through existing or emerging legal "triggers," or authorizations. For physicians or nurses working in hospitals or health clinics, a typical trigger for providing care to patients is often either (1) the appearance of a new patient seeking care, or (2) the request by existing patients for additional health services. However, EMS personnel traditionally do not wait for patients at a fixed location. Rather, they are dispatched to patients' locations, often because the patient may be experiencing an emergency condition requiring rapid, stabilizing care and transportation to a hospital ED or other urgent healthcare setting. As illustrated in **Figure 1**, potential trigger options may arise through various dispatches via multiple means of communication designed to authorize deployment of EMS personnel to different destinations.

FIGURE 1: Triggers for EMS Activities



To the extent that CP, MIH, or similar programs expand the role of paramedics and other EMS personnel to fill healthcare gaps,[41] triggers for their deployment are changing. In Eagle County, Colorado, for example, CP personnel are authorized to respond not only through 9-1-1 dispatches, but also through requests from:

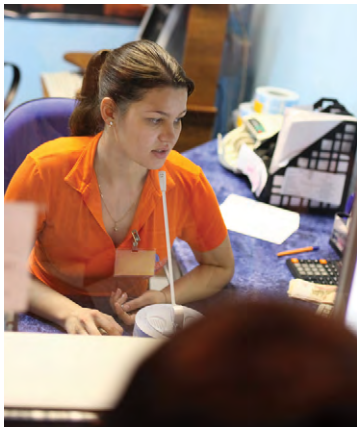
- Primary care providers seeking follow-up after a patient's recent appointment.
- State-based adult and child protection case workers who believe there is a known or potential unmet medical need in the home.
- Medical providers' orders as an alternative to a primary care provider conducting a medical, home-safety, or social assessment.[42]

There are additional triggers for these services. Localities recognize the overwhelming burden on the healthcare system of dispatching EMS resources via 9-1-1 to nonemergency callers. In 2008, 21 people in Fort Worth, Texas, called 9-1-1 at least twice per week. Together, they accounted for almost $1 million in ambulance charges.[43] The following year, Fort Worth's MIH program identified high-frequency users and developed individual care plans for them, including regularly scheduled

home visits by medical personnel. Since creating its "EMS Loyalty" program, Fort Worth is credited with saving more than $3.3 million in healthcare expenditures and reducing 9-1-1 calls from these patients by 86.2 percent.[44] Minnesota's CP program identifies patients in need prior to them arriving at the ED (e.g., via physician or clinic request).[45]

Local public health departments may ask EMS personnel to assist with community-based services (e.g., immunizations, disease investigations, blood draws, and fluoride varnish applications). Physicians' orders[46] can mobilize community paramedics to provide primary care services in a patient's home. While each visit necessitates a discrete order with physician instructions, these visits may be particularly beneficial for chronically ill patients who have difficulty getting to their medical providers' offices, frequently cancel their medical appointments, or require in-home monitoring following their recent hospitalizations.

Many ambulance companies use online request forms[47] or telephone numbers[48] for various providers, including physicians, nursing facilities, other healthcare providers, so patients or family members can request nonemergency transportation (e.g., from the patient's home to the physician's office, behavioral health office, urgent care, skilled nursing facility).[49] Determining who will pay for these services can be problematic, however. Medicare reimburses for nonemergency ambulance transport only when the patient's condition contraindicates another form of transportation because the patients is bed-confined or transport by ambulance is medically necessary.[50] Generally a physician certification statement completed by the patient's physician, stating that transportation is medically necessary, is required.[51] Allowing providers, patients, or family members to request medical assistance rather than mere transportation opens doors for EMS personnel to address multifarious, nonemergency situations. Yet, authorizing and establishing these varied triggers depends on law and policies across states.



AUTHORIZING AND ESTABLISHING PROTOCOLS

The authority to establish and use trigger protocols (i.e., policies and procedures relating to the dispatch of EMS or other CP/MIH personnel)[52] varies between state and local governments. Most existing trigger protocols determine how to prioritize emergency calls, what communication system should be used, what information EMS personnel should receive, and which ambulance supplier should be contacted.[53]

Programs in Texas and Las Vegas, for example, are working to establish trigger protocols designed specifically for CP/MIH programs, based in part on the model noted above in Eagle County, Colorado.[54]

Although the types of protocols often remain the same, such as which communication system should be used and what information the EMS provider should receive, protocol content differs.[55] For example, Eagle County's CP manual outlines the specific procedures for clinic referrals, county health department referrals, and home visits. [56]

Developing new trigger protocols involves multiple entities, including state or local health departments or boards of emergency health services, supervising physicians, ambulance suppliers, and hospitals. State laws often assign broad discretion to local boards,[57] medical directors,[58] and even hospitals and ambulance suppliers[59] to develop detailed protocols. Arizona's statute concerning ambulance services dictates, "In consultation with the medical director of the EMS and trauma system, the EMS council and the medical direction commission, the director of the department of health services shall establish protocols for ambulance services."[60]

Supervising physicians or medical directors may also provide specific guidance in advance of a patient visit.[61] Although physicians' directives typically occur during patient visits, as discussed further in Part III, their orders may also include pre-visit directives for the purposes of CP. Variations in authorities to create new protocols and resulting oversight can impact how well and efficiently CP, MIH, and similar programs are implemented.[62]

Some states offer legal exceptions to protocol enforcement. California statutory law allows flexibility in the scope of practice of EMS professionals in rural areas.[63] "In rural or remote areas … where patient transport times are particularly long and where local resources are inadequate to support an EMT-P program for EMS responses, the director [of the EMS authority] may approve additions to the scope of practice of EMT-IIs serving the local system."[64] Illinois allows its EMS director or the Illinois Department of Public Health director to waive any state law regarding EMS where compliance is a "hardship,"[65] pursuant to requests by EMTs, hospitals, or others.[66] Such flexibility can facilitate the local practice of EMS providers in ways that may otherwise violate state protocols. As discussed further in Part III, although such changes may facilitate expanded roles for EMS providers by enhancing authority related to scope of practice, they generally will not provide specific, independent authorization for CP, MIH, or similar programs.

Although many existing engagement and dispatch protocols still address only 9-1-1 EMS, establishing new protocols and policies at the state or local level can enable implementation of novel EMS programs in rural, urban, or suburban areas. Conversely, insufficient coordination of limited resources can delay the implementation of new protocols. In 2005, for example, the American Heart Association released new guidelines to improve results of out-of-hospital cardiac arrest events.[67] It took about 450 days on average for EMS agencies to implement these guidelines.[68] In a study done by U.S. and Canadian researchers of 34 EMS agencies, 38 percent of the agencies reported implementation delays because of inadequate supplies and decision making issues.[69] New trigger protocols can improve coordination of limited resources, provision of and payment for supplies, and provider selection.

TOPS #1

To the extent that existing trigger protocols in some states only address 9-1-1 EMS situations, state or local development of enhanced, flexible protocols under existing legal authority can provide oversight and address procedures such as clinic or health department referrals and home visits.

COORDINATING LIMITED RESOURCES

Provision and Payment. Operationalizing programs that expand the use of EMS requires the acquisition of, and payment for, essential resources through effective coordination among state and local officials, participating physicians, and the EMS agencies involved. To ensure the availability of these resources, EMS providers should consider which entity is responsible for their provision consistent with contractual or other legal authority.

Many ambulance services are provided directly via municipal fire departments (or other public entities) without the need for specific contracts. However, in some jurisdictions, the provision of supplies for EMS may be addressed via contracts between (1) localities (including fire districts) and their preferred ambulance suppliers and (2) ambulance suppliers and their associated hospitals.[70] In a typical contract for emergency services, the ambulance company must procure and track essential supplies.[71]

Contracts for nonemergency services such as community outreach, public access defibrillation programs, and other health improvement projects also typically assign responsibility of program coordination, including provision of supplies, to ambulance suppliers. Where these suppliers are hospital-owned, like the Jeff STAT ambulance services operated by the Thomas Jefferson University Hospitals in Pennsylvania, New Jersey, and Delaware,[72] the hospital may directly pay for the supplies. This contractual approach may work well for CP or MIH programs because hospitals directly experience cost savings.[73] However, it may also be problematic if patients are served through EMS personnel who are not affiliated with the contracted hospital.

Under another contractual model, localities and private ambulance suppliers share these programs' costs and profits. Still, conflicts may arise. For example, Marengo Memorial Hospital and Iowa County disagreed over who owned a majority share of their county ambulance service.[74] To avoid divisiveness, shared contracts must contain terms to equitably split costs and profits.[75] The locality may also pay for some programs, such as when EMS personnel administer vaccines at a community health fair. For example, the CP program in Wake County, North Carolina, offers both in-home services and community health fairs with direct support from the county.[76]

TOPS #2

To support efficient use of CP, MIH, or similar programs, public and private sector entities must equitably share costs for essential resources and benefits of core services through contractual terms that seek advance agreements on issues of allocation.

Limitations on Selection Among Competing Providers. Development of trigger protocols also raises issues of how providers are chosen. As with resources, local government decision makers, such as city councils and mayors, can choose the ambulance or other providers. If fire districts or departments do not provide EMS, these contracts may be exclusive, single-source agreements with private providers.[77]

Large, multi-million dollar county contracts with ambulance suppliers may lead to disputes.[78] Clackamas County, Oregon, awarded a $30 million ambulance contract to American Medical Response after having rejected it the previous month.[79] The county's approval came after American Medical Response threatened to sue on grounds that the county rejected the only contract in consideration.[80] Typically local government contractual decisions are upheld so long as they are not made in an arbitrary way. For example, a former Mississippi ambulance supplier in 2003 argued unsuccessfully that the county was bound to renew the contract so long as the ambulance company provided adequate services. [81]

Localities seeking to develop CP or MIH programs may have to determine whether they are contractually able to use different providers or must adhere to an existing contract. Contract negotiations between localities and providers may also be subject to state or local laws governing bidding processes among government contractors. In California, for example, each ambulance service area can establish an exclusive provider, but must follow a strict bidding system for selection to avoid antitrust issues[82] (except for providers acting in the same "manner and scope").[83] CP programs in such "grandfathered" areas may have to confine their services or engage in bidding processes.

Not all states place tight limitations on these contracts. In *Trans-Care, Inc. v. Board of Commissioners of the County of Vermilion*, in 2005, the Indiana Court of Appeals found that ambulance supplier contracts were not subject to the state's public purchasing statute because they were bids for personal services.[84] The court also held that the losing bidder could not legally contest the outcome of the bidding process, in part because public policy favors certainty in a contract concerning public safety.[85] Under similar legal guidance, localities may be better positioned to expand EMS of a current contracted ambulance service or opt for another provider. Even in jurisdictions that restrict ambulance suppliers, CP, MIH, or other similar programs may not be implicated if they do not offer emergency services or use ambulances.

TOPS #3

In localities limited in their ability to contract with ambulance or other providers because of strict state or local bidding requirements, exceptions for localities to enter into new or expanded contracts for these programs may be considered.

LIABILITY CONCERNING EMS RESPONSE

No matter how it is triggered, patients generally expect prompt assistance through EMS or CP. System failures related to inconsistent application, execution, or use of existing triggers may lead to patients bringing claims against responsible entities.[86] Patients or their families may argue that public or private entities are legally obligated to respond efficiently and professionally pursuant to triggers designed to mobilize personnel for persons in need.[87] Resulting liability claims may arise.

Whenever state or local governmental entities are directly involved in the administration of a CP, MIH, or a similar program, potential constitutional issues may arise. Patients may argue that failure to properly attend to persons seeking government-run EMS deprives patients of life or liberty interests in violation of constitutional principles of due process. However, the U.S. Supreme Court clarified in *DeShaney v. Winnebago County Department of Social Services* (1989) and subsequent cases that government is not required generally to provide citizens with protective services or aid.[88] Government's mere failure to assist or respond to individuals in need is not itself a constitutional violation.

In contrast, if government actors undertake steps to provide care for specific individuals, an affirmative duty to carry out these services may arise, leading to potential claims if services are performed negligently or the individual is within government's custody (e.g., a minor held via child protective services).[89] Whether an individual that requests a paramedic via a government-operated 9-1-1 system and relies on a response may be owed some "special duty" to assistance depends on the jurisdiction.[90] If EMS or CP services are determined via statute or regulation to benefit the entire community, courts tend to find they do not owe persons any special duties.[91]

For example, in the 1990 case *Johnson v. District of Columbia*, a woman called 9-1-1 and indicated that she needed an ambulance.[92] The dispatcher told her that an ambulance was coming. The woman suffered a heart attack, but no ambulance was sent. Still, the District of Columbia Court of Appeals determined that DC owed her no "special duty" because there was no (1) "specific undertaking to protect a particular individual," and (2) she was not entitled to rely on the service.[93] In such cases, government is effectively immune from liability based upon a failure to respond.[94] Parts III and IV discuss additional liability themes.

TOPS #4

To obviate potential liability for failures to properly operate or follow known triggers for EMS personnel, government must avoid creating a "special duty" to provide care for specific individuals. Programs seeking to reduce their potential liability may frame implementation in broad terms related to communal health benefits rather than specific health services for identified persons.

III. On Closer Inspection: The Changing Nature of Patient Assessment and Corresponding Legal Challenges

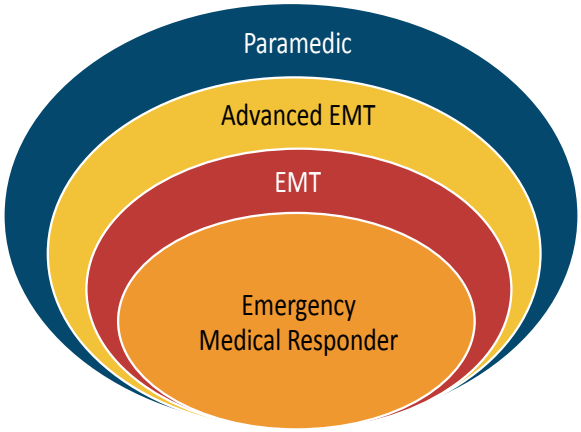
So long as EMS providers are responding to appropriate events via lawfully authorized triggers discussed in Part II, they may engage in a spectrum of routine and emergency patient assessment activities. Specific activities depend on the scope of practice associated with their professional designation and training, among other factors. Although many assessment activities translate readily to CP, expanding the role of existing EMS professionals presents potential legal impediments.

In addition to scope of practice limitations, EMS professionals may be restricted to practicing in certain locations (e.g., the scene of an emergency or in transit to a hospital) that might limit authority to engage in nonemergency care. Requirements that certain classes of healthcare professionals supervise EMS programs may pose practical and legal obstacles to broadening the community role of EMS. Potential civil liability may also increase as the roles of EMS professionals, supervisors, and entities expand through CP and MIH. Protecting patients' health information privacy throughout the delivery of nonemergency services in varied settings implicates additional law and policy concerns. Although these issues have the potential to impede expansion of EMS service, a bevy of legal options, practices, and solutions provide meaningful opportunities to address these concerns.

SCOPE OF PRACTICE FOR EMS PROFESSIONALS

Classifications. EMS personnel include a diverse range of professionals with specific training and education requirements, all of whom may play a potential role in CP and MIH. As illustrated in **Figure 2**, each professional classification also features a specific authorized scope of practice. EMS functions may be performed by individuals licensed or certified as emergency medical responders, EMT, advanced EMT, or paramedics, among other designations, each with broadly authorized scopes of practice.[95]

FIGURE 2: EMS Scopes of Practice



States vary in their approaches to distinguishing scope of practice between these classes of professionals, as per the examples in **Figure 3**. Florida recognizes two types of EMS personnel: (1) EMT and (2) paramedic.[96] Georgia statutes recognize three classes: (1) EMT; (2) paramedic; and (3) cardiac technician,[97] and state administrative regulations and guidance documents further distinguish EMT, EMT-intermediate, and advanced EMT licensure.[98] Idaho recognizes four classifications: (1) EMT; (2) advanced EMT; (3) emergency medical responder; and (4) paramedic.[99] Mississippi recognizes five classifications.[100] In each state, these classifications are associated with authorized scopes of practice.

FIGURE 3: Select State EMS Personnel Classification Examples

FLORIDA	GEORGIA	IDAHO	MISSISSIPPI
• Paramedic • EMT	• Paramedic • EMT • Cardiac Technician	• Paramedic • Advanced EMT • EMT • Emergency Medical Reponder	• EMT-Paramedic Critical Care • EMT-Paramedic • EMT-Intermediate • EMT-Basic • EMT Driver

Other healthcare professionals may also provide services as part of CP or MIH initiatives. These individuals (e.g., RNs, NPs, PAs, physicians, community health workers) also have specific scope of practice authorities and limitations with associated legal issues that may incorporate issues concerning EMS personnel. These professionals may also act in supervisory or delegating capacities with respect to EMS in some circumstances (e.g., when EMS responds to patients under the care of a home care nurse or referred by a NP with an independent practice), raising additional legal considerations underlying scope of practice, delegation authority, and liability.

Authorized Activities. Some basic patient assessment tasks may fall within the scope of practice for most, or all, classifications of EMS professionals. Other authorized patient assessment activities may "ramp up" with higher levels of training. For example, the NHTSA National EMS Scope of Practice Model recommends that all EMS professionals be allowed to perform manual blood pressure monitoring. However, it recommends that only advanced EMTs and paramedics perform blood glucose monitoring, and only paramedics perform electrocardiogram (EKG) interpretation or blood chemistry analysis.[101]

Utah has adopted NHTSA's education standards as the scope of practice for EMS professionals.[102] Idaho has considered NHTSA's model in developing and revising its scope of practice standards.[103] Some states (e.g., Georgia and California) authorize not only specific enumerated functions, but also broader activities ordered by a supervising physician and for which EMS professionals are properly trained to perform. Georgia specifically authorizes some categories of EMS professionals to perform:

- Comprehensive patient assessments.
- Taking and recording of vital signs.
- Basic and advanced airway management.
- Gastric decompression.
- Oxygen management via various devices.
- Management of soft tissue injuries and suspected fractures.
- Blood glucose monitoring.
- EKG initiation, monitoring, and interpretation.
- Blood sample collection.
- Medication administration.
- Prescription drug assistance.[104]

Georgia also authorizes paramedics to "perform any other procedures which they have been both trained and certified to perform" upon the order of a licensed physician.[105] California similarly

authorizes paramedics[106] and EMTs[107] to perform additional functions when appropriately trained and authorized by the relevant medical director. These "local optional scopes of practice" may support development of CP, MIH, or similar programs by circumventing limiting aspects of scope of practice statutes, but do not specifically authorize such programs. Moreover, any additions to scopes of practice require approval of the California's Emergency Medical Services Authority (EMSA), among others.[108]

In states that explicitly list authorized EMS patient assessment activities, practice may be limited to these activities. Expanding the role of EMS personnel may also be constrained by explicit scope of practice limitations premised on emergency- and transportation-oriented conceptions of EMS patient assessment. For example, in a state with an exclusive list of authorized activities (e.g., Oregon),[109] a less traditional activity for EMS (e.g., vaccination in public health context) may fall outside the authorized scope of practice. In contrast, in a state that more broadly authorizes properly trained EMS personnel to perform activities upon physician orders (e.g., Delaware, Georgia, and California),[110] the range of legally permissible activities may be more expansive, allowing maximum utilization of EMS personnel at various certification levels. Alternatively, each activity may need to be specifically authorized by law, such as North Dakota's statutory authorization for paramedics to provide flu vaccination to adult patients as part of established medical protocols if the paramedic has completed the applicable training course (*see* citation for specific statutory language).[111]

TOPS #5

Legal authority for EMS professionals to fully engage in activities like CP may be constrained by existing scope of practice limitations. Provisions authorizing ranges of activities, rather than specific and enumerated tasks, may facilitate an expansion of the traditional EMS role without altering legal scopes of practices.

Standard of Care. Issues concerning scope of practice differ from the legally required standard of care.[112] As noted above, scope of practice—generally derived from statutes and regulations—dictates the boundaries of allowable activities and services among EMS personnel based on their level of licensure, certification, and training. In contrast, standard of care refers to the legal standard used to evaluate whether a health professional has adequately and appropriately performed these duties. The applicable standard of care depends on the circumstances in which care is delivered, as determined by general practice within the profession and locale.

The legal standard of care for health professionals, including EMS personnel, will generally be that of a reasonable professional of the same classification operating in like circumstances. Education and training requirements (commonly at the state level and tied to licensure or certification) play a significant role in defining specific standards of care. For example, California paramedics have a legal duty to conform their actions to the learning, skills, and degree of care generally used by reputable paramedics in the same or a similar location and circumstances.[113] A California court in 1990 upheld a jury verdict against a paramedic who failed to perform an adequate examination because his conduct was "an extreme departure from the standard of care for a paramedic in such a situation."[114] The paramedic performed only a visual examination on a man who had been in a fight and was being detained by police. The man later died of complications from sickle cell crisis that would have been uncovered and corrected if appropriate tests were performed consistent with the expected standard of care for paramedics.[115]

High-level education and training programs, from local programs to potential national curricula and education standards, can improve patient care and help to define legal standards for EMS professionals. Expanded EMS functions may depend on additional, targeted training reflecting specific patient care goals.

Clinical Decision Making. Among the limitations imposed by scope of practice restrictions is the distinction between clinical decision-making authority granted to physicians and some other medical professionals, such as PAs and NPs, compared to EMS personnel. Although these personnel may evaluate a patient's symptoms and presentation, EMS patient assessment does not include providing a medical diagnosis, which focuses on the root causes of a patient's illness or disease.[116] Furthermore, EMS personnel are not authorized generally to prescribe medications, though they may administer them in some jurisdictions when prescribed by a physician.[117] Still, EMS personnel, particularly paramedics, develop and use significant clinical decision-making skills. This includes developing differential diagnoses, field diagnoses, or field impressions based on clinical presentation and assessment to make critical decisions regarding patient care and implement a patient management plan.[118]

EMS personnel will likely increasingly use these clinical decision making skills through CP, MIH, and similar programs, which necessitates clear guidance as to the proper role of EMS personnel to avoid conflict with state scope of practice restrictions. Although distinctions between clinical decision-making by EMS personnel and prohibited medical diagnosis may be subtle, they are legally significant. EMS practitioners with expanded roles, like other health professionals, must determine the immediate causes of a patient's current symptoms, including relevant medical history, and initiate appropriate responses.

Clinical decision-making in traditional roles of EMS personnel rarely conflicts with the legal prohibition against their rendering medical diagnosis because care is typically transferred to physicians or medical teams (e.g., upon arrival at an ED or shortly thereafter). Legal conflicts may increase, however, in the context of expanded EMS roles. These expanded functions may also raise liability concerns. More extensive patient medical history evaluations, additional types of available care, and greater opportunities for patient contact may find these personnel straddling the line between EMS and the practice of nursing or medicine, particularly when care is provided primarily by EMS personnel, such as during a follow-up visit after hospital discharge. Follow-up care, prescription assistance, and chronic disease management, among other services, may be seen as extensions of primary or specialist care, rather than independent care events, thus providing appropriate context for clinical decision-making as part of this practice.

TOPS #6

Adherence to appropriate decision making tools (e.g., protocols and standing orders), medical supervision, and consultation requirements mitigates the risk of overstepping clinical decision making authority. Viewing follow-up care and similar actions as a continuation of, or prelude to, care by other medical professionals reflects key legal distinctions between medical and field diagnoses.

Location Restrictions. Scopes of practice for EMS personnel may restrict not only the lawful types of activities, but also where such activities may take place. EMS personnel are generally authorized to assess and treat patients at the scene of an emergency, during patient transportation, or, in some jurisdictions, within a healthcare facility.[119] However, as further discussed in Part IV, some states may limit the circumstances in which EMS personnel may be deployed (e.g., responding to a medical emergency or transporting a patient to a hospital ED). These restrictions may also constrain EMS professionals' scopes of practice to only these circumstances, which may hamper anticipated broader settings for expanding EMS services.

For example, California EMTs are authorized to perform various functions only "[d]uring training, while at the scene of an emergency, during transport of the sick or injured, or during inter-facility transfer." [120] While patient assessment activities may be fully authorized in these settings, assessment at a patient's home or other locations for nonemergency purposes (e.g., oral health assessment, immunization, or post-discharge follow-up) may fall outside this authority. Other states (e.g., Idaho) more broadly authorize EMS personnel to provide services in various settings as part of documented and planned personnel and resource deployments.[121] A recent trend, especially in rural locations, also utilizes EMS personnel as team members within hospital EDs.[122]

Other laws may permit some patient assessment functions outside traditional EMS settings. Georgia authorizes EMS personnel to evaluate persons who present themselves with an "emergency condition,"[123] defined as "any medical condition of a recent onset and severity" that would lead a layperson to believe immediate medical care is necessary to protect against serious jeopardy to health, impairment of bodily functions, or serious dysfunction.[124] Similarly, Utah defines an "emergency medical condition" as one with symptoms, including pain, that are severe enough to lead a person to expect it would result in "placing the individual's health in serious jeopardy;" "serious impairment of bodily functions;" or "serious dysfunction of any bodily organ or part" absent immediate medical care.[125] Virginia defines "emergency medical services" as those in response "to an individual's perceived needs for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury."[126] Such provisions could facilitate assessment activities for conditions that are serious and sudden (but do not require hospital-based care) irrespective of where the assessment takes place, though other restrictions may apply.

Some states authorize EMS personnel to provide nonemergency care in some circumstances, but this may still be insufficient to enable the full range of activities contemplated in CP, MIH, or similar programs. For example, although Illinois authorizes EMS personnel to provide emergency and non-emergency services, it limits the definition of nonemergency services to care or monitoring "before or during transportation … to or from healthcare facilities."[127] Providing nonemergency care to patients who are not being transported to or from a healthcare facility may fall outside authorized EMS scope of practice in jurisdictions with similar definitions.

In contrast, other states explicitly allow EMS professionals to perform patient care and assessment functions in nonemergency and non-transportation-related circumstances. Florida permits properly trained paramedics and EMTs, as supervised by a medical director, to perform health promotion and wellness activities and blood pressure screenings in nonemergency situations. Paramedics can also immunize persons in nonemergency settings with county health department agreement.[128] These provisions encourage using EMS professionals in community healthcare.[129] Waivers and statutory flexibility in some other states may also further these expansions of the traditional role of EMS providers by authorizing location- or circumstance-dependent expansions of scope of practice.

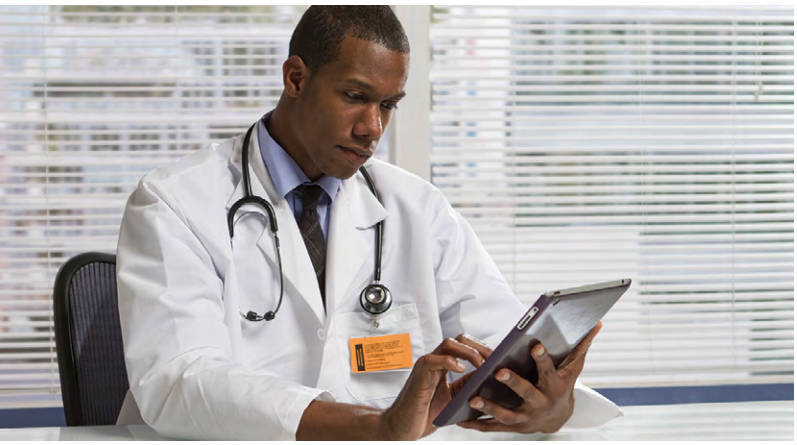
TOPS #7

Nonemergency care may exceed lawful scopes of practice for EMS professionals. However, broadly defined scope of practice provisions may readily allow such care. Even narrower constructions may permit such care consistent with additional statutory authorizations or favorable interpretations of laws defining "emergency condition" or similar terms.

Supervision Requirements. Supervision requirements may curtail EMS personnel's independent abilities to conduct patient assessment activities in some jurisdictions. For example, Delaware authorizes paramedics to provide services only (a) under the supervision of a physician; (b) with voice contact monitored by a physician via radio or telephone; (c) as authorized by a physician for advanced life support; or (d) when the life of a patient is in immediate danger and direct voice communication fails or is not possible.[130] In states with similar provisions, this would require paramedics operating in CP, MIH, or similar programs to be supervised directly or through radio or telephone contact with a physician, much as they do for emergency care. In many instances, supervision requirements can be accomplished in large part through use of decision-support tools (e.g., standing orders, protocols).[131] However, alterations to standard procedures or standing orders generally require direct orders from a supervising medical professional, such as an approved base station physician.[132] Although every patient encounter is potentially unique, expanded functions may entail increased direct, real-time guidance.

Some jurisdictions (e.g., Arizona[133] and Oregon[134]) authorize only physicians to supervise EMS personnel. Georgia requires each ambulance service to be supervised by a medical adviser, who must be a physician.[135] Physician availability may place practical limitations on the extent of services that can be offered. Georgia allows various other medical professionals, including nurses, paramedics, and PAs, to communicate with EMS personnel to relay authorization for specific medical services.[136] Arizona lets physicians providing online medical direction to relay guidance through other individuals, including PAs, nurse practitioners, RNs, paramedics, and EMT-intermediates.[137]

Other states (e.g., Illinois and Montana) authorize a more expansive array of health practitioners to provide supervision for EMS, including PAs[138] or qualified RNs.[139] Designees may also provide advice or orders, but this may be limited to pre-hospital or inter-facility transport circumstances.[140] Treatment activities that incorporate assessment components that diverge from established protocols or guidelines may still require physician authorization in many states. This could be problematic in rural areas where there are an inadequate number of physicians appropriately trained, available, and willing to undertake these supervisory roles.[141] In some jurisdictions, other practitioners, such as NPs, may be able to help address such gaps either directly or as an intermediary,



if legally permissible. Availability problems may be accentuated by potential need for multiple supervising practitioners with different specialties (e.g., primary care, specialty care, emergency care) to advise and supervise the full scope of clinical activities.[142] Emergency medicine physicians are authorized under their own scope of practice to provide guidance on a variety of medical issues, but they may not be ideally trained to respond to all the issues that may arise under CP, MIH, or similar programs. Models utilizing medical control hospitals, where feasible and appropriate, may help provide access to a wider variety of medical professionals.

Some states currently require physicians providing on-line medical direction for EMS to be emergency medicine specialists. For example, Arizona requires on-line physicians either to have emergency medicine certification, prior training in an emergency medicine residency program, or be currently practicing in emergency medicine.[143] Such limitations may exclude otherwise qualified individuals from providing on-line medical direction regarding relevant aspects of programs that expand the role of EMS providers.

Availability concerns of supervising practitioners can be mitigated through developing appropriate decision-support tools, including standing orders and treatment or triage protocols. These tools provide established training and guidance for engaging in specific patient assessment and care activities, and can allow EMS personnel to act without on-line medical direction.[144] Treatment protocols may be developed for precise functions (e.g., flu vaccination),[145] as well as broader disease evaluation and response (e.g., diabetes)[146] and specific populations (e.g., children with special healthcare needs).[147] Consistent with appropriate clinical decision making authority, treatment protocols and other decision-support tools allow physicians or other authorized health professionals to provide advance clinical guidance for patient assessment activities by EMS personnel, rather than requiring consultation for every step and component of clinical decision-making.

TOPS #8

Medical professional oversight and supervision are required for EMS activities, but may be limited by physician availability. Expanded use of appropriate decision-support tools and centralized on-line supervision models can increase the supervision potential of existing, available personnel, including non-physicians.

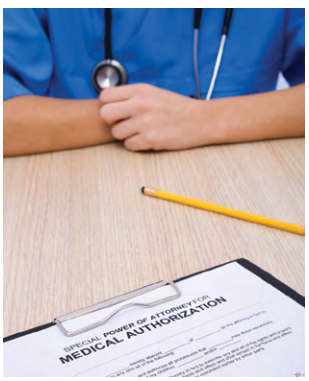
CIVIL LIABILITY AND AVAILABLE PROTECTIONS

EMS Personnel. Potential civil liability for EMS personnel engaged in CP or MIH activities may typically be grounded in claims of negligence, particularly malpractice. Negligence suits require a claimant to prove 4 elements: (1) a duty; (2) breach of that duty; (3) causation; and (4) damages. As discussed in Part II, a duty is generally established through the existence of some form of professional-patient relationship. A breach of that duty in the context of expanded EMS service may be shown if the practitioner's conduct did not meet the applicable professional standard of care. Causation and damages are established by proving that the failure to meet the standard of care caused or exacerbated a patient's injury.

Expanding the role of EMS personnel into new or emerging areas of patient assessment may escalate claims for malpractice if their actions fall below the required standard of care. For example, two Florida paramedics were found liable in a 1990 case for the death of a young child from congestive heart failure after they failed to transport her to a medical center following an inadequate examination and history without a physician consultation.[148] Proper training, physician consultation, and adherence to established protocols and other aspects of the standard of care will help insulate EMS personnel from liability in most circumstances. EMS personnel following an established protocol or standing order may be protected from liability in some jurisdictions,[149] provided they follow physician instructions[150] and their acts do not constitute "gross negligence" (involving a higher degree of carelessness than simple negligence) or intentional, "willful misconduct."[151]

EMS personnel may also be statutorily protected from liability in carrying out their duties at the scene of an emergency. For example, Illinois protects EMS personnel acting in the normal course of their duties unless their actions constitute willful and wanton misconduct (e.g., intentional harm or reckless disregard for safety).[152] Idaho protects EMS professionals from liability provided they do not behave recklessly or in a grossly negligent manner.[153] Georgia provides broad civil liability protection to persons licensed to provide ambulance service when rendering emergency care in good faith.[154] California provides similar protections for EMS personnel and several other professionals, such as police officers, who act in good faith and are not grossly negligent.[155] However, some states' statutory protections apply only to individuals who provide emergency services without compensation (e.g., Georgia),[156] which may severely limit their application to CP and MIH services. Administrative and transportation fees charged by government entities to defray a portion of costs for providing ambulance service may not be viewed as compensation,[157] but Medicaid reimbursement to contracted private ambulance service providers may, potentially rendering statutory protections inapplicable.[158]

These types of civil liability protections can also be limited to specific circumstances, such as the scene of an emergency or during patient transport. EMS personnel in Illinois receive protection for emergency and nonemergency services, but nonemergency services include only those before



or during patient transport to or from a healthcare facility.[159] California protects EMS personnel providing services at the scene of an emergency, during transport, or for activities to protect patient health and safety when in "imminent peril."[160]

In states that do not specifically immunize pre-hospital care providers, protections may still be available under Good Samaritan laws, which broadly protect persons who provide care at the scene of an emergency. Some states (e.g., Florida)[161] explicitly include medical professionals under their Good Samaritan laws. In other states courts may scrutinize claims that Good Samaritan statutes apply to those with a pre-existing duty to provide aid, such as EMS personnel.[162] Additionally, Good Samaritan statutes typically apply only to care provided at the scene of an emergency or emergency care generally,[163] but not apply to many EMS activities in the context of CP, MIH, or similar programs. For example, a Wisconsin court found in 2006 that Good Samaritan protections applied only to care provided before transfer to a hospital or other location was possible and did not apply to nonemergency care provided hours after an initial assessment and evaluation.[164] Although this case involved laypersons, this legal interpretation of a Good Samaritan statute could also apply to care provided by EMS personnel as part of these programs. Courts may look to the legislative purpose in enacting Good Samaritan protections to determine how broadly to apply such provisions.[165]

TOPS #9

In the face of potentially escalating liability claims, protections from ordinary negligence claims available to EMS personnel responding to an emergency may apply to other activities in select contexts. Proper training, medical consultation, and observance of protocols and standing orders are essential to ensure that EMS practitioners with expanded roles comply with established standards of care.

Supervising Professionals and Entities. In addition to direct liability risks for EMS personnel, supervising professionals, hospitals, and other entities may also face liability for actions or omissions by these personnel under their control or direction. For example, in 1990 a Florida regional medical center was held liable for the death of a 5-year-old child because it failed to properly supervise, train, and instruct paramedics involved in the patient's care.[166] Even when EMS professionals individually are protected from civil liability, their employers may not be. In 1983, a Massachusetts city was precluded from claiming immunity for the actions of EMTs it employed that improperly transported a patient to a private home rather than a hospital.[167] While alternative protections may be available for some governmental entities under principles of "sovereign immunity" that bar lawsuits directly against the state, these protections often do not apply to municipalities or private-sector employers.

Some states extend liability protections to medical professionals who advise EMS personnel. Georgia, for example, immunizes physicians acting as medical advisers to ambulance services unless their conduct constitutes willful and wanton negligence.[168] Montana protects physicians, PAs, and RNs from civil liability who provide on-line medical direction to EMS, but only if (a) they do so without compensation or for limited compensation, and (b) their instructions are consistent with established protocols.[169] Utah similarly protects uncompensated physicians, PAs, and RNs who provide oral or written instructions to EMS professionals.[170]

PROTECTING PATIENT HEALTH INFORMATION PRIVACY

Like most other health professionals, EMS personnel must protect the privacy of identifiable patient health information consistent with federal and state health information privacy laws. EMS providers with expanded roles may obtain and use more sensitive patient information than is common in emergency response activities. For example, a more extensive patient history may be obtained while providing follow-up care after a hospital stay, compared to a focus on immediate medical history in responding to a sudden onset of symptoms requiring transportation to an ED.[171] Similarly, these professionals may utilize more sensitive patient information in performing prescription drug compliance functions, compared to emergency-focused EMS.[172] Some states provide explicit privacy protections for medical records related to EMS care, in addition to other privacy protections in state and federal law. Arizona does not allow the release of any information from medical records "developed and kept by a pre-hospital component of the statewide trauma system" without written consent by the patient or the patient's representative unless other laws permit or require such disclosures.[173]

Federal and state health information privacy laws apply to a wide variety of healthcare providers, insurers, and others. The HIPAA Privacy Rule[174] generally prohibits individuals and entities from acquiring, using, or disclosing individually identifiable health information without written authorization by the patient or the patient's representative except in limited, specific circumstances. State privacy laws may provide additional protections or apply to broader classifications of professionals and entities.

These privacy laws allow for use and disclosure of health data in limited circumstances without patient authorization, including, among other purposes, to: (1) provide or coordinate treatment or seek reimbursement; (2) perform healthcare operations, including quality assessment and improvement activities, and (3) notify appropriate governmental and contracted private entities based on specific public health purposes (e.g., communicable disease surveillance).[175] Mandatory reporting requirements for communicable diseases or suspected child or elder abuse may obligate EMS practitioners to provide patient information to designated public health and legal authorities, regardless of whether they are operating in a traditional or expanded role.[176] For these and other specifically authorized uses and disclosures, patient authorization, consent, or notification are not legally required under federal law, though state laws may provide additional requirements and discussions with the patient may be preferable in practice.

Increased patient contact and interaction through programs that expand EMS providers' roles will likely increase the amount of protected health information that these personnel acquire while performing their duties. Expanded access and use of existing data for specific purposes (e.g., protecting vulnerable populations during emergencies) raise further privacy concerns.[177] To avoid potential breaches and resulting administrative sanctions or civil liabilities, these personnel should be trained and supervised in their access, use, and disclosure of such data as their roles expand. Among other benchmarks, HHS sees privacy training and appropriate written policies as hallmarks of a well-designed CP program.[178]

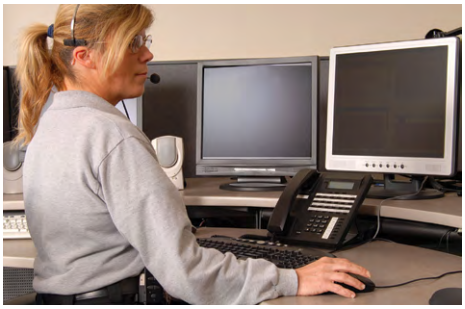
TOPS #10

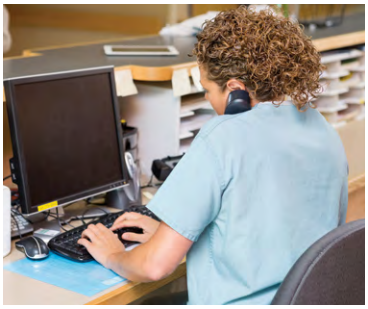
To deter potential health information privacy violations or infringements, CP, MIH, or similar programs may require training for key personnel on privacy protections and develop of formal, HIPAA-compliant written policies addressing permissible uses and disclosures of identifiable health data.

IV. Down the Road: Altering Patient Destinations

Assuming EMS personnel are lawfully triggered to respond and provide adequate patient assessment on the scene, they must then determine where to transport the patient when necessary. The typical destination for most patients following an interaction with EMTs or paramedics is the nearest hospital ED. However, in the context of CP, MIH, and similar programs, the ED may not be an appropriate or cost-effective facility to treat the patient, especially when all the patient needs is follow-up or other nonemergency medical care from the patient's primary care physician, urgent care clinic, or other source. This section focuses on issues of law and policy related to altering the patient's destination from the usual ED and acute care hospitals to other medical or care facilities.

As discussed in Part III, state statutes and regulations may limit EMS personnel's ability to practice outside of a pre-hospital setting, including requirements that patients be taken to the nearest ED. Absent statutory requirements, many states delegate the decision of patient destination to local trauma systems and designated medical control physicians, which often follow medical control protocols directing patient destination and care. Other legal obstacles arise from reimbursement structures. Possible EMTALA violations and other liability concerns may result in patients being funneled to hospitals rather than more appropriate facilities, hindering these expanded practices. Despite these legal hurdles, there are multiple options for programs to alter patient destinations.





LEGAL OPPORTUNITIES TO ALTER DESTINATIONS

Transporting patients to healthcare destinations other than EDs is legally supported in select ways. A few states, like Illinois, explicitly permit patients to be taken to alternate destinations, such as physicians' offices.[179] In some states, flexible legal provisions allow EMS personnel to take patients to the closest and most appropriate medical facility, whether it is an ED or a facility such as a behavioral health unit or urgent care. Additionally, a state's EMS structure may allow medical directors in charge of EMS personnel and ambulance services to establish written protocols directing patient care and destination as needed for the population, locality, and situation.

California's EMSA, noted in Part I, interprets its state's statutes to require EMS personnel to transport patients to a hospital with at least a basic ED[180] based on requirements to make available "advanced life support" [181] through EMS and delivery to an ED.[182] However, through its HWPP program, California has provisionally selected 13 CP pilot projects, four of which allow for patients' destinations to be altered.[183] Establishment of a HWPP allows for the temporary waiver[184] of health code sections that (a) limit destinations to which paramedics may transport patients, or (b) limit paramedics to providing services in emergency settings.

Arizona's director of health services, in conjunction with local EMS medical directors, can establish protocols allowing EMS personnel to transport patients without life-threatening conditions to the most appropriate healthcare institution based on patient choice and provider.[185] Healthcare institutions are defined broadly to incorporate "every place, institution, building or agency … that provides facilities with medical services, nursing services, health screening services, other health-related services, supervisory care services, personal care services or directed care services."[186] Consistent with this statutory allowance, the City of Mesa Fire Department has partnered with Mountain Vista Medical Center to create a PA Unit, which places PAs and NPs aboard smaller fire department units.[187] Not only can PAs and NPs prescribe drugs and suture small wounds, they can transport patients to numerous locations other than EDs, such as a behavioral health authority or a child's pediatrician, pursuant to statutory allowance.[188]

Delaware allows EMS personnel to take patients to locations other than EDs by defining "pre-hospital care" to include emergency medical care prior and during transport to hospitals and other facilities.[189] Similarly, Oregon allows EMS personnel and medical directors'[190] discretion to determine where to transport a patient.[191] Regulations setting the standards for area trauma system plans require EMTs and paramedics to follow the flowchart,[192] "Guidelines for Field Triage of Injured Patients,"[193] indicating when a patient must be taken to a level I or II trauma hospital (usually under clear emergency circumstances).[194] Otherwise, state or local medical control protocols, which set forth guidelines suggesting appropriate locations for patients based upon their present condition, are used to assess where patients are transported.[195]

TOPS #11

CP, MIH, or similar programs that do not explicitly authorize alternative destinations for patients may rely on broad and flexible statutes and regulations allowing sufficient discretion to alter destinations through protocols and supporting flowcharts. Waivers may also permit pilot programs to transport patients to alternative destinations.

LEGAL MANDATES TO TRANSPORT PATIENTS TO EDS

Although programs that expand the role of EMS providers could be instituted in many states based on explicit or interpretative authority, some states' laws may still require patient transport to an approved ED. In addition, licensing standards may dictate how patients are cared for, including where they must be transported.

Regulatory restraints in Massachusetts, for example, may forbid alternate destinations. Massachusetts' definition of "emergency medical services" appears to allow alternate destinations by defining these services to include pre-hospital assessment and treatment during transport to appropriate health-care facilities.[196] However, the state's Department of Public Health limits "appropriate healthcare facility" to an ED that is located within an acute care hospital or an approved satellite emergency facility.[197] For programs in Massachusetts to alter patient destinations, the department would likely have to amend this regulatory definition to include other healthcare facilities.

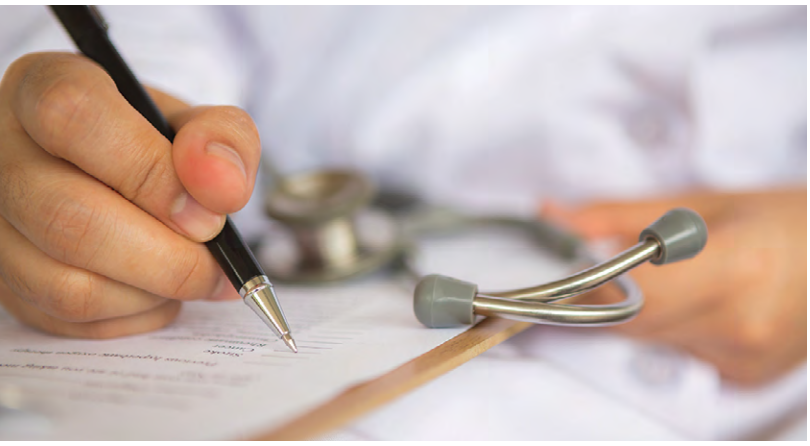
Licensing Requirements. Licensing requirements may present other obstacles, requiring patients to be taken to acute care facilities or permitting ambulance licensure only when deemed necessary. For example, a city ordinance in Independence, Missouri, only allows ambulance licenses to be issued when "public convenience and necessity require the proposed ambulance service."[198]

In 1997, Lifeguard Medical Services, a licensed emergency ambulance supplier in Missouri, applied for a license in Independence to provide nonemergency transport in the city.[199] Independence's health director denied the license on the basis that the service would not provide emergency care, and was thus unnecessary.[200] When challenged, a local court found that the city's health director was empowered to determine necessity in the jurisdiction and upheld the decision to deny the license for nonemergency transport.[201]

TOPS #12

EMS licensing requirements based on necessity can limit opportunities to alter destination for patients in CP or similar programs. State and local officials with discretionary authority to approve ambulance licensure may interpret respective regulations to include such programs, particularly those including nonemergency transport.

Contracts. As discussed in Part II, most EMS response and transport is delivered by local fire departments or public third-service agencies. Some localities, however, require contracts, memoranda of understanding, and prior approval between the municipalities and private EMS providers within their boundaries.[202] These agreements may restrict the types of healthcare facilities where patients may be taken.[203] Contracts between cities, hospitals, and ambulance services may limit patient destinations to previously contracted facilities. For example, Jersey City Medical Center (JCMC) has exclusively held the ambulance contract with Jersey City, New Jersey. Allegations that JCMC diverts patients to its own hospital chain against patient wishes based on internal policies led the city to consider offering contracts to new ambulance services.[204]



Hospitals may also contract with specific ambulance suppliers for nonemergency transport when a patient needs to be taken to a different facility.[205] A patient may prefer a specific provider. Patient choice may be a legally-recognized factor in selecting transportation for medical services, but it is not always determinative.[206] Fresno County, California, has a Hospital Diversion of Ambulance Patients policy that allows the patient to "refuse to be diverted to a facility that is not their primary choice. The ambulance crew will explain to the patient the reason for diversion. If the patient continues to refuse to be diverted, the ambulance crew will consult with the base hospital, have the patient sign a Refusal of Medical Care and Transport … form, [and] transport the patient to the hospital of patients choice (unless the facility is on General Diversion)."[207]

REIMBURSEMENT HINGED ON EMERGENCY MEDICAL CARE

While programs that expand the roles of EMS providers may improve access to healthcare and reduce overall costs, funding models for these programs can be problematic.[208] Many existing projects may not be reimbursed through private health plans or public insurance options like Medicaid or Medicare.[209] Instead they rely on external grants or other funding, leading to budget shortfalls. At the nexus of this funding dilemma are existing EMS reimbursement models that hinge on only paying for limited and essential emergency care. These approaches do not consider care by EMS personnel in settings outside the typical 9-1-1 response and emergency transportation framework as reimbursable.[210]

Public Insurance. Currently, CMS covers ambulance services through Medicare when an emergency exists or other transportation would be detrimental to the patient's health.[211] However, only certain destinations are reimbursed. Medicare covers ambulance transport to the nearest appropriate facility to obtain diagnostic or therapeutic services, as well as return transport under certain circumstances.[212] However, it only allows ambulance transport for emergencies and only to hospitals, critical access hospitals, skilled nursing facilities, the patient's home, and dialysis centers.[213] CMS specifically states that a "physician's office is *not* a covered destination."[214] Other possible destinations, such as behavioral health facilities or urgent care clinics, are not covered.

State Medicaid reimbursements for CP, MIH, or similar services vary, but tend to be limited. In 2012, Minnesota adjusted its Medicaid reimbursement policies to include CP programs that were legislatively authorized the year prior.[215] However, its coverage is limited to a set group of recipients that are known "common users" of EDs, identified as an individual (a) who has received ED services at least three times in a period of four consecutive months in the last year, or (b) whose primary care provider has determined that CP services would likely prevent admission or readmission to a hospital or skilled nursing facility, or allow discharge.[216]

TOPS #13

To address budget crises that limit expanding the use of EMS providers, states may consider authorizing reimbursement for patient transport and EMS services through Medicaid programs beyond cases involving transportation to EDs or acute care centers.

Private Insurance and ACA. ACA's healthcare reforms may change how CP or similar services are delivered and reimbursed, specifically through provisions governing EHBs and promoting ACOs. Pursuant to ACA, HHS set forth its list of 10 EHBs, establishing categories of healthcare services that must be covered by health plans sold on the individual and small group market (*see* Figure 4).[217]

FIGURE 4:

Ten Essential Health Benefits[218]

CMS issued final rules specifying the EHB Benchmark and setting a minimum standard each plan must meet.[219] The exact benefits of plans differ across states, but essentially cover the same services,[220] including EMS.[221] What may vary significantly is the number of services (e.g., the number of office visits per year) that plans must cover, or who can provide the care (e.g., allowing only RNs from a licensed home health agency to make home visits).

Covered EMS are generally limited to actual emergency care, ED services, and transportation by ambulance to an ED during an emergency and nonemergency transport when medically required. For example, California's EHB benchmark limits "emergency transport/ambulance" to instances where an individual reasonably believes a medical condition "requires ambulance services" or the treating physician determines the patient "must be transported to another facility because [the patient's] condition is not stabilized and services are not available."[222] Although most EHBs require plan coverage of ambulance transport only in emergencies or when medically necessary, covered alternate destinations could include skilled nursing facilities, urgent care clinics, and behavioral health facilities.[223] EHBs may not include actual EMS care and transport, coverage of the patients' medical services upon arrival at other facilities may enhance the development of CP, MIH, and similar programs.

Additionally, EHBs merely set a floor for health insurance plans. States' EHB plans may extend coverage to EMS care. In Oregon, home health services are limited to services provided by RNs, LPNs, specific therapists, and social workers provided by licensed home healthcare agencies. Preventative care is limited to a routine physical once every year for those older than 60 years old or once every few years for those under 60.[224] CP, MIH, or similar programs serving patients covered under plans ruled by the EHBs in Oregon could not be reimbursed for programs utilizing preventative care screenings or home visits. Arizona limits the number of home healthcare service visits per year, but does not require the visits to be provided by a licensed home healthcare agency or specific types of health practitioners. Additionally, it allows coverage of only one physical and preventative care screening per year for adults.[225] In contrast, Colorado allows broader and more flexible reimbursements, eliminating many restrictions that would bar these programs from being reimbursed for preventative home healthcare.[226]

TOPS #14

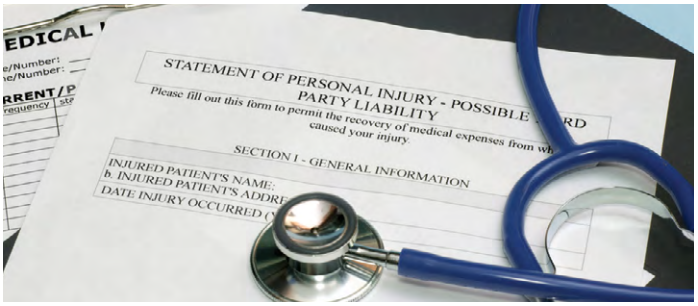
To expand funding of CP, MIH, and similar projects through private health insurance, states may amend their benchmark plans to cover services including home health services, preventative care, and emergency services.

Role of Accountable Care Organizations (ACOs). ACA support for developing ACOs may incentivize hospitals and other clinic partnerships to support an expanded role for EMS. ACOs entail collaboration among doctors, hospitals, and other providers to coordinate care to Medicare patients as a means to lower their overall per patient costs, leading to financial incentives.[227] Abandoning the typical fee-for-service model, CMS pays approved ACOs a flat rate for providing care to a certain group of Medicare beneficiaries, rather than reimburse for each service provided,[228] and will not reimburse for patient readmissions within 30-days for the same medical condition.[229] Because ACOs are not paid by CMS each time a patient enters the ED, they may seek to partner with EMS providers

focused on efficient and cost effective healthcare outside of the ED when medically appropriate. Fort Worth's Medstar partners with a local ACO to provide overnight at-home visits to patients in-home who otherwise would require all-day observation in the hospital.[230]

LIABILITY RELATED TO TRANSPORTATION AND DESTINATION

As discussed in Parts II and III, EMS personnel and supervisors may be subject to many liability claims, but they can also be insulated from liability through various laws.[231] To the extent that these programs allow employees to set new destinations for patients beyond the ED and acute care settings, additional liability avenues may arise for EMS personnel, their medical directors, ambulance suppliers, and the healthcare institutions treating these patients.



The Emergency Medical Treatment and Labor Act (EMTALA). EMTALA[232] is a federal law designed to curb patient-dumping practices concerning under- or uninsured patients with emergency conditions, largely at Medicare-participating hospitals operating EDs.[233] Generally, EMTALA is invoked when a patient with an emergency condition, including active labor, comes to the ED and requests treatment.[234] EMTALA may apply beyond a traditional ED and include urgent care clinics, labor and delivery departments, and psychiatric departments, depending on the number of unscheduled emergency patients seen in the department.[235] In such cases, patients cannot be turned away, but rather must (1) be screened to determine if an emergency condition exists, and (2) if so, stabilized on site or transported to another facility that is willing and able to provide care with patient authorization.[236]

EMTALA's essential purposes may be thwarted through CP, MIH, or similar programs if patients with emergency conditions are improperly transported directly to other healthcare facilities (e.g., an outpatient center) that may refuse patients' admission because these entities are not covered by the act. Although this potential exists, there are safeguards to avoid it.

First, EMTALA's application is not limited solely to patients on participating hospital grounds. It also extends to hospital-owned ambulances. If a hospital ambulance engaged in CP, MIH, or similar activities receives a patient with an emergency condition, EMTALA prohibits the ambulance from dropping off the patient anywhere other than the hospital ED[237] absent patient authorization,[238] though there is an exception when participating in local EMS protocols.[239] In addition, EMTALA may apply to hospital-owned urgent care clinics that use the same Medicare billing number as the qualifying hospital.[240] These clinics are similarly required to screen and stabilize patients if transported to the site. Finally, most EMS personnel are attuned to the need to transport emergency patients to hospital EDs consistent with heir existing training and protocols.

TOPS #15

To avoid potential EMTALA infractions, protocols determining patient destinations should clearly designate hospital EDs as the primary destination for any patient with a known or suspected emergency condition. Procedures should also require a patient's written informed consent (where possible) if the patient refuses emergency transport where possible.

Patient Abandonment. Patient abandonment concerns may arise if healthcare personnel terminate an existing, legally-recognized relationship with a patient without the patient's consent at an unreasonable time or without the patient having a sufficient opportunity to procure alternative care.[241] If the abandonment leads to direct harms to the patient, liability may flow. Although cases of patient abandonment are rare, the threat of liability is genuine. In the 1984 case *McCluskey v. United States*, an EMS practitioner left a patient unattended in a hospital lobby following a patient transfer without notifying the hospital of the patient's presence or condition, and the patient died.[242] The court found that the EMS provider and ambulance supplier were liable for abandoning the patient, leading to the patient's death.[243] In this case, the abandonment claim arose from leaving the individual without properly turning over care to the hospital staff. To obviate claims of patient abandonment when EMS personnel transport patients to hospital ED staff, EMS practitioners follow specific protocols.[244] The crux of these policies is that EMS personnel may not leave a patient until the receiving facility's staff (who are comparably trained, certified, and licensed)[245] are briefed on the patient's condition and assume care for the patient.[246]

Abandonment may also occur if a patient requiring advanced life support is transferred to a facility incapable of providing the necessary medical care.[247] In most 9-1-1 emergencies, hospital staff members know in advance when a patient is en route and the patient's condition. However, through CP, MIH, and similar programs, patients may be taken to different medical facilities (e.g., pediatrician's office) that do not usually interact with EMS personnel and are not subject to EMTALA, increasing the chance of inefficient or unsuccessful patient transfers and potential claims of abandonment. Newly-enacted regulations in Arizona require patients transported by EMS to healthcare facilities other than hospitals to first notify the institution of the intent to transport the patient and receive confirmation that the facility is willing to take the patient.[248]

Other issues of patient abandonment surface when a patient refuses medical treatment or transfer to an appropriate medical facility. In such cases, some EMS agencies require their personnel to contact medical control to determine whether the patient is sufficiently positioned to refuse treatment (e.g., competent adult compared to a minor in an emergency condition).[249] States like Louisiana statutorily endow residents with a right to refuse medical care and transport.[250] Massachusetts extends a right to refuse emergency medical care (though not absolute) based on court decisions and constitutional rights to privacy.[251] To combat issues arising from lack of consent, California pilot CP programs plan to institute a number of protocols and require specific CP consent forms. CP personnel will inform the patient of the program and what it entails. If the patient refuses treatment, CP personnel may immediately transport the patient to the nearest ED. In addition, policies will require patients who lack capacity to consent (e.g., inebriation, mental disability, minors) to be treated according to local EMS rules and regulations.[252]

TOPS #16

To avoid liability for patient abandonment, CP, MIH, and similar programs should ensure adequate communication with appropriate healthcare facilities and patient monitoring by personnel present during medical care and transfer. These programs may also establish written policies regarding patient refusal and accompanying patient rights, as well as patient consent procedures for enrollment and mutually-agreed-upon outcomes.

False Imprisonment/Inappropriate Medical Facility. Although rare, a patient may legally claim that he or she was falsely imprisoned by EMS personnel if forcibly held or transported to a destination without consent, especially if he or she lacks capacity due to age, homelessness, mental or developmental disabilities, or emotional distress.[253] For example, CP, MIH, and similar programs may involve EMS personnel transporting patients with mental health conditions to behavioral health facilities.[254] Following established protocols and emergency treatment and hold procedures, as applicable, can insulate EMS providers from resulting claims of liability.[255]

Sometimes patient choice can be at odds with the patient's well-being, financial interests, and EMS providers' liability. [256] In one case from 1991, a father sued following his son's death after the son was transported to a level II (rather than level I) trauma center based on the son's wishes, but contrary to EMS protocols given the son's condition.[257] The court agreed with the hospital and EMS service that applicable protocols require following a patient's wishes regarding hospital choice so long as the patient is capable of making a decision. In this case, the patient had the capacity to choose which hospital the ambulance took him.[258] Accordingly, some states and many EMS providers encourage EMTs and paramedics to transport patients to a hospital of the patient's choice, unless inappropriate or unreasonable based on the hospital's location or patient's condition.[259] In Arizona, for example, when the patient's condition does not "pose a threat to life or limb," factors to consider in determining destination include "patient choice, the patient's healthcare provider, specialized healthcare facilities, and local protocols."[260]

TOPS #17

False imprisonment and related claims can arise if patients are forcibly held or transported to locations without the patients' valid consent. Programs that use EMS providers in expanded roles should abide by patient choice regarding destination whenever possible. State "emergency hold" procedures for appropriate mental health patients should be relied on where applicable.

In Transit. Negligent operation of ambulance or other emergency vehicles presents potential liabilities for EMS personnel and their companies.[261] Many states' laws allow emergency vehicles to obviate common traffic laws, but do not fully insulate them from all liability when no intentional incidents lead to patient injuries.[262] New York, for example, allows emergency vehicles to exceed speed limits and proceed through red lights while responding to emergencies, but does not relieve the duty to "drive with due regard for the safety of all person nor … from the consequences of [one's] reckless disregard for the safety of others."[263] California similarly provides EMS personnel with

exemptions to standard traffic laws and immunity protections, but only while responding to emergencies calls and situations.[264] Most jurisdictions apply immunity provisions only to designated emergency response vehicles (generally those with lights and sirens) during emergency response or transport, which would exclude most CP, MIH, or similar programs.

However, liability protections can extend to non-emergency transport in some states. Illinois law states that "any person … licensed or authorized who in good faith provides emergency or non-emergency medical services during a department-approved training course, in the normal course of conducting their duties, or in an emergency shall not be civilly liable as a result of their acts or omissions."[265] The Illinois Appellate Court has upheld this provision to apply to a patient's nonemergency transport to a nursing care facility.[266] This may extend immunity related to patient transport to these programs.

To the extent that programs using EMS providers in nontraditional ways increase transportation of patients to varied destinations, liability related to their transportation in ambulances or other vehicles may increase. A survey of EMS practitioners yielded that existing CP and MIH programs utilize a number of types of vehicles, including ambulances (65%), fire trucks (17%), SUVs (51%), cars (18%), and other response vehicles.[267] Use of nontraditional vehicles for emergency transport may heighten liability risks due to substandard restraint mechanisms for patients as compared to ambulances. Vehicular insurance policies can adequately protect personnel and their companies from personal liability, although the costs of these policies will likely rise.

TOPS #18

Liability protections stemming from vehicular transport of patients outside of an emergency setting are limited. States seeking to increase the use of EMS providers in expanded roles may consider extending immunity laws to nonemergency care consistent with a careful balancing of patient and community safety.

Medical Directors. Potential liability risks confront not only EMS personnel, but also medical directors, ambulance suppliers, and healthcare entities. Because most states' laws require a medical director to supervise EMTs and paramedics, resulting liability of these personnel may potentially extend to their director through vicarious liability. Vicarious liability states that a supervisor can be held liable for the actions of subordinates based largely on supervisory failures or negligence.

Extending liability for EMS personnel to medical directors depends, in part, on whether such personnel practice under the director's license. A common misconception in the EMS field is that EMTs and paramedics work under the medical director's license, which would make the medical director directly liable for EMS personnel's acts and omissions.[268] Generally, EMS personnel operate under their own state-authorized, limited licenses or certifications (e.g., Illinois).[269] In Texas, however, EMS personal actually practice under the medical director's license.[270]

Although successful lawsuits are few, online physicians and EMS medical directors can be liable to patients for giving inappropriate medical orders, failing to properly supervise, or because EMS personnel act negligently.[271] In *Estate of Stephanie Stephens v. Geoffrey Mount-Varner, MD,* an injured patient's estate alleged that the medical director of EMS personnel who provided her emergency care was liable for the wrongful acts of the personnel.[272] The claim was based on a DC Official Code section stating that the provision of pre-hospital care is under the license of the medical director.[273] However, the code clarifies that the director is not personally liable for the results of the medical direction of EMS personnel unless the director acts with willful misconduct or gross negligence.

Some states provide additional liability protections for any physician providing on-line medical control. Massachusetts extends liability protections for good faith acts and omissions to any physician providing on-line medical control in the course of EMS oversight.[274]

TOPS #19

Medical directors should adequately supervise EMS practitioners operating in CP, MIH, or similar programs and set protocols that fully and properly direct patients to appropriate medical facilities. Use of approved, vetted flow charts, or other tools may help insulate against claims of negligence in the transportation of emergency patients, while still allowing flexibility to alter destinations as needed.

Conclusion

CP, MIH, and similar programs have the potential to bridge gaps between emergency medical services and primary care by utilizing existing EMS and other health personnel to increase patient access to care, lower healthcare costs, and improve health outcomes. Although programs that expand the role of EMS providers have clear benefits, there are multiple legal and policy hurdles stemming from the deployment and use of EMS and other personnel outside the normal emergency framework.

Statutory or regulatory constraints may limit the triggers for EMS personnel to known emergencies through 9-1-1 calls. They may be permitted to provide care and transport only under emergency conditions due to scope of practice limitations. Risks of liability may hinder active CP, MIH, or similar program participation among personnel, medical directors, and healthcare entities. Liability protections usually afforded to EMS and associated professionals generally apply only in emergency situations, leaving aside services provided by EMS personnel outside typical emergency responses. Healthcare reimbursement schemes may not include CP services causing programs to rely on grants or other resources. Restrictions on when and where patients may be transported to alternate destinations can thwart these programs.

Against these and other legal challenges, federal, state, and local governments, in partnership with private sector entities and stakeholders, are crafting meaningful options, best practices, and solutions. States are amending or waiving laws that prohibit or hinder these practices. Some jurisdictions are specifically authorizing CP reimbursement through pilot programs or Medicaid coverage. ACA provides new avenues for reimbursement and encourages hospitals and ACOs to establish cost-saving programs consistent with CP, MIH, and similar programs. Rapid and extensive development of these programs is contingent on successful navigation and resolution of key law and policy issues among partners within and across jurisdictions.

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[105] Ga. Code Ann. § 31-11-54(a).

[106] Cal. Code Regs. tit. 22, § 100146(c) (2) (A); Cal. Health & Safety Code § 1797.172.

[107] Cal. Health & Safety Code § 1797.171.

[108] Cal. Code Regs. tit. 22, § 100146(c) (2).

[109] *See generally* Or. Admin. R. 847-035-0030 (listing authorized scope of practices for various categories of EMS personnel); *see also* Or. Admin. R. 847-035-0030(2) ("The scope of practice is the maximum functions which may be assigned to an emergency medical services provider by a Board-approved supervising physician.")

[110] Del. Code Ann. tit. 16, § 9807 (authorizing "such services as are set forth in the paramedic's certificate if … provided under the supervision of a physician.")

[111] N.D. Cent. Code § 23-27-04.9(1) ("A licensed emergency medical technician-paramedic working for a hospital or an emergency medical services operation may administer the influenza vaccine to an individual who is at least eighteen years of age if: a. The physician providing oversight for the emergency medical services operation or the hospital medical director has established protocols that meet department standards that may be based on the advisory committee on immunization practices of the federal centers for disease control and prevention; and b. The emergency medical technician-paramedic has satisfactorily completed a department-approved course on administering vaccines.")

[112] *See, e.g.,* Nat'l Highway Traffic Safety Admin., National EMS Scope of Practice Model 15 (2007), *available at* http://www.ems.gov/education/EMSScope.pdf. (distinguishing elements of scope of practice from those of standard of care).

[113] Cal. Civ. Prac. Torts § 32:39, Medical Malpractice (citing Wright v. City of Los Angeles, 219 Cal. App. 3d 318 (Cal. Dist. Ct. App. 1990).

[114] Wright v. City of Los Angeles, 219 Cal. App. 3d 318, 347–48 (Cal. Dist. Ct. App. 1990).

[115] *Id*.

[116] Or. Rev. Stat. Ann. § 682.025(3).

[117] *Id.* § 682.025(3), 682.025(8).

[118] Nat'l Highway Traffic Safety Admin., National EMS Core Content, App. 4: Out-of-hospital/EMS Task Definitions/ Elements 31 (2005), *available at* http://www.ems.gov/education/EMSCoreContent.pdf; [2 Patient Assessment]; Bryan E. Bledsoe, Robert S. Porter & Richard A. Cherry, Paramedic Care: Principles & Practice 239 (2d ed. 2005).

[119] 210 Ill. Comp. Stat. 50/3.55.

[120] Cal. Code Regs. tit. 22, §§ 100063, 100146(c).

[121] Idaho Admin. Code r. 16.02.02.100.

[122] *See* Nat'l Highway Traffic Safety Admin., National EMS Scope of Practice Model 18 (2007), *available at* http://www.ems.gov/education/EMSScope.pdf; Ryan Oglesby, *Recruitment and Retention Benefits of EMT-Paramedic Utilization During ED Nursing Shortages*, 33 J. Emergency Nursing 21 (2007).

[123] Ga. Code Ann. § 31-11-82(a).

[124] Ga. Code Ann. § 31-11-81(1).

[125] Utah Code Ann. § 26-8a-102.

[126] 12 Va. Admin. Code § 5-31-10.

[127] 210 Ill. Comp. Stat. 50/3.10(g).

[128] Fla. Stat. § 401.272.

[129] Fla. Stat. § 401.272(1).

[130] Del. Code Ann. tit. 16, § 9807.

[131] *See, e.g.*, Del. Office of Emergency Med. Servs., Statewide Standard Treatment Protocol Delaware: Basic Life Support Protocols, Guidelines and Standing Orders for Prehospital and Interfacility Patients (2013), *available at* http://statefireschool.delaware.gov/pdfs/BLSStandingOrders2013.pdf (last visited May 23, 2014).

[132] *Id.* at 2.

[133] Ariz. Rev. Stat. Ann. § 36-2201(1).

[134] Or. Rev. Stat. Ann. § 682.245.

[135] Ga. Code Ann. § 31-11-50(a).

[136] Ga. Code Ann. § 31-11-60.1 (b).

[137] Ariz. Admin. Code § R9-25-205(D).

[138] Mont. Code Ann. § 50-6-302(8)–(9).

[139] 210 Ill. Comp. Stat. 50/3.10 (allowing Emergency Communications RNs to provide verbal authorization for various types of EMS).

[140] Mont. Code Ann. § 50-6-302(9).

[141] *See, e.g.*, Joint Comm. on Rural Emergency Care, Nat'l Ass'n of State Emergency Med. Servs. Officials & Nat'l Org. of State Offices of Rural Health, State Perspectives Discussion Paper on Development of Community Paramedic Program 8 (2010), *available at* https://www.nasemso.org/Projects/RuralEMS/documents/CPDiscussionPaper.pdf.

[142] *See* Kenneth W. Kizer, Karen Shore & Aimee Moulin, Community Paramedicine: A Promising Model for Integrating Emergency and Primary Care, UC Davis, Inst. for Population Health Improvement 12–13 (2013), *available at* https://www.nasemso.org/Projects/RuralEMS/documents/IPHI_CommunityParamedicineReport_Final-070913.pdf.

[143] Ariz. Admin. Code § R9-25-205(A).

[144] *See, e.g.,* Ariz. Admin. Code §§ R9-25-101(66) ("'Standing order' means a treatment protocol or triage protocol that authorizes an EMT to act without online medical direction."), R9-25-101(70) ('Treatment protocol' means a written guideline that prescribes … [h]ow an EMT shall perform a medical treatment on a patient or administer an agent to a patient; and …[w]hen online medical direction is required, if the protocol is not a standing order."); R9-25-101(71) ('Triage protocol' means a written guideline that prescribes … [h]ow an EMT shall … [a]ssess and prioritize the medical condition of a patient[; s]elect a health care institution to which a patient may be transported, and … [t]ransport a patient to a health care institution; and … [w]hen online medical direction is required, if the protocol is not a standing order.").

[145] N.D. Cent. Code § 23-27-04.9.

[146] Or. Health Auth. – Pub. Health Div., Training Protocol: Emergency Glucagon Providers (2013), *available at* https://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Diabetes/Documents/Glucagon_Training_Protocol_Manual.pdf.

[147] *See Emergency Medical Services for Children*, Health Res. & Servs. Admin., http://mchb.hrsa.gov/programs/emergencymedical/ (last visited May 22, 2014); *EMS for Children*, D.C. Dep't of Health, http://doh.dc.gov/service/ems-children (last visited May 23, 2014).

[148] Tallahassee Memorial Regional Medical Center, Inc. v. Meeks, 560 So. 2d 778 (Fla. 1990).

[149] *See, e.g.*, Bowden v. Cary Fire Protection Dist., 710 N.E.2d 548 (Ill. Ct. App. 1999).

[150] *See, e.g.*, Browning v. West Calcasieu Cameron Hosp., 865 So. 2d 795 (La. Ct. App. 3d Cir. 2003).

[151] *See, e.g.*, McCoy v. Hatmaker, 763 A.2d 1233 (Md. Ct. Spec. App. 2000).

[152] 210 Ill. Comp. Stat. 50/3.150(a); Meck v. Paramedic Services of Illinois, 695 N.E.2d 1321 (Ill. App. Ct. 1998).

[153] Idaho Code Ann. § 56-1014.

[154] Ga. Code Ann. § 31-11-8(a).

[155] Cal. Health & Safety Code § 1799.106.

[156] Ga. Code Ann. § 31-11-8(c).

[157] *E.g.*, Thomas v. DeKalb County, 489 S.E.2d 58, 61 (Ga. Ct. App. 1997).

[158] *E.g.*, Martin v. Fulton-DeKalb Hospital Authority, 551 S.E.2d 415 (Ga. Ct. App. 2001).

[159] 210 Ill. Comp. Stat. 50/3.150(a), 50/3.10(g).

[160] Cal. Health & Safety Code § 1799.106.

[161] Fla. Stat. § 768.13.

[162] *See* Willard v. Vicksburg, 571 So. 2d 972 (Miss. 1990) (declining to interpret a Good Samaritan statute, but recommending that the legislature review and amend the statute to clarify application to those with a duty to provide care).

[163] Fla. Stat. § 768.13.

[164] Meuller v. McMillian Warner Ins. Co., 290 Wis. 2d 571 (2006); *see also* 68 A.L.R.4th 294 (discussing application of Good Samaritan statutes generally).

[165] *See, e.g.*, Leang v. Jersey City Bd. of Educ., 969 A. 2d 1097 (N.J. 2009) (finding that New Jersey's Good Samaritan Act did not apply to situations where care or transportation was provided to a person who was not the victim of an accident or emergency as envisioned by the legislature in passing the Act); *see also* 68 A.L.R.4th 294.

[166] Tallahassee Memorial Regional Medical Center, Inc. v. Meeks, 560 So. 2d 778 (Fla. 1990).

[167] Taplin v. Chatham, 453 N.E.2d 421 (Mass. 1983).

[168] Ga. Code Ann. § 31-11-8(b).

[169] Mont. Code Ann. § 50-6-317.

[170] Utah Code Ann. § 26-8a-601(1).

[171] *See* Kenneth W. Kizer, Karen Shore & Aimee Moulin, Community Paramedicine: A Promising Model for Integrating Emergency and Primary Care, UC Davis, Inst. for Population Health Improvement 11 (2013), *available at* https://www.nasemso.org/Projects/RuralEMS/documents/IPHI_CommunityParamedicineReport_Final-070913.pdf ("Patients recently discharged from a hospital may benefit from assistance prior to regular scheduled follow-up care in understanding post-discharge instructions, medications, self-care, and the timing and importance of follow-up appointments. CPs could review these with patients and, if applicable, their families. The CP could ensure there is a safe home environment for the patient to recover in and could provide feedback to primary care and emergency care providers about the patient's function at home … CPs will need additional training with protocols for patient assessment, and there will need to be greater and potentially additional types of online medical control … for consultation on patients with complex medical conditions …").

[172] *See Beyond 911: State and Community Strategies for Expanding the Primary Care Role of First Responders*, Nat'l Conference of State Legislatures, http://www.ncsl.org/research/health/expanding-the-primary-care-role-of-first-responder.aspx (last visited May 9, 2014).

[173] Ariz. Rev. Stat. Ann. § 36-2220(B).

[174] U.S. Dep't of Health & Human Servs., Summary of the HIPAA Privacy Rule (2003), *available at* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html.

[175] 45 C.F.R. § 164.512 (2010); *see also* U.S. Dep't of Health & Human Servs., Summary of the HIPAA Privacy Rule (2003), *available at* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html.

[176] *E.g.*, Ariz. Rev. Stat. Ann. § 13-3620(A) (duty to report abuse, physical injury, neglect and denial or deprivation of medical or surgical care or nourishment of minors, including by any person with responsibility for treatment of the minor); Ariz. Rev. Stat. Ann. § 36-664(A) (7) (disclosures mandated by federal or state law are an exception to communicable disease confidentiality requirements); Ariz. Admin. Code R9-6-202 (reporting requirements for health care providers regarding infectious diseases).

[177] *See, e.g.*, Sheri Fink, *U.S. Mines Personal Health Data to Find the Vulnerable in Emergencies*, N.Y. Times, May 15, 2014, at A18.

[178] U.S. Dep't of Health & Human Servs., Office of Rural Health Policy, Community Paramedicine Evaluation Tool (2012), http://www.hrsa.gov/ruralhealth/pdf/paramedicevaltool.pdf.

[179] *See e.g.,* 210 Ill. Comp. Stat. 50/3.5 (defining healthcare facility to include a physician's office); 210 Ill. Comp. Stat. 50/3.10(g) (non-emergency medical services includes transport to any healt care facility).

[180] *Introduction to Community Paramedicine*, Cal. Emergency Med. Servs. Auth., http://www.emsa.ca.gov/Community_Paramedicine (last visited Apr. 14, 2014).

[181] Cal. Health & Safety Code § 1797.52.

[182] Cal. Health & Safety Code § 1797.218.

[183] *Id.*; Community Paramedicine Pilot Projects, California Emergency Medical Services AUTHORITY, *available at* http://www.emsa.ca.gov/Community_Paramedicine (Last visited May 28, 2014).

[184] Community Paramedicine Pilot Project, HWPP #173, Office of Statewide Health Planning & Dev. 5 (2014), *available at* http://www.oshpd.ca.gov/hwdd/pdfs/HWPP/CP_OSHPD_Community_Paramedicine_App.pdf.

[185] Ariz. Rev. Stat. Ann. §36-401(A) (20).

[186] *Id.*

[187] Maria Polletta, *Mesa's PA unit eases load for 1st responders*, Apr. 22, 2013, AZCentral, http://www.azcentral.com/community/mesa/articles/20130418mesa-trv-medical-response.html.

[188] *Id.*

[189] Del. Code Ann. tit. 16, § 9802(19).

[190] Or. Rev. Stat. Ann. § 682.025(14); Or. Rev. Stat. Ann. § 333-250-0010(11).

[191] Or. Rev. Stat. Ann. § 682.027.

[192] Or. Rev. Stat. Ann. § 333-200-0080 Exhibit 2.

[193] Or. Admin. R. 333-200-0080(4); Or. Rev. Stat. Ann. § 333-200-0080 Exhibit 2.

[194] Or. Rev. Stat. Ann. § 333-200-0080(4); Or. Rev. Stat. Ann. § 333-200-0080 Exhibit 2.

[195] Or. Rev. Stat. Ann. § 333-200-0080(4); Or. Rev. Stat. Ann. § 333-200-0080 Exhibit 2.

[196] Emergency Medical Services, Mass. Gen. Laws ch.11, §1.

[197] 105 Mass. Code Regs. § 170.020.

[198] Independence, Miss. Code §§ 19.590–19.711.

[199] Missouri, ex rel. Lifeguard Medical Services, Inc., v. City of Independence, 939 S.W.2d 522 (Mo. App. 1997).

[200] *Id.* at 523.

[201] *Id.* at 524-25.

[202] Agreement for 9-1-1 Ambulance Response and Emergency Medical Services, Augusta, Georgia, Nov. 1, 2005, *available at* http://appweb.augustaga.gov/Planning_and_Zoning/docs/Comprehensive%20Plans/911%20Ambulance11-1.pdf; An Ordinance: Establishing the Terms and Conditions for a Contract Regulating Participating EMS Providers Operating with York County, South Carolina, 2013, *available at* http://rhems.org/images/EMS.pdf.

[203] Agreement for 9-1-1 Ambulance Response and Emergency Medical Services, Augusta, Georgia, Nov. 1, 2005, *available at* http://appweb.augustaga.gov/Planning_and_Zoning/docs/Comprehensive%20Plans/911%20Ambulance11-1.pdf.

[204] Terrance T. McDonald, *War over Jersey City Ambulance Contract Escalates with Charge that JCMC Diverts Patients Against Wishes*, The Jersey Journal (Dec. 16, 2013), *available at* http://www.nj.com/hudson/index.ssf/2013/12/war_over_jersey_city_ambulance_contract_escalates_with_charge_that_jcmc_diverts_patients_against_the.html.

[205] *Interfacility Ambulance*, RuralMetroWest.com, *available at* http://www.ruralmetrowest.com/our-services/interfacility-ambulance.html (last visited Mar. 27, 2014).

[206] Central Cal. Emergency Med. Servs., Emergency Medical Services Administrative Policies and Procedures: Hospital Diversion of Ambulance Patients 3 (Feb. 15, 1993), *available at* http://www.co.fresno.ca.us/uploadedFiles/Departments/Public_Health/Divisions/EMS/content/Policies,_Procedures_and_Memos/content/Fresno,_Kings_and_Madera_Counties/500_-_699/547.1.pdf; Ariz. Dep't of Health Servs., Bureau of Emergency Med. Servs. & Trauma System, Statutes & Rules 12 (Dec. 1, 2013), *available at* http://www.azdhs.gov/bems/documents/statutes-rule-book.pdf.

[207] Central Cali. Emergency Med. Servs., Emergency Medical Services Administrative Policies and Procedures: Hospital Diversion of Ambulance Patients 3 (Feb. 15, 1993), *available at* http://www.co.fresno.ca.us/uploadedFiles/Departments/Public_Health/Divisions/EMS/content/Policies,_Procedures_and_Memos/content/Fresno,_Kings_and_Madera_Counties/500_-_699/547.1.pdf.

[208] Kenneth W. Kizer, Karen Shore, & Aimee Moulin, Community Paramedicine: A Promising Model for Integrating Emergency and Primary Care, UC Davis, Inst. for Population Health Improvement 2, 6 (2013).

[209] *Beyond 911: State and Community Strategies for Expanding the Primary Care Role of First Responders*, Nat'l Conference of State Legislatures, http://www.ncsl.org/research/health/expanding-the-primary-care-role-of-first-responder.aspx (last visited Apr. 14, 2014).

[210] Kenneth W. Kizer, Karen Shore & Aimee Moulin, Community Paramedicine: A Promising Model for Integrating Emergency and Primary Care, UC Davis, Inst. for Population Health Improvement 2, 6 (2013).

[211] Medicare Managed Care Manual, MC86 Chapter 4 Section 20.1 (Aug. 23, 2013), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf.

[212] Medicare Benefit Policy Manual BP102 Chapter 10 Section 3 (Rev. 115, Nov. 11, 2009), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c10.pdf.

[213] *Id*.

[214] *Id*. (emphasis added).

[215] John Erich, *How Minnesota Got Its Community Medics Paid*, EMSWorld, (May 1, 2013), http://www.emsworld.com/article/10913443/medicaid-reimbursement-for-community-paramedics-in-minnesota.

[216] Minn. Stat. Ann. § 256B.0625 (60) (2014Stat. Ann, UC Davis, Instihnicians, d Nat'nsibility objection could be ordered have a big role in caring for children c(b).

[217] *Essential Health Benefits*, Healthcare.gov, https://www.healthcare.gov/glossary/essential-health-benefits/ (last visited Mar. 27, 2014).

[218] *Final Federal Rules on Essential Health Benefits Released*, The Campaign for Modern Med., http://modernmedicines.com/entry.php?id=270 (last visited Apr. 14, 2014).

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[220] *Essential Health Benefit Standards: Ensuring Quality, Affordable Coverage*, CMS.gov, http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ehb-2-20-2013.html (last visited Mar. 27, 2014).

[221] 42 U.S.C. § 18022(b) (B).

[222] *California EHB Benchmark Plan*, Center for Consumer Info. & Ins. Oversight, CMS.Gov, *available at* http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/california-ehb-benchmark-plan.pdf (last visited Apr. 7, 2014); Jean Folger, *Essential Health Benefits Under the Affordable Care Act*, Forbes (Oct. 11, 2013), http://www.forbes.com/sites/investopedia/2013/10/11/essential-health-benefits-under-the-affordable-care-act/.

[223] *See, e.g., Arizona EHB Benchmark Plan*, Center for Consumer Info. & Ins. Oversight, CMS.Gov, *available a*t http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/arizona-ehb-benchmark-plan.pdf (last visited Apr. 7, 2014).

[224] *Oregon EHB Benchmark Plan*, Center for Consumer Info. & Ins. Oversight, CMS.Gov, *available a*t http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/oregon-ehb-benchmark-plan.pdf (last visited Apr. 7, 2014).

[225] *Arizona EHB Benchmark Plan*, Center for Consumer Info. & Ins. Oversight, CMS.Gov, *available a*t http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/arizona-ehb-benchmark-plan.pdf (last visited Apr. 7, 2014).

[226] *Colorado EHB Benchmark Plan*, Center for Consumer Info. & Ins. Oversight, CMS.Gov, *available a*t http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/colorado-ehb-benchmark-plan.pdf (last visited Apr. 7, 2014).

[227] *Accountable Care Organizations (ACO*), CMS.gov, (Mar. 22, 2013) http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/.

[228] *Beyond 911: State and Community Strategies for Expanding the Primary Care Role of First Responders*, Nat'l Conference of State Legislatures, http://www.ncsl.org/research/health/expanding-the-primary-care-role-of-first-responder.aspx (last visited Apr. 14, 2014).

[229] *Accountable Care Organizations (ACO*), CMS.gov (Mar. 22, 2013), http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/.

[230] *Mobile Healthcare Programs – Overview*, Medstar Mobile Healthcare, http://www.medstar911.org/community-health-program (last visited Apr. 7, 2014).

[231] COMMUNITY PARAMEDIC: PROGRESS REPORT APRIL 4, 2013, COLO. DEP'T OF PUBLIC HEALTH & ENV'T, Slide 21, *available at* http://www.colorado.gov/cs/Satellite?blobcol=urldata&blobheadername1=Content-Disposition&blobheadername2=Content-Type&blobheadervalue1=inline%3B+filename%3D%22April+4%2C+2013.pdf%22&blobheadervalue2=application%2Fpdf&blobkey=id&blobtable=MungoBlobs&blobwhere=1251854448519&ssbinary=true.

[232] Emergency Medical Treatment and Active Labor Act, § 1867, 42 U.S.C.A. § 1395dd.

[233] Emergency Medical Treatment and Active Labor Act, § 1867, 42 U.S.C.A. § 1395dd; Beller v. Health and Hosp. Corp. of Marion County, Indiana, 703 F.3d 388 (7th Cir. 2012).

[234] Emergency Medical Treatment and Active Labor Act, § 1867, 42 U.S.C.A. § 1395dd.

[235] Dedicated Emergency Department under EMTALA is defined as "any department or facility of the hospital that either 1) is licensed by the state as an emergency department; 2) held out to the public as providing treatment for emergency medical conditions; or 3) on one-third of the visits to the department in the preceding calendar year actually provided treatment for emergency medical conditions on an urgent basis." 42 C.F.R. § 489.24 (b) (4).

[236] Emergency Medical Treatment and Active Labor Act, § 1867, 42 U.S.C.A. § 1395dd.

[237] 42 C.F.R. § 413.65(b).

[238] Hospitals meet the stabilization requirement of EMTALA if they offer further treatment, explain the risks and benefits of the treatment to the patient, and the patient refuses. 42 C.F.R. §489.24(d)(1) & (3). Hospitals should attempt to get patients' written informed consent. Id. Courts have found that patients have the right to refuse emergency medical treatment, but the right is not absolute. *Norwood Hospital v. Munoz*, 409 Mass. 116, 122-126 (citing to a common law right and statutory right of privacy). Other states' statutes specifically provide a person rights to refuse medical treatment (Nothing contained [in the Louisiana Medical Consent Law] shall be construed to abridge any right of a person 18 years of age or over to refuse to consent to medical or surgical treatment as to his own person, LA. REV. STAT. ANN.§ 40:1299.56) which courts have used to defeat a plaintiff's claim that paramedics were liable for failing to bring the patient to an ED following refusal of medical care by a competent adult. *Lemann v. Essen Lane Daiquiris, Inc.*, 923 So.2d 627, 636 (La. 2006).

[239] 42 C.F.R. § 489.24.

[240] *Id.*

[241] Reid v. Johnson, 851 S.W.2d 120, 121 (Mo Ct. App E.D. 1993) (*citing* Miller v. Greater Southeast Community Hospital, 508 A.2d 927, 929 (D.C.Ct.App.1986)).

[242] McCluskey v. U.S., 583 F .Supp. 740, 750-51 (S.D. NY 1984).

[243] *Id.* at 752.

[244] *See, e.g.,* Patient Abandonment vs. Prudent Use of EMS Personnel Policy Statement, McLean County Area EMS System, *available at* http://www.mcleancountyems.org/documents/17PatientAbandonmentvsPrudentUseofEMSPersonnel.pdf (last visited Apr. 14, 2014); Patient Abandonment, Central DuPage Emergency Medical Services System (2009), *available at* http://www.cdh.org/~/media/Files/PDFs/Emergency%20Medical%20Services/8%20CDEMSS%20System%20Specific%20Policies%20PDFs/Medical%20Legal/Patient%20Abandonment1.ashx.

[245] Patient Abandonment vs. Prudent Use of EMS Personnel Policy Statement, McLean County Area EMS System, *available at* http://www.mcleancountyems.org/documents/17PatientAbandonmentvsPrudentUseofEMSPersonnel.pdf.

[246] Patient Abandonment vs. Prudent Use of EMS Personnel Policy Statement, McLean County Area EMS System, *available at* http://www.mcleancountyems.org/documents/17PatientAbandonmentvsPrudentUseofEMSPersonnel.pdf; Patient Abandonment, Central DuPage Emergency Medical Services System (2009), *available at* http://www.cdh.org/~/media/Files/PDFs/Emergency%20Medical%20Services/8%20CDEMSS%20System%20Specific%20Policies%20PDFs/Medical%20Legal/Patient%20Abandonment1.ashx.

[247] Patient Abandonment, Central DuPage Emergency Medical Services System (2009), *available at* http://www.cdh.org/~/media/Files/PDFs/Emergency%20Medical%20Services/8%20CDEMSS%20System%20Specific%20Policies%20PDFs/Medical%20Legal/Patient%20Abandonment1.ashx.

[248] ARIZ. ADMIN. CODE § R9-25-504(C) (2013).

[249] Patient Abandonment vs. Prudent Use of EMS Personnel Policy Statement, McLean County Area EMS System, *available at* http://www.mcleancountyems.org/documents/17PatientAbandonmentvsPrudentUseofEMSPersonnel.pdf.

[250] Nothing contained [in the Louisiana Medical Consent Law] shall be construed to abridge any right of a person eighteen years of age or over to refuse to consent to medical or surgical treatment as to his own person. LA. REV. STAT. ANN. § 40:1299.56 (1975).

[251] *Norwood Hospital v. Munoz*, 409 Mass. 116, 122-126 (citing to a common law right and statutory right of privacy, MASS. GEN. LAWS ch. 214, § 1B (1974)).

[252] COMMUNITY PARAMEDICINE PILOT PROJECT, HWPP #173, OFFICE OF STATEWIDE HEALTH PLANNING & DEV. 28 (2014), *available at* http://www.emsa.ca.gov/Media/Default/PDF/CP_OSHPD_Community_Paramedicine_App.pdf.

[253] BRYAN E. BLEDSOE, ROBERT S. PORTER & RICHARD A. CHERRY, PARAMEDIC CARE: PRINCIPLES & PRACTICE 130 (2d ed. 2005).

[254] KENNETH W. KIZER, KAREN SHORE & AIMEE MOULIN, COMMUNITY PARAMEDICINE: A PROMISING MODEL FOR INTEGRATING EMERGENCY AND PRIMARY CARE, UC DAVIS, INST. FOR POPULATION HEALTH IMPROVEMENT (2013); Maria Polletta, *Mesa's PA Unit Eases Load for 1st Responders*, Apr. 22, 2013, AZCENTRAL, http://www.azcentral.com/community/mesa/articles/20130418mesa-trv-medical-response.html.

[255] *See e.g., Catlett v. New Jersey State Police*, Civil No. 12-153, 2013 WL 2181273 (D. N.J. May 20, 2013); *Tracz v. Charter Centennial Peaks Behavioral Health Systems*, 9 P.3d 1168 (Co. Ct. Apps 2000).

[256] *See e.g.*, Thomas M. Burton, *Stroke Victims Are Often Taken to Wrong Hospital*, WALL STR. J. (May 09, 2005).

[257] *Smith v. Medical Center East,* 585 SO.2D 1325, 1326-27 (Ala. 1991).

[258] *Id*.

[259] GA. COMP. R. & REGS. 511-9-2-.07(k); BRYAN E. BLEDSOE, ROBERT S. PORTER & RICHARD A. CHERRY, PARAMEDIC CARE: PRINCIPLES & PRACTICE 128 (2d ed. 2005).

[260] ARIZ. DEP'T OF HEALTH SERVS., BUREAU OF EMERGENCY MED. SERVS. & TRAUMA SYS., STATUTES & RULES 12 (2013), *available at* http://www.azdhs.gov/bems/documents/statutes-rule-book.pdf.

[261] Ryan Stark, *Liability for EMS Providers*, PAGE, WOLFBERG & WIRTH: THE NATIONAL EMS INDUSTRY LAW FIRM, Slide 49, *available at* http://www.ncemsf.org/about/conf2010/presentations/stark_liability.pdf; BRYAN E. BLEDSOE, ROBERT S. PORTER & RICHARD A. CHERRY, PARAMEDIC CARE: PRINCIPLES & PRACTICE 131 (2d ed. 2005).

[262] BRYAN E. BLEDSOE, ROBERT S. PORTER & RICHARD A. CHERRY, PARAMEDIC CARE: PRINCIPLES & PRACTICE 118 (2d ed. 2005).

[263] N.Y. LAW § 1104 (MicKinney).

[264] CAL. VEHICLE CODE § 21055.

[265] 210 ILL. COMP. STAT. 50/3.150(a).

[266] *Wilkins v. Williams*, 991 N.E.2d 308, 312 (Ill. 2013) (*citing Wilkins v. Williams*, 968 N.E.2d 1074 (Il. Ct. App. 2013).

[267] COMMUNITY PARAMEDICINE/MOBILE INTEGRATED HEALTHCARE SURVEY SUMMARY: OCTOBER 2013, NAT'L ASS'N OF EMERGENCY MED. TECHNICIANS, Slide 10, 26 (2013), *available at* http://www.naemt.org/about_ems/MobileIntegratedHC/MobileIntegratedHC.aspx.

[268] W. Ann "Winnie" Maggiore, *Liability for EMS Licensing: Whose License Is It, Anyway?*, JEMS (Feb. 2, 2011), *available at* http://www.jems.com/article/administration-and-leadership/liability-ems-licensing/.

[269] *See, e.g.*, 210 ILL. COMP. STAT. 50/3.50; W. Ann "Winnie" Maggiore, *Liability for EMS Licensing: Whose License Is It, Anyway?*, JEMS (Feb. 2, 2011) http://www.jems.com/article/administration-and-leadership/liability-ems-licensing/.

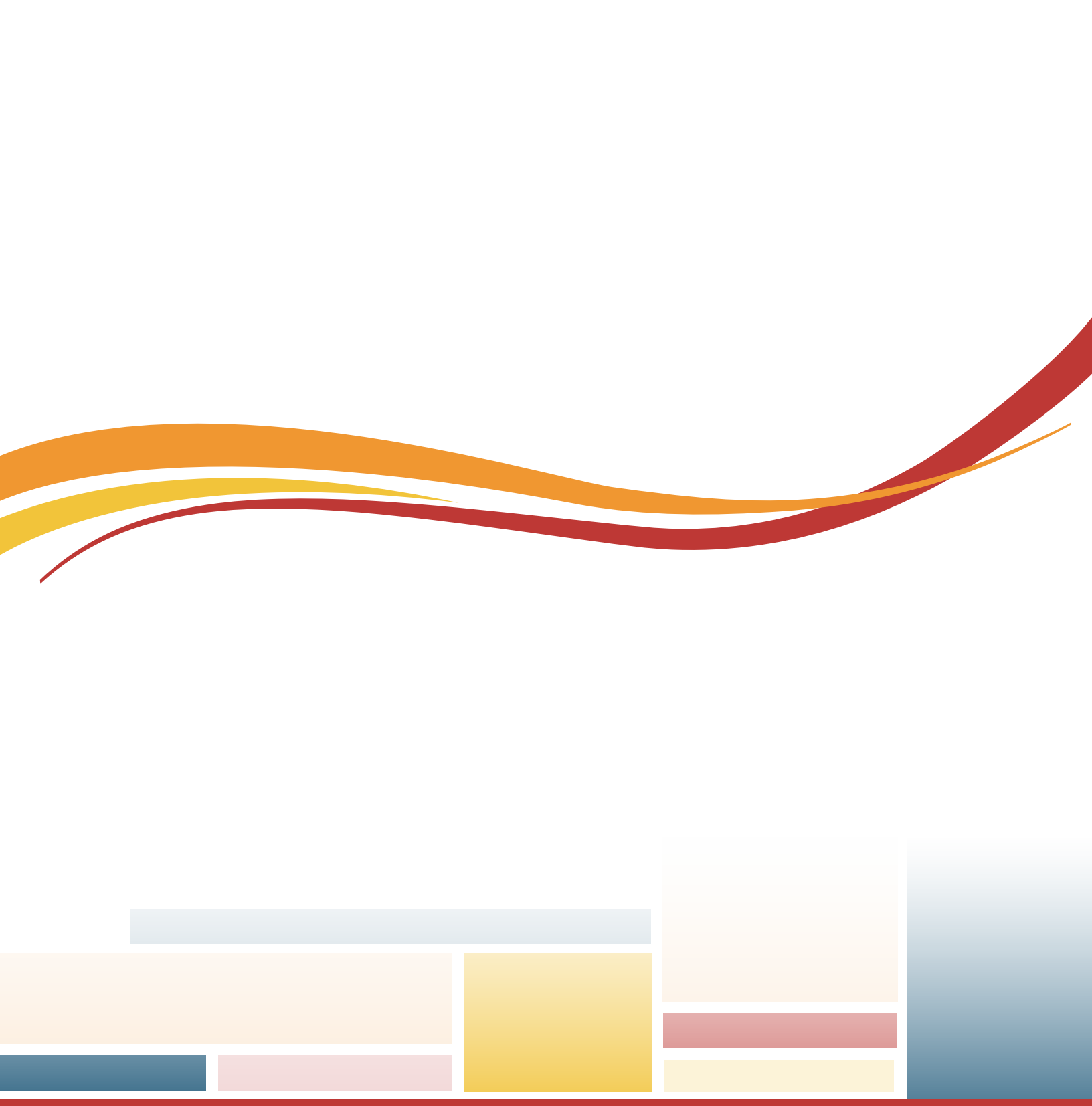
[270] TEX. ADMIN. CODE tit. 22, § 197.2- 197.4.

[271] BRYAN E. BLEDSOE, ROBERT S. PORTER & RICHARD A. CHERRY, PARAMEDIC CARE: PRINCIPLES & PRACTICE 122 (2d ed. 2005).

[272] Complaint, *Estate of Stephens v. Mount-Varner*, 2010 WL 4256222 (D.C.Super.).

[273] D.C. CODE § 5-404.01(e)(1).

[274] M.G.L. c. 111C, § 20: Protection from Liability for Physicians Providing Medical Oversight to MA Ambulance Services, Advisory Op. Mass Exec. Office Health & Human Servs (2013), *available at* http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/healthcare-quality/health-care-facilities/hospitals/medical-control/faqs-of-medical-control-service.html#4.



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FINAL REPORT

SAN BERNARDINO COUNTY CIVIL GRAND JURY 2016-2017

FINAL REPORT

SAN BERNARDINO COUNTY CIVIL GRAND JURY 2016-2017

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The Editorial Committee acknowledges and thanks the following individuals for their hard work and invaluable assistance in the preparation of the Final Report of the 2016-2017 San Bernardino County Grand Jury:

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June 30, 2017

Honorable Raymond L. Haight III, Presiding Judge
Superior Court of California, County of San Bernardino
247 West Third Street, Eleventh Floor
San Bernardino, CA 92415-0302

Dear Judge Haight,

The 2016-2017 San Bernardino County Grand Jury is pleased to present this Final Report to you, the San Bernardino County Board of Supervisors and the citizens of San Bernardino County.

On July 1, 2016 nineteen citizens came together, each bringing their own individual experiences and knowledge towards our common goal of ensuring our County, Cities and Special Districts are governed honestly and efficiently.

Throughout our term, Grand Jury members met and interviewed numerous county employees. The Grand Jury believes these employees are dedicated and want to improve each department's service to the San Bernardino County citizens. To them, the Grand Jury extends their deepest gratitude.

This was a year of many changes that led to growth and progress for the Grand Jury. We welcomed a new administrative secretary, Norma Grosjean, who is doing an excellent job. The Grand Jury suite needed technological updates. The Grand Jury Website is being updated and improved to allow greater access to citizens and we are working with the Board of Supervisors to raise the Per Diem for future Grand Jurors. These changes will improve the next Grand Jury's investigative endeavors.

The Grand Jury would also like to thank Presiding Judge Raymond Haight and the San Bernardino County Board of Supervisors for their support. Special thanks go to our Legal Advisors, Deputy District Attorney Michael Dauber, Jean Rene Basle and Michelle Blakemore of County Counsel for their expertise and assistance throughout the year. And I thank every one of my fellow Grand Jury colleagues for their tenacious dedication to service. It has been my honor to serve in the capacity of foreperson of the 2016-2017 San Bernardino County Grand Jury.

Respectfully,

Susan S. Brewster

Susan S. Brewster, Foreperson
San Bernardino County Civil Grand Jury

2016-2017 CIVIL GRAND JURY
SAN BERNARDINO COUNTY

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Darrell Freeland, Foreperson Pro Tem	Victorville
Bob Turley, Secretary	Redlands
Rick Penaflor, Assistant Secretary	Twentynine Palms
Bruce Hollenbeck, Sergeant-at-Arms	Apple Valley
Ernie Armenta, Assistant Sergeant-at-Arms	Rialto

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Kent Fogleman	Redlands
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Don Newton	Chino Hills
Michael Pichler	Upland
Lynn Pidal	Highland
Tim Smith	Yucaipa
Ron Zurek	Rancho Cucamonga

FORMER MEMBERS

Jerry Santana (Resigned 10/18/16) – Yucaipa
Robert Sturges (Resigned 1/20/17) - Apple Valley
Richard Williams (Resigned 7/19/16) - San Bernardino

ADMINISTRATION

Presiding Judge	Raymond L. Haight, III
Legal Advisor	Michael Dauber
Grand Jury Assistant	Norma Grosjean
Former Grand Jury Assistant	Sarah Mayne

2016-2017 CIVIL GRAND JURY
SAN BERNARDINO COUNTY

Back Row (left to right): Ernie Armenta, Richard "Kim" Chitwood, Ruth McMillan, Susan Brewster, Michael Pichler, Steve Miller, Allen "Skip" Burt, Lino Martinez, Tim Smith

Middle Row (left to right): Don Newton, Ron Zurek, Kent Fogleman, Rick Penaflor, Lynn Pidal, Darrell Freeland, Bob Turley

Front Row (left to right): Jan Flammang, Bruce Hollenbeck, Dave Hutson

Honorable
Raymond L. Haight, III

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FINAL REPORT

COMPLAINTS


COUNTY OF SAN BERNARDINO
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GRAND JURY

COMPLAINTS

The Grand Jury received and investigated various complaints from our citizens. Every complaint is carefully reviewed by the Grand Jury and a determination is made regarding jurisdiction.

If jurisdiction is confirmed and the complaint warrants investigation, it is assigned to the appropriate committee. An investigation ensues and the outcome reported to the full Grand Jury. A written report regarding a specific complaint may or may not be included in this year-end Grand Jury Final Report.

The process to submit a complaint is to obtain a Confidential Citizen Complaint Form from either the Grand Jury Website (http:cms.sbcounty.gov.grandjury/Home.aspx) or by calling the Grand Jury Office at (909) 387-9120. Once fully completed, the form is returned to the office at 172 West Third Street, Second Floor, San Bernardino CA 92415. Although the Grand Jury normally does not investigate unsigned complaints, depending on the issue, it may conduct an investigation from an anonymous source.

The 2016-2017 Grand Jury received nineteen complaints. Of those three were assigned and investigated. Two complaints were not within the jurisdiction of the Grand Jury, one was anonymous and two were already resolved or in litigation. Eight were rejected by the Grand Jury for various reasons other than jurisdiction and three are being referred to the 2017-2018 Grand Jury.

REPORTS


COUNTY OF SAN BERNARDINO
COUNTY OF SAN BERNARDINO
1853
Quaerite Veritatem
GRAND JURY

GRAND JURY FINAL REPORTS
INTRODUCTION

The following penal institutions, which are designated detention centers by the County of San Bernardino, were inspected and are included in this 2016-2017 Final Report under the authority of California Penal Code 919(b) which states:

> "The Grand Jury **shall** inquire into the condition and management of the public prisons within the County."

California Institution for Men
California Institution for Women
Desert View Modified Community Correctional Facility
Glen Helen Rehabilitation Center
Central Valley Juvenile Detention and Assessment Center

The Grand Jury conducted investigations for the following reports for inclusion in this, the 2016-2017 Grand Jury Final Report under the authority of California Penal Code Section 925 which states:

> "The Grand Jury shall investigate and report on the operations, accounts, and records of the officers, departments, or functions of the county including those operations, accounts, and records of any special legislative district or other district in the county created pursuant to state law for which the officers of the county are serving in their ex officio capacity as officers of the districts. The investigations may be conducted on some selective basis each year, but the grand jury shall not duplicate any examination of financial statements which has been performed by or for the board of supervisors pursuant to Section 25250 of the Government Code; this provision shall not be construed to limit the power of the grand jury to investigate and report on the operations, accounts, and records of the officers, departments, or functions of the county. The Grand Jury may enter into a joint contract with the board of supervisors to employ the services of an expert as provided for in Section 926".

Children & Family Services
High Desert Ambulance Availability and Bed Delay
Request for Proposal for the Indigent Adult Appointed Representation Service Contract.
San Bernardino County Department of Veterans Affairs
San Bernardino County Facilities, Site Security and Public Safety

The following reports were investigated under the authority of Penal Code 933.5 which states:

> "A Grand Jury may at any time examine the books and records of any special-purpose assessing or taxing district located wholly or partly in the county or the local agency formation commission in the county, and, in addition to any other investigatory powers granted by this chapter, may investigate and report upon the method or system of performing the duties of such district or commission."

Apple Valley Unified School District Police Department
Oversight of San Bernardino County Charter Schools

APPLE VALLEY UNIFIED SCHOOL DISTRICT
POLICE DEPARTMENT

BACKGROUND

The Apple Valley Unified School District (AVUSD) is located in the High Desert of San Bernardino County. Its service area is generally to the east of Interstate 15 and is bisected by Highway 18. It includes most of the Town of Apple Valley and the surrounding unincorporated area. According to the District's website (http://www.avusd.org) the District maintains fifteen schools and *"serves just over 13,000 students ranging from preschool through twelfth grade, and offers an adult education program linked with Victor Valley College. AVUSD provides a safe, encouraging, and challenging learning environment in which students are given the opportunity to reach their full potential."*

On April 3, 2002, the AVUSD Board of Trustees approved a Policy creating the Apple Valley Unified School District Police Department (AVUSD-PD) in accordance with California Education Code Section 38000 which permits establishment of such a department. Subdivision (b) of Section 38000 indicates the District *"... may employ peace officers, as defined by subdivision (b) of Section 830.32 of the Penal Code, to ensure the safety of school district personnel and pupils, and the security of the real and personal property of the school district."* Penal Code Section 830.32 qualifies the authority of such school police officers as *"... peace officers whose authority extends to any place in the state for the purpose of performing their primary duty."*

The current configuration of the AVUSD-PD is a Chief, five regular officers and six-part time reserve officers plus one dispatch supervisor, one dispatcher and two part-time clerical staff.

The San Bernardino County Grand Jury received a report of possible issues involving the AVUSD-PD pertaining to disposal of district vehicles. The Grand Jury elected to conduct an investigation under the authority of Section 933.5 of the California Penal Code.

During the course of that inquiry, it was immediately determined that district vehicles were not involved, but rather that, from January 2014 through December 2016, the AVUSD-PD had ordered over 700 vehicles towed from public roadways. The adjoining Hesperia Unified School District Police Department did not tow any vehicles during that same time period. The Snowline Unified School District Police Department in nearby Phelan towed only one abandoned vehicle during the same time frame. The San Bernardino Unified School District Police Department, an agency four times as large as AVUSD-PD, towed 272 vehicles during the same time period while the Fontana Unified School District Police Department, with 64 officers, towed only 169 vehicles. All of the vehicles ordered towed by the AVUSD-PD were towed by a single tow company in Apple Valley. An unknown number of the privately owned vehicles were subsequently lien sold by the tow company for fees and towing charges accrued.

METHODOLOGY

The Grand Jury utilized the following methodologies in their examination of the AVUSD-PD: personal interviews, telephonic interviews, sworn testimony, data received from the AVUSD and the AVUSD-PD, data received from Fontana Unified School District, data received from San Bernardino Unified School District, data received from the Hesperia Unified School District, data received from the Snowline Unified School District, information received from the California Commission on Peace Officer Standards and Training, information from the California Highway Patrol, personal inspection of sites and facilities, examination of reports, records, hiring a Graphic Information System (GIS) mapping expert, and a legal opinion provided by San Bernardino County Counsel's Office.

FACTS

A legal opinion prepared by the San Bernardino County Counsel's Office, at the request of the Grand Jury, found that school police officers are limited duty peace officers whose primary duty is to ensure the safety of school district personnel and pupils, and the security of the real and

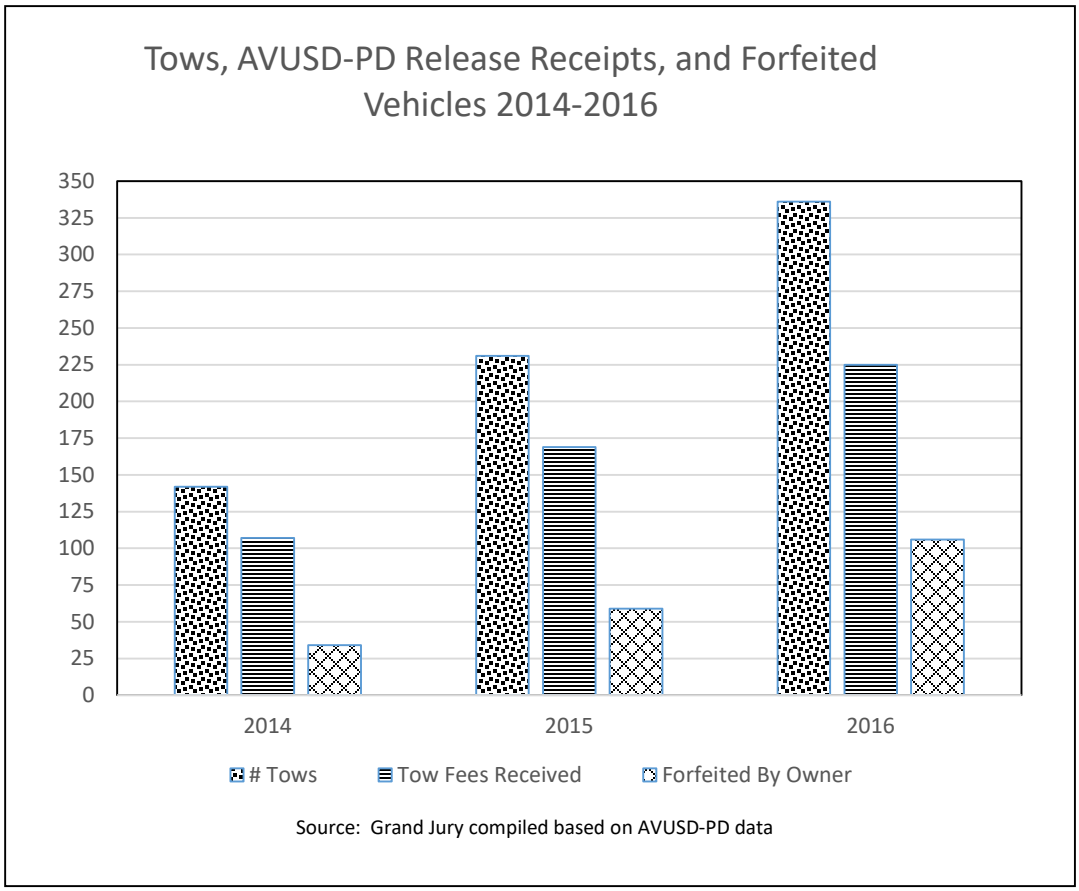
personal property of the school district. These officers have additional authority in Penal Code section 830.32 to make arrests when there is an ***immediate danger to persons or property,*** or the escape of the perpetrator of that offense. By application, the ***school police would not have general police powers off school property*** unless there was an immediate danger to a person or property or to the escape of the perpetrator of that offense. This opinion also quoted *People v. Landis* (2007) 156 Cal. App. 4th Supp. 12, which found that local peace officers with general police powers are limited in their authority to issue citations for infractions to only the jurisdiction of their agency, absent exigent circumstances.

All of the Apple Valley Unified School District police officers that were interviewed by the Grand Jury believed that Penal Code Section 830.32 permitted them to stop, cite, and tow vehicles anywhere in the state of California. None of the police officers were able to cite any legal opinion from the School District's legal counsel or the School District's administration. The Grand Jury was unable to find any School District actions directing officers to exert that level of authority.

The Town of Apple Valley Police Department has primary jurisdiction for all police services within the Town Limits. The Town contracts with the San Bernardino County Sheriff's Department to provide those services. Most law enforcement agencies that have concurrent jurisdiction with another law enforcement agency have a Memorandum of Understanding (MOU) to delineate responsibilities and coordinate procedures between the agencies. The Grand Jury requested a copy of the MOU between AVUSD and the Town of Apple Valley Police Department. AVUSD was unable to produce a copy of the MOU that had been signed or approved by either the Town or the District. They did produce a draft MOU from 2012, but it was unsigned and did not appear to have been approved by any of the entities. The lack of such an MOU can lead to mishandled investigations, miscommunication between agencies, and uncertainty over what types of crimes will be handled by each agency. The opinion of the San Bernardino County Counsel's Office does stress that an MOU with a general law enforcement agency **cannot** convey to a school district police department any greater authority than they have under the Education Code and the Penal Code.

In order to more fully understand the laws pertaining to towing of vehicles, an expert from the California Highway Patrol (CHP) was invited to instruct the Grand Jury. This expert reported that a law enforcement agency may tow or store a vehicle on a public roadway for a variety of reasons, but in all cases, it must provide notice to the registered owner and the legal owner of their right to a hearing on the legality of the tow. The CHP 180 form is a vehicle report for towed or impounded vehicles. The CHP provides the form (CHP180) at no charge to any such agency to facilitate a uniform method of notification.

Examination of the records of the AVUSD-PD, coupled with testimony from the AVUSD-PD clerical staff and officers, revealed that CHP 180 forms generally were completed for the vehicles ordered towed. However, the forms were never sent to the registered owner and the legal owner as mandated by Section 22852(a) of the California Vehicle Code unless there was a lien holder listed as the legal owner. CVC 22852(a) "*Whenever an authorized member of a public agency directs the storage of a vehicle, as permitted by this chapter, or upon the storage of a vehicle as permitted under this section (except as provided in subdivision (f) or (g)), the agency or person directing the storage shall provide the vehicle's registered and legal owners of record, or their agents, with the opportunity for a poststorage hearing to determine the validity of the storage."* AVUSD-PD officers interviewed said they sometimes gave a printed sheet to the driver that explained how to pay the administrative Vehicle Release Form Fee and retrieve the vehicle from the tow yard; however, an explanation to the driver of the process to request a poststorage hearing was not included. AVUSD-PD clerical staff reported that they assumed that the tow company would send the CHP 180 information to the interested parties. The clerical staff only sent a CHP 180 form to the legal owner when it appeared that there was a lienholder for the vehicle.



TOWED, RELEASE FEE RECEIPTS and FORFEITED VEHICLES

Following the tow of a vehicle, the driver must pay a Vehicle Release Fee to AVUSD-PD before the vehicle will be released by the tow company. An increasing number of drivers forfeited their car by not paying the fee.

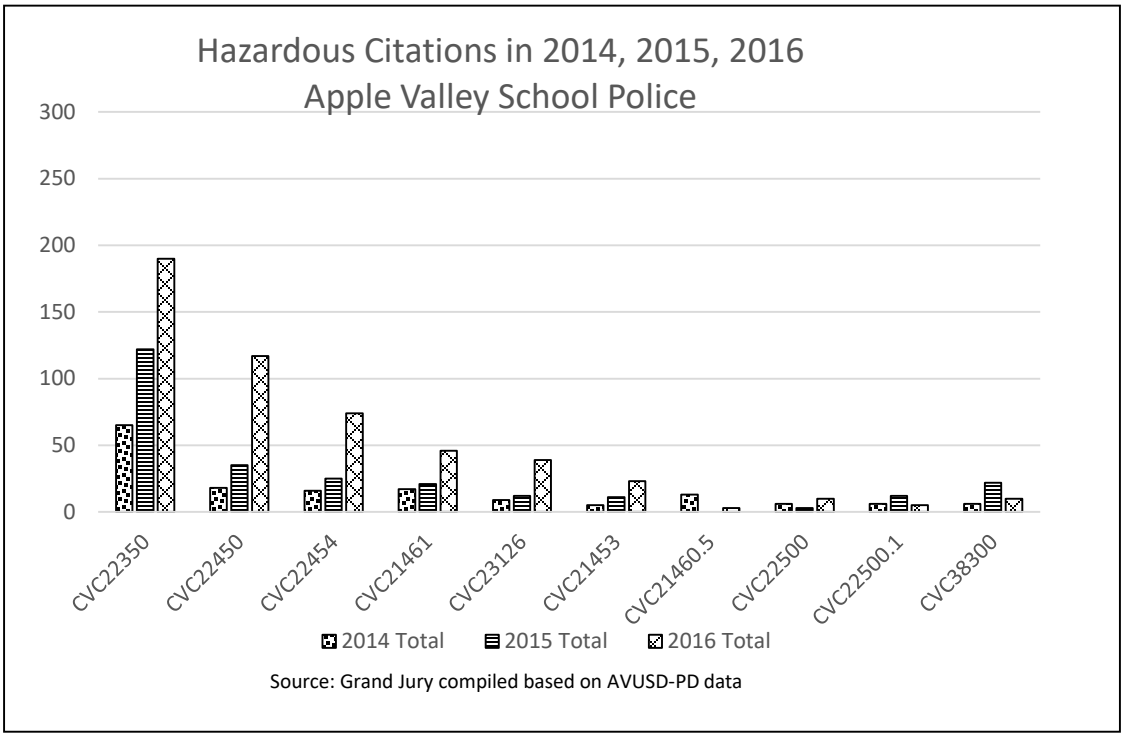
The Grand Jury reviewed almost 3,000 citations issued by the AVUSD-PD for the years 2014, 2015, and 2016. A significant majority of the citations were for non-hazardous moving vehicle code violations such as expired registration, equipment violations, expired driver's license, no driver's license in possession or not wearing a seat belt. For purposes of brevity in this report, the Grand Jury will discuss the most recent year, 2016, which continues the patterns seen in 2014 and 2015.

CVC Code	Brief Description	Ranking	Towed 2014	Not Towed 2014		Towed 2015	Not Towed 2015		Towed 2016	Not Towed 2016
CVC22350	Excessive Speed	Hazard	3	62		22	100		7	183
CVC22450	Ignoring Signs	Hazard	1	17		6	29		11	106
CVC4000	Car Registration	Not a Hazard	54	39		106	52		171	83
CVC16028	Lack of Insurance	Not a Hazard	30	29		60	34		64	80
CVC22454	Flashing Bus Lights	Hazard	1	15		3	22		8	66
CVC12951	License Not Available	Not a Hazard	2	13		5	24		3	48
CVC27360	Seat Belt Issue	Not a Hazard	1	3		0	3		7	45
CVC12500	No License	Not a Hazard	53	26		67	20		83	43
CVC21461	Disobeying Sign	Hazard	3	14		4	17		5	41
CVC23126	Cell Phone in Use	Hazard	0	9		1	11		3	36
CVC14601	Suspended License	Not a Hazard	43	9		54	16		93	24
CVC21453	Red Light Violation	Hazard	0	5		0	11		0	23
CVC21460.5	Illegal Left Turn	Hazard	1	12		0	0		0	3
CVC22500	Pedestrian Crosswalk	Hazard	1	5		3	0		1	9
CVC22500.1	Red Bus Zone	Hazard	0	6		0	12		2	3
CVC38300	Disobeying Sign	Hazard	1	5		1	21		2	8
CVC24252	Lighting Equipment	Not a Hazard	0	1		0	0		4	15

Source: Grand Jury compiled based on AVUSD-PD data

CVC SECTION, BRIEF DESCRIPTION, CLASSIFICATION, TOWED/NOT TOWED

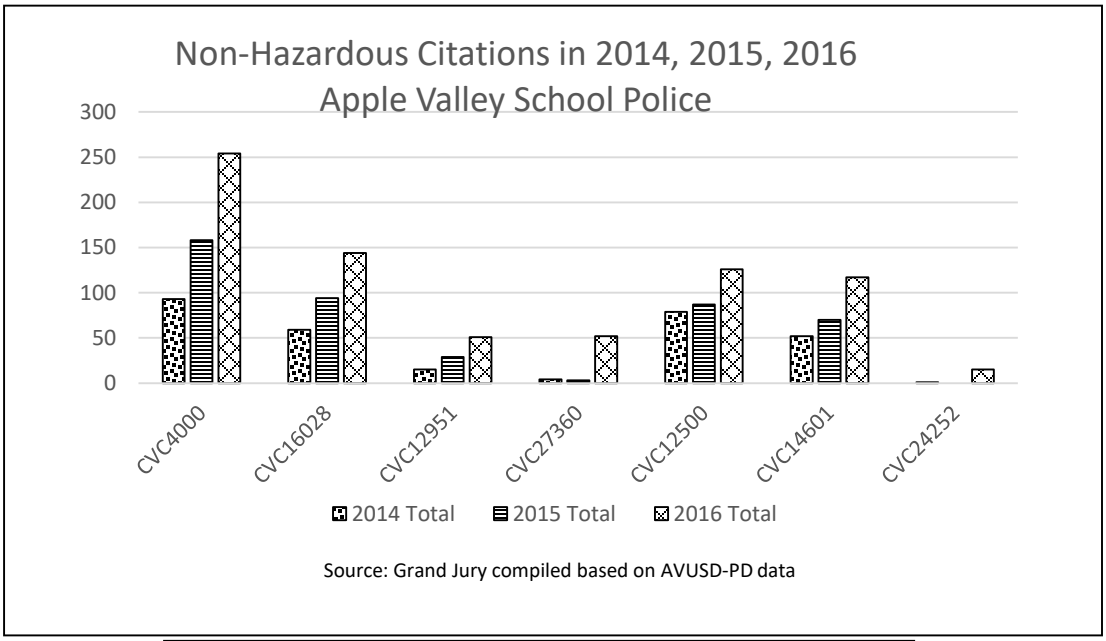
The most frequent types of infractions are noted along with a brief description of the violation. Some appeared to be hazardous to students and pedestrians near a school site, but others were not hazardous to the general public.



Source: Grand Jury compiled based on AVUSD-PD data

HAZARDOUS CITATIONS BY YEAR

Most frequent hazardous violations cited. Excessive speed violations increased from 122 to 180 from 2015 to 2016.



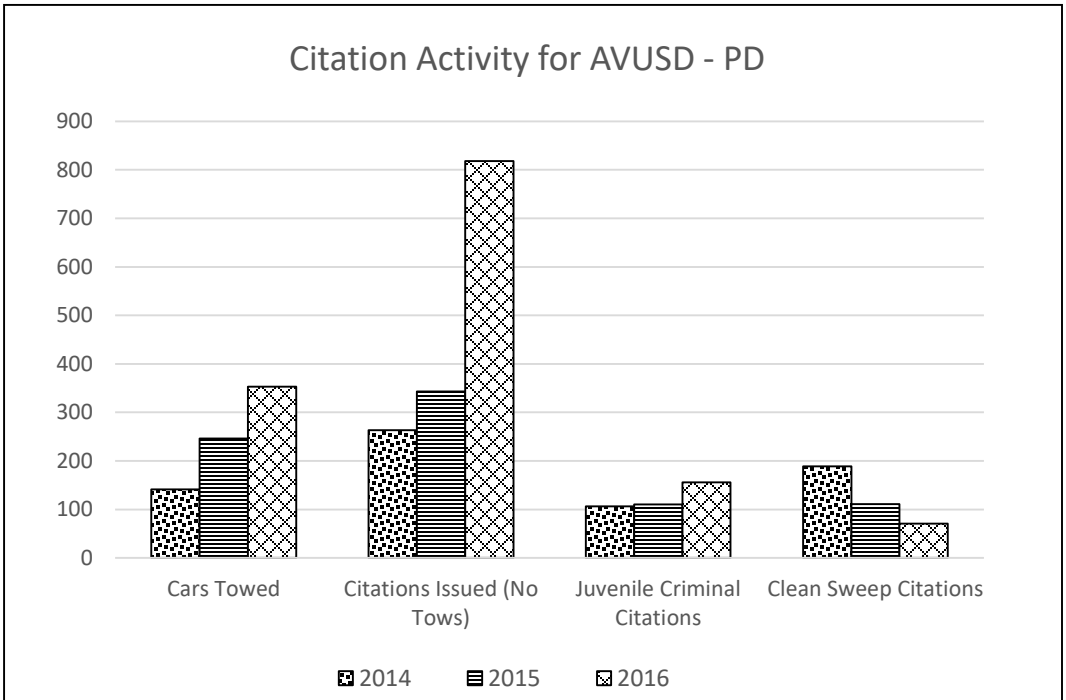
Source: Grand Jury compiled based on AVUSD-PD data

NON-HAZARDOUS CITATIONS BY YEAR

Almost one hundred more registration violations were cited in 2016 than in 2015. Lack of insurance violations ranked as the second most frequent citation. Neither represents a danger to staff or students.

The Grand Jury's examination of copies of the citations that were issued by AVUSD-PD in conjunction with the towing of vehicles revealed that most vehicles were not stopped for hazardous moving violations but for equipment or registration violations, and thus, outside of the authority of the AVUSD-PD to stop and detain drivers on a public roadway.

Over the three-year period that was examined by the Grand Jury, it appears that, as traffic citations and traffic activity by the AVUSD-PD increased, there was a corresponding decline in student related interactions, such as operation Clean Sweep, (a youth diversion program for minor or first offense violations) or on-campus citation activity.



Source: Grand Jury compiled based on AVUSD-PD citation data

AVUSD-PD CITATION ACTIVITY

2016 saw an increase of 107 cars towed over 2015. Juvenile criminal citations increased while the Clean Sweep diversion program citations decreased in 2016.

Several drivers of vehicles ordered towed by the AVUSD-PD were interviewed by the Grand Jury. One woman reported that she was stopped by AVUSD-PD on October 6, 2016 on Bear Valley Road and Central Avenue in Apple Valley at 11:23 p.m. at night because the license plate light on her vehicle was inoperative. The officer determined the vehicle had an expired license registration and ordered her vehicle towed and issued a citation. The driver did not feel comfortable in the presence of the officer and refused his offer of giving her a ride home. She subsequently walked about a mile to her home. She was unable to pay the fees to retrieve her car and it was ultimately lien sold at auction by the tow company. She was not at or near a school when she was stopped. In another incident, a man was stopped on Christmas Day 2016, at 8:45 p.m. The officer stopped him for an expired registration. The officer learned the man had a suspended driver's license. The driver told the Grand Jury that his suspended license was a surprise to him because he had only experienced a difficulty with a late child support payment. The officer cited the man for both violations and had his car towed to a storage facility, even though the driver's son was in the car with a valid driver's license and could have driven the vehicle home. While the driver was stopped near a school, it was 8:45 p.m. and school was not in session due to winter break.

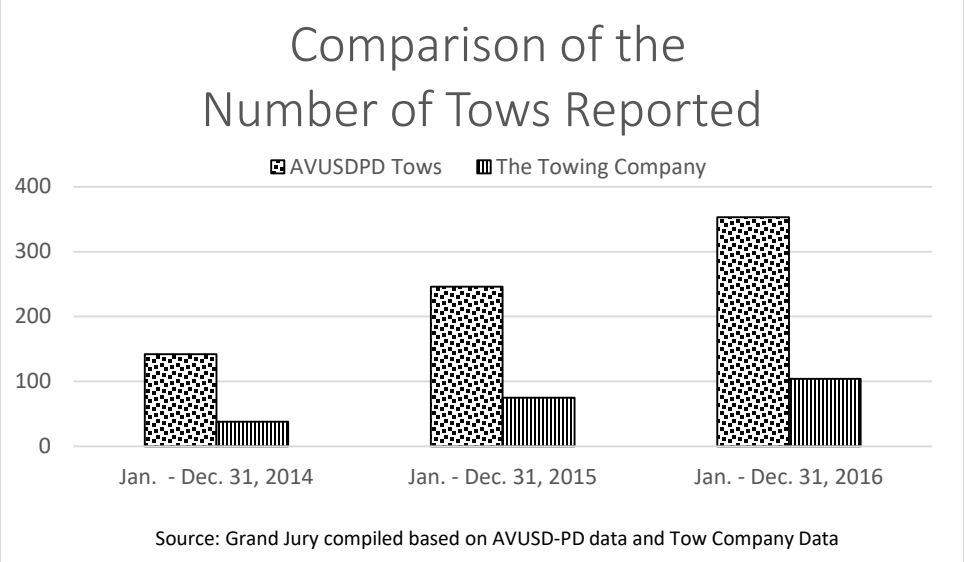
The AVUSD-PD "TOWED VEHICLE LOG" document is a manually completed chronological list of vehicles ordered towed by the AVUSD-PD. It includes the following columns: Date, Report Number, Veh. description, License, L/O, 180 sent, Date Released, Fee Receipt #. Each page contains 17 lines for entry of information. Examination of the document shows the "180 Sent" column was completed only when a lienholder was listed. All other lines showed the column as blank. There is no indication that the vehicle's registered owner or the legal owner was ever notified of their right to a hearing to determine the validity of the seizure and towing of a vehicle ordered towed by the AVUSD-PD, and thus, the registered and legal owners were often deprived of their right to a poststorage hearing. Vehicle Code 22852 (e) states: *" The agency employing the person who directed the storage shall be responsible for the costs incurred for towing and storage if it is determined in the poststorage hearing that reasonable grounds for the storage are not established."* The AVUSD-PD administration could only recall one instance when a post storage hearing was requested.

The administrative Vehicle Release Form is currently completed by the clerical staff at the AVUSD-PD office upon payment of $120.00 and verification that any registration or licensing deficiencies have been rectified. Once the Vehicle Release Form is completed and provided to the driver or owner, the vehicle may then be retrieved from the tow company upon payment of towing and storage fees, currently a minimum of $250.00 plus $50.00 per day beyond the first day.

The Grand Jury visited the office of the tow company and examined its storage area to estimate the capacity for storage and retention of towed vehicles. The inspection failed to locate any price schedules posted in the area accessible to the public as required by CA Vehicle Code 22651.07(a)(1)(A) "*Except as provided in subparagraph (B), post in the office area of the storage facility, in plain view of the public, the Towing Fees and Access Notice and have copies readily available to the public."* Interviews with drivers who had their vehicle ordered towed by AVUSD-PD also reported that they saw no fee schedules posted and that, in several cases, the tow company required that the fees be paid by cash.

In December of 2016, after the Grand Jury commenced this inquiry, the AVUSD-PD changed its tow methodology to utilize a weekly tow rotation system amongst three local tow companies. It was reported that these two additional tow companies were approved and vetted for utilization and used by the San Bernardino County Sheriff Department. The Grand Jury independently confirmed that information. This three-tow rotation was done without any advice or guidance from the AVUSD Administrative Services division that is responsible for all contracts for service within the District. The AVUSD did not execute any contracts, MOUs or written understandings with any of the tow companies.

The Grand Jury requested information from the tow company as to the disposition of all of the 700 plus vehicles ordered towed by AVUSD-PD over the past three years. The tow company was only able to produce disposition information for 217 of the 727 vehicles ordered towed.



TOW VEHICLES REPORTED

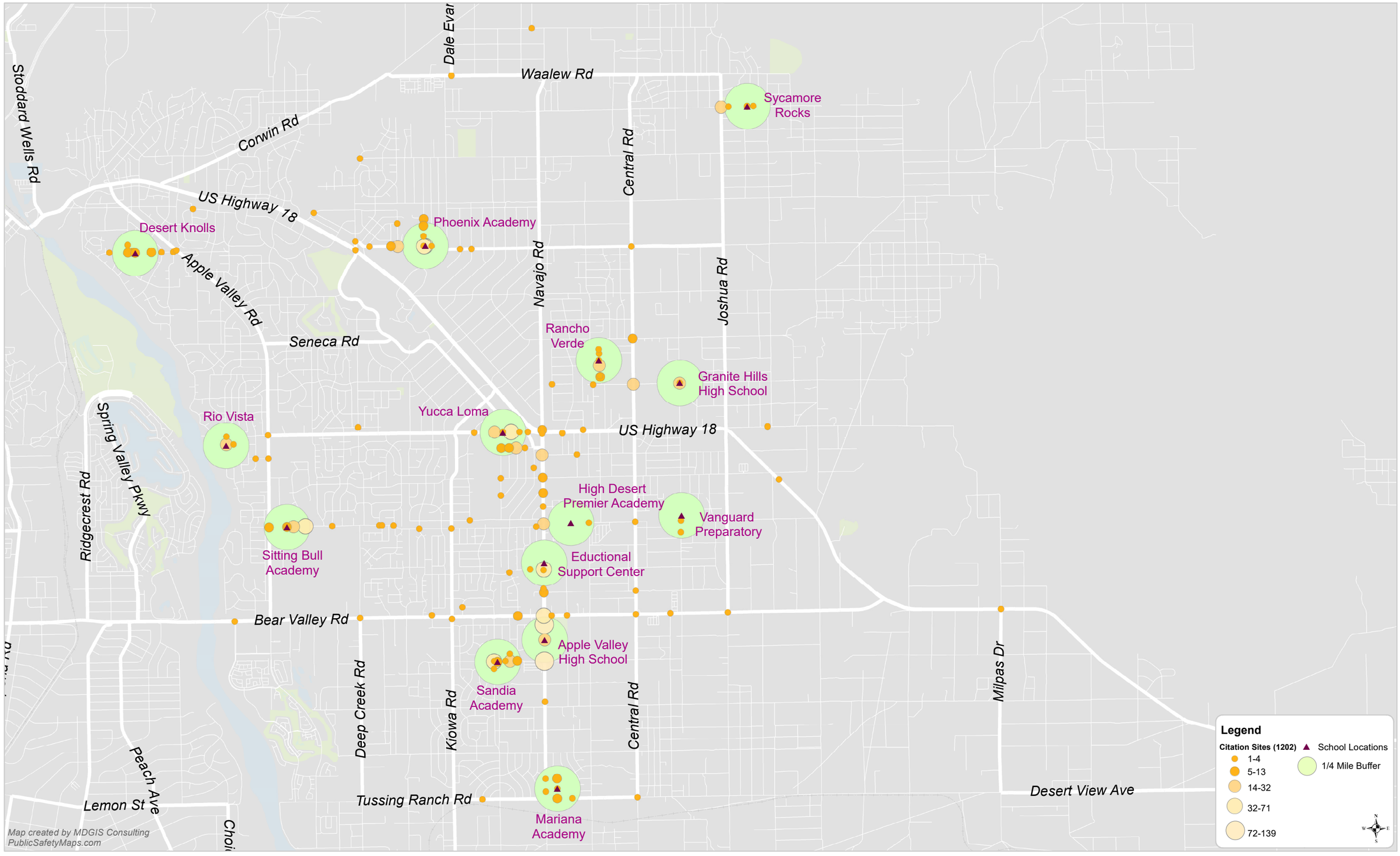
Towed vehicles reported by AVUSD-PD compared to the number of vehicles the towing company reports processing.

Sworn testimony by the representative of the tow company was that the information they produced was a complete and accurate representation of their files. The representative could not explain, nor accept, that there was a discrepancy of 510 vehicles unaccounted for in their records. The Grand Jury will leave to other agencies or organizations any attempt to examine the inability of the tow company to account for 510 vehicles that AVUSD-PD indicated were towed by them. On May 21, 2015 the Governing Board of the AVUSD, relying on CA Vehicle Code 22850.5 (a), approved a motion to increase the Vehicle Release Fee from $95.00 to $120.00. CA Vehicle Code 22850.5 (a) states, in part, "***A city, county, or city and county, or a state agency*** *may adopt a regulation, ordinance, or resolution establishing procedures for the release of properly impounded vehicles to the registered owner or the agent of the registered owner and for the imposition of a charge equal to its administrative costs relating to the removal, impound, storage, or release of the vehicles to the registered owner or to the agent of the registered owner. Those administrative costs may be waived by the local or state authority upon verifiable proof that the vehicle was reported stolen at the time the vehicle was removed." (**emphasis added)***

The Vehicle Code used to justify the increase does not permit a school district to charge a Vehicle Release Fee because a school police department is not a "city, county, or city and county, or a state agency" but is a Special District. The Grand Jury was unable to establish any legal basis for charging such a fee by the AVUSD-PD

The AVUSD-PD sponsors Explorer Post Unit 95. This Explorer Post is open to students who have an interest in law enforcement. The Advisors are officers of the AVUSD-PD who volunteer their time to mentor the students. Several past members have advanced to law enforcement careers, including with the AVUSD-PD. The Post serves as a crime diversion program for at-risk youths.

Apple Valley Unified School District - Citation Locations



FINDINGS

F1: The AVUSD relied on California Vehicle Code section 22850.5(a) to charge a vehicle release fee and to make increases in that fee. The vehicle code section relied upon gives authority to charge this fee to "...a city, county, or city and county, or a state agency." AVUSD-PD is not a city, county, or city and county or a state agency, and thus has no authority to charge this fee.

F2: Based on interviews with several AVUSD-PD personnel and several owners/drivers of vehicles that were towed at the direction of AVUSD-PD, the registered owners and legal owners were not notified of their right to a poststorage hearing to determine the validity of the storage, as mandated by California Vehicle Code section 22852(a).

F3: After interviewing several AVUSD personnel and owners/drivers of some of the vehicles that were towed by the authority of AVUSD-PD, proper notice of their right to a tow hearing was not given as mandated by California Vehicle Code section 22852(a).

F4: Through the combined interviews conducted by the Grand Jury of AVUSD personnel, interviews with drivers/owners of vehicles that were towed at the direction of the AVUSD-PD, review of documents provided by AVUSD-PD, and a legal opinion from San Bernardino County Counsel, it was determined that, in many cases, the AVUSD-PD did not have authority to stop, cite, and tow vehicles. Many owners could not pay the tow and storage fees, and their vehicles were subsequently lien sold.

F5: Based on interviews with AVUSD and AVUSD-PD personnel and based on a review of documents submitted by AVUSD, the AVUSD-PD was authorizing the towing of vehicles using only one tow service for a number of years, with no written contract, no signed Memorandum of Understanding, and without the involvement of the AVUSD Administrative Services Division.

F6: Based on interviews with AVUSD-PD personnel, interviews with AVUSD personnel, and a review of California Penal Code section 830.32, Education Code 38000, and case law, the majority of instances where the AVUSD-PD stopped, cited, and authorized the towing of vehicles exceeded the authority of the AVUSD police officers, since most instances did not indicate an immediate threat to persons or property.

F7: Based on the examination of citations written by the AVUSD-PD during the years 2014, 2015 and 2016, there is a constant increase in the number of citations written and vehicles being towed, with the vast majority of citations being for non-hazardous vehicle code violations. This activity results in the officers being taken away from their primary duty, which is the protection of school children, school personnel, and school property.

F8: The AVUSD has operated without a signed MOU with SBCSD.

F9: Based on the tow log received by the AVUSD-PD on all cars that department ordered to be towed by the only tow company used during the years 2014, 2015, and 2016, and compared to the cars that the tow company received during 2014, 2015, and 2016, over 500 cars are unaccounted for even though both the AVUSD-PD and the tow company stand by their records.

RECOMMENDATIONS

17-01: Refund any monies collected by Apple Valley Unified School District – Police Department for Vehicle Release fees.

17-02: Develop a procedure to assure the Apple Valley Unified School District – Police Department notifies the legal and registered owners of vehicles towed in the future of their right to a tow hearing.

17-03: Refund any towing and storage fees paid by any legal owner or registered owner who was denied the opportunity to request a tow hearing.

17-04: Provide restitution to any vehicle owner whose vehicle was lien sold as a result of the vehicle being ordered towed by Apple Valley Unified School District – Police Department in excess of their legal authority to do so.

17-05: Engage in a Request for Proposal (RFP) process for any non-district services requested by Apple Valley Unified School District – Police Department.

17-06: Clarify to all members of the Apple Valley Unified School District – Police Department their geographical area of responsibility and the limits of their authority.

17-07: Prioritize the duties and responsibilities of the Apple Valley Unified School District – Police Department to confirm with their primary duty of protecting school children, school staff, and school property.

17-08: Review all Memorandum of Understandings with school police departments and the San Bernardino County Sheriff's Department to insure that jurisdictional authority has not been exceeded by school police departments.

17-09: The appropriate state agency opens an investigation into this matter which is beyond the jurisdiction of the Grand Jury.

AGENCY	**RECOMMENDATIONS**	**DUE DATE**
Apple Valley USD	17-01 through 17-07	10/1/2017
San Bernardino County Sheriff's Department	17-08 through 17-09	9/1/2017

CHILDREN AND FAMILY SERVICES

BACKGROUND

In 2011, Children and Family Services (CFS) requested the County Board of Supervisors (BOS) to hire Deloitte Consulting LLP (Deloitte) at a cost of $250,000. Deloitte, which consults on children and family services, conducted a study of the CFS organizational operations and services and recommended improvements. The BOS hired Deloitte in response to a competitive Request for Proposal. Their six-month study resulted in the 148-page "San Bernardino Business Redesign Project: Final Recommendations," published on July 6, 2012. The projected timeline for full implementation of the redesign was five years. As July 2017 approaches, CFS acknowledges they have been unable to meet the five-year deadline due to unanticipated factors such as additional government mandates.

The 2012-2013 findings and recommendations regarding CFS were published in the Grand Jury Final Report. On behalf of CFS, the BOS officially responded to the Grand Jury's investigation. The 2016-2017 Grand Jury followed up on the implementation of the five-year Deloitte redesign and the recommendations of the 2012-2013 Grand Jury regarding public accountability.

CFS has nine offices throughout the County. There are approximately 950 employees, approximately half of whom are Social Service Practitioners (SSP). Intake SSPs respond to reports of child abuse, assess the situation, make recommendations for placement of the child, and develop a treatment plan for the child and family as the situation warrants. Placement and treatment may require CFS to provide foster care and adoption services. Carrier SSPs administer and monitor services in accord with the plan. Administrative, managerial, supervisorial, social work, technical, clerical, and other staff members provide guidance and support for the SSPs. Employees at all levels were involved in the redesign effort leading up to the hiring of Deloitte.

The Grand Jury is an independent civil watchdog agency that investigates County agencies, towns and cities, and special districts within San Bernardino County. California Penal Code 925 is the civil Grand Jury's jurisdiction authority for this investigation.

METHODOLOGY

The 2016-2017 Grand Jury interviewed representatives of CFS management regarding the systematic implementation of the Deloitte recommendations. By request, the interviewees provided annual and System Improvement Plan (SIP) reports for the prior two years and information on current public relations operations. The Grand Jury interviewed a sample of SSPs who had been selected randomly from a list provided by County Human Services. The Grand Jury returned to management for a follow-up interview and requested additional documentation.

This report consists of two parts, which echo and update those of the 2012-2013 Grand Jury Final Report:

- Part 1. CFS Implementation of the Deloitte recommendations, and
- Part 2. CFS obligation to provide an annual report for full accountability to the public.

FACTS

Part I: Deloitte Redesign

Deloitte made 44 recommendations/objectives. CFS management distilled them into task initiatives and assigned them to a Deputy Director and Manager. They formed multi-level work groups to implement actions and the attendant policies and procedures. CFS added the County-wide Training initiative with three additional objectives. Work groups are focusing on the three on-going objectives and the six in-progress objectives. Management recently created and hired a Project Coordinator. The Project Coordinator keeps staff on track to complete the remaining task objectives and monitors objectives to measure their effectiveness. Table 1 shows the scope of the initiatives.

Deloitte Redesign Recommendations

Table 1. CFS Initiative Name and Goals	Status
Unit Configuration and Caseload Management	
1. Consider moving towards sibling and permanency units	Completed
2. Continue to use Geo-Staffing for case distribution and introduce an overflow method	Completed
3. Consider implementing a rotation or cross training program to promote growth for all staff	Completed
4. Formalize recommended caseloads	Completed
5. Develop method to support workload balancing	Completed
6. Implement recommended caseloads and unit configuration for redesign and assure social worker to caseload ratio is appropriate. Evaluate clerical staffs workflow and adjust to new unit configuration process	Completed
Supervision and Organizational Structure	
1. Enable supervisors to focus on individual area of expertise	Completed
2. Centralize court supervisors at court and reassign J/D Court staff to regions	Completed
3. Supervisors to support clerical teams to promote a teaming and customer service focus	On-going
Optimized Operational Scheduling	
1. Configure CFS operational and staff scheduling to meet customers' needs	In Progress
2. Evaluate a Command Post Strategy	Completed
Hiring Retention and Classification	
1. Leverage approaches to hiring that have yielded positive results and create incentives that enhance retention	Completed
Optimized Staff Classification, Duties, Assignments and Support	
1. Consider career development opportunities for entry level professionals	Completed
2. Explore the use of a lead worker position	Completed
3. Consider expanding the Parent Partner program by enhancing the roles and responsibilities	Completed
4. Consider adding additional Education Liaisons to extend services under the age of 10	Completed
5. Research ways to increase the capacity of PFAs, bilingual workers and PHNs	Completed

~~6. Consider the use of Paralegal's in the regions~~	*See below
7. Review the overall referral workload for the agency and determine if the appropriate assignments/duties are being completed by the appropriate personnel.	Completed
7a. Process Redesign Study	In-Progress
8. Consider utilizing time study for all professionals to maximize resources	In-Progress
Effective Use of Technological Tools	
1. Identify current technologies, programs, databases and tools. Provide users with access, training, and support to increase day to day work	Completed
2. Identify technologies to enhance mobility with a focus on safety	Completed
3. Formalize an IT helpdesk for enhanced support and learning opportunities	Completed
4. Implementation of the Mobile Device Management System	Completed
5. Implementation of Mass text Messaging	On Hold
6. Implementation of Laptops	Completed
Risk Assessment Practice/Warrant Process Training	
1. Implementation of SDM	Completed
2. Consider implementing and training staff on supplemental risk and safety tools that supports risk assessment, decision making , and caseload management	Completed
3. Review screening process for referrals	Completed
4. Introduce additional structure to the Risk Assessment Meetings (RAM/DARE/CAF)	Completed
4a. Streamline RAM Process to reduce of bottleneck of referral closures safely	Completed
5. Prioritize and increase the number of TDM's being performed	Completed
6. Consider joint response with law enforcement	On-going
7. Continue to evaluate and train on warrant processes	Completed
Visitation	
1. Consider opening visitation resources center/s to meet the needs of children and families	Completed
Accountability	
1. Find ways to communicate mission, vision, goals and changes to help staff continuously be accountable	In-Progress
Culture of Modeling and Innovation	
1. Continue to foster a culture that promotes positive re-enforcement, encourages modeling, coaching and training, and supports innovation	Completed

2. Continue to heighten executive and management level engagement in day to day activities to support improvement, collaboration and morale	Completed
Communication Organization-Wide	
1. Formalize a CFS Business Redesign communication plan	Completed
2. Formalize and strengthen a CFS-wide communication plan	Completed
3. Simplify communications related to process and policy	On-going
4. Social Media	Completed
Incorporate Data into Future Planning Process	
1. Enhance data analysis to continue to drive decision making and strategic Planning	In-Progress
Objectives outside of the Business Redesign: Countywide Training Committee	
1. Consider new approach to the training unit to improve professional development and training delivery	Completed
2. Reconfigure training unit to further support agency goals	Completed
3. Consider contracting out Pride Training after hours and weekends	In-Progress

*CFS eliminated the objective to add paralegals to the staff as it would necessitate hiring an attorney to supervise them.

SOURCE: CFS, data from February 22, 2017

Table 2 summarizes the record of accomplishment in five years.

TABLE 2	
Objectives	
Completed	36
In progress	6
Ongoing	3
On hold	1
Eliminated	1
TOTAL	47

SOURCE: CFS, data from February 22, 2017

Definitions

Jurisdiction/ Disposition (J/D)

The primary goal of the Jurisdiction/Disposition (J/D) Hearing is to determine the least intrusive intervention to ensure the safety and well-being of the families. In either Family Reunification or Family Maintenance, the social worker is to provide resources and support to children and families through family centered casework. Family centered casework utilizes the family's strengths in order to evaluate and provide the necessary resources to either stabilize the family or reunify the child with his/her parents. Alternatively, every child has a right to permanency and legislation requires that this be secured within 12 months from the date the child entered foster care.

The purpose of the Jurisdiction and Disposition Hearings and the information required for the J/D Hearing Report. Although in San Bernardino County the Jurisdiction and Disposition hearings are combined and usually held on the same day, they are two distinct court hearings:

Jurisdiction Hearing	Disposition Hearing

Court determines whether:	Court determines whether:
• There is sufficient evidence provided by the Social Worker (SW) to support each of the allegation(s) in the Petition, or • The Parent or Guardian who provides an admission, plea of no contest, or submission to the allegations in the Petition understands the nature of the allegations and consequences of the admission, or • The allegations in the Petition are not proven by a preponderance of the evidence.	• To declare the child a dependent of the Court, and. • To place the child with the parent(s) on Court Family Maintenance and provide services, or. • To dismiss Petition with custody to non-offending parent, or. • To dismiss Petition In lieu of Voluntary Family Maintenance (VFM), or. • To remove the child from the parent(s) and place him/her with a relative, non-relative extended family member (NREFM), foster parent, or group home, and. • To offer parents reunification services, or. • To remove the child from the parents and not offer them reunification services (No-FR).

Reference: CFSHB Volume 6, Chapter B.

Continued on next page

Definitions, Continued

Structured Decision Making (SDM)

Structured Decision Making (SDM) is an assessment tool that promotes safety and well-being for children at risk and their families. SDM combines research with best practices, offering social workers a framework for consistent decision making.

SDM criteria is used for screening an investigation, determining response priority, identifying immediate threatened harm and estimating the risk of future abuse and neglect. Child and family needs and strengths are identified and considered in developing and monitoring progress toward a case plan.

Reference: IIN 16-018 and 16-019.

Daily Risk Assessment Meeting (DARE)

Daily Assessment Review Evaluation (DARE) is a part of the peer review/case consultation processes. The DARE process is part of an integrated approach to view families in terms of their strengths and evaluates the necessary resources Children and Family Services (CFS) can offer. When removal is necessary, it is imperative to work diligently with the family and community to restore the family's capacity to resume their parental responsibilities.

DARE was created to provide an arena for the social worker (SW) to obtain necessary support and consultation for child removal decisions. DARE is a required consultation and review of the responding SW's casework through a supportive process with the SW's peers and supervision. The DARE Team reviews referrals resulting in a petition being filed (post Team Decision Making [TDM] meeting) and will occur following an Immediate Response (IR)/Risk Assessment Meeting (RAM).

Reference: CFSHB Volume 3, Chapter B, Section 2.

Case Assessment Forum (CAF)

The Case Assessment Forum (CAF) is a peer case review process and a tool to use when group discussion is helpful during case planning. It is designed to assist case carrying social workers to deal with complex case issues. For example, a Family Maintenance (FM) worker may request a CAF to help in deciding the appropriateness of extending FM services beyond the federal/state-funded maximum 12-months for a given case. A Family Reunification (FR) worker may request a CAF in order to learn about alternative programs and services that would help deal with difficult mental health issues in order to help the family successfully reunify. The CAF differs from the Concurrent Planning Review (CPR) process in that the CPR reviews FR or Planned Permanent Living Arrangement (PPLA) cases in order to determine whether the proposed Permanent Plan remains appropriate.

Reference: CFSHB Volume 3, Chapter B, Section 3.

Team Decision Making (TDM)

Team Decision Making (TDM) enables those closest to a child to participate in problem solving. Instead of a single caseworker determining what to do in a crisis that requires consideration of out-of-home care because of child abuse or neglect, TDM brings together parents, family, community members and others to assess the situation and determine how best to keep the child safe. TDM provides the family with a voice in each and every placement related decision.

TDM allows Children and Family Services (CFS) to maintain responsibility to make the decisions, supports the social worker in difficult decisions, reinforces the core strategies of strengthening the family and partners in the decisions regarding the needs of the child.

Reference: CFSHB Volume 3, Chapter F.

Prior to the February 22, 2017, follow up interview with management, the 2016-2017 Grand Jury submitted a number of pre-interview requests and questions. One question concerned post-measurements of staff response to changes to compare with those responses obtained by Deloitte in 2011. In their prepared remarks for the interview, management wrote ". . . [A] survey to obtain staff feedback regarding the ongoing organizational changes is an excellent idea . . .This will help us in mapping out areas needing further adjustment or improvement."

The Grand Jury inquiry determined that CFS has not reported on the redesign progress and its impact on the organizational operations to the BOS. Also, the CFS management has not reported on the full redesign progress to its staff.

A Focus on CFS Task Initiatives

Unit Configuration and Case Load Management

CFS followed Deloitte's advice to replace blended units with side-by-side units. In a blended unit a multi-level team, including intake and carrier workers, followed a child from referral to placement and through maintenance to permanence. The side-by-side unit model serves a child with independent intake and carrier specialists. Their desks are intermingled to provide services when needed.

Optimized Operational Scheduling

CFS response is needed 24 hours a day. Until recently, Intake Workers and their support staff routinely had to work long hours after the offices closing time of 5:00 p.m. In remote locations some still do. In 2016, CFS opened an After-hours Response Center (ARC) that established a swing shift from 5:00 p.m. - 11:00 p.m. and a night shift from 10:00 p.m. - 8:00 a.m. At the time of the first Grand Jury visit on September 23, 2016, ARC was recently implemented in San Bernardino and serviced the entire County. Days of service were Monday through

Thursday. On the second visit, on February 22, 2017, management stated that ARC service had been extended to include Friday through Sunday. San Bernardino's ARC continues to cover the County, and a satellite ARC in Victorville has just begun service to the High Desert.

Hiring and Retention Classification

In 2014, the union representing SSPs reached an impasse with management. After mediation, the parties were unable to come to an agreement. The Board of Supervisors declared a collective bargaining imposition, a forced contract that reduced salaries by seven percent. As a consequence, the attrition rate rose to 23 percent. Later SSPs changed their union affiliation. In 2016, the seven percent salary reduction was fully restored with an additional two percent raise in 2017 and another three percent raise planned for 2018. CFS is currently approaching full staffing.

Recruitment efforts intensified to a great extent, but formal training takes four to five months. The training takes at least one to two years on-the-job to become a worker who requires limited supervision.

CFS adopted an expanded classification system for SSPs from two to five classes, (I-V) with attendant salary increases. Outreach efforts include three approaches: job fairs, moving from once-a-year recruitment at local colleges to year round searches with outreach beginning in public schools, and extending recruitment efforts across state lines. A recently formed Department Diversity Committee has joined in the effort to address attrition and retention. The Labor-Management Committee, formed in conjunction with the union, is working on a number of issues including a reduction in the number of cases and workloads. It should be noted that caseloads vary with the intensity of workload, e.g., caseloads for disabled foster children are small. In spite of professional standards and efforts to reduce case and workloads, they remain excessively high, especially in the High Desert.

A remote assignment incentive has recently been offered for SSP I-V to work in Barstow, Needles, Victorville and Yucca Valley for the period July 9, 2016, through June 30, 2019. Employees who meet the eligibility requirements receive $500 upon hire and an additional $500 upon completion of 2,080 hours at those remote locations.

Title IV-E is a federally funded program that enables CFS employees to earn a Bachelor of Arts in Social Work or a Master of Social Work degree from California State University, San Bernardino or Loma Linda University in order to advance their careers. Enrolled employees are given an internship and reduced caseload to support their studies. Upon completion, the employee is contractually obligated to work for a child welfare services agency, generally for two years.

Optimized Staff Classification, Duties, Assignments and Support

Increasing the classes of SSPs from two to five is an inducement to retention. During the Grand Jury interviews with SSPs, nearly all who had received a promotion, indicated that other than salary, there were no clear distinctions among the classes. Some who said they had received a major promotion under the new classification system said they did not know what their job description included. When the Grand Jury asked management about this confusion, management assured the Grand Jury a job description would be forwarded. When management failed to respond, the Grand Jury requested the job descriptions in writing. A listing of qualifications and respective salaries of the jobs was received. However, nothing received distinguished the classes in terms of relative duties, rights, responsibilities, and performance standards.

Effective Use of Technological Tools

Teleconference technology interconnects all the offices. It is used for weekly executive meetings and the “First Monday View” live broadcasts fostering communication and best practices. Management circulates around the regions for these broadcasts. In the past, staff used personal

cell phones. CFS had just issued smart phones to personnel before the first Grand Jury visit on September 23, 2016, CFS has since issued 100 new laptops to staff members who requested them.

Risk Assessment Practice/Warrant Process Training

Workers and management agree that the new tool for assessment of child safety and decision-making protocol, Structured Decision Making, is a great improvement over the prior system. Coordination with law enforcement is enhanced. The warrant process is now part of training in a simulation training facility shared with Riverside County. The training facility is located in that county.

Communication Organizations-Wide

"First Monday View," a live staff-wide teleconference, is broadcast on the first Monday of each month. The teleconference location moves among the regions and offices to highlight people, activities and operations. The programs are archived and available for later viewing in-house. The Director and Assistant Director travel around the regions for regular listening tours. Employees acknowledge the importance of these activities and like finding out what is happening in other offices.

FACTS

Part II: A CFS Annual Report for Accountability to the Public

In their official response to the 2012-2013 Grand Jury Final Report, the Board of Supervisors agreed with the following: "CFS has an obligation to measure its accountability to the public and express it in terms which can be understood by the public."

The 2012-2013 Grand Jury Recommendation 13-9 stated: "CFS devise more suitable means of reporting its accountability to the public in an annual publication presented in understandable terminology and easy to access . . .".

CFS does not yet publish an annual accountability report expressed in terms that can be understood by the public. One CFS annual report, the in-house staff report, can be adapted for public accountability. It is already public as it is posted on the CFS website. It includes CFS mission, functions, programs, activities and services in an easy to understand format.

In order to be more accountable, the statistics cited need to be more informative. The 2012-2013 Grand Jury recommended that the annual report should go beyond a recitation of raw numbers served and the 2016-2017 Grand Jury concurs. Raw numbers have little informative value without a context or basis for comparison; annual trending data and percentages provide more information. For instance, compare the number of children provided services over the last three years. Another instance would be stating the percentage of eligible children who participated in the annual Sports Faire would be more informative than the raw number of children participating. The annual trend data has been provided to a limited extent in the current report. CFS has its own statistics unit that can provide the comparative statistical measures.

The goal of the revised Annual Report should be to provide information to account for public support for the agency. At the same time, the feedback provided by more meaningful data will serve CFS staff and management as an annual report card on their services.

The CFS Website

In the intervening five years, the CFS website, "http://hs.sbcounty.gov/cfs" has improved. In addition to resource information on Child Abuse Services, Foster Parents and Adoption, and links to resources and educational videos, there is a window, "CFS Business Reports." This window currently features the CFS Annual Report for 2015 which always has a one-year publication delay. The Redesign Executive Summary and the SIP Roadmap remain unchanged from year to year. The "Contact Us" page does not include the telephone number and email address for the Administrative Offices.

FINDINGS

F1: CFS has made steady progress on implementing changes in organizational objectives.

F2: No progress reports have been made directly to the BOS to apprise them of the value of investing $250,000 in the redesign.

F3: A disconnect exists between the implementation of the redesign elements and the changes brought about in organization and operations.

F4: Workers who had been part of blended units expressed a preference for them for their teamwork aspect.

F5: Although CFS is approaching full staffing, professional training takes one to two years. Therefore, it will be some time before current staff members, whose case and workloads remain high, feel the effects of full staffing.

F6: There were no clear job descriptions to distinguish among SSP classes I-V.

F7: CFS has begun to provide ARC shifts in outlying offices.

F8: Staff welcomed the issue of new technological tools. In the field these tools will enable staff to better utilize time and communicate with offices and clients.

F9: The wording of 2012-2013 Grand Jury Recommendation 13-10 lacked specificity: "Enhance the Annual Report for this purpose." The "Annual Report" that the Grand Jury recommended to be upgraded for the purpose of accountability to the public was not SIP. It was the former in-house report intended for the staff, which CFS has since made a public document on the CFS website.

F10: Updating of CFS website is limited.

RECOMMENDATIONS

17-10: Implement fully the Deloitte methodology and replicate portions of it that would reveal Children Family Services staff perceptions of the redesign changes.

17-11: Review Deloitte's research methodology and replicate relevant tools to compare pre- and post- measurements of staff perceptions toward changes in operations, organization and their work lives resulting from the redesign.

17-12: Provide a full progress report to the Board of Supervisors.

17-13: Present a full progress report to the Children Family Services staff.

17-14: Survey the Children Family Services staff on the effectiveness of blended units.

17-15: Maintain intensified efforts to hire, train, and retain professional workers to lower cases and workloads, particularly in the High Desert and other remote locations.

17-16: Provide Children Family Services staff with full job descriptions for each Social Service Practitioner classification (I-V).

17-17: Give increased priority to expand After-hours Response Center shifts, particularly in remote offices in 2018.

17-18: Adapt the former in-house annual report as the Children Family Services Annual Report for accountability to the public. Replace raw numbers with statistical numeric and percentage comparisons for data in the revised Annual Report.

17-19: Update the status of the Redesign Executive Summary and the System Improvement Plan Roadmap on the Children Family Services website annually.

17-20: Provide the telephone numbers and email address for Children Family Services Administrative Offices on the “Contact Us” page of the website.

AGENCY	RECOMMENDATIONS	DUE DATE
Children and Family Services	17-10 through 17-20	10/1/2017

HIGH DESERT AMBULANCE AVAILABILITY AND BED DELAY

BACKGROUND

Bed delay is the time between arrival of an ambulance at a hospital Emergency Department (ED) and the ED receiving the patient. The first 25 minutes after arrival to the Hospital are excluded from the bed delay calculation. The bed delay contributing factors are the result of several issues: only three high desert hospitals with an ED, none of which have trauma centers; a lack of ambulances at peak times; the misuse by the public of the EDs; and the overuse of 9-1-1 calls for non-emergencies. Other contributions are a lack of interest of private hospitals to expand or build new services which leads to a shortage of beds. Only three hospitals have EDs that can receive patients via ambulances. There are a high number of Medicare and Medi-Cal clients in the High Desert. These factors put a strain on the use of resources between San Bernardino County Fire Department (SBCFD) and American Medical Response (AMR) in the High Desert. The nearest trauma centers for the High Desert are Loma Linda University Medical Center and Arrowhead Regional Medical Center.

Recently, there were newspaper articles that referenced the response time and bed delays concerning SBCFD and AMR. This is a concern for adequate Emergency Medical Services (EMS) for residents in the High Desert communities. For this report the High Desert includes the following cities: Adelanto, Apple Valley, Victorville, Hesperia, and Victor Valley. "Current trends and changes in the healthcare delivery system suggest that a greater impact on the medical system and higher demand on EMS will continue into the foreseeable future." (Attachment 1, page i)

The Grand Jury's jurisdiction for this report is Penal Code §925.

METHODOLOGY

The Grand Jury gathered information through interviews to track the response times and level of services for AMR and SBCFD to determine whether there are adequate resources to provide the required level of service. The Grand Jury interviewed representatives from Inland Counties Emergency Medical Agency (ICEMA). The Grand Jury also interviewed reporters, representatives of SBCFD, and AMR regarding the bed delay issue. San Bernardino County (SBC) Purchasing Department was also interviewed regarding the AMR contract. The Grand Jury studied the complete process from receipt of the 9-1-1 call through obtaining a bed or chair in the ED. ICEMA provided the Grand Jury with two attachments: "ICEMA Centralized Medical Control Proposal" (Attachment 1) and "ICEMA Bed Delay Report" (Attachment 2). To publicly access these reports go to http://www.sbcounty.gov/icema/, look under reports in the blue field on the left hand side of the home page.

FACTS

ICEMA is a Joint Powers Authority (JPA) that covers three counties: San Bernardino, Inyo, and Mono. ICEMA as a JPA is an entity permitted under the laws of California, whereby two or more public authorities not necessarily located in the same county, may jointly exercise any power common to all of them. San Bernardino County activities are grouped into three primary programs: Pre-Hospital and Trauma Care, Performance Based Contracts, and Medical Disaster Preparedness, including the Hospital Preparedness Program. The ICEMA Medical Director provides medical direction and oversight to all Emergency Medical Services (EMS) personnel within the three counties.

ICEMA provides quality customer services, certification, and accreditation of Emergency Medical Technicians (EMTs), Emergency Medical Technicians – Paramedics, and Mobile Intensive Care Nurses. ICEMA is responsible for all pre-hospital patient care protocols,

education, and materials for paramedics, hospitals, and educators. In addition, it oversees ambulance response time monitoring, inspection and permitting, and medical disaster planning for hospitals and the citizens of the County of San Bernardino. ICEMA establishes criteria for policy and procedures for adult and pediatric trauma centers and cardiac care hospitals. By meeting these objectives, ICEMA fulfills its medical oversight responsibility and legal requirements to the counties of San Bernardino, Inyo, and Mono. All five San Bernardino County Board of Supervisors are also members of the ICEMA governing board.

"APOD [or Ambulance Patient Offload Delays] not only impacts the transfer of care of patients, it delays the return of ambulances to respond to other calls for emergency services. The downstream effect of APOD is that first responders, including fire service and law enforcement personnel, must remain on scene longer than necessary thus delaying responses to a variety of emergencies including medical, fire, hazardous materials and crime related incidents." (Attachment 1, page ii) In Bed Delay Task Force discussions, the Hospital Association of Southern California and the 18 CEOs of San Bernardino County hospitals proposed exploring the creation of a centralized medical control and transportation hub to better address and implement solutions.

A media source interviewee stated that there are multiple contributing factors to bed delay. These factors are a lack of ambulances at peak times, shortage of ED beds and the public's misuse of the ED, and the lack of incentive for private hospitals to expand or build new services due to the high usage of Medicare and Medi-Cal in the area. Medicare and Medi-Cal reimburse providers at a lower rate than standard medical insurers.

SBCFD mentioned one solution to the bed delay issue is the communication with AMR ambulances. A single source communication system does not exist as SBCFD and AMR are not on the same radio frequency. Other solutions include an increase in hospital staff and open bidding on the Emergency Transportation contract. Finally, the public needs to be educated on appropriate 9-1-1 usage.

One potential solution to addressing bed delays includes: "Implementation and adoption of emerging technologies to assist the EMS personnel in the triage of both 9-1-1 patient responses and in the evolving community paramedicine models, including post discharge patient encounters." (Attachment 1, page iii) Another solution includes: "Implementation on pre-hospital triage strategies, such as 9-1-1 call screening and increased utilization of existing nurse advice lines designed to identify patients that do not require the historical EMS response or an ED to provide care for the patient's medical complaint." (Attachment 1, page ii)

Ambulance Delay

An impact of the EMS system in bed delay is "the inability to move patients from ambulance gurney to ED beds or chairs due to ED [or hospital] overcrowding." (Attachment 1, page i) Once the ambulance is within 250 feet of one of the three hospitals, the responsibility of care transfers to the hospital and the two ambulance personnel are considered defacto employees of the hospital. Last year, AMR lost 72,000 personnel hours due to bed delay while Riverside County lost 24,000 personnel hours. San Bernardino County had 36,000 hours of bed delay compared to Riverside County that had 12,000 hours of bed delay.

Ambulance Callouts

AMR and the SBCFD both use an Emergency Medical Dispatch System that classifies 9-1-1 calls as A B C D E.

A and B are Basic Life Support (BLS) which represent 42% of the calls.

LETTER	SERIOUS LIFE THREAT	RESOURCES	RESPONSE
Alpha 20%	Non-life Threatening	Basic Life Support	Non-emergency
Bravo 22%	Possibly Life Threating	Basic Life Support	Emergency
Charlie 24%	Life Threatening	Advanced Life Support	Emergency
Delta 32%	Serious Life Threat	Advanced Life Support	Emergency
Echo 2%	Life Status Question	Closest Available	Emergency

SOURCE: Annual report SBCFD July 2015 through June 2016

A minimum of 20 percent, Alpha calls, have an emergency unit dispatched to the call site for non-emergency situations due to the overuse or misuse of the 9-1-1 system. This results in non-emergency calls being responded to unnecessarily.

The average number of daily medical responses within the High Desert's Exclusive Operating Area (EOA) 12 is 100-110. The High Desert may have as many as 15 AMR ambulances during peak deployment and as few as six during low peak hours. EOAs are designated areas within the County by which ICEMA ensures the effectiveness and success of a medical transportation system. Those ambulance services awarded an EOA are under contract to ICEMA and SBC. AMR is contracted to operate 12 of the 27 EOAs in SBC.

According to SBCFD, they have 16 County ambulances assigned to the High Desert. Ten are assigned in Apple Valley and Victorville; six ambulances are assigned to all the other areas in the High Desert. SBCFD and AMR operate on different radio frequencies. SBCFD receives all 9-1-1 calls based on the EOA and they may be relayed to AMR. This results in time delays when SBCFD units are closer to an AMR call and the response could be handled quicker. The opposite situation may also occur. SBCFD covers for AMR when ambulances are not available. In the last calendar year, SBCFD took 1,396 calls for AMR and AMR took 300 calls for SBCFD.

SBCFD utilizes a system called First Watch which monitors the usage of all the 16 County ambulances related to the bed delay issue. The determination of which hospital to transport to is decided several ways: the closest hospital, the patient's choice, and the bed status at the hospital. The SBCFD ambulance has real time contact with their dispatch to keep them updated as to the status at local hospitals.

Hospital Coordination

There is no coordination between the three High Desert hospitals when a bed shortage leads to ambulance delays. Riverside County does not have the same number of bed delays because there is cooperation between hospitals and their systems utilize an Emergency Medical Dispatch.

Ambulance Tracking

The clock for response time starts for AMR once the call or relay to AMR is made. AMR has a 9 minute 59 second response time in urban areas. The County and City Fire departments do not have any response time expectations because they are not under contract with ICEMA. SBCFD tracks and maintains the statistical data of the emergency response time of their ambulances. The SBCFD starts their tracking from the time they receive the call to the time they arrive at the location.

Ambulance Staffing

Each ambulance for AMR and SBCFD must have, at a minimum, of one Emergency Medical Technician (EMT) and a Paramedic. The cost is $1 million to maintain one ambulance on the street for 24 hours for one year. This includes all costs including vehicle cost and maintenance plus staffing. AMR Ambulance staff turnover is an issue due to SBCFD offering benefits and career growth opportunities that are better than what AMR offers.

There are three hospitals in the High Desert area with Emergency Departments:

Desert Valley Hospital Center (DVMC) - 110 BEDS
Saint Mary Medical Center (STMMC) - 210 BEDS
Victor Valley Global Medical Center (VVGMC) - 101 BEDS

According to the 2010 Census there are 306,976 residents of Victorville, Hesperia, Apple Valley, and Adelanto.

	DVMC	STMMC	VVGMC	TOTALS
Total Bed Delay Hours	4,213:20	4,232:59	3,250:13	11,695:92
Bed Delay Transports	7,000	6,715	4,093	17,808
Total Transports	11,167	11,708	7,053	29,928
Bed Delay Percentage	62.7%	57.4%	58.0%	59.5%

The contributing factors to the data include several issues:

- "An increase in the number of newly insured patients as a result of healthcare reform placing higher demands on already strained, over-crowded ED"
- "Further pressure on a county where the demand for inpatient beds is already significantly greater than the supply"
- "A disproportionately low number of local primary and specialty care physicians"
- "An aging population with additional medical needs, and the evolving role of EMS in healthcare systems, e.g., community paramedicine." (Attachment 1, page i)

FINDINGS

F1: Demands on the 9-1-1 system are influencing the need for a re-evaluation of the EMS system. It was designed "to provide better management of resources, real-time exchange of medical information, and improvement in the delivery of appropriate, safe, cost effective, and quality healthcare." (Attachment 1, page i).

F2: Bed delay directly affects the safety of patients and the general public who experience emergencies.

F3: A shortage of ED beds and the lack of a trauma center exist in the High Desert. This shortage leads to hospital and emergency department overcrowding resulting in bed delays.

F4: The misuse of the 9-1-1 system on a regular basis overloads dispatch and decreases the availability of ambulances.

F5: A lack of coordination occurs among the three high desert hospitals, AMR, and SBCFD regarding overcrowding.

F6: Communication problems result from AMR and SBCFD not operating on the same radio frequency.

F7: Enhanced 9-1-1 call screening data is collected but not utilized.

F8: No effective action has taken place to begin implementation of the ICEMA "Centralized Medical Control Proposal."

RECOMMENDATIONS

17-21: Implement the Inland Counties Emergency Medical Agency's "Centralized Medical Control Proposal."

17-22: Educate the general public for the correct use of the 9-1-1 system.

17-23: Implement and utilize enhanced 9-1-1 call screening of pre-hospital triage strategies. Include utilization of existing nurse advice lines designed to identify patients who do not require the traditional Emergency Medical Services response or an Emergency Department to provide care for the patient's medical complaint.

17:24: Track dispatches between American Medical Response and San Bernardino County Fire Department to determine the number of patients each hospital can serve based on the availability of beds to ease the number of bed delays.

17-25: Create a process to facilitate access to a common radio frequency between American Medical Response and San Bernardino Fire Department that will aid in the real time monitoring of their ambulances.

17-26: Build a new San Bernardino County hospital in the High Desert similar to Arrowhead Regional Medical Center that includes a trauma center.

AGENCY	RECOMMENDATIONS	DUE DATE
Inland Counties Emergency Medical Agency (ICEMA)	17-21 through 17-25	10/1/2017
Board of Supervisors	17-26	9/1/2017

Attachment 1

Inland Counties Emergency Medical Agency (ICEMA)

Centralized Medical Control Proposal

Introduction:

Current trends and changes in the healthcare delivery system suggest that a greater impact on the medical system and higher demand on Emergency Medical Services (EMS) will continue well into the foreseeable future. This is due, in part, to the change from a fee for service to value based care reimbursement model.

Additional factors include:

• An increase in the number of newly insured patients as a result of healthcare reform placing higher demands on already strained, over-crowded emergency departments (ED).

• Further pressure on a county where the demand for inpatient beds is already significantly greater than the supply.

• A disproportionately low number of local primary and specialty care physicians.

• An aging population with additional medical needs, and the evolving role of EMS in the healthcare system, e.g., community paramedicine.

These demands are influencing the need for an unprecedented, proactive reevaluation and remodeling of the EMS system designed to provide better management of resources, real-time exchange of medical information and improvements in the delivery of appropriate, safe, cost effective and quality healthcare.

The extent that these changes will ultimately impact EMS remains unclear, but it is evident that there are already increased demands on the EMS system and hospital EDs to provide primary care to the newly insured. There is also continued pressure to provide behavioral health services in the emergency setting. This results in the exacerbation of long-standing system inefficiencies, resource shortages and ED overcrowding.

From the EMS perspective, the most tangible impact on the EMS system is ambulance patient offload delays (APOD) or the inability to move patients from ambulance gurneys to ED beds or chairs due to ED overcrowding. The number of APOD hours has been increasing out of proportion to the increases in 9-1-1 requests for medical assistance. APOD exceeded 20,000 hours in 2014. Without systemic interventions, the 2015 APOD numbers are on track to exceed 30,000 hours.

APOD not only impacts the transfer of care of patients, it delays the return of ambulances to respond to other calls for emergency services. The downstream effect of APOD is that first responders, including fire service and law enforcement personnel, must remain on scene longer than necessary thus delaying responses to a variety of emergencies including medical, fire, hazardous materials and crime related incidents.

APOD directly affects the safety of patients and the general public that experience emergency response delays.

Potential Solutions:

An APOD Task Force comprised of stakeholders from San Bernardino and Riverside Counties identified a number of potential solutions to address these issues to promote better management of current resources, improve patient care and reduce APOD time resulting in the transfer of care and subsequent expeditious release of ambulances from EDs.

These solutions include:

• Implementation of pre-hospital triage strategies, such as enhanced 9-1-1 call screening and increased utilization of existing nurse advice lines designed to identify patients that do not require the historical EMS response or an ED to provide care for the patient's medical complaint.

• Development, implementation and continuation of ongoing public education strategies to address appropriate utilization of the EMS system and changing expectations that calling 9-1-1 always results in transportation to the ED. This must occur in partnership with healthcare insurance organizations, hospitals, EMS providers, and all levels of healthcare practitioners.

• Implementation of EMS personnel on scene screening of non-critical patients, through approved protocols, that results in routing these lower acuity 9-1-1 patients to appropriate non-emergency department medical facilities i.e., urgent care centers and clinics.

• Development of additional resources to support law enforcement and EMS personnel that encounter behavioral health patients and assist with the decision making regarding the placement of mental health holds commonly referred to as 5150s.

• Development of protocols to guide the transportation of patients with behavioral health conditions such as a 5150 without a medical condition that meet specified screening criteria to appropriate behavioral healthcare settings.

• Implementation and adoption of emerging technologies to assist the EMS personnel in the triage of both 9-1-1 patient responses and in the evolving community paramedicine models, including post discharge patient encounters.

The possible solutions are in line with current regulations in California that allow for a variety of options and alternatives in the delivery of EMS patient care. However, a centralized medical control mechanism and process to manage the online medical direction to EMS personnel in a uniform manner does not currently exist in San Bernardino County. The concept of a centralized medical control is critical to implementing the possible solutions.

Following APOD Task Force discussions, the Hospital Association of Southern California (HASC) and the 18 San Bernardino County hospital CEOs proposed exploring the creation of a centralized medical control and transportation hub, or MedCon for discussion purposes, to better address and implement these solutions. HASC and the hospital CEOs then asked the Inland Counties Emergency Medical Agency (ICEMA) to prepare a proposal for an ICEMA managed MedCon.

It is believed that a centralized approach to providing medical direction to triage patients to appropriate destinations would better utilize current resources and provides a platform for the development and inclusion of identified solutions. This centralized medical control approach would also provide a focal point for the technologies necessary to address the challenges in effectively managing the strategies. It would also reduce medical control duplication and the costs associated with patient transport to inappropriate venues of care, i.e., EDs.

The MedCon would require real-time situational awareness. This would be accomplished by leveraging and incorporating existing and emerging technologies so the centralized medical control staff, including on-duty emergency medicine physicians, can provide real-time medical direction to EMS personnel thereby improving community health in line with the San Bernardino County Board of Supervisors Countywide Vision.

Based on the HASC and hospital CEOs request, ICEMA investigated the centralized medical control concept, including operational, financial and logistical needs associated with developing and managing such an operation. ICEMA concludes that the MedCon concept has merit and further exploration is warranted in order to achieve the objectives of responding to the changing healthcare environment, reducing overall costs by transporting patients to appropriate

destinations for care, improving patient satisfaction and decreasing if not eliminating APOD and its effects on public health and safety.

MedCon Functions:

Under ICEMA's Medical Director oversight, MedCon staff would provide the following value added operational functions:

• Receive and approve EMS field personnel requests for treatment orders during 9-1-1 responses, specialty patient interfacility transfers and for community paramedicine (CP) post discharge follow-up visits if or when a local CP pilot program is fully implemented.

• Approve patient requests for refusal of care or transportation against medical advice (AMA). This will also provide the opportunity for the patient to speak directly to an emergency medicine physician in complex cases where the AMA could have life threatening implications.

• Provide real-time medical direction to EMS field personnel to approve non-urgent and non-acute patient transportation to pre-designated care facilities i.e., urgent cares and clinics.

• Approve medical treatment of non-critical patient's on scene and the subsequent release of non-critical patients for follow-up by the patient's primary healthcare provider at a later time.

• Provide a centralized point of access to behavioral and public health personnel when needed.

• Utilize clinically persuasive technologies to aid in management of various illnesses, i.e., congestive heart failure (CHF) and diabetes.

• Provide physician directed continuous quality improvement.

• Provide a collaborative, integrated environment where behavioral health, law enforcement and the emergency medicine physician in the MedCon can work together, in real-time, to assist law enforcement and EMS field personnel in determining the appropriate use of 5150 holds.

• Provide medical clearance for 5150 patient transportation to appropriate behavioral health facilities through the use of telemedicine (video conferencing) technologies leveraging the expertise of the MedCon emergency medicine physician.

• Screen or authorize low acuity 9-1-1 call referrals using an established Emergency Medical Dispatch tier known as the Omega level, instead of dispatching the normal EMS response to all 9-1-1 requests that result in unnecessary and costly EMS resource utilization and patient transports to EDs.

• Monitor availability of 9-1-1 receiving hospitals and specialty care centers (STEMI, stroke and trauma) to manage transportation to the closest most appropriate medical facility.

• Assist in facilitating interfacility transfers, including STEMI, stroke and trauma patients, using continuation of care protocols.

• Expedite interfacility transfers outside the ICEMA region using the mutual aid system when local resources are depleted.

• Direct patient destination and other care decisions during Multiple Casualty Incidents (MCIs) and disasters.

• Authorize and monitor EMS aircraft utilization.

• Authorize and help facilitate ambulance strike team deployment or other medical mutual aid requests.

• Assist in the preemptive treatment and transport of patients at long-term and/or convalescent facilities.

• Manage the initial screening and notifications for infectious disease responses, i.e., Ebola.

• Facilitate the dispatch and transportation of the Hospital Emergency Response Team (HERT) comprised of trauma center surgeons and nurses to provide care during complex extrications of entrapped patients.

• Function as the ICEMA duty officer to manage any EMS system issues.

• Function as the conduit to the Medical Health Operation Area Coordinator (MHOAC), a role shared by the Public Health Officer and EMS Administrator.

• Provide centralized access to the Inland Empire Health Information Exchange (IEHIE) portal for patient care information based on an existing agreement between ICEMA and the IEHIE.

Logistics/Planning/Finance:

The potential roles of the centralized medical control require significant front end planning to develop and implement the MedCon. This includes the technical requirements to fully leverage existing and emerging technologies, and to utilize and develop best practices. ICEMA envisions that telemedicine; computer aided dispatch linkage, geographical information systems (GIS) and advanced computer augmented communication technologies will be needed to provide appropriate functionality.

ICEMA will require additional human resources, not currently available; to fully explore the logistical, operational and fiscal requirements of the ICEMA operated MedCon. Therefore, ICEMA recommends establishing an Ad Hoc MedCon advisory task force comprised of subject matter experts familiar with logistics, planning and finance that would be headed by the ICEMA EMS Administrator.

ICEMA or contract personnel would provide direct project planning oversight. The ICEMA EMS Administrator and ICEMA Medical Director would provide overall project planning and design oversight.

The MedCon requirements will include identifying needs, such as a location, technical and communications equipment, and human resources i.e., emergency medicine physicians, to develop, implement and sustain the center. In addition, ICEMA staff resources will be needed to develop appropriate policies, treatment protocols and quality improvement methodologies to support the centralized medical control concept.

The full impact on the ICEMA budget for the resources necessary to develop, implement and operate the MedCon are yet to be determined. Additional anticipated expenses include the development of contracts with alternate destination providers, i.e., urgent care centers, the promulgation of supporting policies and protocols, and the ongoing quality improvement processes to monitor the effectiveness of the MedCon.

Additional evaluation of the funding streams must occur as part of the detailed planning process. Part of the analysis should include the anticipated decreases in ED and EMS resource utilization and associated savings of using lower cost points of care upon MedCon implementation. Healthcare insurance organizations, hospitals and EMS providers will see a corresponding and likely substantial reduction in operating costs. As a result, those entities could be considered as potential funding sources to support the development and implementation of the MedCon.

The location of the ICEMA operated MedCon is one of the logistical needs that requires further exploration. Estimated total space to accommodate all of the functions is yet to be identified until the full scope of the MedCon operations are determined. At the minimum staff and supervisor workstations, space for server and voice/computer cabinets and equipment racks must be included.

ICEMA recommends that board certified or eligible emergency medicine physicians provide the online centralized medical control services. This could be accomplished by using an emergency.

medicine physician group or ICEMA contract physician employees with ICEMA provided support services.

Anticipated positons include, but may not be limited to:

• Emergency medicine physician(s)

• Technical support staff

• Shift supervisor

• Omega call screener(s)
• Incoming call taker(s)
• Office Assistant III(s)
• EMS Specialist(s)

Technologies would include hardware and software components necessary to provide required functionality. The infrastructure, such as the computer networks and hardware to host the technologies, would be available through the San Bernardino County Information Services Department at a cost to be determined based on need. Communications resources using the County's 800 MHz system would be required to provide online access to EMS providers throughout the region. Enhanced services, such as the use of telemedicine technologies, will require software solutions that are HIPAA compliant and use existing communication technologies.

Technical equipment required:

• Server
• Redundant server
• Workstation computers
• Communication devices
• Video conferencing and software

A Geographical Information System (GIS) would also be needed for real-time situational awareness. This system would integrate existing information sharing platforms, such as weather and road conditions, hospital status/bed availability, location of key infrastructure/facilities and the status for air/ground resources, into separate layers on a scalable visualization tool. The system would aggregate existing data from these information sources into an interoperable common operating picture for complete situational awareness. The use of GIS is in line with the Countywide Plan process that includes the use of a single GIS system that incorporates multiple information sources that can be accessed as needed by various users. The cost of developing the required GIS layers and integrating into the emerging countywide system are yet to be determined.

MedCon will require computerized workstations that would include a minimum of a communications monitor, video monitor, and situational awareness monitor at each station with access to GIS and various other information sources including voice and software.

ICEMA recommends the development and implementation of redundant MedCon capabilities that would be used in the event of failure of the primary MedCon. This redundancy can potentially be established with the evolving Riverside County EMS Agency centralized transportation hub to assure full information sharing and resulting in additional redundant capabilities that can be implemented during emergencies affecting one of the facilities.

Satellite communications should also be incorporated to provide redundant communication capabilities during local or large scale disasters. This would allow fail-safe contingency services to occur in the event of a disruption of standard communication services including internet, phone, and radio. These services would use a variety of systems, including voice over internet technologies (VOIP), to achieve communications with and to assure redundancy and survivability.

Conclusion:

ICEMA would like to begin the detailed planning process in conjunction with key EMS system stakeholders to fully develop the MedCon as soon as possible. The concept has been discussed extensively in the APOD Task Force and in a number of other forums. ICEMA has received generally positive feedback during these discussions. In fact, the need to proceed rapidly is a continuing theme that has emerged from these discussions. Based on the feedback received this clearly represents an unprecedented opportunity to be proactive rather than reactive to the many challenges that are occurring in healthcare in the United States that directly affect the provision of EMS. The implementation of the MedCon concept has been identified as central to the strategy of reducing APOD and its unintended consequences.

Attachment 2

Inland Counties Emergency Medical Agency

Bed Delay Report

January 2016 – December 2016

Report Detail

This report collects and summarizes the "Bed Delay" for a selected group of hospitals. "Bed Delay" is the time between arrival of an ambulance at a hospital and the hospital receiving the patient. The first 25 minutes are excluded from consideration. The only type of transports that are considered are 911 calls where the patient is treated and transported via ambulance.

Abbreviated Name	Full Name
ARMC	Arrowhead Regional Medical Center
BCH	Barstow Community Hospital
BVCH	Bear Valley Community Hospital
CVMC	Chino Valley Medical Center
CRMC	Colorado River Medical Center
CHSB	Community Hospital San Bernardino
DVMC	Desert Valley Hospital Center
HDMC	Hi-Desert Medical Center
KHF	Kaiser Hospital Medical Center - Fontana
KHO	Kaiser Hospital Medical Center - Ontario
LLUMC	Loma Linda University Medical Center
MHMC	Montclair Hospital Medical Center
MCH	Mountains Community Hospital
RDCH	Redlands Community Hospital
SARH	San Antonio Regional Hospital
STBMC	St. Bernardine Medical Center
STMMC	St. Mary Medical Center
VALL	JLP VA Loma Linda
VVGMC	Victor Valley Global Medical Center

ICEMA, ePCR Database. Compiled 1/9/2017, PW.

Total Bed Delay Hours* and Bed Delay Transports by Hospital

January 2016 – December 2016

Hospital	Total Bed Delay Hours	Bed Delay Transports	Total Transports	Bed Delay Percentage	Average Bed Delay by Patient	Median Bed Delay by Patient
ARMC	2073:08	4,552	13,314	34.2%	0:27	0:15
BCH	312:40	770	5,630	13.7%	0:24	0:14
BVCH	36.33	169	1,702	9.9%	0:12	0:06
CVMC	399.15	1,007	5,475	18.4%	0:23	0:11
CRMC	18:02	35	808	4.3%	0:30	0:11
CHSB	2077:03	3,298	6,214	53.1%	0:37	0:19
DVMC	4213:2	7,000	11,167	62.7%	0:36	0:20
HDMC	207:43	722	5,072	14.2%	0:17	0:09
KHF	3087:22	5,115	13,534	37.8%	0:36	0:17
KHO	1841:43	3,000	7,890	38.0%	0:36	0:19
LLUMC	2849:14	5,778	13,472	42.9%	0:29	0:16
MHMC	481:23	885	2,885	30.7%	0:32	0:17
MCH	10:45	44	512	8.6%	0:14	0:09
RDCH	3033:13	5,265	9,514	55.4%	0:34	0:20
SARH	3522:47	5,803	14,571	39.8%	0:36	0:18
STBMC	4288:59	7,673	13,754	55.8%	0:33	0:17
STMMC	4232:59	6,715	11,708	57.4%	0:37	0:18
VALL	104:30	6,715242	1,162	20.8%	0:25	0:13
VVGMC	3250:13	4,093	7,053	58.0%	0:47	0:21
Total	36040:59	62,167	145,437	42.7%	0:34	0:18

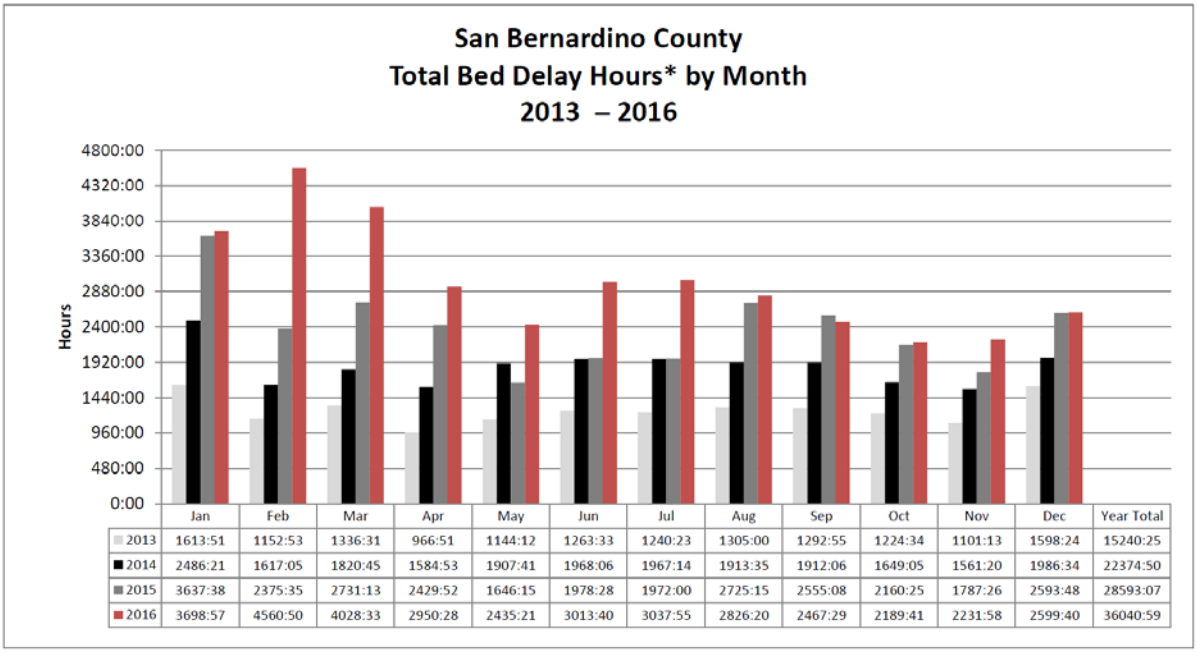
*Note: Bed Delay Hours excludes the first 25 minutes of each transport. As of 01/01/2016, includes San Bernardino County Fire Department.
ICEMA, ePCR Database. Compiled 1/9/2017, PW.

Total Monthly Bed Delay Hours* by Hospital
January 2016 – December 2016

Hospital	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Average Bed Delay by Month
ARMC	185:18	221:20	202:30	141:42	121:17	154:18	219:20	185:26	175:26	183:36	158:05	124:45	2073:08	172:45
BCH	29:01	46:59	54:45	37:10	10:30	38:56	43:57	7:49	8:46	7:32	15:29	11:42	312:40	26:03
BVCH	7:57	3:40	1:01	4:41	0:30	1:46	2:34	2:21	3:14	3:50	1:01	3:53	36:33	3:02
CVMC	50:02	86:38	59:38	18:13	24:21	17:05	28:52	29:39	25:19	20:07	22:56	16:19	399:15	33:16
CRMC	0:30	1:11	0:09	0:29	0:06	0:11	0:59	7:54	1:59	1:07	0:52	2:29	18:02	1:30
CHSB	161:30	270:47	188:45	173:23	105:22	161:59	179:34	198:40	168:36	132:05	178:13	158:05	2077:03	173:05
DVMC	393:35	432:34	515:12	381:38	303:49	385:36	321:51	308:42	315:45	216:50	284:06	353:36	4213:20	351:06
HDMC	8:16	23:27	38:10	16:01	10:58	20:17	8:36	22:40	13:10	8:40	13:21	24:01	207:43	17:18
KHF	326:13	380:38	272:33	185:50	216:08	295:51	331:00	250:38	189:31	199:31	160:39	278:44	3087:22	257:16
KHO	239:41	291:58	164:49	103:50	84:13	158:05	179:54	112:50	157:27	101:41	99:51	147:18	1841:43	153:28
LLUMC	297:28	345:26	325:02	267:05	186:36	218:54	222:08	210:56	203:52	229:22	148:43	193:36	2849:14	237:26
MHMC	51:15	131:46	66:28	49:01	26:52	27:04	27:37	27:32	27:59	13:34	19:10	12:59	481:23	40:06
MCH	1:12	1:00	0:27	1:39	0:13	0:56	1:44	0:59	1:43	0:15	0:11	0:20	10:45	0:53
RDCH	328:45	471:45	310:59	225:53	207:41	220:13	249:35	241:21	179:42	184:46	182:31	229:57	3033:13	252:46
SARH	503:19	517:05	402:12	280:13	205:34	255:57	242:54	213:05	244:44	220:27	181:40	255:31	3522:47	293:33
STBMC	309:57	509:10	456:59	365:46	332:43	373:01	386:51	400:15	280:09	265:09	239:22	369:30	4288:59	357:24
STMMC	462:46	478:09	564:51	398:49	328:04	379:01	293:00	313:15	243:58	226:32	298:23	246:04	4232:59	352:44
VALL	4:59	15:42	18:42	10:57	3:32	5:27	10:41	8:48	6:14	6:15	8:54	4:13	104:30	8:42
VVGMC	337:04	331:26	385:13	287:59	266:42	298:55	286:37	283:21	219:47	168:13	218:22	166:29	3250:13	270:51
Total	**3698:57**	**4560:50**	**4028:33**	**2950:28**	**2435:21**	**3013:40**	**3037:55**	**2826:20**	**2467:29**	**2189:41**	**2231:58**	**2599:40**	**36040:59**	**3003:24**

*Note: Bed Delay Hours excludes the first 25 minutes of each transport. As of 01/01/2016, includes San Bernardino County Fire Department.

ICEMA, ePCR Database. Compiled 1/9/2017, PW.



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Year Total
2013	1613:51	1152:53	1336:31	966:51	1144:12	1263:33	1240:23	1305:00	1292:55	1224:34	1101:13	1598:24	15240:25
2014	2486:21	1617:05	1820:45	1584:53	1907:41	1968:06	1967:14	1913:35	1912:06	1649:05	1561:20	1986:34	22374:50
2015	3637:38	2375:35	2731:13	2429:52	1646:15	1978:28	1972:00	2725:15	2555:08	2160:25	1787:26	2593:48	28593:07
2016	3698:57	4560:50	4028:33	2950:28	2435:21	3013:40	3037:55	2826:20	2467:29	2189:41	2231:58	2599:40	36040:59

Total Bed Delay Hours* and Bed Delay Transports by Hospital
2014 – 2016

	2014				2015				2016			
Hospital	Total BD Hours*	BD Transports	Total Transports	BD %	Total BD Hours*	BD Transports	Total Transports	BD %	Total BD Hours*	BD Transports	Total Transports	BD %
ARMC	1183	3,187	11,533	27.6%	1506	3,648	12,214	29.9%	2073	4,552	13,314	34.2%
BCH	171	393	4,389	9.0%	300	685	4,947	13.8%	312	770	5,630	13.7%
BVCH	28	95	1,558	6.1%	50	206	1,790	11.5%	36	169	1,702	9.9%
CVMC	72	341	4,149	8.2%	137	581	4,541	12.8%	399	1,007	5,475	18.4%
CRMC	2	7	655	1.1%	17	28	689	4.1%	18	35	808	4.3%
CHSB	879	2,168	5,791	37.4%	2106	3,297	6,318	52.2%	2077	3,298	6,214	53.1%
DVMC	1621	2,606	4,138	63.0%	1855	2,813	4,688	60.0%	4213	7,000	11,167	62.7%
HDMC	12	40	2,369	1.7%	30	102	2,630	3.9%	207	722	5,072	14.2%
KHF	1521	3,555	11,436	31.1%	2412	4,600	12,687	36.3%	3087	5,115	13,534	37.8%
KHO	643	1,511	5,630	26.8%	1445	2,503	6,922	36.2%	1841	3,000	7,890	38.0%
LLUMC	2247	4,585	11,068	41.4%	2270	5,380	12,960	41.5%	2849	5,778	13,472	42.9%
MHMC	94	348	2,171	16.0%	175	510	2,445	20.9%	481	885	2,885	30.7%
MCH	7	34	103	33.0%	5	29	111	26.1%	10	44	512	8.6%
RDCH	3337	5,039	8,987	56.1%	2331	4,788	9,648	49.6%	3033	5,266	9,514	55.4%
SARH	782	2,998	15,189	19.7%	2831	6,069	15,969	38.0%	3522	5,803	14,571	39.8%
STBMC	2956	5,872	13,946	42.1%	4480	7,184	13,234	54.3%	4288	7,673	13,754	55.8%
STMMC	3736	5,394	9,384	57.5%	3551	5,707	10,067	56.7%	4232	6,715	11,708	57.4%
VALL	27	132	1,072	12.3%	43	164	1,117	14.7%	104	242	1,162	20.8%
VVGMC	3050	4,693	8,100	57.9%	3042	4,183	7,673	54.5%	3250	4,093	7,053	58.0%
Total	**22374**	**42,998**	**121,668**	**35.3%**	**28593**	**52,477**	**130,650**	**40.2%**	**36040**	**62,167**	**145,437**	**42.7%**

*Note: Bed Delay Hours excludes the first 25 minutes of each transport. As of 01/01/2014, includes Rialto Fire Department. As of 01/01/2016, includes San Bernardino County Fire Department.
ICEMA, ePCR Database. Compiled 1/9/2017, PW.

INSPECTIONS OF JAILS/PRISONS/DETENTION CENTERS WITHIN THE COUNTY OF SAN BERNARDINO

BACKGROUND

The Grand Jury, per California Penal Code 919(b), is mandated as follows: "The grand jury shall inquire into the condition and management of the public prisons within the county." The Grand Jury modified and used the document entitled, "Inspection Form" included in the Jail Inspection Handbook for Grand Jurors provided by the California Board of State and Community Corrections as noted in the California Grand Jury Association Web site www.cgja.org. Visitation Inspection reports were written on each visited jail/prison/detention center referred to below and are incorporated herein. The Grand Jury inspected the following five jails/prisons/detention centers:

- California Institution for Men
- California Institution for Women
- Desert View Modified Community Correctional Facility
- Glen Helen Rehabilitation Center
- Central Valley Juvenile Detention and Assessment Center

CONCLUSION

There are no major discrepancies found at any of the five jails/prisons/detention centers the Grand Jury inspected. The Grand Jury was impressed with the professionalism and knowledge demonstrated by all personnel during each site visit.

REPORTS

CALIFORNIA INSTITUTION FOR MEN

For the purpose of this report, the Grand Jury obtained information from the following: interview with the Acting Warden and his Executive Staff; a guided tour by the Public Information Officer (PIO); the California Code of Regulations (CCR), Title 15 Crime Prevention and Corrections, Division 3; the California Institution for Men Institutional Guidebook; the California Department of Corrections and Rehabilitation (CDCR) Web site www.cdcr.ca.gov; and personal observations by the Grand Jury members.

Inspection Form

FACILITY NAME: California Institution for Men	INSPECTION DATE: August 15, 2016
FACILITY CAPACITY: 4,728 inmates Current population of 3,643 inmates	TYPE OF FACILITY: State Prison housing male inmates.
ADDRESS: 14901 Central Avenue, Chino, CA 91710	TELEPHONE NUMBER: 909-597-1821

California Institution for Men (CIM) opened in San Bernardino County in 1941 on 2,500 acres of land. CIM is the third oldest state prison in California after San Quentin State Prison (1852) and Folsom State Prison (1881). CIM is a large complex consisting of four separate facilities under the administration of one warden.

- Facility A has an inmate population of approximately 1,113 Level-II Sensitive Needs Yard (SNY) inmates. The facility consists of eight dormitory housing units and each housing unit has a capacity of approximately 140 inmates. The California Code of Regulations defines a Level-II as consisting primarily of open dormitories with a secure perimeter, which may include armed coverage.

- Facility B has an inmate population of approximately 977 medium/maximum custody level inmates and serves as a reception center receiving and processing male inmates who have been newly committed to CDCR primarily from Riverside and San Diego County. The Reception Center completes diagnostic tests, medical/mental health screening, and literacy assessments for classification in order to determine the inmate's appropriate institutional placement. In addition to the reception center mission, Facility B includes Palm and Cypress Halls as designated Administrative Segregation Units. These Administrative Segregation units receive inmates from CIM, California Rehabilitation Center, Local CDCR/Cal Fire camps, inmates serving Security Housing Unit terms, and inmates in route to court or other CDCR Institutions.
- Facility C has an inmate population of approximately 760 Level-II SNY inmates, many of whom are serving life sentences. The facility consists of four housing units with a capacity of approximately 200 inmates. Facility C is located approximately 2 miles east of CIM's main complex.
- Facility D has an inmate population of approximately 2,000 general population inmates and is designated as a Secure Level-I. The facility consists of twelve housing units with each housing unit having a capacity of approximately 200 inmates. The California Code of Regulations defines a Level-I as consisting primarily of open dormitories with a low security level. Inmates with 0 to 18 points (least likely to misbehave) are housed in Level-I facilities. Inmates with minimum custody can be housed and work outside the secure perimeter where inmates with medium custody are housed and work inside the secure perimeter but can live in a dormitory environment.

General Information

Note: Responses to Grand Jury questions are in bold.

- What is the capacity of the facility? **4,728 inmates. Current population of 3,643 inmates.**
- What is the number of pretrial/presentenced inmates? **Numbers vary for Penal Code 1203.03 (referred to as a presentence diagnostic case). Inmates are housed at Facility B reception center for up to 90 days for evaluation and sentencing recommendation to the court.**

- Has the facility exceeded capacity since the last state inspection? **No per CDCR population report for CIM.**
- What is the average length of detention? **Four years plus for determinate (fixed period) sentenced inmates. CIM also houses Lifer inmates with indeterminate sentences.**
- Are inmates oriented to rules and procedures? **Receive CCR Title 15 and Orientation.**
- Are rules and grievance procedures posted? **Yes.**
- Are rules and grievance procedures understood by inmates? **Each inmate is assigned a Correctional Counselor to provide assistance.**
- Number of suicides 2015 to 2016. **One transgender inmate in April 2015.**
- Number of attempted suicides 2015 to 2016. **None reported.**
- Number of deaths from other causes 2015 to 2016. **None.**
- Numbers of escapes 2015 to 2016. **None.**
- Date of last fire/emergency drill. **Conducted quarterly.**

Staffing

- Is there enough staff to monitor inmates? **Total staffing 1,709 employees: 896 custody staff (uniformed peace officers) and 813 non-custody staff.**
- What is number of funded positions? **1,709 employees.**
- How many vacant positions are there? **No custody vacant positions. Non-custody staff can be up to 8% vacant.**
- Does staff communicate in language that an inmate can understand? **Yes.**
- Diversity of staff. **White, Black, Hispanic, Asian represented.**
- Impression of staff. **Staff was professional and knowledgeable.**

Programs

- Educational Programs? **General Educational Development (GED), Pre-Release, English as a Second Language (ESL), Literacy and Adult Basic Education (ABE), California State University San Bernardino Visual Arts. College Education Program - inmates enrolled in community college correspondence classes. Prison**

Education & Arts Program - College students tutoring and providing educational resources to inmates who participate in the volunteer education program. Students and program participants are from California Polytechnic State University Pomona.

- Self Help Programs? **Narcotics Anonymous, Alcoholics Anonymous, Criminal Gang Anonymous, Celebrate Recovery, Veterans in Prison, Prison Fellowship Pre-release Program, Center for the Empowerment of Families Fatherhood Group, Victim Offender Education Group, Toastmasters, Global Youth Connection, Alternative to Violence, Fatherhood Program. ASK mentoring program (program mentors inmates that receive little or no visits from family). Celebrate Recovery -12-step recovery program for dysfunction including drugs, alcohol, sexual abuse, and anger. Victim Offender Education Group (VOEG) (restorative justice program helping participants understand the impact of the crimes and effect on the victim, family and community). PRIDE (Prisoners Reaching Independent Decision to Educate) group helps at-risk youth in community through education. Life Changing Mentoring Program (Program provides mentors to the children of incarcerated parents in an effort to break the cycle of crime.)**
- Drug Treatment Programs? **CIM offers a Substance Abuse Program (SAP) with a 150 inmate program enrollment for those inmates that may need addiction recovery assistance.**
- Work Programs/Vocational Programs? **Prison Industry Authority (PIA) laundry (service for California Institution for Men, California Institution for Women, California Rehabilitation Center, and Patton State Hospitals), PIA juice processing and packaging plant, Marine Technology Training Center deep sea diver training program, Janitorial services, Landscape design, Automotive and Electronics repair.**
- Religious Services? **Religious Services are provided by State Chaplains who supervise a total of 500 volunteers from 93 Community Churches and Ministries. Prison Fellowship Pre-release Program - works with inmates who meet the 12 to 18 month release date. Program outline includes one-on-one life coaching skills, care team of volunteers, pre-release curriculum, and seminars.**

- Exercise:
    - Is it inside or out? **Outside track and sports field.**
    - How frequently is it offered? **Seven days a week during designated daylight/evening hours when not programming in a work/academic/vocational assignment.**
    - How much time is each inmate offered? **All inmates have equal access with varied times according to privilege level.**

Telephone

- Do inmates have access to telephones? **Yes, collect calls. Inmates sign up for telephone use.**

Correspondence

- Is there limited free postage for inmates without money? **Free postage, paper, envelopes for indigent inmates with less than $1.00 on their account for 30 consecutive days.**
- Incoming/outgoing – are inmates aware that mail can be read? **Yes, by staff.**
- Confidential correspondence – letter to attorneys, legislators, etc., - how is it handled? **Outgoing Confidential mail will be designated "Confidential" on the face of the envelope. Staff will inspect the contents of the letter without reading in front of the inmate. Staff will seal the letter and sign his/her name and date on the back of the envelope. Incoming Confidential mail will be opened by staff in front of the inmate without staff reading contents. Inmate will sign in logbook for the receipt of the Confidential mail.**

Visiting

- Is there adequate space, convenient times or accommodations to family's work schedule, etc.? **Visiting Days: Saturday, Sunday and Designated Holidays (*New Year's Day, Independence Day, Thanksgiving Day, and Christmas Day).* Visiting Hours: 8:30 a.m. to 3:00 p.m.**

- Are there provisions for special visits with attorneys/clergy? **Yes.**
- Does staff supervise visits? **Staff monitors regular visits. Attorney visits are held in a confidential area if requested.**
- Do all inmates have access to visiting? **Yes. Visiting can be restricted based on privilege level.**

Grievances

- What are the most common types of grievances filed by inmates? **Varies; inmates can appeal any decision, action, conditions, or omissions that have an adverse effect on the welfare of inmates.**
- Is there a record kept based on type and number? **Appeals Coordinator maintains logbook.**
- What is the grievance process? **Documented in writing on CDCR 602 form, Inmate/Parolee Appeal.**

Meals/Nutrition

- The kitchen area – Is it clean? **Did not tour.**
- Are meals served in the cell? If not where? **Normally in the culinary or kitchen.**
- Are inmates permitted to converse during meals? **Yes.**
- Length of time allowed for eating? **A minimum of fifteen minutes shall be allowed for the actual consumption of each meal.**

Health

- Medical Services and Dental Services:
    - How frequently is medical/dental staff onsite? **Medical staff is available 24/7. Normal dental treatment is available Monday-Friday during regular work schedule.**
    - How long do inmates wait to be seen? **Daily sick call, inmates sign up to be seen the same day.**
    - Is a physician/dentist available by phone or come inside? **Yes, both.**

- What type of onsite health facility is available to inmates? **CIM Hospital is not accredited, but can handle most medical and dental procedures.**

- Mental Health Services:
  - How frequently is mental health staff onsite? **Daily Monday-Friday excluding holidays.**
  - How long do inmates wait to be seen? **Same day Monday-Friday or next working day.**
  - What is the process to handle mentally challenged inmates? **Inmate self-referral or Staff Referral of inmate to Psychiatrist or Clinical Psychologist.**
  - Is there special housing and staff training? **Yes.**
  - Are there Contracted offsite Hospitals, Dental clinics? **CIM has a contract with the Riverside University Health System (RUHS) to provide urgent or emergency hospital care for inmates at the Riverside Hospital. Dental treatment is completed at CIM.**
  - How are inmates transported to off-site facilities? **Contracted ambulances for emergencies or CDCR van transports for contracted referred medical treatment.**
  - How is security handled? **Inmate is put in waist and leg restraint gear unless medical restrictions. Correctional staff accompany inmate to and from the hospital.**

Site Tour

Note the following items as you tour the facility:

- Condition of the exterior and interior of the building noting graffiti, peeling paint, unpleasant odors, or other signs of deterioration. **The facility is old but it has been maintained satisfactorily. Renovations are underway.**

- Condition of the grounds, exercise areas, playing fields, and exercise equipment. **Condition is satisfactory. The drought has taken its toll on the greenery and old trees dying and diseased are being removed. Grass is no longer green or growing; plants are dead and turned to tumbleweeds. Water conservation is mandated.**
- General cleanliness of the facility including windows, lighting, lockers, desks, conditions of the mattresses, bedding and pillows. **Satisfactory.**
- Condition of sleeping room door panels. **Not inspected.**
- Temperature of living units. **Living units were hot. The temperature outside was 105 degrees. Inmates could benefit from an efficient cooling system.**
- Safety and security issues including fencing, outdoor lighting, location of the weapons locker. **Satisfactory.**
- If a court holding area is present in the facility, ensure access to toilet and drinking water. **Not inspected.**

INTERIOR OF BUILDINGS (walls, paint, floors, drains, plumbing fixtures working, air vents, windows)

- Are cleaning fluids and chemicals labeled and safely stored? **Did not observe these items in open areas. Stored in supply closets.**
- Weapons locker present. **Not inspected.**
- Recreation/sports equipment. **Track and sports field.**
- Are the hallways clear, are doors propped open or closed? **Hallways were clear, doors were open or closed as appropriate.**
- Holding areas (cells/rooms) – (if present), is there access to drinking water and toilet? **Did not observe.**
- Are there individual cells/rooms, or dormitories? **There are four facilities on the grounds. They contain both dorms and cells.**
- Beds – Type of bed and is it off the floor? **Bunk beds attached to wall. They appear adequate.**
- Adequate lighting. **Yes.**

- Temperature. **No air conditioning in the cells and central rooms. Cooling provided by large fans and swamp coolers.**

INDIVIDUAL CELLS/ROOM

- Condition of walls. **Did not observe.**
- Personal possessions allowed in cell/room (Art, Books, Etc.). **Yes.**
- Graffiti present. **No.**
- Ample bedding. **Yes.**

PERSONAL APPEARANCE OF INMATES

- What is the appearance of inmates (dirty, unkempt, well groomed, etc.)? **Well groomed.**
- Showers – frequency, privacy, maintained. **Daily showering.**
- Are there any reported assaults by inmates on inmates? **Yes.**
- Condition of clothing (does the clothing fit; is it appropriate for the weather, etc.)? **Clothing appropriate.**

CALIFORNIA INSTITUTION FOR WOMEN

For the purpose of this report, the Grand Jury obtained information from the following: interview with the Acting Warden and her Executive Staff; a guided tour by the Public Information Officer (PIO); the California Code of Regulations, Title 15 Crime Prevention and Corrections, Division 3; the California Institution for Women Institutional Guidebook; the California Department of Corrections and Rehabilitation Web site www.cdcr.ca.gov; and personal observations by the Grand Jury members.

Inspection Form

FACILITY NAME: California Institution for Women	INSPECTION DATE: October 11, 2016 and November 7, 2016
FACILITY CAPACITY: 2,042 inmates Current population of 1,886 inmates	TYPE OF FACILITY: State Prison housing female inmates.
ADDRESS: 16756 Chino-Corona Rd., Corona, CA 92880	TELEPHONE NUMBER: 909-597-1771

The California Institution for Women (CIW) opened in 1952. Until 1987, CIW was California's only prison for female felons. CIW was originally called "California Institution for Women at Corona," but Corona residents objected to the use of their city in the prison's name and it was changed March 1, 1962 to "Frontera," a feminine derivative of the word *frontier* - a new beginning. The campus-like design was in keeping with the 1950's progressive notion of rehabilitation.

The mailing address for CIW is in the City of Corona in Riverside County; however, the prison has been physically located in the City of Chino since 2003 following an annexation of land in an area that was previously San Bernardino County.

The California Institution for Women (CIW) accommodates all custody levels of female inmates. In addition to its large general population, CIW houses inmates with special needs such as pregnancy, psychiatric care, methadone, and medical problems such as HIV infection. CIW serves as a hub institution for the selection and physical fitness training of female firefighters selected for camp placement. The institution also serves as a higher security facility for female inmates in Administrative Segregation.

General information

Note: Responses to Grand Jury questions are in bold.

- What is the capacity of the facility? **2,042 inmates. Current population of 1,886 inmates.**
- What is the number of pretrial/presentenced inmates? **Numbers vary for Penal Code 1203.03 Diagnostic 90 day cases at reception center.**
- Has the facility exceeded capacity since the last state inspection? **No per CDCR population report for CIW.**
- What is the average length of detention? **2 years plus for determinate sentenced inmates. CIW also houses approximately 300 Lifer inmates with indeterminate sentences**.
- Are inmates oriented to rules and procedures? **Receive CCR Title 15 and Orientation.**
- Are rules and grievance procedures posted? **Yes.**
- Are rules and grievance procedures understood by inmates? **Each inmate is assigned a Correctional Counselor to provide assistance.**
- Number of suicides 2015 to 2016. **2 suicides. Last suicide April 14, 2016.**
- Number of attempted suicides September 2015 to September 2016. **45 attempted suicides. Reduced from January 2016 to September 2016 (17 attempted suicides).**
- Number of deaths from other causes 2015 to 2016. **Two.**
- Numbers of escapes 2015 to 2016. **None.**
- Date of last fire/emergency drill. **Conducted quarterly. Last completed October 20, 2016.**

Staffing

- Is there enough staff to monitor inmates? **Yes. Total staffing 1,259 employees: 378 Custody staff, 412 non-custody staff and 469 Mental Health/Medical/Dental.**
- What is number of funded positions? **1,259**
- How many vacant positions are there? **No Custody vacant positions. Non-custody can be up to 8% vacant.**

- Does staff communicate in language that an inmate can understand? **Yes.**
- Diversity of staff. **White, Black, Hispanic, Asian represented.**
- Impression of staff. **Staff was professional and knowledgeable.**

Programs

- Educational Programs? **Adult basic education, English Secondary Language (ESL), GED, Literacy program, Chaffey College (Associate degree), Coastline (Associate degree), Palo Verde (Associate degree), UCLA African American Studies (Bachelor degree program), California Coast University (Bachelor degree program), Choice Theory Connection Program.**
- Self Help Programs? **Narcotics Anonymous, Alcoholics Anonymous, Victim Awareness, Bike refurbishing program with repaired bikes donated to charities. Prison Puppy Program to train service dogs. Avon Cancer walk that raised over $42,000 by inmates and staff. "Continuing the Dream" program where inmates volunteer to participate in video conferences with the San Bernardino Unified School District to discourage kids from getting into crime. Lifer Summit in which 30 former Lifer inmates came back to CIW to discuss with currently incarcerated inmates on how they are dealing in a free society.**
- Drug Treatment Programs? **Currently 96 inmate enrollment for the Substance Abuse Program. Adding an additional 50 inmate positions in the future.**
- Work Programs/Vocational Programs? **Prison Industry Authority (PIA): Clothing and textile manufacturing (shirts, shorts, jeans, smocks, aprons, bedspreads, handkerchiefs, bandanas, Nomex firefighting clothing), and construction. Prison Puppy program. Computer training, Data Processing, Word Processing, Building Maintenance, Cosmetology. Forestry/Camp Training and Pre-Forestry training program for Forestry Firefighters.**
- Religious Services? **Services provided for Jewish, Catholic, Protestant, Native American, Buddhist, Jehovah Witness, and Wicca.**
- Exercise:
    - Is it inside or out? **Outside track and sports field.**

- How frequently is it offered? **Seven days a week during designated daylight/evening hours when not programming in work/academic/vocational assignment.**
- How much time is each inmate offered? **All inmates have equal access with varied time according to privilege level.**

Telephone

- Do inmates have access to telephones? **Yes, collect calls. Inmates sign up for telephone use.**

Correspondence

- Is there limited free postage for inmates without money? **Free postage, paper, envelopes for indigent inmates with less than $1.00 on their account for 30 consecutive days.**
- Incoming/outgoing – are inmates aware that mail can be read? **Yes, by staff.**
- Confidential correspondence – letter to attorneys, legislators, etc., - how is it handled? **Outgoing Confidential mail will be designated "Confidential" on the face of the envelope. Staff will inspect the contents of the letter without reading in front of the inmate. Staff will seal the letter and sign his/her name and date on the back of the envelope. Incoming Confidential mail will be opened by staff in front of the inmate without staff reading contents. Inmate will sign in logbook for the receipt of the Confidential mail.**

Visiting

- Is there adequate space, convenient times or accommodations to family's work schedule, etc.? **Visiting Days: Saturday, Sunday and Designated Holidays (*New Year's Day, Independence Day, Thanksgiving Day, and Christmas Day).* Visiting Hours: 8:30 a.m. to 3:00 p.m.**
- Are there provisions for special visits with attorneys/clergy? **Yes.**
- Does staff supervise visits? **Staff monitors regular visits. Attorney visits are held in a confidential area if requested.**

- Do all inmates have access to visiting? **Yes. Visiting can be restricted based on privilege level.**

Grievances

- What are the most common types of grievances filed by inmates? **Inmates can appeal any decision, action, condition, or omission that have an adverse effect on the welfare of inmates.**
- Is there a record kept based on type and number? **Appeals Coordinator maintains logbook.**
- What is the grievance process? **Documented in writing on CDCR 602 form, Inmate/Parolee Appeal.**

Meals/Nutrition

- The kitchen area – Is it clean? **Yes.**
- Are meals served in the cell? If not where? **In the kitchen. Daily two hot meals and one sack lunch.**
- Are inmates permitted to converse during meals? **Yes.**
- Length of time allowed for eating? **A minimum of fifteen minutes shall be allowed for the actual consumption of each meal.**

Health

- Medical Services and Dental Services:
    - How frequently is medical/dental staff onsite? **Medical staff is available 24/7. Normal Dental treatment is available Monday-Friday during regular work schedule.**
    - How long do inmates wait to be seen? **Daily sick call. Inmates sign up to be seen the same day.**
    - Is a physician/dentist available by phone or come inside? **Yes, both.**
    - What type of onsite health facility is available to inmates? **Medical Clinic that can handle most medical and dental procedures.**

- Mental Health Services:
    - How frequently is mental health staff onsite? **Mental Health staff is available 24/7.**
    - How long do inmates wait to be seen? **Same day if required**.
    - What is the process to handle mentally challenged inmates? **Inmate self-referral or Staff Referral of inmate to Psychiatrist or Clinical Psychologist.**
    - Is there special housing and staff training? **Yes.**
- Are there Contracted offsite hospitals, dental clinics? **CIW has a contract with the Riverside University Health System (RUHS) to provide urgent or emergency hospital care for inmates at the Riverside Hospital. CIW also has contracts with Chino Valley Medical Center, Pomona Valley Medical Center, and Kaiser Hospital. Dental treatment is completed at CIW.**
    - How are inmates transported to offsite facilities? **Contracted ambulances for emergencies or CDCR van transports for contracted referred medical treatment.**
    - How is security handled? **Inmate is physically put in restraint gear and Correctional staff accompany inmate to and from the hospital.**

Site Tour

Note the following items as you tour the facility:

- Condition of the exterior and interior of the building noting graffiti, peeling paint, unpleasant odors, or other signs of deterioration. **Buildings need repairs because of age, built in 1953.**
- Condition of the grounds, exercise areas, playing fields, and exercise equipment. **All dirt because no watering permitted because of the drought. Few plants.**
- General cleanliness of the facility including windows, lighting, lockers, desks, conditions of the mattresses, bedding and pillows. **Windows dirty.**
- Condition of sleeping room door panels. **Small two person cells. Clean and tidy.**
- Temperature of living units. **Humid in some cells. Large fans used for air circulation.**

- Safety and security issues including fencing, outdoor lighting, location of the weapons locker. **Outside areas well lit.**
- If a court holding area is present in the facility, ensure access to toilet and drinking water. **N/A.**

INTERIOR OF BUILDINGS (walls, paint, floors, drains, plumbing fixtures working, air vents, windows)

- Are cleaning fluids and chemicals labeled and safely stored? **Yes**
- Weapons locker present. **Not inspected.**
- Recreation/sports equipment. **Exercise class daily for one hour.**
- Are the hallways clear, are doors propped open or closed? **Hallways clear. Doors open or closed as appropriate.**
- Holding areas (cells/rooms) – (if present), is there access to drinking water and toilet? **Yes.**
- Are there individual cells/rooms, or dormitories? **2 person cells.**
- Beds – Type of bed and is it off the floor? **Bunk type with mattresses.**
- Adequate lighting. **Yes.**
- Temperature. **No air conditioning in the cells and central rooms. Cooling provided by large fans and swamp coolers. Inmates could benefit from a more efficient cooling system.**

INDIVIDUAL CELLS/ROOM

- Condition of walls. **Clean.**
- Personal possessions allowed in cell/room (Art, Books, Etc.). **Books allowed and some personal items.**
- Graffiti present. **No.**
- Ample bedding. **Yes.**

PERSONAL APPEARANCE OF INMATES

- What is the appearance of inmates (dirty, unkempt, well groomed, etc.)? **Inmates clean and well groomed.**
- Showers – frequency, privacy, maintained. **Daily showering.**
- Are there any reported assaults by inmates on inmates? **Occasionally.**
- Condition of clothing (does the clothing fit; is it appropriate for the weather, etc.)? **Prison issued, appropriate for weather.**

DESERT VIEW MODIFIED COMMUNITY CORRECTIONAL FACILITY

For the purpose of this report, the Grand Jury obtained information from the following: interview and site tour with the Warden; the California Code of Regulations, Title 15 Crime Prevention and Corrections, Division 3; the California Department of Corrections and Rehabilitation Web site www.cdcr.ca.gov; and personal observations by the Grand Jury members.

Inspection Form

FACILITY NAME: Desert View Modified Community Correctional Facility	INSPECTION DATE: October 11, 2016 and November 7, 2016
FACILITY CAPACITY: 700 inmates	TYPE OF FACILITY: State Prison housing male inmates.
ADDRESS: 10450 Rancho Rd., Adelanto, CA 92301	TELEPHONE NUMBER: 760-246-1171

The Desert View Modified Community Correctional Facility (MCCF) is a restricted, medium security facility designed to house custody inmates and parole violators for the California Department of Corrections & Rehabilitation (CDCR), who are designated as Level-II custody.

Facility Description

The 96,963 sq. ft. one-story masonry building was financed, designed and built by GEO Group, private corporation, on 20 acres of land. It has a health care unit and rooms for classroom instruction, counseling, and visitation. Educational areas include a computer laboratory, a library, and outdoor recreational areas. The facility is well furnished with a fully equipped kitchen and dayrooms and dormitory sleeping areas are clean and comfortable. The dormitory style facility has 2 dorms with 86 beds and 6 dorms with 88 beds, and an additional 13 single-bunked cells for inmate segregation. Two cells with single bunks are reserved for medical purposes. The facility design enables modern correctional techniques such as direct supervision. The building perimeter and control centers utilize state-of-the-art electronic surveillance and detection techniques. Security enhancement measures include a central control room that contains closed circuit television monitors allowing staff to survey interior as well as perimeter areas. Housing units are designed so that inmates can move about freely under the direction of officers who monitor their activities and movement between areas.

General Information

Note: Responses to Grand Jury questions are in bold.

- What is the capacity of the facility? **700 inmates.**
- What is the number of pretrial/presentenced inmates? **None.**
- Has the facility exceeded capacity since the last state inspection? **No per CDCR population report for Desert View MCCF.**
- What is the average length of detention? **5 years.**
- Are inmates oriented to rules and procedures? **Receive CCR Title 15 and Orientation.**
- Are rules and grievance procedures posted? **Yes.**
- Are rules and grievance procedures understood by inmates? **Given a handbook upon arrival.**
- Number of suicides 2015 to 2016. **None.**
- Number of attempted suicides 2015 to 2016. **None.**
- Number of deaths from other causes 2015 to 2016. **None.**
- Numbers of escapes 2015 to 2016. **None.**
- Date of last fire/emergency drill. **Conducted monthly.**

Staffing

- Is there enough staff to monitor inmates? **Yes. Total staffing 156 employees: 90 custody staff and 66 non-custody staff.**
- What is number of funded positions? **90**
- How many vacant positions are there? **Two vacancies.**
- Does staff communicate in language that an inmate can understand? **Yes.**
- Diversity of staff. White, Black, Hispanic, Asian represented. **Yes, 50 percent female staff.**
- Impression of staff. Staff was professional and knowledgeable. **Yes.**

Programs

- Educational Programs? **GED, Adult Basic Education, Coastline College (AA) degree.**
- Self Help Programs? **Narcotics Anonymous, Alcoholics Anonymous, Pre-release life/social skills development programs.**
- Drug Treatment Programs? **Yes, Substance Abuse Program (SAP).**
- Work Programs/Vocational Programs? **Yes.**
- Religious Services? **32 volunteers to assist in any and all denominations including a sweat lodge for Native Americans.**
- Exercise:
    - Is it inside or out? **Outside track and sports field.**
    - How frequently is it offered? **Seven days a week during daylight hours.**
    - How much time is each inmate offered? **All inmates have equal access.**

Telephone

- Do inmates have access to telephones? **Yes, collect calls. A record is kept of telephone numbers that inmates are not allowed to call based on court orders such as restraining orders or victim's rights.**

Correspondence

- Is there limited free postage for inmates without money? **Free postage, paper, envelopes for indigent inmates is provided.**
- Incoming/outgoing – are inmates aware that mail can be read? **Yes, by staff.**
- Confidential correspondence – letter to attorneys, legislators, etc., - how is it handled? **Outgoing Confidential mail will be designated "Confidential" on the face of the envelope. Staff will inspect the contents of the letter without reading in front of the inmate. Staff will seal the letter and sign his/her name and date on the back of the envelope. In-coming Confidential mail will be opened by staff in front of the inmate without staff reading contents. Inmate will sign in logbook for the receipt of the Confidential mail.**

Visiting

- Is there adequate space, convenient times or accommodations to family's work schedule, etc.? **Visiting Days: Saturdays and Sundays, Designated Holidays (*New Year's Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day*). Hours of Operation: 8:00 a.m. to 3:00 p.m.**
- Are there provisions for special visits with attorneys/clergy? **Yes.**
- Does staff supervise visits? **Staff monitors regular visits. Attorney visits are held in a confidential area if requested.**
- Do all inmates have access to visiting? **Yes. Restricting visiting is no longer used as punishment.**

Grievances

- What are the most common types of grievances filed by inmates? **Varies, inmates can appeal any decision, action, conditions, or omissions that have an adverse effect on the welfare of inmates.**
- Is there a record kept based on type and number? **Appeals Coordinator maintains logbook. Appeals are coordinated by CDCR.**

- What is the grievance process? **Documented in writing on CDCR 602 form, Inmate/Parolee Appeal.**

Meals/Nutrition

- The kitchen area – Is it clean? **Spotless.**
- Are meals served in the cell? **Meals are served in the dining room. Trays are given in a "blind delivery" system. Server does not see recipient.**
- Are inmates permitted to converse during meals? **Yes.**
- Length of time allowed for eating? **Twenty minutes is allotted for the meal but seldom does it take that long.**

Health

- Medical Services and Dental Services:
    - How frequently is medical/dental staff onsite? **The Doctor is present 40 hours per week. The Dentist is present 20 hours per week. In case of emergency a local hospital would be used.**
    - How long do inmates wait to be seen? **Daily sick call. Inmates sign up to be seen the same day.**
    - Is a physician/dentist available by phone or come inside? **Yes, both.**
    - What type of onsite health facility is available to inmates? **This facility has an infirmary type medical facility. Major cases are taken to Arrowhead Regional Medical Center, emergencies go to St. Mary Medical Center or Desert Valley Hospital.**
- Mental Health Services:
    - How frequently is mental health staff onsite? **Inmates requiring Mental Health treatment are transferred to the State Hub Prison in Lancaster.**
    - How long do inmates wait to be seen? **Transferred to State Hub Prison as soon as possible, normally same day.**

    - What is the process to handle mentally challenged inmates? **Desert View MCCF does not provide Mental Health treatment. Inmates identified for Mental Health treatment are transferred to the State Hub Prison in Lancaster.**
    - Is there special housing and staff training? **No special housing. Staff trained to refer inmate requiring Mental Health Services for transfer to State Hub Prison for treatment.**
- Are there Contracted offsite Hospitals, Dental clinics? **Yes.**
    - How are inmates transported to offsite facilities? **Contracted ambulances for emergencies or CDCR van transports for contracted referred medical treatment.**
    - How is security handled? **Inmate is transferred by transfer team.**

Site Tour

Note the following items as you tour the facility:

- Condition of the exterior and interior of the building noting graffiti, peeling paint, unpleasant odors, or other signs of deterioration. **Clean except for graffiti on the interior replacement "Lexan" window in dorms.**
- Condition of the grounds, exercise areas, playing fields, and exercise equipment. **All clean**.
- General cleanliness of the facility including windows, lighting, lockers, desks, conditions of the mattresses, bedding and pillows. **Clean except the interior windows of the dorms**.
- Condition of sleeping room door panels. **Clean, painted and not damaged**.
- Temperature of living units. **Air conditioned with outside air temperature of 87 degrees, pleasant**.
- Safety and security issues including fencing, outdoor lighting, location of the weapons locker. **Weapons locker kept by CDC personnel. Indoor lighting fixtures good. This was a daytime inspection. The Grand Jury cannot comment on outdoor lighting.**
- If a court holding area is present in the facility, ensure access to toilet and drinking water. **N/A.**

INTERIOR OF BUILDINGS (walls, paint, floors, drains, plumbing fixtures working, air vents, windows)

- Are cleaning fluids and chemicals labeled and safely stored? **Yes**.
- Weapons locker present. **Kept by CDC personnel, locked up in secure area.**
- Recreation/sports equipment **Yes.**
- Are the hallways clear, are doors propped open or closed? **Hallways clear and clean, doors closed.**
- Holding areas (cells/rooms) – (if present), is there access to drinking water and toilet? **All holding cells had water and a toilet**.
- Are there individual cells/rooms, or dormitories? **Dormitories**.
- Beds – Type of bed and is it off the floor? **All beds off the floor, one-piece mattress and pillow system.**
- Adequate lighting **Yes.**
- Temperature. **Satisfactory.**

INDIVIDUAL CELLS/ROOM

- Condition of walls. **Clean, one wall had just been painted as we walked through**.
- Personal possessions allowed in cell/room (Art, Books, Etc.) **Yes**.
- Graffiti present. **Only on aforementioned window.**
- Ample bedding. **Yes.**

PERSONAL APPEARANCE OF INMATES

- What is the appearance of inmates (dirty, unkempt, well groomed, etc.)? **Inmates appeared clean with clean clothes.**
- Showers – frequency, privacy, maintained. **Inmates have unlimited showers, as many as they want each day. Showers are only closed so that they may be cleaned in the evening each day.**

- Are there any reported assaults by inmates on inmates? **There is possibly one altercation per month, nothing of a major nature, more like a push or disrespectful speech.**
- Condition of clothing (does the clothing fit; is it appropriate for the weather, etc.)? **Clothing looks adequate for the season.**

GLEN HELEN REHABILITATION CENTER

For the purpose of this report, the Grand Jury obtained information from the following: interview and guided tour with the Captain of the facility from the San Bernardino Sheriff Department; the California Code of Regulations, Title 15 Crime Prevention and Corrections, Division 1, Board of State and Community Corrections, Minimum Standards for Local Detention Facilities; personal observations by the Grand Jury members; and the San Bernardino County Sheriff/Coroner Department Web site: http://cms.sbcounty.gov/sheriff/CourtsCorrections/GlenHelenRehabilitationCenter.

Inspection Form

FACILITY NAME: Glen Helen Rehabilitation Center	INSPECTION DATE: September 9, 2016
FACILITY CAPACITY: 324 Female inmates and 1,024 Male inmates	TYPE OF FACILITY: County Female and Male inmates housed in separate facilities.
ADDRESS: 18000 Institution Road, Devore, CA 92407	TELEPHONE NUMBER: 909-473-3689

The Glen Helen Rehabilitation Center lies on nine acres of land and consists of three inmate-housing facilities under the command of a Captain from the San Bernardino County Sheriff Department. Glen Helen is San Bernardino County's primary facility for housing both male and female inmates sentenced to County commitments.

There are three levels of inmate classification. GP for general population ranked 1 through 7 with 1 being the highest risk based on offense(s). There is an HS classification for High Security inmates, and RH classification for Restricted Housing (pregnancy, bullied inmates, etc.).
The Male Facility opened in 1960 as a work camp and had a capacity of 100 inmates in a maximum housing unit. The original site was also used as the Sheriff's Basic Academy until many years later when the training center was moved to the property just north of the jail. The current facility has two Minimum Security Housing Units and a Maximum Security Housing Unit. Glen Helen has a maximum capacity of 1,024 inmates and averages a daily population of 1,020.

Glen Helen's Female Facility originally opened in 1988 with three dorm units for the housing of county sentenced inmates. An additional Maximum Security Unit was added in 2003 and the complex now houses both pretrial and sentenced females. The Female Facility has the capacity to house 326 inmates and averages an inmate population of 240 inmates per day.

General Information

Note: Responses to Grand Jury questions are in bold.

- What is the capacity of the facility? **1,024 Male inmates. 326 Female inmates. Capacity will increase when housing units M1 and M2 are fully remodeled.**
- What is the number of pretrial/presentenced inmates? **720 inmates.**
- Has the facility exceeded capacity since the last state inspection? **No.**
- What is the average length of detention? **143 days.**
- Are inmates oriented to rules and procedures? **Yes.**
- Are rules and grievance procedures posted? **Yes.**
- Are rules and grievance procedures understood by inmates? **Yes.**
- Number of suicides 2015 to 2016. **None.**
- Number of attempted suicides 2015 to 2016. **None.**
- Number of deaths from other causes 2015 to 2016. **None.**

- Numbers of escapes 2015 to 2016. **None, last escape in 2013.**
- Date of last fire/emergency drill. **August 2016 during the Blue Cut vegetation fire.**

Staffing

- Is there enough staff to monitor inmates? **Yes, fourteen inmates to one staff member.**
- What is number of funded positions? **60 custody staff (25% women).**
- How many vacant positions are there? **Four. These positions will be filled by Sept. 8, 2016 academy graduation class.**
- Does staff communicate in language that an inmate can understand? **Yes, several languages are available. Outsourcing is also used for less common languages.**
- Diversity of staff. **Very diverse staff evident.**
- Impression of staff. **Very professional and knowledgeable.**

Programs

- Educational Programs? **GED (General Education Diploma). The Sheriff's Department partners with Chaffey Adult School, California State University San Bernardino, San Bernardino County Superintendent of Schools, and the County Department of Workforce Development to offer a variety of occupational training to increase an inmate's chance to gain employment upon release.**
- Self Help Programs? **Alcoholics Anonymous, Narcotics Anonymous, Anger Management, Individual and Group Counselling, Veteran's Administration assistance, Parent and Child Connection (PAAC), Teaching and Loving Kids (TALK), Gift a Quilt Program, Health Education, and Life Skill Development during Pre-Release class.**
- Drug Treatment Programs? **Substance Abuse, "INROADS" (Inmate Rehabilitation Through Occupational and Academic Development). Inmates who enter the INROADS program without a high school diploma are required to attend classes and earn their GED while in custody.**

- Work Programs/Vocational Programs? "**Work Release Program." Under the direction of the court, the inmate can be released before the maximum sentence has been completed in order to reestablish ties with his/her family. In this way, the individual can return to his/her former employment and serve the community on his/her non-scheduled workdays. Vocational classes available while in custody for Commercial Baking, Culinary Arts, Custodial Occupations, and Microsoft Office Specialist Certification.**
- Religious Services? **Yes, inmates are allowed on a voluntary basis to participate in religious services conducted by in-house chaplains and volunteers from various religions and organizations. Muslim inmates are accommodated with prayer rugs for prayer times at three intervals per day. Special religious events and meals are observed by the institution.**
- Exercise:
    - Is it inside or out? **Outside, basketball courts available.**
    - How frequently is it offered? **Daily.**
    - How much time is each inmate offered? **Mandated minimum of three hours per week; however, the average time higher at eight to nine hours per week.**

Telephone

- Do inmates have access to telephones? **Yes.**

Correspondence

- Is there limited free postage for inmates without money? **Inmates who are without funds shall be permitted at least two postage paid letters each week to permit correspondence with family members and friends but without limitation on the number of postage paid letters to his or her attorney and to the courts.**
- Incoming/outgoing – are inmates aware that mail can be read? **Yes, by staff.**

- Confidential correspondence – letter to attorneys, legislators, etc., - how is it handled? **Jail staff shall not review inmate Confidential mail to or from state and federal courts, any member of the State Bar or holder of public office; however, jail staff may open and inspect Confidential mail only to search for contraband, cash, checks, or money orders and in the presence of the inmate.**

Visiting

- Is there adequate space, convenient times or accommodations to family's work schedule, etc.? **Visiting hours Tuesday-Saturday 8:00 a.m. - 5:30 p.m.**
- Are there provisions for special visits with attorneys/clergy? **Yes.**
- Does staff supervise visits? **Staff monitors regular visits. Attorney visits are held in a confidential area if requested.**
- Do all inmates have access to visiting? **Yes. Visiting can be restricted based on privilege level.**

Grievances

- What are the most common types of grievances filed by inmates? **25 grievances were reviewed from January-August 2016. Grievances varied for different issues with no observable pattern in one area over another.**
- Is there a record kept based on type and number? **Yes.**
- What is the grievance process? **An inmate may appeal and have resolved grievances relating to any conditions of confinement, included but not limited to: medical care; classification actions; disciplinary actions; program participation; telephone, mail, and visiting procedures; and food, clothing, and bedding.**

Meals/Nutrition

- The kitchen area – Is it clean? **Kitchen area is exceptionally clean, no mold or unusual smells.**
- Are meals served in the cell? If not where? **Meals and special dietary meals are prepared in the kitchen. Inmates take their meals in the dorm area; there is no**

talking and no passing of food. Inmates receive two hot meals and one cold meal daily.

- Are inmates permitted to converse during meals? **No.**
- Length of time allowed for eating? **A minimum of fifteen minutes shall be allowed for the actual consumption of each meal.**

Health

- Medical Services and Dental Services:
    - How frequently is medical/dental staff onsite? **Available 24 hours, 7 days a week.**
    - How long do inmates wait to be seen? **A daily sick call conducted for all inmates. Policies and procedures to ensure emergency and medically required dental care is provided to each inmate.**
    - Is a physician/dentist available by phone or come inside? **Yes, both.**
    - What type of onsite health facility is available to inmates? **Medical, Dental, Eye Care. Limited Mental Health services. Inmates with more severe Mental Health issues are typically transferred to West Valley Detention Center.**
- Mental Health Services:
    - How frequently is mental health staff onsite? **Daily Monday-Friday excluding holidays.**
    - How long do inmates wait to be seen? **Same day Monday-Friday or next working day.**
    - What is the process to handle mentally challenged inmates? **Inmate self-referral or Staff Referral of inmate to Psychiatrist or Clinical Psychologist. Severe Mental Health cases are transferred to West Valley Detention Center or Arrowhead Regional Medical Center.**
    - Is there special housing and staff training? **Yes.**
    - Are there Contracted off site Hospitals, Dental clinics? **YES, Arrowhead Regional Medical Center for cases not able to accommodate at the Glen Helen Rehabilitation Center.**

- How are inmates transported to offsite facilities? **Contracted ambulances for emergencies or Sheriff van transportation to contracted referred medical treatment facilities.**
- How is security handled? **Inmate is put in waist and leg restraint gear unless medical restrictions. Correctional staff accompany inmate to and from the hospital.**

Site Tour

Note the following items as you tour the facility:

- Condition of the exterior and interior of the building noting graffiti, peeling paint, unpleasant odors, or other signs of deterioration. **No graffiti seen; paint in reasonable condition; no unpleasant odors of any kind especially in the living areas. Buildings M1 and M2 are undergoing remodeling. Kitchen equipment needs updating.**
- Condition of the grounds, exercise areas, playing fields, and exercise equipment. **Satisfactory, grass is green, some stress evident from reduced watering during the drought, exercise areas are clean with no debris, exercise equipment appears to be in good condition.**
- General cleanliness of the facility including windows, lighting, lockers, desks, conditions of the mattresses, bedding and pillows. **Very good, pillows are incorporated into the mattress, lighting fixtures area reasonably clean, lighting is good, lockers and desks are not damaged.**
- Condition of sleeping room door panels. **Satisfactory.**
- Temperature of living units. **Satisfactory, outside air temperature approximately 84 degrees at 11:30 a.m., inside satisfactory.**
- Safety and security issues including fencing, outdoor lighting, location of the weapons locker. **All appear in good condition and functioning.**
- If a court holding area is present in the facility, ensure access to toilet and drinking water. **Did not observe.**

INTERIOR OF BUILDINGS (walls, paint, floors, drains, plumbing fixtures working, air vents, windows)

- Are cleaning fluids and chemicals labeled and safely stored? **No cleaning fluids and chemicals stored in open.**
- Weapons locker present. **Did not observe.**
- Recreation/sports equipment. **Available for checkout.**
- Are the hallways clear, are doors propped open or closed? **Hallways clear, doors open or closed as appropriate.**
- Holding areas (cells/rooms) – (if present), is there access to drinking water and toilet? **Did not observe.**
- Are there individual cells/rooms, or dormitories? **Dormitories and cells.**
- Beds – Type of bed and is it off the floor? **Three-tier bunk beds off the floor. Top bunk is considered the best.**
- Adequate lighting. **Yes.**
- Temperature. **Good.**

INDIVIDUAL CELLS/ROOM

- Condition of walls. **Clean.**
- Personal possessions allowed in cell/room (Art, Books, Etc.). **Yes, stored in tubs/boxes under bunk.**
- Graffiti present. **No graffiti observed.**
- Ample bedding. **Yes.**

PERSONAL APPEARANCE OF INMATES

- What is the appearance of inmates (dirty, unkempt, well groomed, etc.)? **Well groomed.**
- Showers – frequency, privacy, maintained. **Showers clean and available as requested.**
- Are there any reported assaults by inmates on inmates? **Some but minor in nature.**
- Condition of clothing (does the clothing fit; is it appropriate for the weather, etc.)? **Yes.**

CENTRAL VALLEY JUVENILE DETENTION & ASSESSMENT CENTER

For the purpose of this report, the Grand Jury obtained information from the following: interview and guided tour with the Superintendent; the California Code of Regulations, Title 15 Crime Prevention and Corrections, Division 1 Minimum Standards for Local Detention Facilities; the San Bernardino County Probation Department Juvenile Detention and Assessment Center Orientation Handbook; the San Bernardino County Probation Department Web site www.joinprobation.org; a Computer Disk containing 366 files San Bernardino County Probation Department policy and procedures documents; and personal observations by the Grand Jury members.

Inspection Form

FACILITY NAME: Central Valley Juvenile Detention & Assessment Center	INSPECTION DATE: September 1, 2016
FACILITY CAPACITY: 280 juvenile inmates Current population of 33 Female inmates and 182 Male inmates	TYPE OF FACILITY: County Female and Male juvenile inmates housed in separate facilities referred to “Youth or Minor.”
ADDRESS: 18000 Institution Road, Devore, CA 92407	TELEPHONE NUMBER: 909-473-3689

The Central Valley Juvenile and Assessment Center (CVJDAC) was completed for 62 million dollars and opened in 2011. CVJDAC consists of a group of buildings in a "campus" style arrangement with related site developments and utilities. The design reflects the current emphasis on consolidating services such as dining, medical, education and others as much as possible in order to streamline operations and minimize the need for transporting individuals from one area to another.

CVJDAC is located on a 9.7-acre site. The housing consists of three 80-bed housing units and one 40-bed housing unit arranged in 20-person modules for a total of 280 beds. Each module measures one story and 75,000 square feet and is composed of classrooms and program space for group therapy, religious activities and medical services. To create an interior courtyard area offering indoor activity space for juvenile detainees, modules were designed in a triangular fashion with basketball courts for each housing unit. Consolidated support facilities include classrooms, common areas, exercise areas, outdoor sports facilities, an intake/booking area, a warehouse, kitchen, and a 47,000-square-foot, single-story administrative building. The administration building includes intake, clinic, library, central control station, as well as offices. CVJDAC is also equipped with a state-of-the-art security system.

General Information

Note: Responses to Grand Jury questions are in bold.

- What is the capacity of the facility? **280 bed facility (three 80-bed housing units and one 40-bed housing unit). Current population of 215 inmates (182 males, 33 females).**
- What is the number of pretrial youth? **Varies.**
- Has the facility exceeded capacity since the last inspection? **No, population divided between two Juvenile Detention Assessment Centers. (CVJDAC and High Desert Juvenile Detention Assessment Center).**
- What is the average length of detention? **Approximately 60 days.**
- Are youths oriented to rules and procedures? **Yes, Probation Correction Officers (PCO) orientation staff will provide information about facility procedures, rules, behavior expectations, services and programming. Orientation shall be provided no later than 24 hours after arrival to a unit.**
- Are rules and grievance procedures posted? **Yes.**
- Are rules and grievance procedures understood by youths? **Yes, provisions are made to provide information to youths who are impaired, disabled or do not speak English.**
- Number of suicides 2015 to 2016. **None.**
- Number of attempted suicides 2015 to 2016. **Unknown, none reported.**

- Number of deaths from other causes 2015 to 2016. **None.**
- Numbers of escapes 2015 to 2016. **None.**
- Date of last fire/emergency drill. **Conducted monthly.**

Staffing

- Is there enough staff to monitor youths? **Yes, youths are monitored by Probation Correction Officers (PCO's) along with the use of Closed Circuit Television Security System. Cameras monitor and record youth activities and interactions with other youths and staff 24 hours a day, 7 days per week. In order to maintain privacy, Closed Circuit Cameras are not located in restrooms, showers or youth's sleeping rooms.**
- What is number of funded positions? **139 full time staff. Ratio: 1 supervision staff to 10 youths. (5 female Probation Corrections Supervisor I, and 3 female Probation Corrections Supervisor II).**
- How many vacant positions are there? **Eight vacancies.**
- Does staff communicate in language that a youth can understand? **Yes, provisions will be made to provide information to youths who are impaired, disabled or do not speak English.**
- Diversity of staff. **Very diverse.**
- Impression of staff. **Professional and knowledgeable.**

Programs

- Educational Programs? **Every youth entering a Juvenile Detention and Assessment Center is provided a quality educational program that includes instructional strategies designed to respond to the different learning styles and abilities of students for K-12 grade. School has 14 full time teachers. Teaching staff work closely with each youth's former high school to earn him/her a high school diploma.**
- Self Help Programs? **Yes, drug and alcohol.**
- Drug Treatment Programs? **Volunteer and/or court mandated drug and counseling programs available to all youths.**

- Work Programs/Vocational Programs? **Regional Occupational Program (ROP) career technical training.**
- Religious Services? **Yes, the Religious Services Coordinator maintains oversight of all religious activities within each facility and along with the Chaplains, assigns religious volunteers to provide services to youths. Religious Volunteers in Probation have passed a background check and have been trained and approved by the Religious Services Coordinator or Volunteer Coordinator. Religious services Wednesday and Sunday open to all youths.**
- Exercise:
    - Is it inside or out? **On a daily basis, unit programs and activities are scheduled by staff, which includes indoor activities-approved television/radio programs, video games, board games/card games, art activities, reading material, indoor games, letter writing, phone calls and outdoor activities-basketball, kickball, soccer, calisthenics.**
    - How frequently is it offered? **Youths participate in recreational or exercise activity for a minimum of 3 hours a day, and up to 5 hours a day on weekends, providing behavior is appropriate.**

Telephone

- Do youths have access to telephones? **Yes, youths are allowed access to the unit/staff telephone ONLY to contact their Probation Officer or Attorney. Youths may contact family or others on the unit's collect-only telephones.**

Correspondence

- Is there limited free postage for youths without money? **There is no limit on the volume of mail you may send or receive. Youths will be provided with pencils, paper, envelopes, and staff will ensure that sufficient time is set aside to write letters. Correspondence is not permitted between probation facilities. Letters to other correctional facilities are permitted to immediate family members, but only with written approval from both facilities.**

- Incoming/outgoing – are youths aware that mail can be read? **Yes, prior to mail leaving the facility, staff will ensure that mail is properly addressed, not sealed, no slogans or symbols shall appear on the outside of an envelope.**
- Confidential correspondence – letter to attorneys, legislators, etc., - how is it handled? **Staff without reading, screen for contraband in front of youth.**

Visiting

- Is there adequate space, convenient times or accommodations to family's work schedule, etc.? **Visiting days and times are specifically scheduled for each unit. Daily Visiting is for 2 hour durations from 9:30 a.m. - 11:30 a.m., 2:30 p.m. - 4:30 p.m., and 6:00 p.m. - 8:00 p.m.**
- Are there provisions for special visits with attorneys/clergy? **Right to contact your attorney by telephone, during business hours (8:00 a.m. to 5:00 p.m.) Monday through Friday. Once the religious/spiritual leader has been cleared at the request of the youth, the approved visit will be scheduled.**
- Does staff supervise visits? **Visits will be supervised by Probation Correctional Officer at all times.**
- Do all juvenile inmates have access to visiting? **Yes, regular visits with Parents, Grandparents, and Legal Guardians.**

Grievances

- What are the most common types of grievances filed by youths? **Varies, youths can grieve anything.**
- Is there a record kept based on type and number? **Yes, Superintendent reviews all grievances.**
- What is the grievance process? **Grievance forms available in each housing unit. Youths have the right to file a grievance if any staff has violated the youth's rights in the facility, or living conditions, medical, food, religious issues and/or school issues. After completing a grievance form, a Probation Correction Officer will attempt to resolve the issue within 4 days. If the issue remains unresolved, a Supervisor will review the grievance and make a determination. If still not satisfied with the**

outcome, a request for an appeal will be sent to a facility administrator. The San Bernardino County Superintendent of Schools, not probation, would address grievances involving school state or conditions.

Meals/Nutrition

- The kitchen area – Is it clean? **Yes.**
- Are meals served in the cell? If not where? **Meals are prepared in the kitchen and then delivered to each pod. Youths eat in common dining area in each of the pods.**
- Are youths permitted to converse during meals? **Yes.**
- Length of time allowed for eating? **A minimum of fifteen minutes shall be allowed for the actual consumption of each meal.**

Health

- Medical Services and Dental Services:
    - How frequently is medical/dental staff onsite? **A Correctional Nurse is available 24 hours, 7 days a week. Chief Medical Officer regular hours Monday, Wednesday, and Friday and also on call 24 hours a day for emergencies. Dentist regular hours every other Thursday. Optometrist regular hours every other Thursday.**
    - How long do youths wait to be seen? **Youths sign up for sick call to be seen by the Correctional Nurse within the same day at the clinic.**
    - Is a physician/dentist available by phone or come inside? **Doctor and Dentist on call.**
    - What type of onsite health facility is available to youth? **Medical clinic that provides medical services for sick call, dental services, and optometry.**
- Mental Health Services:
    - How frequently is mental health staff onsite? **24 hours, 7 days a week.**
    - How long do youths wait to be seen? **Youths may at any time request counseling services if experiencing an emotional crisis, feeling sad, wanting to hurt himself/herself, are depressed, or cannot emotionally adjust to a detention setting. Youths will be referred to FAST (Forensic Adolescent**

Services Team) for services. FAST will see the youth immediately, within 24 hours, within 48 hours, or within 14 days based on the level of care required.

- What is the process to handle mentally challenged youths? **Youth self-referral or staff referring youth for mental health/counselling treatment.**
- Is there special housing and staff training? **Yes, all staff trained to recognize need to refer youth for Mental Health services based on youth's stress, anxiety, etc.**
- Are there Contracted offsite Hospitals, Dental clinics? **Appointments or treatment may be completed at the Medical Clinic, Arrowhead Regional Medical Center (ARMC), Loma Linda University Medical Center, Dental provider, or by referrals to youth's private medical physician.**
- How are juvenile inmates transported to off-site facilities? **Youths are transported in transport vans by Probation Correction Officers for non-emergency appointments or ambulances for emergencies.**
- How is security handled? **Emergency and non-emergency appointments/treatment, youths are placed in physical restraints typically waist and leg restraints unless medical restrictions and accompanied by Probation Correctional Officers.**

Site Tour

Note the following items as you tour the facility:

- Condition of the exterior and interior of the building noting graffiti, peeling paint, unpleasant odors, or other signs of deterioration. **Very well maintained clean facility with no signs of graffiti.**
- Condition of the grounds, exercise areas, playing fields, and exercise equipment. **Green and clean.**
- General cleanliness of the facility including windows, lighting, lockers, desks, conditions of the mattresses, bedding and pillows. **No broken or cracked windows. All areas well lit. Lockers, desks, and tables all in excellent condition. New mattresses with pillows part of mattress.**
- Condition of sleeping room door panels. **Clean.**

- Temperature of living units. **Air conditioned, comfortable temperature.**
- Safety and security issues including fencing, outdoor lighting, location of the weapons locker. **No safety or security deficiencies noted.**
- If a court holding area is present in the facility, ensure access to toilet and drinking water. **Not applicable.**

INTERIOR OF BUILDINGS (walls, paint, floors, drains, plumbing fixtures working, air vents, windows). **Clean and well maintained. Noted some sign of discoloration (black soot) around air vent.**

- Are cleaning fluids and chemicals labeled and safely stored? **Yes, youths do not have access to cleaning fluids or chemicals unless under direction supervision of Probation Correction Officer.**
- Weapons locker present. **Yes, for staff, no youth access.**
- Recreation/sports equipment. **Basketball courts.**
- Are the hallways clear, are doors propped open or closed? **Hallways clear, doors not propped open. Doors closed.**
- Holding areas (cells/rooms) – (if present), is there access to drinking water and toilet? **Rooms have toilet and sink.**
- Are there individual cells/rooms, or dormitories? **Most two-person rooms, a few one-person rooms.**
- Beds – Type of bed and is it off the floor? **Two-person room: lower bunk-concrete slab with mattress and upper bunk-solid metal frame with mattress. Single room: concrete slab bed off the floor with mattress.**
- Adequate lighting. **Yes, all areas well lit.**
- Temperature. **Air conditioned, comfortable temperature.**

INDIVIDUAL CELLS/ROOM

- Condition of walls. **Clean and well maintained.**
- Personal possessions allowed in cell/room (Art, Books, Etc.). **Limited property.**

- Graffiti present. **No.**
- Ample bedding. **Yes, pillow part of mattress.**

PERSONAL APPEARANCE OF JUVENILE INMATES

- What is the appearance of juvenile inmates (dirty, unkempt, well groomed, etc.)? **Youth observed clean and well groomed.**
- Showers – frequency, privacy, maintained. **Clean and well maintained, with swinging shower door for privacy.**
- Are there any reported assaults by youth on youth? **Occasional fights.**
- Condition of clothing (does the clothing fit; is it appropriate for the weather, etc.)? **Clothing appears appropriate.**

OVERSIGHT OF SAN BERNARDINO COUNTY CHARTER SCHOOLS

BACKGROUND

Statistics from the Charter Authorizers Regional Support Network reveal that, "In the 2015-2016 school year, California had 1,228 operating charter schools representing almost 12% of California public schools and serving 572,752 students, or 9% of California's public school children." The Parent Empowerment Law (also known as the "Parent Trigger") signed in January 2010 allowed parents to change the administration of a school into a charter school. Charter schools have authorizing agents such as local school districts, a county, or the State of California. In San Bernardino County, Desert Trails Elementary was originally part of Adelanto Elementary School District (AESD). Education Code Sections 53300-53303 established the Parent Empowerment Act. Parents of pupils in persistently low-achieving schools had a choice of four interventions: the turnaround model, restart model, school closure, and transformation model. Petitions were signed by parents or legal guardians of at least one-half of the pupils attending Desert Trails Elementary. Parents formed Desert Trails Parents Union and sought proposals for new schools from several charter operators. The Desert Trails Parent Union selected Desert Trails Preparatory Academy which had the same charter school administration as Laverne Preparatory Academy in Hesperia, California.

Desert Trails Preparatory Academy (DTPA) signed a Charter Facilities Agreement with Adelanto Elementary School District June 26, 2013, and existed three years under the oversight of AESD. November 30, 2015, AESD passed Resolution 15-16-09 and denied the petition to renew. DTPA petitioned and was approved as a charter school from the San Bernardino County Office of Education which is the authorizing agency of DTPA. Oversight for DTPA in 2016-2017 is through the San Bernardino County Superintendent of Schools (SBCSS). DTPA continues to exist as a charter at the same school location it has occupied since 2013.
The Grand Jury also studied Norton Science and Language Academy (NSLA) in San Bernardino. NSLA has been under SBCSS supervisorial oversight for ten years as a charter school.

Other charter schools in San Bernardino County have garnered attention in local newspapers after being the focus of critical audits conducted by the Fiscal Crisis and Management Assistance Team. When local districts for those charter schools have withdrawn support and not renewed the charters, the charter schools have sought to enter the supervisorial oversight through SBCSS. The possibility of the San Bernardino County Office of Education having supervisorial oversight for more than two charter schools is increasing as more districts are not renewing charter schools including Oxford Preparatory Academy in Chino Hills and Hope Academy in Morongo. The San Bernardino County Office of Education denied the charter petition from Oxford Preparatory Academy.

Since more charters may eventually come under the auspices of the SBCSS, the Grand Jury focused on the role that the SBCSS serves in supervisorial oversight of charter schools. Consequently, the Grand Jury focused on Desert Trails Preparatory Academy (DTPA) and Norton Science Language Academy.

The Grand Jury elected to conduct an investigation under the authority of Section 933.5 of the Penal Code.

METHODOLOGY

Members of the San Bernardino Civil Grand Jury conducted interviews with a SBCSS administrator and other personnel. Interviews were held several times throughout the six month study. Interviews were held with representatives from Adelanto Elementary School District representing administration and the central office staff. Grand Jurors attended a board meeting for one charter school, DTPA, and two board meetings for the other charter school, NSLA. Board meetings were held at the school sites so Grand Jurors examined the facilities to see if Ralph M. Brown Act requirements were met at the meeting site. The Ralph M. Brown Act Government Code Sections 54950-54962 provide information to governmental boards regarding notification of meetings, agendas, and minutes. Documents requested and received included the Charter Facilities Agreement between AESD and DTPA and the Memorandum of Understanding

Regarding Charter School Oversight and Operations between SBCSS on behalf of the San Bernardino County Board of Education and Desert Trails Preparatory Academy. Other documents obtained included a Charter School Facility Inspection dated August 9, 2016, for DTPA and a copy of the Final Award 01-16-0000-7169 reached by the American Arbitration Association Commercial Arbitration Tribunal between Claimant Desert Trails, Inc. and Respondent Adelanto Elementary School District Board of Trustees, the Governing Body of the Adelanto Elementary School District. DTPA staff provided repair invoices for high priority facility items that needed to be repaired. In addition, the Grand Jury studied specific provisions of the California Education Code regarding charter schools.

FACTS

Grand Jury members visited three charter schools and attended three board meetings. The three charter schools visited included locations previously used by the local school district as well as a charter school built from charter school funds. A Charter School Facility Inspection form for DTPA was conducted as an initial facility inspection on August 9, 2016, when the SBCSS initially began serving as the oversight agent (Attachment 1). The visit resulted in a ranking of six high priority items, two medium priority items, and seven low priority items. The six high priority items included one active class without a functioning air conditioner, another classroom without a functioning air conditioner, and major trip hazards through and around the basketball courts. Other high priority items included exposed landscape fabric causing a trip hazard due to depleted wood chips, violations in the sand play area with a cracked slide and holes in the rubberized play surface, and the lack of a handicap ramp to the upper number 700 building which is accessible only by three stairs (Attachment 2).

The Charter Facilities Agreement by and between Adelanto School District and Desert Trails Preparatory Academy dated June 26, 2013, states in the Section 9 Recital titled Maintenance, "The District shall be responsible for the major maintenance of the Site. For purposes of this section, 'major maintenance' includes the major repair or replacement of plumbing, heating,

ventilation, air conditioning, electrical, roofing, and floor systems, exterior and interior painting, and any other items considered deferred maintenance under Education Code Section 17582." Routine maintenance and minor repairs are the responsibility of the charter school.

The Condition of Property Section 11 of the Charter Facilities Agreement states, "The District shall remain responsible for all legal compliance with, for example, the Americans with Disabilities Act (ADA), Fair Employment and Housing Act, environmental laws, and other applicable building code standards, for any condition of the Site or existing compliance issue prior to the date of the charter school's occupancy of the Site." Conditions of schools were noted when the *Eliezer Williams, et al. v. State of California, et al* ("Williams Case") was filed as a class action lawsuit in 2000 against the State of California and state education agencies, including the California Department of Education. The *Williams Case* settled in 2004 with funding to provide equal access to instructional materials, safe and decent school facilities, and qualified teachers. When Adelanto Elementary School District had oversight responsibilities for Desert Trails Elementary, the SBCSS noted ADA compliance issues with the stairs accessing the 700 Building when SBCSS conducted inspections for the *Williams Case*. Stairs violated ADA requirements as stairs deny access for people with mobility issues.

DTPA has paid independent companies to complete repairs when AESD did not respond in a timely manner to major maintenance repair requests (See Attachments 3 – 6). Names are redacted in compliance with a court order. Attachment 3 – Vern's Glass $2,110.77 – $1,000 paid by DTPA and insurance paid $1,110.77; Attachment 4 – Aace's Heating and Air Conditioning 8/15/2016 $750; Attachment 5 – Aace's Heating and Air Conditioning 9/2/2016 $2,300; Attachment 6 – Santiago Roofing 3/8/2017 $140.

When AESD denied DTPA's petition for renewal for 2016-2017, AESD believed that DTPA would be seeking other facilities to use. DTPA planned to remain at the same school location. To reach a solution regarding use of the school location, legal counsel for each entity agreed to select one arbitrator from a list of ten arbitrators. American Arbitration Association of the Commercial Arbitration Tribunal was selected and a three-day hearing was conducted on

July 5, 6, and 7, 2016. The Final Award 01-16-0000-7169 stated "Under the Charter Facilities Agreement, Desert Trails Preparatory Academy has the right to exclusive use of the school site located at 14350 Bellflower Street in Adelanto, California for the full duration of its Charter, including through the current term of the Charter, any renewed terms of the Charter, and any appeals related to the renewal of DTPA's Charter." So even though DTPA is no longer under the chartering authority of AESD, the District needs to comply with the Charter Facilities Agreement it signed with DTPA on June 26, 2013.

Education Code 47604.33 charges each charter school to prepare and submit reports to its chartering authority. These reports include first and second interim financial reports. The Grand Jury noted interim financial reports appeared on the Board agenda of both charter schools, DTPA and Norton Science and Language Academy; the NSLA January 2017 Board Meeting and the DTPA Board meeting in March 2017 reviewed the topic. The two schools for which the SBCSS serves as the supervisorial oversight agency are complying with Education Code 47604.33 on those issues.

The Charter Facilities Agreement Section 8 Utilities states, "Charter school shall be solely responsible for the cost of utilities used or consumed by the charter school on the site..." The note on the Work Order stated: "City of Adelanto water department suspects that there is a leak on campus. We need someone to come out and assess the problem." The staff at DTPA submitted Work Order 22305 on 9/14/2016 and by 2/22/2017 little progress was made on the repair. At the December AESD Board Meeting, it was reported in the public comment time that water consumption for a six-month period at DTPA showed twice as much consumption as in a previous six-month period. If the major repair or replacement of the valve had occurred in a timely manner by AESD, funds that would have been spent on the scholars and their educational programs would not have been expended on wasting water during a multi-year California drought.

Another major repair issue on air conditioning was noted. Work Order 22305 was originally submitted May 20, 2016, for Room 31. The second date on the Work Order was July 5, 2016. Charter School Oversight from SBCSS is found in Education Code Section 47613 (a). "A chartering authority may charge for the actual costs of supervisorial oversight of a charter school not to exceed 1 percent of the revenue of the charter school." The exception is found in Education Code 47613 (b): "A chartering authority may charge for the actual costs of supervisorial oversight of a charter school not to exceed 3 percent of the revenue of the charter school if the charter school is able to obtain substantially rent-free facilities from the chartering authority." NSLA paid $70,000 to SBCSS as noted in the financial reports provided at the Board meeting in January 2017 which is one percent of its revenue.

Education Code Section 47604.32 charges each chartering authority to identify at least one staff member as a contact person for the charter school. The SBCSS charter liaison provides multiple services to the two charter schools, DTPA and NSLA, for which the County has supervisorial oversight. While Education Code 47604.32 requires the liaison to visit the sites only once a year, the liaison has made significantly more visits. The liaison provides to the site a written response for each visit to report its compliance including Ralph M. Brown Act regulations, board agendas, minutes, and board information packets. The liaison's visit can be announced or unannounced. The SBCSS charter liaison participated in the initial facility inspection of DTPA on August 9, 2016, along with a team from SBCSS. The liaison serves as one of six leaders on a statewide organization overseeing charter schools due to a breadth of knowledge. The liaison helped DTPA achieve more consistent Internet access in 2016 with the installation of additional switches so the school would not have the same connectivity issues it experienced during state testing in 2015. The scholars had to restart the online state test repeatedly when computers lost Internet access. The liaison was offered an opportunity to participate in interviews for CEO for the Academy for Academic Excellence, of which NSLA is associated, but declined due to the liaison's perceived conflict of interest.

Governance of DTPA and SBCSS is covered in Section H of the Memorandum of Understanding between SBCSS on behalf of San Bernardino County Board of Education. Information that must be posted on the charter's website includes the Articles of Incorporation and Bylaws, roster and biographies of current governing Board members, and an annual calendar of governing Board meetings, including a description of how parents and community members will be notified of meetings. Governing Board meetings of Desert Trails, Incorporated must be conducted in compliance with the requirements of the Ralph M. Brown Act. The March 2017 Board meeting was held in a classroom that could only be accessed by climbing stairs and therefore did not meet ADA requirements for the meeting site. A review of the Desert Trails' website in late May 2017 showed that biographies of current governing Board members were not available and a description of notifications for meetings was missing. Approved Board minutes from previous meetings were not available on DTPA's website as of May 30, 2017. Two current Board members of DTPA are employees of Laverne Preparatory Academy, which has the same charter school administration as DTPA. These two members will finish their current terms ending on June 30, 2017. The two new Board members for 2017-2018 should not be family members or officers of either DTPA or Laverne Preparatory Academy, and should not have a financial interest in the charter school according to the Memorandum of Understanding (MOU) between SBCSS and DTPA approved May 9, 2016, and May 12, 2016. According to the MOU, the Governing Board of Desert Trails, Incorporated shall have a parent member seat on the Board at all times. While a parent is currently represented on the Board, Grand Jurors did not see the representative present at the March 2017 meeting. The Grand Jury did not see parents or community members present at the March Board meeting. Little notice was available on the Desert Trails' website regarding the meeting. Grand Jurors noted a lack of available child care for non-school age children during the meeting time.

Parent representatives serving as Board members on the Norton Science and Language Academy Board attended both Board meetings that Grand Jurors attended in January 2017 and March 2017. One topic on the Board meeting for the Lewis Center for Educational Research, the parent organization for NSLA, was the focus of the Board's meeting time. Administration reported that

teachers have complained that they could not attend due to the 7:00 AM starting time. This conflicted with their teaching responsibilities in their classrooms. Grand Jurors noticed the length of the Board meeting which lasted longer than four hours.

FINDINGS

F1: DTPA does not meet ADA requirements for an accessible campus as the Grand Jurors observed at the March 2017 Board meeting.

F2: DTPA has major maintenance issues regarding its site.

F3: AESD has not complied with its Charter Facilities Agreement with DTPA regarding major maintenance.

F4: DTPA does not utilize its website for required postings of information regarding biographies of Board members, of the Articles of Incorporation or the Bylaws, and of the approved minutes of previous meetings.

F5: NSLA does not utilize its website for required posting of approved meeting minutes within five days of their approval according to requirements of the Ralph M. Brown Act.

F6: Ralph M. Brown Act provisions regarding the posting of approved minutes on the charter school's website, and holding Board meetings in an ADA accessible meeting room, are not complied with during and after Board meetings at DTPA.

F7: SBCSS as the supervisorial oversight agent for DTPA and NSLA provides extensive services from its charter liaison to each charter it oversees.

F8: A cooperative relationship exists between the charter liaison and the two charters.

F9: A cooperative relationship between DTPA and AESD was breached when an outside arbitrator was needed to resolve issues regarding school site usage.

F10: DTPA has paid for major maintenance repairs when Adelanto Elementary School District should have paid per the MOU of June 26, 2013.

F11: At charter school Board meetings scheduled in January 2017 for NSLA and in March 2017 for DTPA, NSLA had few teachers present and DTPA had none.

F12: Parents attending Board meetings at NSLA and DTPA were limited in number and usually were the ones serving as Board members.

F13: The charter school liaison exceeds the minimum number of charter school visits which is one per school year.

F14: Work orders are prioritized by AESD but not repaired accordingly.

RECOMMENDATIONS

17-27: Update charter school websites at Desert Trails Preparatory Academy and Norton Science and Language Academy with approved minutes of Board meetings within the Ralph M. Brown Act required five-day window following each Board meeting.

17-28: Update charter school websites on an annual basis to include a list of Board members and their biographies. Include information and forms regarding enrollment.

17-29: Schedule charter school board meetings at times that are convenient for Board members, parents, and teachers to attend. Anticipate meeting the needs of parents who bring non-school age children.

17-30: Provide major maintenance repairs at Desert Trails Preparatory Academy on a timely basis.

17-31: Continue providing more than the required one visit a year from the charter liaison who has a broad understanding of charters.

17-32: Communicate among school district administration, charter school administration, the County school personnel, and central office staff when there are issues regarding oversight and operations.

17-33: Prioritize work orders received by Adelanto Elementary School District by ranking the repairs needed and repair accordingly.

17-34: Report by the liaison on the high priority facility repairs made on the Desert Trails Preparatory Academy Charter School Facility Inspection Form dated August 9, 2016, to the San Bernardino County Office of Education which serves as the authorizing agency.

17-35: Compensate Desert Trails Preparatory Academy for major maintenance repairs paid by the school because Adelanto Elementary School District is responsible for major repairs according to the Charter Facilities Agreement of June 26, 2013.

AGENCY	RECOMMENDATIONS	DUE DATE
San Bernardino County Superintendent of Schools	17-27 through 17-29 & 17-31 through 17-32 & 17-34	9/1/2017
Adelanto Elementary SD	17-30 & 17-33 & 17-35	10/1/2017

Attachment 1

DTPA Site Visit Report
August 9, 2016

PRIORITY ORDER

- **HIGH PRIORITY**

  Rooms 26 & 36

  Air Conditioners not working (One has active class)

  Rooms 25, 36, 37, 38

  Broken Windows

  Outside Basketball Courts

  Multiple large cracks running directly through and around basketball courts/ Major Trip Hazard
  Drainage Problems – Landscape Areas drain directly on to basketball courts and play area (no standing water at time of pictures as that particular day was not a watering day).

  Play Structure

  Wood Chips have been completely depleted / Exposed Landscape Fabric causes trip hazard

  Sand Play Area

  Slide is Cracked
  Holes is rubberized play surface

  No Handicap Ramp or designated path of travel to upper 700 buildings – Only path of travel is over broken asphalt of basketball court through locked back gate.

- **MEDIUM PRIORITY**

  Boys Restroom

  Urinal broken from wall / Needs remounted (Pic 3884)
  End toilet furthest from entry door / Bolt needs cut and capped for safety (Pic 3885)
  Toilet Cracked/ Needs Replaced / Bolt needs cut and capped for safety
  Exhaust Fans Not working

  Girls Restroom

  Lighting Fixture Not Working (Most likely burned out ballast) – Is emergency Back Up Light
  Exhaust Fans not working

- **LOW PRIORITY**

  MPR

  Wallpaper is damaged or missing in multiple locations / Poor Wall Patches
  Stained Ceiling Tile center of room (Leak has been repaired)
  Small cracks in floor tile along foundation seam

Attachment 2

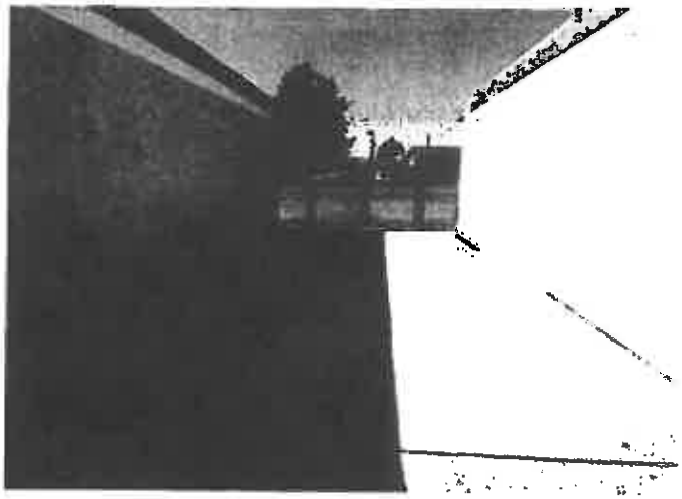
Desert Trails Preparatory Academy
Facility Inspection Pictures
August 9, 2016

HIGH PRIORITY ITEMS

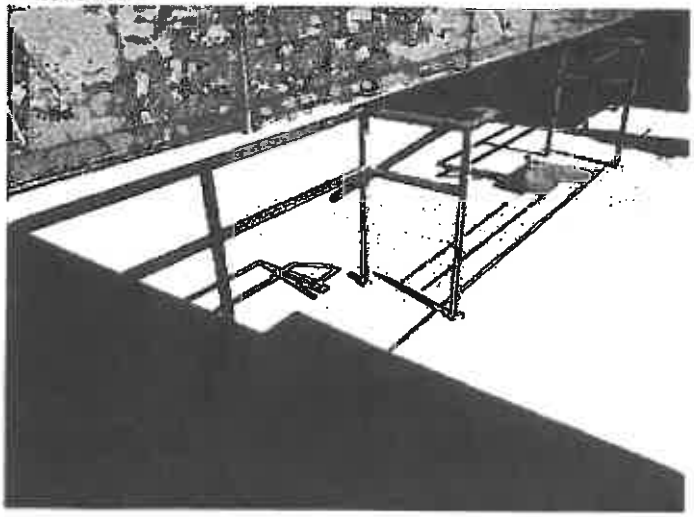
No handicap ramp or designated path of travel to upper 700 buildings. Only path of travel is over broken asphalt of basketball court through locked back gate.

Picture 3913

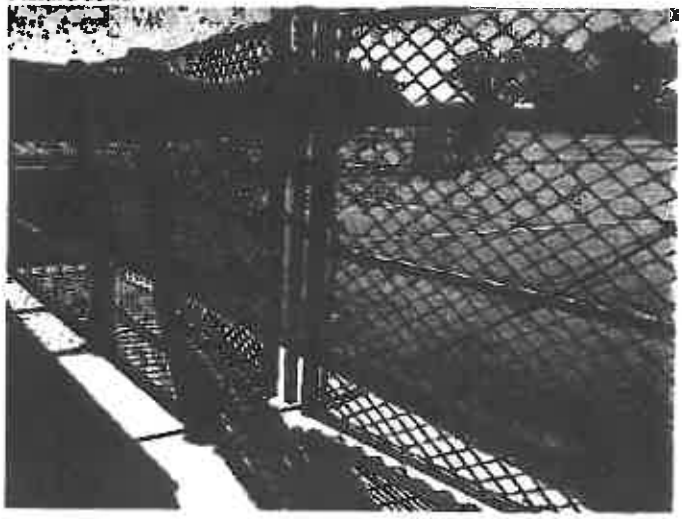
Picture 3917



Picture 3914



Picture 3918



Attachment 3

Verns SINCE 1957 GLASS

Remit To:
P.O. Box 368
Victorville, CA 92393

verns@vernsglass.com
Phone # 760.[illegible]
Fax # [illegible]

PAID 08/22/2016

Invoice

Date	Invoice #
8/22/2016	17002
S.O. No.	

Bill To

DESERT TRAILS ELEMENTARY
DEBRA TARVER
PO BOX 400880
HESPERIA, CA 92345

Ship To

14350 BELLFLOWER ST
ADELANTO, CA 92301

Customer Phone	Customer Contact	Customer Alt. Phone	P.O. No.	Terms
760-530-7680-				

Quantity	Description	Each	Amount
1	5/8" OA DUAL UNIT 1/8" BRONZE/CLEAR-TEMPERED WITH DARK SPACER 33-7/8" X 42-3/4"	172.48	172.48T
1	5/8" OA DUAL UNIT 1/8" CLEAR/CLEAR-TEMPERED WITH DARK SPACER 33-7/8" X 42-3/4"	151.04	151.04T
3	5/8" OA DUAL UNIT 1/8" DARK GRAY/CLEAR-TEMPERED WITH DARK SPACER 47-3/8" X 46-3/8"	396.10	1,188.30T
	TRIP CHARGE AND INSTALLATION	478.00	478.00

THIS IS A CUSTOM ORDER! BY PLACING THIS ORDER YOU UNDERSTAND THERE ARE NO RETURNS OR REPLACEMENTS ON CUSTOM ORDERS AND ALL SALES ARE FINAL! PLEASE BE SURE TO UNDERSTAND YOUR ORDER BEFORE PLACING IT!
All balances must be paid in full at the time of delivery and/or completion unless terms have been agreed upon prior. Payments not received within 7 days of due date will be subject to 18% APR finance charges and a late fee of 25.00 or 5% outstanding balance, whichever is higher. Accepted payment methods are cash, check, money order, Discover, Visa and Mastercard.

Subtotal	$1,989.82
Sales Tax (8.0%)	$120.95
Total	$2,110.77
Payments/Credits	-$2,110.77
Balance Due	$0.00

Attachment 4

1-800-535-8071
1-760-983-4342
1-909-829-5027

LIC. # 918978
BONDED • LICENSED • INSURED
COMMERCIAL • RESIDENTIAL

15183

Name: Desert Tiels ☐ Owner ☐ Tenant
Job at: Kellflower
City: Adelanto Zip:
Telephone: (760) 810-2258

Bill to:
at: Tech: [redacted] Inst:
City: Zip: P.O. # Auth.#
Telephone: Email:

Date: 8/15/16

DESCRIBE FULLY: Nature of work done and specify exact location of each fixture of repair made. Continue on reverse side if necessary.

	AMOUNT
Replaced 208-230 Voltage blower motor, hook-up electrical components, run cap.	
Replace Squad caps for motor, connect all together	
Add Freon to system	
	paid
1yr Warranty	

SEE "NOTICE TO PAYOR" and statement required on contract on reverse side.

WORK AUTHORIZATION

TO PROCEED WITH THE ABOVE DIAGNOSIS/SOLUTION - I, the undersigned, am owner/authorized representative/tenant of the premises at which the work mentioned above is to be done. I hereby authorize you to perform Diagnosis/Solution, and to use such labor and materials as you deem advisable. If payment is not made in the agreed manner, a monthly service charge of 1.5% will be added after 30 days. If your check bounces, you could be liable for three times the amount of the check or $100.00, whichever is more, plus the face value of the check and court costs. I have read, agree to and have received a copy of the contract and Notice to Payor on reverse side.
All parts removed will be discharged unless otherwise specified.

$ 750.00

Signature of Owner/Authorized Representative/Tenant: X
ACCEPTANCE OF WORK PERFORMED - I find service and materials rendered and installed in connection with the above work mentioned to have been completed in a satisfactory manner. I agree that the amount set forth on this contract in the space labeled "TOTAL" is the total and [illegible] charge.

Acceptance Signature: [redacted]

TERMS:
☐ CASH ☐ CHECK CK# 131
☐ CREDIT CARD
C.D.L. # EXP
CARD #
☐ PIN: AUTH# EXP
REF # AMT $
Signature

Flat Rate	
Truck Stock	
Service Call	
Total Job	
Less Discount	
Amount Due	750 00

Attachment 5

1-800-535-8071
1-760-983-4342
1-909-829-5027

AAace's

LIC. # 918978
BONDED • LICENSED • INSURED
COMMERCIAL • RESIDENTIAL

15219

Name: Desert trails ☐ Owner ☐ Tenant
Job at: 14250 Bellflower
City: Adelanto Zip: 92301
Telephone:

Bill to:
at:
City: Zip: P.O. # Auth.#
Telephone: Email:
Date: 9/2/16
Tech: [redacted] Inst:

DESCRIBE FULLY: Nature of work done and specify exact location of each fixture of repair mode. Continue on reverse side if necessary.

	AMOUNT
Install new Compressor For Wall Mount unit Re-Weld copper-lines adapted electrical components, Vacuum lines, Re-Charge unit	
$2300.00 - $250.00 credit = $2050.00	
Paid	
1yr Warranty	
Flat Rate	
Truck Stock	
Service Call	
Total Job	
Less Discount	
Amount Due	2,050.00

SEE "NOTICE TO PAYOR" and statement required on contract on reverse side.

WORK AUTHORIZATION

TO PROCEED WITH THE ABOVE DIAGNOSIS/SOLUTION - I, the undersigned, am owner/authorized representative/tenant of the premises at which the work mentioned above is to be done. I hereby authorize you to perform Diagnosis/Solution, and to use such labor and materials as you deem advisable. If payment is not made in the agreed manner, a monthly service charge of 1.5% will be added after 30 days. If your check bounces, you could be liable for three times the amount of the check or $100.00, whichever is more, plus the face value of the check and court costs. I have read, agree to and have received a copy of the contract and Notice to Payor on reverse side.
All parts removed will be discharged unless otherwise specified.

[redacted] $ 2,050.00

Signature of Owner/Authorized Representative/Tenant: X

ACCEPTANCE OF WORK PERFORMED - I find service and materials rendered and installed in connection with the above work [redacted] completed in a satisfactory manner. I agree that the amount set forth on this contract in the [redacted] to be the total of flat rate/minimum charge.

Acceptance Signature: X [redacted]

TERMS:
☐ CASH ☑ CHECK CK# 1262
☐ CREDIT CARD
C.C.I. # EXP
CARD #
☐ FIN: AUTH# EXP
REF # AMT $
Signature

Attachment 6

SANTIAGO ROOFING COMPANY
14631 Nanticoke Rd.
Apple Valley, CA 92307
Phone & Fax: 760-961-9482

716057

Invoice

SOLD TO	SHIP TO Desert Trails Prep
ADDRESS	ADDRESS
CITY, STATE, ZIP	CITY, STATE, ZIP

CUSTOMER ORDER NO.	SOLD BY	TERMS	F.O.B.	DATE
				3-8-17

ORDERED	SHIPPED	DESCRIPTION	PRICE	UNIT	AMOUNT	
	35	Pcs Eagle Tile @ $4.00 ea.			$140	00
		Paid cash				
		[redacted]				

A-6869 T-45700/45721 01-41

REQUEST FOR PROPOSAL FOR THE INDIGENT ADULT APPOINTED REPRESENTATION SERVICE CONTRACT

BACKGROUND

The Grand Jury examined the policies and procedures used by the County of San Bernardino's Purchasing Department. Specifically, the Grand Jury examined the process that was used for the Request for Proposal (RFP) for the Indigent Adult Appointed Representation Service Contract No.: CRT114-COURT-0733. Since the contract was awarded in 2014, it has been the subject of several newspaper articles.

This contract was announced for proposal in September 2013 and approved on March 11, 2014, by the Board of Supervisors (BOS) in an amount not to exceed $8,000,000 annually and $20,000,000 total over the 30-month term of the April 1, 2014, through September 30, 2016, with two additional one-year options if in the best interest of the County.[1] The first of the two options for extending the contract was approved in April 2016 for the period of October 2016 through September 2017. [2] The second option of the contract is expected to be extended for the final one-year option in June 2017.

The County Administrative Office (CAO) had the responsibility to complete the RFP for this contract by utilizing a “template” that was provided by the County’s Purchasing Department. The final RFP totaled 40 pages of information. The Grand Jury focused on the following areas of that RFP:

[1] Report/Recommendation to the Board of Supervisors San Bernardino County, California and Record of Action dated March 11, 2014

[2]Copy of letter sent to current contract holder from Purchasing Department dated April 14, 2016

- **Purpose** (RFP page 3, Section 1, Part A)
- **Overview of Selection Process** (RFP page 3, Section 1, Part B)
- **Payment Provisions** (RFP page 11, Section C)
- **Evaluation Criteria** (RFP page 29, Section VII, Part B)

In September 2013, the CAO forwarded the completed RFP to the County Purchasing Department. The Purchasing Department was responsible for the process from the announcement to the awarding of the contract. The Purchasing Department assigned a Buyer to this specific RFP whose duties included:

- Review the RFP to make sure it was completed correctly and met the policies and procedures of the department
- Set up the bidding process (included the posting online and mailing of letters)
- Verify the bid packets were completed as required
- Work closely with the assigned analyst from the CAO in the selection of the evaluation panel members
- Compile the evaluation scores into a spreadsheet
- Contact all RFP proposers with the decision regarding the contract award
- Issue the Intent to Award which allows appeals to be filed before the actual contract has been approved and awarded
- Attach contract to the Board of Supervisor's agenda and forward to CAO for submission to the Board of Supervisors for final approval

The Grand Jury conducted the investigation under the authority of California Penal Code Section 925. The Grand Jury's Legal Advisor recused himself from providing any legal advice and attending any meetings in which this investigation was discussed. All advice and directions were provided by County Counsel.

METHODOLOGY

The Grand Jury conducted interviews with management and staff from the following groups: Purchasing Department, County Administrative Office, County Counsel, a former County employee, and a proposer involved in this process. The Grand Jury reviewed policies, procedures, internal emails, bid proposals and additional documents related to the process.

FACTS

Purpose: At the time the RFP was issued in September 2013, under "Purpose" it stated: “The current contracts, effective 2008, were awarded to private law firm administrators, and are set up by four non-overlapping regions that cover the entirety of San Bernardino County..."

- West Valley (Rancho Court District and the court district formerly serviced by the closed Chino Courthouse)
- East Valley (San Bernardino and Fontana Court Districts)
- North Desert (Victorville Court District and the court districts formerly serviced by the limited use Barstow Courthouse and the closed Needles Courthouse)
- East Desert (Joshua Tree Court District)

Historically, this type of contract had been awarded by region within the County of San Bernardino.[3] Interviews of those directly involved with this bid process were under the impression that the contract would continue to be awarded as it had been in the past, as four separate contracts. When the Notice of Intent to Award was issued, it was to one proposer and it included all four regions. After the Notice of Intent was issued, the Purchasing Department received two appeal letters from two of the six proposers. After analyzing the appeal letters, the Purchasing Department determined that there was no basis for the appeals and denied them.

[3]RFP Page 3 Section A

The Grand Jury's interviews revealed inconsistencies as to what defines changes within this RFP that would have required a re-issue of a new RFP. If an appeal is filed and affirmed, then the Purchasing Department would go back and void the RFP and re-issue a new one. Those interviewed indicated that they were under the impression that the contract would continue to be awarded, as in the past, as four separate contracts.

Overview of Selection Process: A review panel composed of two judges from the San Bernardino County Superior Court, two attorneys from County Counsel and a representative from the CAO. They were responsible for the reviewing and scoring of the qualified proposals in all five categories (Capability and Resources, Company Reliability and/or Financial Resources, Professional References, Workplan and the Cost Evaluations). Prior to the panel members meeting, the representative from the CAO had withdrawn due to unavailability.

All proposers must provide the number of years they have been operating under the present business or law firm name, as well as prior business or law firm names.[4] Based upon the Grand Jury's interviews, it was stated that one of the proposers was not a legal entity based upon the information provided in its bid proposal. The Purchasing Department does not have any policies or procedures in place to validate that any businesses submitting a proposal is a legal entity.

Payment Provisions: The contractor shall be paid on a flat fee basis per case, per hearing, or per proceeding. Although the contract was awarded for $8,000,000 annually, any funds remaining and not billed are returned to the County General Fund.

Evaluation Criteria: Proposals were subject to a review/evaluation process developed by the County's Purchasing Department. Proposers must meet the mandatory requirements as specified in the RFP. As stated in the RFP, "Failure to meet all these requirements will result in a non-responsive proposal that will be rejected with no further evaluation or consideration."[5]

[4] RFP Page 3 Section D #2
[5] RFP Page 29 Section B #16

The Grand Jury was assured during interviews that the panel members' identities were kept confidential during this process. Prior to the panel members meeting as a group they had already reviewed the proposals and completed their portion of the scoring. As a group, they met behind closed doors for a portion of one day to review and discuss their scoring. After the panel members' meeting, all documents and notes were collected from the panel members by the facilitator to maintain the integrity of the process.

The evaluation members were provided with instructions on the scoring process that discussed wide variations in individual scoring. The purpose of these instructions was to avoid wide variations of scoring within the same categories.

The scoring was broken down into three categories with two of the categories assigned points [6]:

1. Initial Review: Pass/Fail
   This review was completed by the Purchasing Department.

2. Technical Review: 70 points
   This scoring was completed by the evaluation panel.

3. Cost Evaluation: 30 points
   This portion was initially reviewed and scored by the evaluation panel. When the Purchasing Department reviewed the scoring, they decided to utilize a set formula for all the proposers to obtain a more consistent scoring than that of the evaluation panel. The completed panel evaluations along with their suggested formula costs were forwarded to the CAO for final review and approval. The CAO also looked at different cost formulas and a decision was made to consolidate and award the contract to only one proposer to better meet the needs of the County of San Bernardino.

The Technical Review was broken down into four sub-categories and assigned individual points to equal 70 points:

1. Capability and resources to provide the required contract administration, fiscal recordkeeping, and audit compliance services, including credentials and experience of the proposed program administrator and job descriptions and qualifications of key administrative and fiscal personnel (10 points)

[6] RFP Page 29-30, Section VII, B1-3

2. Company reliability and/or financial resources (5 points)

3. Strength of professional references that support the proposer's ability to administer a contract of this nature and scope (5 points)

4. The strength of proposer's workplan (50 points)

Documentation received indicated that the evaluation panel had completed and scored all the above categories including the Cost Evaluation. Based upon the Grand Jury's interviews it was stated that the contacting of the references was not completed by the evaluation panel members that this would have been completed by the Purchasing Department. The Grand Jury was not to obtain any supporting documentations as to who contacted the references or how the scoring of the references was reached by the evaluation panel or the Purchasing Department.

In reviewing the scoring completed by the evaluation panel, those interviewed were unable to explain to the Grand Jury why there were wide variations among the evaluators.

This chart provides only the areas in which the Grand Jury questioned the variations of scoring within the evaluation panel members:

	Maximum Points	**Evaluator A**	**Evaluator B**	**Evaluator C**	**Evaluator D**
Proposer #1					
Cost Evaluation	**30**	25	27	27	22
Proposer #2					
Capability and Resources	**10**	10	6	9	8
Company Reliability and/or Financial Resources	**5**	5	3	3	4
Professional References	**5**	5	3	4	4
Workplan	**50**	40	35	46	40
Cost Evaluation	**30**	20	21	25	25
Proposer #3					
Capability and Resources	**10**	2	8	7	8

Professional References	**5**	1	3	4	4
Workplan	**50**	15	40	40	30
Cost Evaluation	**30**	10	21	20	15
Proposer #4					
Capability and Resources	**10**	9	7	6	5
Company Reliability and/or Financial Resources	**5**	5	2	3	2
Professional References	**5**	4	3	3	3
Workplan	**50**	45	37	45	30
Cost Evaluation	**30**	25	22	28	25
Proposer #5					
Capability and Resources	**10**	8	7	9	7
Professional References	**5**	3	3	4	3
Workplan	**50**	40	36	45	25
Cost Evaluation	**30**	24	25	28	25
Proposer #6					
Professional References	**5**	2	2	3	2
Workplan	**50**	25	25	42	20
Cost Evaluation	**30**	20	16	28	25

Source: Summary Spreadsheet provided by the Purchasing Department.[7]

Concerns were expressed in regards to the potential conflict of interest since the County Counsel represents the county agencies by providing legal assistance and advice. When contracts are presented to the Board of Supervisors issues may arise with respect to the process in which they would seek guidance from County Counsel with the possibility they may have participated on that evaluation panel. Written policies of the Purchasing Department provides guidelines in determining the use of members from the County Counsel and the State of California's Superior Court Judges.[8]

[7]California Public Record Act
[8] Purchasing Department's Procurement Manual Page 15

During the Grand Jury's interviews, it was stated that the Purchasing Department is working on developing new training modules specifically for the RFP process.

FINDINGS

F1: When the contract was awarded in March 2014, a decision was made to issue the contract to only one proposer to cover all four regions. The Grand Jury was informed that there was a catch-all statement within the RFP that authorized the proposal to be issued to either one region or to all four regions. When the interviewees were asked to locate this statement in the RFP, they were unable to do so.

F2: The Grand Jury determined that based upon interviews and the terms used within the purpose of this RFP, the proposers were led to believe that the contract would be awarded based upon past practices.

F3. The Grand Jury found that the statement including one or more regions, up to all four regions, was omitted from this RFP.

F4: Based upon the Grand Jury's interviews and documentation received, the Purchasing Department had no guidelines to define when a RFP should be re-issued.

F5: When the Grand Jury inquired why State's Superior Court Judges were included, it was stated that they would be in the best position to know the reputations of the attorneys submitting the bid proposals.

F6: The Grand Jury does not have jurisdiction to request interviews or obtain any documentation from the State's Superior Court Judges who served as two members of the panel.

F7: Two attorney from County Counsel served as members of this panel.

F8: No process was in place to validate the legal entity of the proposer.

F9: In reviewing the appeal letters, it was discovered by the Purchasing Department that one of the proposers was not a legal entity at the time the proposal was submitted.

F10: The justification of the scoring of references could not be validated as no documentation could be located.

F11: The Grand Jury noted that there were wide variations among the evaluators' scores within the same categories.

F12: The Purchasing Department is currently working on training modules that will include specific guidelines for issuing of RFPs.

RECOMMENDATIONS

17-36: Clearly state on the RFP whether one region or all four regions will be considered for awarding a contract.

17-37: Follow written guidelines from the Purchasing Department when choosing panel members who evaluate proposals for RFPs.

17-38: Assemble stakeholders to determine who would best serve as evaluation panel members. Explore using representatives from other counties as potential panel members.

17-39: Require that each proposer submit a copy of a valid business license with its bid proposal.

17-40: Create a permanent tracking log that lists each step in the process, including who is responsible for each step and the date it was completed.

17-41: Use the median score to lessen the effect of the highest and lowest scores on the final score.

17-42: Implement training modules specific to the RFP process.

AGENCY	RECOMMENDATIONS	DUE DATE
Purchasing Department	17-36 through 17-42	10/1/2017

SAN BERNARDINO COUNTY FACILITIES, SITE SECURITY AND PUBLIC SAFETY

BACKGROUND

The Waterman Incident at the Inland Regional Center at 1365 South Waterman Avenue in San Bernardino on December 2, 2015, created an emergency under Public Contract Code Section 22050 (a) (1) which states: "In the case of an emergency, a public agency, pursuant to a four-fifths vote of its governing body, may repair or replace a public facility, take any directly related and immediate action required by that emergency, and procure the necessary equipment, services, or supplies for those purposes, without giving notice for bids to let contracts."
The San Bernardino County Board of Supervisors (BOS) on December 7, 2015, in closed session, unanimously approved the use of County Code Section 14.0106, County Policy 11-04, and County Policy 11-05 to permit the Purchasing Agent to procure any goods, services, and equipment needed for the continued operation of the County, including but not limited to, contracts with other public agencies to provide aid.

METHODOLOGY

The Grand Jury interviewed many County officials from Facilities Management-Real Estate Services and the Sheriff's Department. Documents were requested and reviewed from several sources to clarify the full scope of the BOS Emergency Proclamation 2015-228.

FACTS

County officials realized the security and public safety of its citizens must be in the forefront of the County. This realization required immediate action to prevent and/or mitigate the loss or impairment of life, health, property, and essential services to the public. In response, on December 4 and December 7, 2015, the BOS issued an Emergency Proclamation determining the Waterman Incident to be an emergency with recommendations outlining the necessity of remodeling/renovating of four County buildings and facilities. Pursuant to Government Code

Section 8630 (c) "The governing body shall review the need for continuing the local emergency at least once every 30 days until the governing body terminates the local emergency." The Emergency Proclamation by the BOS included a criteria of security measures through assessments of the following County owned and/or leased buildings:

- County Government Center, 385 N. Arrowhead Ave., San Bernardino
- Old Hall of Records, 172 W. 3rd St., San Bernardino
- County Office Building, 8575 Haven Ave., Rancho Cucamonga
- Rancho Cucamonga Court House, 8303 Haven Ave., Rancho Cucamonga

The initial scope of the 2016-2017 Grand Jury was to investigate the four County owned/leased buildings. The Grand Jury learned that Phase One of the remodeling/renovating included eight buildings, so the Grand Jury expanded its focus from the initial four buildings to include all eight buildings.

The BOS aided in providing the needed funds to proceed with this project. The County allocated approximately $10.2 million in funds toward improving security at County facilities. This allocation included $8.2 million in immediate improvements to facilities, such as expanded security services, upgraded security cameras, key card access installations, and $2.0 million to conduct a security assessment of all County facilities. Funds were allocated by the County Administrative Office from Discretionary General Funds included in the Capital Improvement Program to procure the equipment, services and supplies to advance the project. On February 12, 2016, a Request for Proposal (RFP) was released to secure on-call consultant services. On March 18, 2016, six responses were received to the RFP. The responses were reviewed by a Selection Committee comprised of a total of seven members from County Real Estate Services, the Sheriff's Department, Facilities Management, Risk Management and Information Services Department. Four of the six potential security consultants were invited to give oral presentations to the Selection Committee.

On May 24, 2016, the BOS approved agreements with both TRC Engineers and Guidepost Solutions not-to-exceed the amount of $500,000 each. TRC Engineers, based in Irvine, was selected to conduct facility assessments and propose physical improvements to County facilities. TRC Engineers had experience in conducting facility assessments that would allow the County to plan its security needs. These assessments would cover physical security, interior/exterior security, access control, motion detectors, Closed Circuit Television (CCTV) surveillance, communications, and the placement of uniformed security personnel at the eight selected facilities. Guidepost Solutions, with an office in Los Angeles, was selected because it demonstrated the technical ability in employee training programs, project management, and specific physical improvement documentation to assist the County in executing the project.

On July 25, 2016, a Notice to Proceed was issued to TRC Engineers for initial assessments of the eight buildings. These buildings were selected as representative of typical County facilities.

- County Government Center, 385 N. Arrowhead Ave., San Bernardino
- Arrowhead Regional Medical Center – Medical Office Building, 400 N. Pepper Ave., San Bernardino
- Senior Center & Library, 1331 Opal Ave., Mentone
- High Desert Government Center, 15900 Smoke Tree St., Hesperia
- Transitional Assistance Department, 265 E. 4th St., San Bernardino
- San Bernardino County – Probation, 150 W. 5th St., San Bernardino
- Public Health – Annex, 340 N. Mt. View Ave., San Bernardino
- Ontario Preschool Services Department, 555 W. Maple, Ontario

The County formed an Internal Security Subcommittee to oversee all phases of the project. It is comprised of individuals from the Sheriff's Department, Information Services, and Real Estate Services. This Subcommittee is using methodology developed by the Department of Homeland Security (DHS) and the Interagency Security Committee for federal facility security assessments.

DHS standards establish baseline requirements for the protection of people and property at all County owned and/or leased facilities. This methodology includes six areas:

- Determine the Facility Security Level
- Identify the baseline Level of Protection and countermeasures (armed guards, screening, cameras and access cards as needed)
- Identify and assess risks
- Conduct a gap analysis of needs to determine the Level of Protection required to address the risk or the highest Level of Protection
- Implement countermeasures
- Measure performance and monitor compliance

For Phase One of the assessment project, the High Desert Government Center was selected to be the initial pilot site. On August 15, 2016, TRC Engineers issued a draft of the Facility and Site Security Assessment for the High Desert Government Center. The additional seven sites were assessed within a 12-week period that began on July 16, 2016. Phase Two consists of assessing the master planning and security needs for the remaining 190 County owned and/or leased facilities which was to be completed over a 38-week period. Phase Three consists of Physical Improvement Solutions, Training Programs and Program Management. It was to be completed over a 52-week period beginning concurrently when the Phase Two assessments were completed. Phase Four is the final phase comprising Construction and Project Development. It began in December 2016 as Phase Three was in the process of completion.

A preliminary kick-off meeting was held with Guidepost Solutions on October 11, 2016. Training programs began in December 2016. Separately from the Guidepost Solutions training, the Sheriff's Department – Office of Safety and Security produced a PowerPoint presentation on workplace safety dealing with work-related crime prevention, workplace safety and workplace violence. The presentation advises employees how to deal with an active shooter situation and is given upon request of County Departments.

To quickly communicate information on impending dangers, the San Bernardino County Sheriff and Fire Departments can now send high speed mass notifications via telephone and text messages. This system is called the Telephone Emergency Notification System (TENS). The County uses a database of landline telephone numbers for County offices, which is updated every six months, to send emergency messages to the landline phone numbers in the database. TENS alerts are rarely sent to all County offices and employees; they are targeted only to affected areas. The Sheriff's Information Technology staff is overseeing the initial installation of the TENS equipment and security configurations. Residents can receive emergency text messages on their cell phones and devices using Voice Over Internet Protocol (VOIP) and can manage their own account using a valid email address. County Information Services Department is responsible for the installation, maintenance, and administration of the VOIP system. The Web site to register for this service is http://www.sbcounty.gov/SBCFire/Tens/TENScontact.aspx. Those without Internet access can sign up by calling 2-1-1 or (888) 435-7565. The County of San Bernardino utilizes multiple ways to notify residents of impending danger, but warns residents not to wait for, or rely exclusively on, a single notification system.

CURRENT STATUS

On March 3, 2017, the Grand Jury received from Real Estate Services a progress report regarding the status of the buildings mentioned in the BOS proclamation and the eight buildings included in Phase One of the RFP.

(1) Of the four buildings mentioned in the Emergency Proclamation, only one, the County Government Center in San Bernardino, completed a full security assessment on August 16, 2016. Also new security access devices were installed on all County department access doors. The County Sheriff handles security guards through a contract with Allied Barton which requires contractor compliance with all State and Federal laws and regulations pertaining to privacy and security of confidential information. These guards remain on site. The three remaining buildings have not completed full assessments, but some improvements have already been made.

(2) The Old Hall of Records, 172 W. Third Street, San Bernardino, had security access devices previously installed at key points throughout the building. Security guard services were added to and their presence was increased at this building.

(3) County Office Building, 8575 Haven Avenue, Rancho Cucamonga, has been completed and previous user groups have re-occupied the updated offices.

(4) The Rancho Cucamonga Courthouse, 8303 Haven Avenue, has existing security devices to screen the public seeking access to the Courts. Security protocols and access are in the process of being upgraded.

All eight buildings included in Phase One completed security assessments in January 2017. As of March 3, 2017, the cost incurred for Phase One was $5,666,720.

TRC Engineers submitted its executive summary findings and recommendations to the County's Internal Security Sub-Committee. The Sub-Committee is reviewing these documents as the start of Phase Two. The next step includes a recommended Plan of Action be submitted to the Chief Executive Officer for implementation. The Plan of Action is projected to proceed in a systematic fashion, assessing the remaining County owned and/or leased buildings and facilities by obtaining approval for the scope of work, funding for the assessed properties, and scheduling the approved work for construction and completion.

FINDINGS

F1 The County Security Sub-Committee is using best practice standards as outlined by Department of Homeland Security and Interagency Security Committee standards when assessing the buildings mentioned.

F2 Employee training on security procedures and best methods is an important component to overall safety.

F3 Remodeling, renovations and training for enhanced security come at a considerable financial cost.

RECOMMENDATIONS

17-43 Best practice standards as outlined by Department of Homeland Security and Interagency Security Committee be continued in all phases of this project.

17-44 All future new construction should incorporate Department of Homeland Security and Interagency Security Committee standards.

17-45 Training by the Sheriff's Department regarding Safety and Security be scheduled regularly for all County departments.

17-46 Regular training, such as that provided by Guidepost Solutions, be made a priority for all County employees.

***Note: Some information/documentation given to the Grand Jury was not for public disclosure and it is not discussed in this report.**

AGENCY	RECOMMENDATIONS	DUE DATE
Facilities Management and Real Estate Services	17-43 through 17-46	10/1/2017

VETERANS AFFAIRS

"The willingness with which our young people are likely to serve in any war, no matter how justified, shall be directly proportional to how they perceive the veterans of earlier wars were treated and appreciated by their nation." --President George Washington

BACKGROUND

The San Bernardino County Department of Veterans Affairs (SBC VA) was the first in California and one of the first in the nation. The mission of the SBC VA is to assist all County veterans who served honorably in the armed services with filing claims for all eligible benefits. This mission includes claims for veterans, dependents and survivors. Benefits and eligibility guidelines are constantly changing, presenting increasing challenges for the County's Veteran Service Representatives (VSRs) who provide the front-line service to the veterans and their families. The Grand Jury has concerns whether the staffing levels are adequate to meet the needs of approximately 113,725 veterans (as of 2016) throughout San Bernardino County. This number does not include spouses, dependents and survivors of veterans.

The Grand Jury conducted the investigation under the authority of California Penal Code Section 925.

METHODOLOGY

The Grand Jury conducted its investigation by collecting information through research, interviews, and documents requested from both State and the SBC VA.

FACTS

Through the efforts of the SBC VA, in the fiscal year 2014-2015 new benefit claims for veterans totaled over $51 million which is the highest in the State. These efforts bring the total annual benefit claims for San Bernardino County veterans to over $398 million. These benefits come from both State and Federal programs. Seventy-two percent of the SBC VA budget comes from

the San Bernardino County General Fund. In 2016 SBC VA received $1,570,326 from the $2,994,500,000 total County General Fund. This amount represents .000524 of the budget. In 2011 it received $1,643,547 from the $2,209,900,000 total County General Fund; more than was contributed in 2016. The SBC VA stated there are plans for increased veteran services which are dependent on the County increasing their budget. Currently, the SBC VA is unable to proceed with these plans, as they are unfunded.

State and Federal funds are distributed by the State on a pro-rata basis, using the workload unit to determine how much is allocated to each county. A workload unit, as defined by the California Department of Veterans Affairs (CALVET) State Manual, is a claim that has a reasonable chance of obtaining a monetary or medical benefit (United States Department of Veterans, Department of Defense or State) for a veteran, dependent(s), widow/widower or survivors. A workload unit is also the completion of any form from the approved list of auditable forms also found in the CALVET Manual. These forms must be initiated, completed and submitted by a County Veteran Service Office. The more claims filed, the more funding a county receives from the State.

There are technically four levels of a VSR: the VSR Trainee, VSR I, VSR II and SVSR (supervising). The VSR Trainee studies several State and Federal claim manuals and learns laws and procedures. The general progression is to take the certification exam after six months, and then complete six months' probation before becoming a VSR I. Currently there are no VSRs in training. A VSR Trainee is only hired when a VSR I position becomes available and has one year to complete the program or be terminated.

The duties of a VSR I may include but are not limited to the following:

- Interviews and advises veterans, veterans' widows, orphans, and dependents concerning entitlement to benefits under Federal, State and local provisions
- Explains applicable laws and regulations
- Assists applicants in obtaining benefits, such as pension, compensation, education, insurance, medical care, housing and burial

- Assists applicants in completing necessary documents
- Counsels applicants regarding financial, medical, educational and vocational benefits
- Searches, analyzes, and screens all supporting evidence bearing on entitlement under the law
- Advises applicants in the filing of appeals when appropriate
- Secures affidavits, military discharge certificates, birth certificates, death certificates, certificates of naturalization, marital documentation and other types of supporting evidence
- Contacts lawyers, physicians, clergyman, and various officials and private parties to obtain supporting evidence for claims
- Prepares briefs of claims and letters of transmittal
- Makes home and hospital visits when necessary
- Trains new personnel in the processing of claims
- Supervises clerical staff when needed
- Prepares necessary correspondence and reports, maintains records
- Provides vacation and temporary relief as required

The duties of a VSR II are the same as a VSR I with additional responsibilities:

- Handles the most difficult or complex cases involving interaction with executive, administrative, professional and medical staff and/or military personnel to determine eligibility for benefits
- Acts in a lead capacity in training, guiding, reviewing and checking the work of a VSR I
- Assists staff on the most difficult cases
- Gives presentations to large groups of individuals

Although SVSRs process claims and work directly with veterans, their primary job description is supervising, training and administrative duties.

The current staffing level is seven VSR Is, four VSR IIs and two SVSRs. Currently all thirteen VSR positions are filled. These VSRs staff four full-time offices (San Bernardino, Rancho Cucamonga, Hesperia and Loma Linda VA Ambulatory Care Center); also three part-time satellite offices (Yucca Valley, Twentynine Palms and Fort Irwin). These part-time offices are only open one day a week. In addition to these locations, the need for an office in Barstow has become evident and is in the planning stage. The staff works nine hours Monday through Thursday, eight hours on Friday, and off work every other Friday (9/80 schedule).

Week 1

Location	Monday	Tuesday	Wednesday	Thursday	Friday
San Bernardino	A - Supervisor VSR	A - Supervisor VSR	A - Supervisor VSR	A - Supervisor VSR	A - Supervisor VSR
	C - VSR II	G - VSR I	G - VSR I	C - VSR II	C - VSR II
	G - VSR I	H - VSR I	H - VSR I	G - VSR I	F - VSR II
	H - VSR I	I - VSR I	I - VSR I	H - VSR I	I - VSR I
	L - VSR Trainee	L - VSR Trainee	L - VSR Trainee	L - VSR Trainee	L - VSR Trainee
Hesperia	B - Supervisor VSR	B - Supervisor VSR	B - Supervisor VSR	B - Supervisor VSR	Office Closed
	E - VSR II	E - VSR II	E - VSR II	E - VSR II	
	J - VSR I	J - VSR I	J - VSR I	J - VSR I	
	K - VSR I	K - VSR I	K - VSR I	K - VSR I	
Rancho Cucamonga	F - VSR II	F - VSR II	F - VSR II	F - VSR II	Office Closed
	I - VSR I			I - VSR I	
Loma Linda VA ACC	D - VSR II	D - VSR II	D - VSR II	D - VSR II	Office Closed
Yucca Valley		C - VSR II			
Twenty Nine Palms			C - VSR II		
Fort Irwin*		E - VSR II *			

* 1st and 3rd week of each month

Week 2

Location	Monday	Tuesday	Wednesday	Thursday	Friday
San Bernardino	A - Supervisor VSR	A - Supervisor VSR	A - Supervisor VSR	A - Supervisor VSR	D - VSR II
	C - VSR II	G - VSR I	G - VSR I	C - VSR II	G - VSR I
	G - VSR I	H - VSR I	H - VSR I	G - VSR I	H - VSR I
	H - VSR I	I - VSR I	I - VSR I	H - VSR I	
	L - VSR Trainee	L - VSR Trainee	L - VSR Trainee	L - VSR Trainee	
Hesperia	B - Supervisor VSR	B - Supervisor VSR	B - Supervisor VSR	B - Supervisor VSR	B - Supervisor VSR
	E - VSR II	E - VSR II	E - VSR II	E - VSR II	E - VSR II
	J - VSR I	J - VSR I	J - VSR I	J - VSR I	J - VSR I
	K - VSR I	K - VSR I	K - VSR I	K - VSR I	K - VSR I
Rancho Cucamonga	F - VSR II	F - VSR II	F - VSR II	F - VSR II	Office Closed
	I - VSR I			I - VSR I	
Loma Linda VA ACC	D - VSR II	D - VSR II	D - VSR II	D - VSR II	Office Closed
Yucca Valley		C - VSR II			
Twenty Nine Palms			C - VSR II		
Fort Irwin*		E - VSR II *			

* 1st and 3rd week of each month

A challenge for the SBC VA is to retain trained and experienced VSR Is to staff all the full-time and satellite facilities. The approximate cost to the SBC VA for the training and certification of a VSR Trainee is $10,000 (which does not include their salary and benefits). A VSR Trainee is

promoted to a VSR I after passing the certification exam and meeting the time requirement and is qualified to perform the same duties as a VSR II in reference to filing claims. The requirement for a VSR I to promote to a VSR II is two years of full-time experience developing and processing veterans' claims for an accredited national veterans service organization, or a federal, state or county veterans service office. The SBC VA stated to the Grand Jury that within 24 months, working under the supervision of a VSR II or a SVSR, a VSR I gains the experience needed, and is ready to be promoted to a VSR II.

However, it is the policy of the SBC VA that a VSR I cannot advance to a VSR II position until there is a VSR II vacancy. It was stated to the Grand Jury this obstacle was both an experience and funding issue. This policy has led to a turnover rate for VSR Is of 71 percent in the last five years. Five out of seven left after approximately 20 months taking with them valuable training and vital experience. Of the five that left, four left for promotional (career) opportunities with other departments or agencies. In comparison, the SBC VA only lost two of the four VSR IIs, both to retirement. It was stated to the Grand Jury that the reasons for the VSR Is leaving was salary and a chance for upward mobility. The mean difference in the salary range of a VSR I and a VSR II is $3,484 annually or approximately $290 per month.

VSRs face more challenges every day to provide the best possible service to a veteran with state and federal VAs constantly changing procedures and eligibility requirements, the increase in PTSD cases and the present increase of female veterans to name a few. The staff interviewed stated that one of the major concerns was the longer wait to see a service representative as the office became busy. The VSRs felt they could not take as much time as they would like with each client. SBC VA had to minimize discussing options with the veterans and focus on the one issue at hand. There was no time to cover other benefits they may be eligible for such as food stamps, Save Your House California, or other programs that would enhance the quality of life for the veteran and his/her family.

The time required to serve a veteran visiting the county office can vary from a few minutes to pick up a form or get a signature, to over an hour to file a new claim or an appeal. Offices, particularly those with only one VSR, can fill up with veterans very quickly. They are told that they could not be seen that day and would need to return another day. The offices do not track the veterans that may leave due to extended wait times, but the service representatives are aware it does happen. The Grand Jury was informed some veterans return for assistance, and others do not return.

Through interviews conducted and documentation received, it is evident to the Grand Jury that the SBC VA is putting forth a valiant effort to provide the best possible service to the veterans of San Bernardino County. Veteran benefits enhance a County veteran's quality of life. Many times it may make the difference in a veteran's ability to buy or keep a home. Sufficient staffing and resources are not available to reach out to each and every veteran in the County in order to make sure benefits are received.

FINDINGS

F1: There are limited promotional opportunities from the VSR I classification to the VSR II classification as one can only be promoted when a VSR II position becomes vacant.

F2: VSR Is are leaving their job to pursue positions with better advancement, taking valuable training and experience with them.

F3: The County General Fund contributed $1,570,326 in 2016. The 2016 allotment was less than the amount received in 2011.

F4: The State and Federal Departments of Veteran's Affairs are constantly changing the procedures and eligibility requirements for claims and benefits.

F5: Because the State funding is distributed to counties on a pro-rata basis, the more claims filed by a county with a reasonable chance of approval result in more funding that the county receives.

F6: The current staffing numbers of experienced VSRs does not allow adequate staffing of satellite facilities and contributes to long wait times for veterans.

RECOMMENDATIONS

17-47: Increase staffing to reduce veterans wait times and relieve the current workload on the VSRs. Allow the SBC VA to staff satellite offices more than one day a week. Open the full time offices five days a week and allow staffing for additional locations as identified while maintaining the 9/80 employee work schedule.

17-48: Create an upward mobility track that would allow a qualified VSR I to promote to VSR II when requirements are met and he/she can demonstrate the ability to perform the duties of a VSR II.

17-49: Revisit the County's funding to allow for additional VSR II positions to meet the needs of veterans in the County.

AGENCY	RECOMMENDATIONS	DUE DATE
Veterans Affairs	17-47 through 17-49	10/1/2017

RESPONSE ACCOUNTABILITY

RESPONSE ACCOUNTABILTY

The Grand Jury is required by Penal Code §933(c) to submit a Final report to the Presiding Judge of the Superior Court with appropriate recommendations and results from investigations conducted by the Grand Jury.

The Grand Jury chose to include a section of the Final Report this year to an investigation which reviewed two prior Grand Jury reports, recommendations and responses. A Response Accountability Report contains follow-up interviews and information gathered to determine if the agencies and/or departments are complying with the recommendations and responses given to these prior reports.

This section of the Final Report contains an update on the Bullying and San Bernardino International Airport investigations contained in the 2014-2015 San Bernardino County Grand Jury Final Report.

RESPONSE ACCOUNTABILITY
BULLYING

BACKGROUND

The 2014-2015 Grand Jury investigated bullying in two school districts; the Fontana Unified School District (FUSD) and the Victor Valley Union High School District (VVUHSD). The 2014-2015 Grand Jury investigation resulted in three specific recommendations presented to each District. The charge of the 2016-2017 Grand Jury was to undertake a Response Accountability Report. The purpose of this Response Accountability Report is two-fold: examine the initial responses each District submitted to the Grand Jury in 2015 pertaining to each recommendation and report on the present status of each recommendation within each District as reported by the Districts.

THE FONTANA UNIFIED SCHOOL DISTRICT

RECOMMENDATION 15-04: MAINTAINING A POSITIVE SCHOOL CLIMATE:

Stated: All Administration, staff, and parents must consider bullying and maintaining a positive school climate as serious issues.

RESPONSE TO RECOMMENDATION 15-04 FOR THE FUSD:

The recommendation has been in progress as the data collected from previous California Healthy Kids Survey, the California School Climate Staff Survey, and Local Control Accountability Plan (LCAP). Parent input collections have indicated that bullying is a concern that needs to be addressed. All sites have been provided with training and information to post informing students on whom to contact in case they are bullied. The District has written in the LCAP that Positive Behavior Intervention Support (PBIS) will be the focus for the following three years to combat negative and toxic environments where bullying tends to thrive. Also, the District is in the

process of developing a district-wide Code of Conduct to properly address the behaviors of students as well as adults in the Fontana Educational Community. The Code of Conduct was a two-year process developed by a committee comprised of parents, teachers, students, administrators and community members at large.

CURRENT STATUS OF RECOMMENDATION 15-04 FOR FUSD:

Data collected indicated that bullying was a concern. The Office of School Culture and Social Emotional Learning Supports (OSCSELS) was created to focus on a culture shift at all levels to combat negative and toxic environments where bullying tends to thrive and provide trainings in restorative practices. The creation of the OSCSELS was to address bullying, as well as positive climates, restorative practices, and youth mental health. This Office is composed of the Coordinator of Positive Culture and Climate, Coordinator of Social Emotional Support, two Social Emotional Specialists, and an At-Risk Counselor. Leading this team is the Executive Director of Student Services whose task is to lead the process of providing training and services regarding PBIS, Restorative Practices, Anti-Bullying, and Youth Mental Health district-wide through partnerships with community and outside agencies.

RECOMMENDATION 15-05: IMPROVING PROGRAM WITHOUT GRANT FUNDS:

Stated: Continue to improve a positive school climate and anti-bullying programs following the termination of the grant funds, and include the community and families in that effort.

RESPONSE TO RECOMMENDATION 15-05 FOR THE FUSD:

The recommendation is in progress as site funds and LCAP funds will continue to be allocated for programs such as PBIS, providing a Coordinator for Positive Culture and Climate as well as an At-Risk Counselor. Individual sites are currently implementing programs such as Character Counts and No Excuses University using site allocated funding whose focus is to provide students with positive attitude and behavioral skills to continue progress through their academic careers.

CURRENT STATUS OF RECOMMENDATION 15-05 FOR FUSD:

Goal 5 of the LCAP will continue to focus on engaging students in school to maintain their interest in education and to graduate from school. Funds are allocated for programs such as PBIS, Restorative Practices, Youth Mental Health, and LGBTQ Awareness and staff for the Office of School Culture and Social Emotional Learning Support.

RECOMMENDATION 15-06: PROGRAMS INCLUDE PARENTS AND STAFF:

Stated: Promote and maintain programs that include parents, caregivers, and staff to combat bullying behavior.

RESPONSE TO RECOMMENDATION 15-06 FOR THE FUSD:

The recommendation is in progress as the LCAP has provided for a Family and Community Engagement (FACE) Coordinator whose focus is to work with parent training seminars which include workshops on anti-bullying. This training focuses on how parents can help their children become academically and socially successful.

THE VICTOR VALLEY UNION HIGH SCHOOL DISTRICT

RECOMMENDATIONS

Stated: 15-04 All Administration, staff, and parents must consider bullying and maintaining a positive school climate as serious issues.

Stated: 15-05 Continue to improve a positive school climate and anti-bullying programs following the termination of the grant funds and include the community and families in that effort.

Stated: 15.06 Promote and maintain programs that include parents, caregivers, and staff to combat bullying behavior.

RESPONSE TO RECOMMENDATIONS 15-04, 15-05, AND 15-06:

PBIS – The PBIS initiative, a three-year rollout in the District, began in the 2013-2014 school year. For the 2015-2016 school year, Cobalt Institute of Mathematics and Science joined the cohort and University Preparatory joined later. PBIS is a systematic approach to proactive, school-wide behavior based on a Response to Intervention (RTI) model. PBIS applies evidence-based programs, practices, and strategies for all students designed to increase academic performances, improve safety, decrease problem behavior, and establish a positive school culture. In addition, district schools such as Silverado High School are beginning to implement the PLUS [Peer Leaders Uniting Students] program as part of their PBIS efforts. The PLUS program allows students to have an active role in the PBIS process. PLUS teams are made up of student leaders who serve as a liaison group to the student body to impact the behavior change in their peers. These student leaders work alongside PBIS coaches (staff members) to analyze data and create action steps. The purpose of the PLUS Team is to create a culture on campus and the community where inclusion is a reality for everyone. Within the PLUS Program are also PLUS Forums that are led by PLUS student leaders. The PLUS Program activities include student surveys, interactive activities, and small group events that provide insight into what kinds of issues are prevalent on campus thus allowing corrective actions to take place. This program also supports the District's anti-bullying measures.

Counselor Training – There are greater efforts to provide training for all VVUHSD counselors, particularly the District's Intervention Counselors who were hired in 2014-2015. All counselors were afforded two days of in-service prior to the start of the 2015-2016 school year with more training planned throughout the school year. The focus of the training was on self-harm vs. suicide. Counselors were also trained to support students who are victims of bullying and harassment from their peers. Desert Mountain Children's Center representatives facilitated the training and continue to be a great resource for the District.

Improved Data Collection - This year is the first year that districts are mandated to complete the Civil Rights Data Collection (CRDC). As part of this process, VVUHSD began the process to not only ensure student equity and access, but to also began to create procedures to collect accurate data and reporting. Four new items were added to the student information system: stalking, bullying, mobbing, and harassment. Discipline administrators, such as Assistant Principals and Deans were trained on the new features in the system and scenario-based training incorporated topics of bullying, mobbing, and harassment. In addition, discipline secretaries were also trained in the process of data inputting.

National Bullying Prevention Month – For the 2015-2016 school year, VVUHSD began a district-wide campaign called "Band Against Bullying." All sites developed a Bullying Prevention Plan highlighting activities to bring about awareness of the effects that bullying has on students. In addition, the district ordered plastic wristbands featuring the “Band Against Bullying” slogan for all students and staff in the District along with banners to be hung at the District and each school site. This effort is part of the National Bullying Prevention Month in October. Lakeview Leadership Academy has adopted their slogan “Be a buddy, not a bully” as part of the school’s 7 Habits of Highly Effective Teens leadership focus.

Bullying Prevention Grants – VVUHSD applied for anti-bullying grants as a collaborative effort between the Education Services division and transportation department accomplish three things: install updated cameras in school buses, develop an essay contest on bullying prevention, and purchase plastic wristbands and other items that bring awareness to anti-bullying measures. As research has shown, it is only when “bullying interventions are developmentally based, gender and culturally sensitive, and addresses all types of bullying” will schools reduce the problem of bullying (2014-2015 San Bernardino County Grand Jury – Bullying). VVUHSD will continue to make every effort to reduce the cases of bullying in schools and encourage parents and community leaders to get involved in this effort to decrease bullying.

CURRENT STATUS OF RECOMMENDATIONS:

VVUHSD is committed to continuing the good work that was begun as a result of the original findings. To that end, the district made great strides in the implementation of many measures to ensure both equity and safety for students.

VVUHSD has continued to be proactive in improving the culture and climate of the district in an effort to increase student achievement. School Climate and Student Engagement are two of eight state priorities being addressed in the district's LCAP. The district improved data retrieval, data analysis and its monitoring system and thus are in an improved place to study issues and promote change for students. The district has made a commitment to assist staff members to reach cultural proficiency.

VVUHSD has partnered with Association of California School Administrators for the past two years to provide an Equity Institute. Approximately forty administrators and staff have spent forty hours reflecting on equitable practices in schools. One of the institute's goal is the creation of a plan that challenges adults and students to be conscious of one's biases.

CURRENT STATUS

Each comprehensive high school and parent choice school utilizes a program called Link Crew as an additional intervention and support program. Link Crew is a high school transition program that welcomes freshmen and makes them feel comfortable throughout the first year of their high school experience. Built on the belief that students can help students succeed, Boomerang Project's proven high school transition program trains mentors from grades 11 and 12 to be Link Crew Leaders. As positive role models, Link Crew Leaders are mentors and student leaders who guide the freshmen to discover what it takes to be successful during the transition to high school and help facilitate their well-being and social-emotional support.

The comprehensive high schools also encourage attendance and positive behavior through the use of ProScan or HERO, which are both versions of behavior tracking software that works in conjunction with student information systems to better manage and collect data regarding students' behaviors. The programs send immediate feedback to parents regarding attendance, grades, etc. Both programs also afford each school site the ability to create a positive behavior incentive system through a points system that encourages the positive behavior expectations on school campus. The points may be redeemed for a variety of students rewards. Current feedback from parents indicates that they are pleased to receive immediate attendance information regarding issues before they become problems. Parent involvement in the area of bullying is a priority for school sites. As part of the LCAP, school sites agree to the hiring of a Family Engagement Liaison (FEL) which is a new resource for parents to receive support and information about helping their children with bullying and harassment. The FELs have attended training at the county level through the Family Engagement Network and the Family Engagement Leadership Academy. Each training has areas of support to provide the FELs skills which support parents with such concerns. Technology has taken a place in anonymous reporting of bullying behavior as well, with some sites choosing to replace "bully boxes" (where students could report incidents of bullying) with a button on the school website where students, parents and others can report incidents of bullying and cyberbullying.

Adelanto High School is also pleased to offer a variety of life skills courses including anger management and drug and alcohol resistance education through the coordination of their School Resource Officer. These social-emotional support classes require parent permission in order for students to be involved. Students are referred to the programs by counselors, administrators and teachers based on recurring student behaviors including bullying or harassing. Adelanto is also proud to offer an Extracurricular Club Faire at the beginning each school year, offering their students opportunities to be engaged in a number of positive social activities to increase school connectedness.

Silverado High School’s Do Something Club organizes a Special Ed Prom for severely handicapped, profoundly intellectually challenged students at the comprehensive high schools; Gay Straight Alliance recognizes a Day of Silence for students without a voice; Black Student

Union supports increased awareness of positive behaviors and academics to benefit the school and community. Other programs creating a significant impact on student culture are Hawks for Christ, Mom's Mob and Men's Mob, as well as Gentlemen of Quality. Programs such as these include a partnership with adults in the community in a mentoring capacity.

Two middle schools in VVUHSD are using one of two different models to make connections within peer groups. Hook Junior High School is using Rachel's Challenge during a school-wide advisory period to bring attention to the issue of bullying, and provide support. Lakeview Leadership Academy is using Sean Covey's 7 Habits of Highly Effective Teens to instill leadership qualities during a LIM or Leader in Me course taught for 7th graders on their campus. The Lakeview Leadership Academy is also investigating the possibility of providing a Peer Counseling course for the next school year.

Staff Professional Development – As VVUHSD continues to focus on supporting the skills and efforts to provide additional support and other means of correction training to all staff, focus is on counselors, particularly the district's Intervention Counselors who were hired in 2014-2015. The district has continued to support these positions in the Strategic Plan and the LCAP in an effort to reduce suspensions and bullying. All counselors were afforded two days of in-service prior to the start of the 2015-16 and 2016-2017 school years with more training planned throughout the school year. Counselors were trained to support students who are victims of bullying and harassment from their peers. Interventions and student academic needs are supported throughout the year with monthly Counselor Collaborative Meetings. The efforts to provide teachers and other school staff with additional training and skills when dealing with bullying and student social-emotional issues have been prevalent through the summer professional development days. During August 2016, two specific courses for certificated staff were offered; *Emotional Well Being of Students* and *Student Emotional Health*. In addition, a workshop called *Gun Fire in the Hallway* was also offered which also addressed the concerns of bullying and harassment and how it may lead to violence on school campuses. The district has also contracted with WestEd and offered training during the 2016-2017 school year for Multi-Tiered Systems of Support. The training offers insights to reduce bullying and harassment and creates other means of support for students who are victims of bullying or engaging in types of

bullying behaviors. The August 2017 summer professional development is planning to include a unique strand for teachers to access The Medal of Honor Character Development Program created by the Congressional Medal of Honor Foundation to provide teachers access to multimedia, interactive lessons. The lessons provide middle and high school students with opportunities to explore the important concepts of courage, commitment, sacrifice, patriotism, integrity and citizenship and how these values can be exemplified on campus and help prevent incidents of bullying and harassment.

Improved Data Collection – VVUHSD continues to complete the CRDC. The District has greatly improved data entry, data analysis, and data monitoring. Suspension data is monitored monthly at district LCAP meetings. In 2015-2016 VVUHSD saw an 8.3 percent reduction district-wide in the rate of suspension. Discipline training will occur monthly provided by the Child Welfare and Attendance Department. Garnett and Associates spent three hours working with Assistant Principals to ensure that suspension and expulsion procedures are fair and equitable across the district. To guarantee that VVUHSD is meeting the new California Dashboard requirements for School Climate and Parent Engagement, VVUHSD has administered the California Healthy Kids Survey, California School Parent Survey and California School Staff Survey both in 2015-2016 and 2016-2017. Since the original submission we had six student forums at each of our sites to gauge the social emotional well-being of district students. The findings of the student forums and surveys have led district administration to make some changes and begin reflective practices, such as the Equity Institute. Sites have begun to use the student data to inform each high school's Western Association of Schools and Colleges self-studies.

National Bullying Prevention Month – For the 2015-2016 school year, Victor Valley Union High School District began a district-wide campaign "Band Against Bullying." All sites developed a Bullying Prevention Plan highlighting activities to bring about awareness of the effects that bullying has on students.

During the beginning of each school year, each school offers anti-bullying assemblies. These assemblies are tailored to meet the needs of each school community. Whether it was Kaiser, Rachel's Challenge, Armando Quitano, or another speaker, presentations were matched to grade spans and reinforced through the school year.

RESPONSE ACCOUNTABILITY
SAN BERNARDINO INTERNATIONAL AIRPORT

BACKGROUND

The 2010-2011 Grand Jury investigated the operations of the San Bernardino International Airport (SBD) and made several recommendations in its final report. The 2016-2017 Grand Jury followed up on a sampling of the recommendations, responses and the current status of those recommendations.

RECOMMENDATION 1.2 - INTERNAL CONTROLS

Direct management to refine processes for ensuring the comprehensive documentation of business processes and transactions.

RESPONSE

Agree. SBIAA [San Bernardino International Airport Authority] efforts in the document production process for the San Bernardino County Grand Jury enabled SBIAA staff to determine areas where business processes and transactions could potentially be improved. This will be an ongoing effort to be presented to the SBIAA Commission to continually refine processes by and through the SBIAA Finance and Budget Committee and establishment of other SBIAA Commission formed committees as appropriate for formal submission to the SBIAA Commission. Timeline for completion: Within 12 months

CURRENT STATUS

Has been completed. The SBIAA Commission continues to implement and refine this practice in its adopted policies and procedures which require annual review and update every October. That continued process has led to implementation of industry best practices, adoption of a new

Strategic Plan, as well as several process enhancements such as implementation of new Finance and Accounting software, property management and compliance systems, and electronic records management systems.

RECOMMENDATION 1.4 - INTERNAL CONTROLS

Adopt a policy to rotate financial auditing firm every five years.

RESPONSE

Agree. The SBIAA Commission will develop such a policy within the current fiscal year. Timeline for completion: Within 12 months

CURRENT STATUS

Has been completed. The SBIAA Commission continues to implement this practice as it is included in its adopted policies and procedures. The current financial audit firm was contracted in 2013. A procurement process is currently being initiated for the forthcoming audit year and will be completed by July 2017.

RECOMMENDATION 2.1c - CONSTRUCTION MANAGEMENT

Enforcing all provisions in the Terminal and Fixed Base Operator (FBO) leases requiring the developer to provide detailed monthly progress reports. The Commission should also require the developer to provide and present such reports at all Commission meetings.

RESPONSE

Agree. The SBIAA Commission will require the Chief Financial Officer to submit copies of detailed First American Fund Control reports and other documentation on the Terminal and FBO

projects to the SBIAA Commission on a monthly basis at its regularly scheduled public meetings as an adjunct to its Register of Demands information. At the discretion of the SBIAA Commission, the developer may be required to provide additional information upon demand. Timeline for completion: 1 month

CURRENT STATUS

Has been completed. The Terminal and FBO leases, as well as related contracts, were terminated in their entirety in 2012. The most recent construction policies and procedures document was last updated on October 26, 2016, and requires traditional design-bid-build construction contracts.

RECOMMENDATION 2.1d - CONSTRUCTION MANAGEMENT

Engage the services of a reputable, independent auditing firm to examine all expenses incurred as a result of the Terminal Development and FBO Projects. The scope of such an audit should include a review of the construction meeting minutes to determine if the developer purposely inflated costs.

RESPONSE

Agree. On February 10, 2010, a Special Compliance Audit Report of the San Bernardino Airport Terminal Renovation Project, covering the period July 1, 2008 through June 30, 2009, was filed with the SBIAA Commission, and an additional compliance audit covering the period July 1, 2009 through December 31, 2010, for the other aspects of (i) the Terminal Development and (ii) the FBO and Customs building are currently in progress. Upon completion, additional independent reviews will be conducted as requested by the SBIAA Commission pursuant to the conditions precedent under the existing development, and prior to consideration of acceptance of any ownership interest in any improvements by the SBIAA Commission. Timeline for completion: Within 12 months

CURRENT STATUS

Has been completed. The Terminal and FBO projects were completed. All related contracts were terminated in their entirety in 2012 via court order. All such capital assets are now 100% owned and operated by SBIAA.

RECOMMENDATION 3.3 - EQUIPMENT ACQUISITION

Set a regular schedule for reviewing, revising and formally approving updates to the purchase policy.

RESPONSE

Agree. All current SBIAA policies and procedures, including the Strategic Plan, include a provision requiring annual evaluations and/or update. Many of these coincide with the annual SBIAA budget approval process. All proposed and future updated SBIAA policies and procedures will include such annual evaluations and/or update provisions. Timeline for completion: Within 12 months

CURRENT STATUS

Has been completed. The SBIAA Commission continues to implement this practice as it is included in its adopted policies and procedures. All policies and procedures, including the purchasing policy, are reviewed and updated in October of every year. The most recent update was approved by the SBIAA Commission on October 26, 2016.

RECOMMENDATION 4.1 - LAWSUIT SETTLEMENT

Engage the services of a reputable, independent auditing firm to examine the representations and warranties made by Norton Aircraft Maintenance Services (NAMS) and SBD management in connection with the *Settlement and Mutual Release Agreement* and, if found to be false or untrue, demand immediate repayment of the Insurance Loan, Rent Credit and Temporary Aircraft Rehabilitation Loan balance.

RESPONSE

Agree. The SBIAA Commission will seek proposals from independent legal experts to review the referenced documents and to provide recommendations to the SBIAA Commission accordingly. Timeline for completion: Within 12 months

CURRENT STATUS

Has been completed. The contracts with NAMS and SBD were terminated in their entirety in 2012 via court order.

RECOMMENDATION 5.1 - CONTRACTOR RELATIONS

Direct staff to review current contracts for construction services and Airport operations to identify modifications that may be necessary to protect Inland Valley Development Agency and SBIAA from potential future risk.

RESPONSE

Agree. On July 27, 2011, the SBIAA Commission received the memorandum of a noted aviation attorney specializing in U.S. Department of Transportation (DOT) and Federal Aviation Administration (FAA) regulatory matters. The SBIAA Commission will seek proposals from

other independent legal experts to review the referenced agreements. Timeline for completion: 12 months

CURRENT STATUS

All contracts with such entities were terminated in their entirety in 2012 via court order. Current adopted policies and procedures include industry best practices and protective provisions.

Information regarding the
San Bernardino County Grand Jury
or an application to serve on the Grand Jury
can be obtained by contacting the

Office of the Grand Jury
172 West Third Street, Second Floor
San Bernardino, CA 92415-0243

Office: (909) 387-9120

Information is also provided on the website at http://cms.sbcounty.gov/grandjury/Home.aspx

HOSPITAL ASSOCIATION OF SOUTHERN CALIFORNIA

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Inland Regional Office
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(951) 222-2284

Keven Porter, *Regional Vice President*

August 18, 2017

San Bernardino County Civil Grand Jury
172 West Third Street, Second Floor
San Bernardino, CA 92415-0243

RE: Comments in response to the June 30, 2017, San Bernardino County Civil Grand Jury Report.

Dear San Bernardino County Civil Grand Jury:

The Hospital Association of Southern California (HASC) welcomes the opportunity to respond to the SB County Civil Grand Jury (CGJ) Report related to "High Desert Ambulance Availability and Bed Delay."

HASC, founded in 1923, is a not-for-profit 501(c)(6) regional trade association. HASC is dedicated to effectively advancing the interests of hospitals in Los Angeles, Orange, Riverside, San Bernardino, Santa Barbara, and Ventura counties. We are comprised of 184-member hospitals and 40 health systems, plus numerous related professional associations and associate members, all with a common goal: to improve the operating environment for hospitals and the health status of the communities they serve. HASC represents 18 Acute Care Hospitals as well as several rehabilitation and behavioral facilities in San Bernardino County (SB County).

The Grand Jury Report states:

> *Bed delay is the time between arrival of an ambulance at a hospital Emergency Department (ED) and the ED receiving the patient. The first 25 minutes after arrival to the Hospital are excluded from the bed delay calculation. The bed delay contributing factors are the result of several issues: only three high desert hospitals with an ED, none of which have trauma centers; a lack of ambulances at peak times; the misuse by the public of the EDs; and the overuse of 9-1-1 calls for non-emergencies. Other contributions are a lack of interest of private hospitals to expand or build new services which leads to a shortage of beds. Only three hospitals have EDs that can receive patients via ambulances. There are a high number of Medicare and Medi-Cal clients in the High Desert. These factors put a strain on the use of resources between SB County Fire Department (SBCFD) and American Medical Response (AMR) in the High Desert. The nearest trauma centers for the High Desert are Loma Linda University Medical Center and Arrowhead Regional Medical Center.*

We agree that there is an Ambulance Patient Offload Delay (APOD) problem in the High Desert and across SB County. Similar issues are being observed in other counties and states. Additionally, we believe that there are more factors contributing to off load delays than those mentioned by the CGJR that need to be addressed.

A coalition comprised of the California Hospital Association (CHA) and Local Emergency Medical Services Agencies (LEMSAs) came together to develop a toolkit to reduce APOD in hospital Emergency Departments (EDs). They published their report in August 2014. The report stated that APOD is not an isolated issue, but is a symptom of a much larger problem. Research and expert opinion connect ED overcrowding, ambulance diversion, patient offload delay, and ED patient boarding with obstructions in hospital throughput.[1][2][3] Many factors have been identified as contributing to decreased patient throughput that include but are not limited to:

- Increasingly complex medical conditions
- Increased 5150s or psychiatric holds due to fewer mental health community resources
- Significant increase in drug-related ED visits
- Shortage of specialists
- Lack of community primary care providers
- Increased difficulty in placement and arrangements for follow-up care

The common endpoint is that ED beds are full with emergent and admitted patients, and the ED cannot free gurneys and staff quickly enough to accept new patients arriving by EMS. A back log at one hospital often times will impact other hospitals. This "domino effect" occurs when one hospital becomes heavily impacted with patient arrivals regardless of whether they are walk-ins or brought in by EMS. Once full, the patient volume moves to the next, closest hospital until they, in turn, are beyond capacity. This effect continues until the entire area is saturated beyond the system's capacity.

Area hospitals have been and continue to actively pursue ED throughput and other operational best practices to decrease APOD; however, a shortage of primary care physicians, mental health backlogs, misuse of 911 and EDs, along with population growth, have added to the long-term problem for which there is no immediate cure. Multidimensional issues require actions on many fronts and a large array of resources.

SB COUNTY CGJ RECOMMENDATIONS

The SB County CGJ made the following recommendations:

17-21: Implement the Inland Counties Emergency Medical Agency's "Centralized Medical Control Proposal".

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[1] http://www.emsa.ca.gov/Media/Default/PDF/Toolkit-Reduce-Amb-Patient.pdf
[2] www.chcf.org/publications/2009/07/reducing-ambulance-diversion-in-california-strategies-and-best-practices
[3] http://www.gao.gov/new.items/d09347.pdf

17-22: Educate the public on correct use of 9-1-1 system.

17-23: Implement and utilize the 9-1-1 pre-hospital triage strategies-including use of existing nurse advice lines.

17-24: Track dispatches between [American Medical Response] (AMR) and [San Bernardino County Fire Department] (SBCFD) to determine the number of patients each hospital can serve based on the availability of beds.

17-25: Create a process to facilitate access to a common radio frequency.

17-26: Build a new SB County hospital with a trauma center in the High Desert.

BACKGROUND

Demographics of SB County

SB County consists of 2.139 million residents and 307,000 of those residents live in the High Desert (Southern California Association of Governments, 2017). There are two trauma centers in SB County: Arrowhead Regional Medical Center (ARMC) and Loma Linda University Medical Center (LLUMC). ARMC is a 456-bed, university-affiliated, teaching hospital with a Level II Trauma Center. LLUMC is a 1,071-bed, university-affiliated, teaching hospital with a Level I Trauma Center (Loma Linda University Health Annual Report, 2016, p. 34).

In 2016, ARMC had approximately 110,000 ED visits. The trauma center served 3,200 patients. Five hundred sixty-eight patients were from the High Desert of which 161 were air lifted to ARMC (ARMC Trauma Registry, 2016). LLUMC had 103,162 ED visits with approximately 2,730 trauma patients per year of which 383 were from the High Desert. Of the 383 brought to LLUMC from the High Desert, 144 were air lifted (LLUMC Trauma Registry, 2016).

The SB County CGJ reports three High Desert hospitals – Desert Valley Hospital (DVH), Saint Mary's Medical Center (SMMC), and Victor Valley Global Medical Center (VVGMC) – with 421 combined beds. **It is important to note that this report did not include the 30 beds at the 4th High Desert Hospital, Barstow Community Hospital**. According to the Henry J. Kaiser Family Foundation (2015), the national ratio of hospital beds per 1,000 people is 1.8. Using this ratio it appears that the High Desert is short approximately 131 beds.

Health Manpower Shortage in SB County

According to a report commissioned by the California Health Care Foundation (2014), the Inland Empire's supply of physicians is far below state levels (Inland Empire at 120 physicians per 100,000 or 2,566 physicians compared to the state average of 194 physicians per 100,000 or 3,197 actual physicians – a 631 physician shortage in the Inland Empire). Dr. David Wong,

ARMC Chief of Trauma, opines that this is the real issue: "It's the appropriate level of care needed, not another hospital. Patients will continue to be transferred to ARMC and LLUMC because there isn't the appropriate level of care in the High Desert."

Katy Katz (2014) from Rasmussen College[4] reports that there will be a shortage of 193,100 nurses by 2030. California Hospital EDs are required by regulation to operate at a ratio of one nurse to every four patients or must meet the impatient staffing ratio e.g. if a patient is admitted to the Intensive Care Unit, the ED nurse to patient ratio changes to one nurse to two patients maximum. When a patient's acuity is very high, the nurse-staffing ratio may be one nurse to one patient. EDs must maintain significant flexibility to meet the demands of these staffing regulations, thus, increasing the challenge of managing incoming patients.

RESPONSES TO RECOMMENDATIONS

17-21: Implement the Inland Counties Emergency Medical Agency's "Centralized Medical Control Proposal".

The Hospital Association of Southern California responded to Inland Counties EMS Agency's (ICEMA) draft proposal of "Centralized transport communications and coordination function with online medical control capabilities" on February 29, 2016 (Attachment A). In our response there was a request for clarity on 13 different points; we have not seen clarification from ICEMA on these points.

Additional analysis suggests that there may be financial and legal implications that require further review to assure that a program of this nature is not in violation of current regulatory or legal standards.

17-22: Educate the public on correct use of 9-1-1 system.

HASC supports this recommendation in theory, but needs to better understand the issues related to: how the target population would be identified, how the message would be developed, and the communication platform that will be used.

17-23: Implement and utilize the 9-1-1 pre-hospital triage strategies-including use of existing nurse advice lines.

There is literature to support implementing and utilizing a 9-1-1 pre-hospital triage strategy. HASC supports recommendation #17-23 although the published evidence does not appear to be robust. We believe that evaluation of pre-hospital triage should be separate from the evaluation of the MedCon proposal because each has several different elements that will require review. Also, often the discussion of pre-hospital triage is associated with alternative destination

[4] http://www.rasmussen.edu/degrees/nursing/blog/nursing-shortage-by-state/

(alternatives to hospital EDs). This concept too needs to be evaluated separately from the other two concepts.

We urge caution when implementing this type of strategy. A recent, compelling, double-blind study conducted at ARMC examined the different perceptions of patient acuity between paramedics and emergency physicians in a sample of 503 patients. The study found that field personnel under-triaged 19.3% of cases and over-triaged 8.9% of cases. Over-triage is unlikely to result in poor outcomes, while under-triage may result in a tragedy or disaster.

Lastly, in some circumstances, the concept of field triage and alternative destinations might be worthy of investigation and possibly implementation to ease hospital ED overcrowding. If these strategies are pursued, safety must be kept in the forefront and the risks noted in the ARMC study would have to be addressed and mitigated. For such strategies to be successful and safe, consideration would need to be given to paramedic training, care oversight, care supervision and communication / technology to name a few. Hospitals will need to be included in any further discussion of this topic should it be pursued.

17-24: Track dispatches between AMR and SBCFD to determine the number of patients each hospital can serve based on the availability of beds.

HASC needs to better understand recommendation #17-24. We believe that there is a spurious relationship between ambulance units dispatched and hospital capacity at best. Hospitals clearly understand the multiple factors that impact hospital capacity and are the best source of information regarding the availability of beds. Trying to make the analytic leap from dispatches to bed capacity would be an empty exercise.

Additionally, this recommendation infers that that hospital bed availability is the predominant contributor to APOD. As has been stated earlier in this response and in multiple forums, hospital APOD is an excess demand problem – not a hospital bed problem – that is related to a shortage of primary care physicians, a broken mental health system, and poor access to specialty services, among other factors.

17-25: Create a process to facilitate access to a common radio frequency.

HASC supports recommendation #17-25, not just for SBCFD, but for all 9-1-1 medical responders. We believe that a common radio frequency is an important adjunct to disaster situations like the SB County Shooting in 2015.

17-26: Build a new SB County hospital with a trauma center in the High Desert.

HASC does not support recommendation #17-26. Furthermore, a thorough review of literature including cost and quality does not support this recommendation.

We believe that the greatest return on county-invested dollars would be to expand the hours of the counties' Federally Qualified Health Clinics (FQHC) located in the High Desert. This expanded access allows greater access for families and reduces the demand for primary care services delivered in the ED.

In addition to this, expanded mental health services in the High Desert area would be merited. Mental health patients spend an average 11.5 hours in EDs; however, some patients may stay two to three days or longer in the ED awaiting treatment or release. Increasing the number of crisis stabilization units and inpatient mental health treatment beds would result in a decrease of ED congestion.

Developing an incentive program to recruit primary care and specialty care providers to the High Desert would positively affect this under-resourced area. Lack of physician availability drives up ED visits as patient use the ED for primary care services.

Hospitals are the costliest types of structures to build, costing nearly 2.2 million dollars per bed to construct. Running a trauma center is also very costly because specialty physicians and other labor-related costs are high. Additionally, there are high costs associated with maintaining operating room access, on-site specialty services, regulatory oversight, audits related to utilization of the trauma services, and low reimbursement rates. We believe that building another hospital in the High Desert area would further stress the professional workforce, physicians, and nurses.

Thank you for your consideration and availability to discuss this important issue. HASC and its member hospitals are committed to working with our communities and our EMS partners to explore all opportunities for improving care delivery across San Bernardino County. We believe that APOD is a symptom of a complex and intertwined relationship between outpatient clinic access, lack of behavioral health outpatient and inpatient treatment portals, primary care physician availability, the population's perception of using 9-1-1, recuperative and long-term care availability, and many, many other confounding factors. The solutions should be holistic in nature and address the root causal factors in an informed, thoughtful process.

Sincerely,

Keven Porter MS BSN RN
Regional Vice President
Hospital Association of Southern California

CC:
Norma Grosjean, Grand Jury Assistant, San Bernardino County Civil Grand Jury
Robert Lovingood, Chairman, 1st District, San Bernardino County Board of Supervisors
Janice Rutherford, 2nd District, San Bernardino County Board of Supervisors
James Ramos, 3rd District, San Bernardino County Board of Supervisors
Curt Hagman, Vice Chairman, 4th District, San Bernardino County Board of Supervisors
Josie Gonzales, 5th District, San Bernardino County Board of Supervisors
Dena Smith, Interim CEO, San Bernardino County
Tom Lynch, EMS Administrator, Inland Counties Emergency Medical Agency

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Attachment A

February 29, 2016

Tom Lynch, EMS Administrator
Inland Counties EMS Agency
1425 South "D" Street
San Bernardino, CA 92415-0060

Subject: Centralized transport communications and coordination function with online medical control capabilities

Dear Mr. Lynch:

Thank you for preparing and sharing the Inland Counties EMS Agency (ICEMA) proposal for centralized transport communications and coordination function with online medical control capabilities. On behalf of all of the hospitals and health system members of the Hospital Association of Southern California (HASC), we would like to express our sincere appreciation for the continued collaboration and work of the Ambulance Patient Offload Delay (APOD) Task Force. We remain engaged to actively identify solutions to address the multifaceted issues related to ED overcrowding and EMS System overburden. In this work, we cannot lose sight our shared goal of patient safety.

Hospital CEOs took decisive action by approving the Pilot Redirection Program which began last May. Hospital CEOs have again risen to the occasion through careful review of the ICEMA proposal. It is our belief that there may be some good, actionable solutions that come from the proposal. The review of the proposal has generated some general comments, questions, and considerations which we would like to share and hopefully gain further clarity on.

Comments, Considerations, Questions Regarding the Proposed Centralized Base Station (CBS)

1. Clarify or identify specific conditions / situations to be positively impacted by this program.
2. What would be the metrics that would be established to measure the success of the program?
3. What will be the staffing levels, the competencies and ratios of staff be for the CBS (physicians, MICN, others)?
4. What will be the competencies of paramedics/transportation providers in the context of field triage?
5. What specific technologies will be considered / utilized for field triage (i.e. telemedicine, Google glasses, mobile clinical monitoring and testing equipment)?

6. Where will the CBS be housed? It is our opinion that the CBS should be housed in a "neutral" location to eliminate perceived or actual bias in the new process.
7. Will the CBS include dispatch (appears not to be mentioned in the proposal)?
8. Whether now or in the new system, can patient continuity of care issues be addressed so that patients can be transported to the facilities that provide their care (i.e. Kaiser and other hospitals that are in risk type payment arrangements)? This topic might be something that does not have to wait for the implementation of a CBS.
9. Who will provide oversight of this new base station concept to ensure that objectives are being met, issues are addressed timely and the system is operating as designed?
10. What quality/efficiency/outcomes metrics will be instituted to aid in the oversight of EMS response, patient evaluation, patient transport and the care?
11. Are there other alternatives to be evaluated that might result in a better cost / benefit outcome (i.e. augmenting existing base and trauma stations with telemedicine and protocols to govern field triage)?
12. The concept of emergency transport providers to deliver patients to alternative destinations is one that is not supported by most of the members.
13. Should there be sub-regional strategies deployed given the diversity and expanse of the county? Given the diverse characteristics and expanse of the county, the design of a CBS or other strategies should consider these factors.

Hospital CEOs would like to reiterate their commitment to solving ambulance patient offload delay in the region. We believe one tool that has been implemented in Riverside County and proven very successful is the First Watch Transfer of Care function. We understand this took has been piloted in San Bernardino County and is in the process of being rolled out. We would appreciate any assistance ICEMA can give to help roll out the implementation more expeditiously. There is strong support to implement this tool at the CEO level to help improve visibility of incoming ambulance rigs to help hospitals prepare as well as to increase accountability to the issue on both sides.

As we spoke to the hospitals throughout San Bernardino County we have identified several concerns regarding the current Pilot Redirection Program we would like to bring forth as well. Many of these concerns were raised at the last APOD Task Force Committee meeting. Just to reemphasize the concerns include:

Concerns Regarding the Current Redirect Program

1. Need to decrease the number of 5150's in emergency departments or transition to appropriate level of care more expeditiously.

2. San Bernardino County consideration of reopening mothballed psychiatric beds and extending operational hours of the high desert FQHC.
3. Moving patient's excessive distances to achieve redirection (rigs out of area for extended periods undermining the purpose of redirection.
4. "Flooding" hospitals not on redirect (no monitoring of redirection to identify approaching overcrowding at "open" hospitals).
5. Response to transport provider issues in the High Desert (i.e. having to call for permission to transport patients for higher level of care).

Hospital CEOs would like to be a part of crafting solutions that meet the needs of the communities we all serve. We believe that needs to be a clear statement of the top problems the proposal is trying to solve and a clear understanding of how this proposal will resolve those identified problems. We look forward to working on pilotable implementable solutions to resolve the ED overcrowding issues faced by the region.

Sincerely,

Jan Remm
Regional Vice President
H.A.S.C

NorCal Clinical Consensus Group:

Workflows for Care Recommendation Creation

June 7, 2017
Hemal Kanzaria, Maria Raven, Travis Smith, Gabriel Waters

CollectiveMedical TECHNOLOGIES

Meeting Update

- Last Meeting: Continued Care Recommendation workflow discussions, highlighted the Sutter and CHOMP experience
- Today: Discuss Care Recommendation needs for NorCal and discuss how UCSF/ ZSFG are using Edie.
- Next time: Cover results from other regions.

Agenda

- Network Update
- CURES Update
- 42 CFR part 2
- SF General Start Up Process
- UCSF Start Up Process
- Early Data
- Next Steps (When, Topics?)

Northern California Footprint

- Alameda - Alameda
- Alameda - Highland
- Alameda - John George Psych - EDIE
- Alameda - San Leandro
- Chinese Hospital
- Community Hospital of the Monterey Peninsula
- Contra Costa
- Fairchild
- Modoc Medical
- San Francisco General
- St. Joes - Petaluma Valley Hospital
- St. Joes - Queen of the Valley Medical Center
- St. Joes - Redwood Memorial Hospital
- St. Joes - Santa Rosa Memorial Hospital
- St. Joes - St. Joseph Hospital, Eureka
- Sutter - Alta Bates Summit (2)
- Sutter - Delta
- Sutter - Eden
- Sutter - CPMC - California West
- Sutter - CPMC - Davies
- Sutter - CPMC – Pacific
- Sutter - CPMC - St. Luke's
- Sutter - Medical Center of Sacramento
- Sutter - Mills-Peninsula
- Sutter - Solano Medical Center
- Sutter - Roseville Medical Center
- Sutter - Novato Community
- Sutter - Auburn Faith
- Sutter - Santa Rosa Regional Hospital
- Sutter - Amador
- Sutter - Memorial Hospital, Los Banos
- Sutter - Tracy Community Hospital
- UCSF - Mission Bay
- UCSF – Parnassus
- Watsonville
- Placer County WPC
- San Francisco Health Plan
- Coming
  - Adventist Health – Ukiah
  - Adventist Health – Frank R. Howard
  - Contra Costa WPC
  - Contra Costa Health Plan
  - Contra Costa Hospital
  - Verity - Seton

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CURES Update

Agenda

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42 CFR Part 2

Agenda

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San Francisco General

Initial Steps

- Identify funder
- Have Pre-Manage/EDIE vetted by health system IT, legal, security, privacy, & contracts departments
- Develop IT interface and data linkage between Pre-Manage/EDIE and ZSFG EHRs (pulsecheck & lifetime clinical record)

San Francisco General

Post-Implementation Steps

- Establish internal taskforce to develop protocols/standards for use and troubleshoot
- Train ZSFG staff, including ED MDs, residents, charge RNs, social workers
- Train DPH staff, including ambulatory care management programs
- Coordinate amongst above groups, and with other County-wide initiatives (e.g., health homes, whole person care etc.)

San Francisco General Social Work Group

Initial Steps

- Identify a social worker champion
- Logistics of getting log-ins, training staff member who work different shifts
- Standardizing care plans and work flow during shifts
- Prioritizing patients if ≥50/d meet high-risk criteria

Agenda

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UCSF Medical Center: Learnings from EDIE Implementation Process

Maria Raven, MD, MPH, MSc
Christina Genetti, Health Navigator
Marina Rosenberg, Health Navigator

UCSF Medical Center

Pre-Implementation: Staffing

- Should sites who are implementing EDIE use existing staff or hire new, dedicated EDIE staff?
  - Do social work or case management staff that serve ED currently exist?
  - If so, what are current job duties, hours, capacity and interest in high-utilizer population
  - Funds to hire new FTE
  - Degree to which you expect docs/other providers to be proactive
- What is ideal staff type?

UCSF Medical Center

Pre-Implementation: Workflow

- How much do we already know about this patient population?
- Lots of alerts each day: how do we prioritize?
- What do we want to know about our EDIE patients?
  - Screening tool, data entry
- What interventions should we consider based on feasibility, existing resources, and timeframe?
  - Timing, location
- Follow-up:
  - How long should follow-up period be?
  - What information should we obtain?

UCSF Medical Center

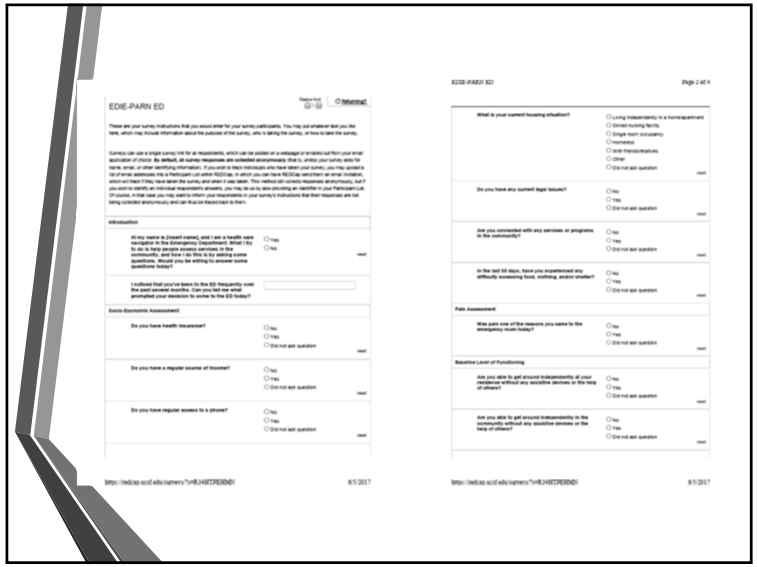
Implementation phase: Prioritization of Patients

Threshold: 3+ hospitalizations in a 3 month period, OR 5+ hospitalizations in 12 months

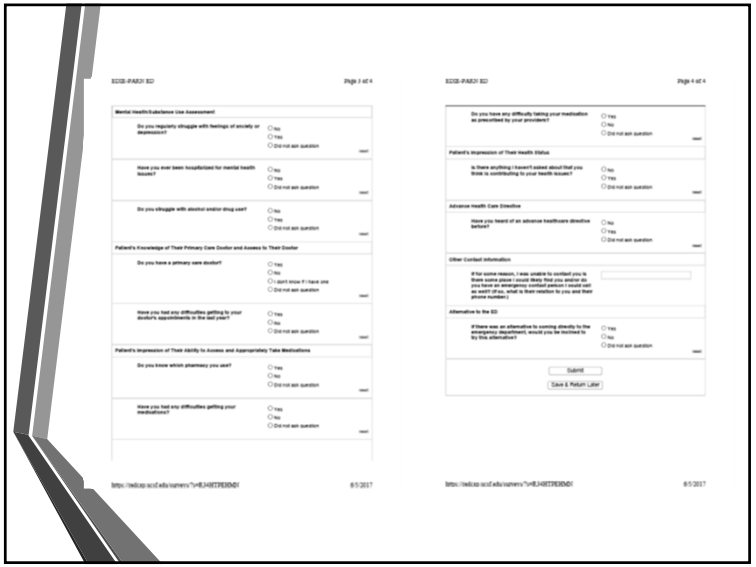
- San Francisco Health Plan members
- Patients already seen by providers in the ED
- Referrals from ED staff
- Patients admitted for psychiatric concerns will only be seen by HCNs if social workers refer patients

UCSF Medical Center

Screening tool


EDIE-PARN ED

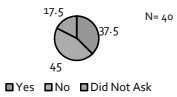
EDIE-PARN ED


EDIE-PARN ED

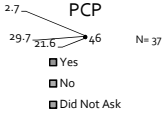
EDIE-PARN ED

Preliminary Screening Tool Data

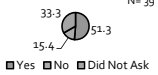
Connected With Services/Programs in The Community



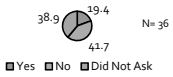
Patient's with a PCP



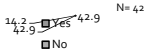
Pain As A Reason For Presenting to...



Trouble Obtaining Medications



Access To A Phone



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Interventions in the ED

1. Most interventions done on-site in the ED. Examples include:
   - Setting up a primary care appointment
   - Obtaining a reservation on the shelter bed wait list
   - Linking patients to concrete resources (free phone programs, clothing, etc.)
   - Completing a benefits application
   - Referring a patient to case management services
   - Collaborating w/ inpatient social workers
2. On-site interventions are effective for patients who do not have alternative means to communicate with HCNs after hospitalization

UCSF Medical Center

Interventions in the community

Types of interventions to be offered:

- Accompaniment to PMD appointments
- Assistance w/ intake processes for case management
- Assistance w/ benefits applications

Benefit to community-based interventions:

- More time to build rapport with patients and strengthen relationship between HCN and patient
- Ensures patient follow-through with referral
- Less acute setting

UCSF Medical Center

Phone Screening for Missed EDIE Patients

Some patients missed due to high volume, others present during non-HCN hours or are admitted and roomed before interview

Workflow plan:

- Time permitting, HCN will perform daily review of EDIE portal and will call all patients who have a phone number to interview.
- Admitted EDIE patients are interviewed by HCN after consultation with inpatient social worker

UCSF Medical Center

Follow up Phone Calls

- Eligibility criteria for follow-up calls:
  - Every patient who receives an intervention is eligible for a f/u phone call
  - Patient must have access to a phone
2. HCN maintains a list of patients who need f/u phone calls; this is not visible in EDIE portal
3. HCNs will continue to engage patients (including repeat patients) until they no longer meet criteria for high utilization of EDs

UCSF Medical Center

Training of HCNs

- HCNs have weekly meetings with Maria Raven, and Meher Singh to discuss complex patient matters and provide supervision
- Shadowing ED staff (social workers, RNs, MDs)
- EDIE Portal Training (Initial training and Care Recommendations for Beginners)
- HCNs review each drafted Care Pla

UCSF Medical Center

Building bridges in the community

- HCNs have visited various community agencies to learn about their services and eligibility criteria including:
  - Harbor Lights
  - Medical Respite & Sobering Center
  - Social Security
  - MSC South shelter
- HCNs are also routinely attending specific community meetings including:
  - HUMS (High Utilizers of Multiple Services)
- HCNs have met w/ SFHP to better understand their case management services service providers

UCSF Medical Center

Progress to Date

- 43 EDIE patients interviewed (not including repeat patients)
- Over 20 care recommendations input
- Connections made with multiple community based organizations and within UCSF
- 2nd HCN started this week: more ED coverage

UCSF Medical Center

Outstanding Questions

- How long should the HCNs "follow" the patient post-discharge?
- Target volume be per shift (i.e. 5 patients to screen/shift?)
- Best hours to capture maximum patient volume
- How to best coordinate with other EDIE EDs in San Francisco around Care Guidelines and "ownership"
- Who will have access to the EDIE portal
- What type of access (read or edit information in EDIE)

UCSF Medical Center

Thank You and Questions

- Maria Raven
  - maria.raven@ucsf.edu
- Meher Singh
  - meher.singh@ucsf.edu
- Christina Genetti and Marina Rosenberg: 415-502-2588
  - christina.genetti@ucsf.edu and marina.rosenberg@ucsf.edu

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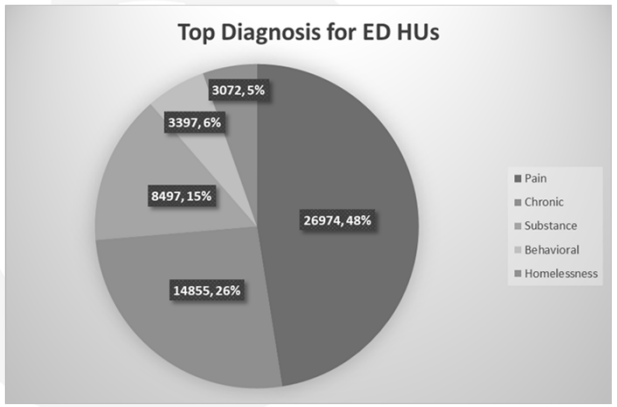
NorCal ED Visit Metrics – Jun 1, 2016 – May 30, 2016)

NorCal Total ED Visits	High Utilizer Visits at NorCal Hospitals	% of Visits by High Utilizers
404,898	110,755	27.3%

Distinct Patients	High Utilizers	% of Patients
232,368	18,875	8.1%

- Finding: High utilizer patient population is significant
  - 8.1% of patients generating 27.3% of visits
- Finding: As more hospitals come online, we're getting better at identifying the region's high utilizers.
- Conclusion: Opportunity to share community-wide, patient-specific care plans through PreManage with other providers to reduce overutilization

Top 10 Dx Codes for HUs



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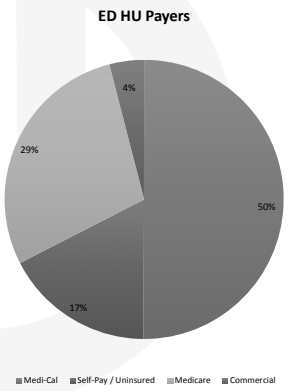

Next Steps

- Encourage network participation
- Plan next meeting
  - Finalize Care Campaign Plans and provide structure to accomplish this

Northern California Clinical Consensus Group

Overview of Roles and Responsibilities

February 10th, 2017

CollectiveMedical TECHNOLOGIES

Agenda

- **CMT & Product Review**
- Perspective: PreManage ED in Alameda
- Clinical Consensus Group Roles and Responsibilities
- Progress Reports:
  - Network
  - Legal and Legislation
- Future Committee Structure
- Next Steps

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Collective Medical Technologies

- Started by an ED social worker
- >8 years since first go-live
- OR, WA, CA, MT, NM, NH, WV, MA, +…
- >900 hospitals, UCs, clinics
- Thousands of providers
- ~60 million unique visits
- **100% customer retention**
- Endorsed by:

American College of Emergency Physicians® ADVANCING EMERGENCY CARE

PROVIDENCE Health & Services
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UNIVERSITY OF WASHINGTON MEDICAL CENTER UW Medicine
Amerigroup RealSolutions
CENTENE Corporation
PREMERA BLUE CROSS
Humana.
KAISER PERMANENTE
UnitedHealthcare
HCSC Health Care Service Corporation New Mexico
MOLINA HEALTHCARE
PacificSource
CAMBIA
Regence

PreManage Platform

Identification

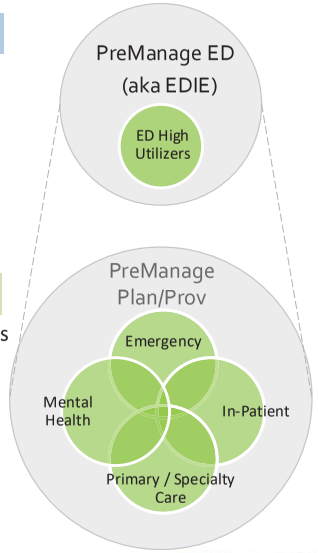
PreManage ED (aka EDIE): Hospital Partnerships

- Notifications to ED Providers for ED/In-Patient visits
- Shared platform for ED care coordination information
  - High utilization / complex ED patients
- **Specific User Base** (ED Physicians & Care Managers)
- **Focused Population** (High Utilization / Complex ED Patients)

Prevention

PreManage Prov/Plan: Payer/Provider + Partnerships

- Notifications to multiple parties across ED/ In-/Out-patient visits
- Shared platform for all care coordination information; complimentary Service to PreManage ED built on same technology
- **Broad User Base** (Primary / Specialty Care, CCOs, CBOs. Health Plans, Care Coordinators, Social Workers, ED Guides, others)
- **Entire Population** (Active patient population or member base)
  - Medical Homes, Mental Health, Medical Groups, Juvenile, Security, etc.



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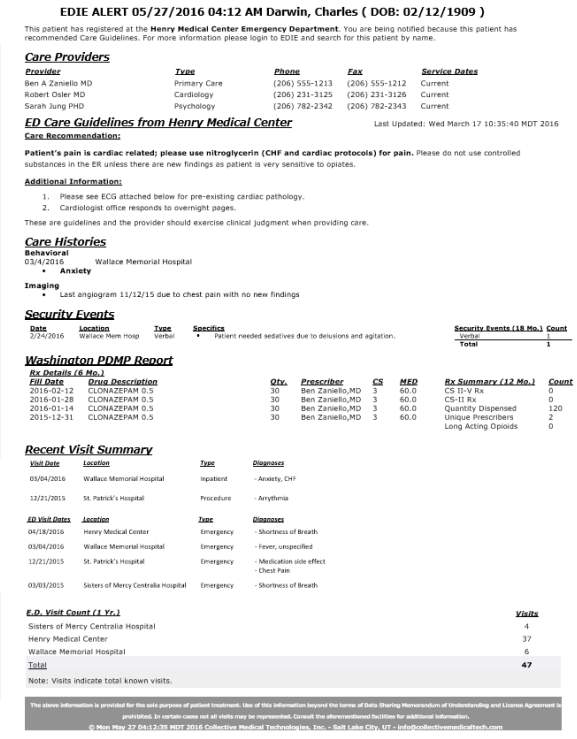

EDIE ALERT 05/27/2016 04:12 AM Darwin, Charles (DOB: 02/12/1909)

This patient has registered at the **Henry Medical Center Emergency Department**. You are being notified because this patient has recommended Care Guidelines. For more information please login to EDIE and search for this patient by name.

Care Providers

Provider	Type	Phone	Fax	Service Dates
Ben A Zaniello MD	Primary Care	(206) 555-1213	(206) 555-1212	Current
Robert Osler MD	Cardiology	(206) 231-3125	(206) 231-3126	Current
Sarah Jung PHD	Psychology	(206) 782-2342	(206) 782-2343	Current

ED Care Guidelines from Henry Medical Center

Last Updated: Wed March 17 10:35:40 MDT 2016

Care Recommendation:

Patient's pain is cardiac related; please use nitroglycerin (CHF and cardiac protocols) for pain. Please do not use controlled substances in the ER unless there are new findings as patient is very sensitive to opiates.

Additional Information:

1. Please see ECG attached below for pre-existing cardiac pathology.
2. Cardiologist office responds to overnight pages.

These are guidelines and the provider should exercise clinical judgment when providing care.

Care Histories

Behavioral
03/4/2016 Wallace Memorial Hospital
- **Anxiety**

Imaging
- Last angiogram 11/12/15 due to chest pain with no new findings

Security Events

Date	Location	Type	Specifics
2/24/2016	Wallace Mem Hosp	Verbal	• Patient needed sedatives due to delusions and agitation.

Security Events (18 Mo.)	Count
Verbal	1
Total	1

Washington PDMP Report

Rx Details (6 Mo.)

Fill Date	Drug Description	Qty.	Prescriber	CS	MED
2016-02-12	CLONAZEPAM 0.5	30	Ben Zaniello,MD	3	60.0
2016-01-28	CLONAZEPAM 0.5	30	Ben Zaniello,MD	3	60.0
2016-01-14	CLONAZEPAM 0.5	30	Ben Zaniello,MD	3	60.0
2015-12-31	CLONAZEPAM 0.5	30	Ben Zaniello,MD	3	60.0

Rx Summary (12 Mo.)	Count
CS II-V Rx	0
CS-II Rx	0
Quantity Dispensed	120
Unique Prescribers	2
Long Acting Opioids	0

Recent Visit Summary

Visit Date	Location	Type	Diagnoses
03/04/2016	Wallace Memorial Hospital	Inpatient	- Anxiety, CHF
12/21/2015	St. Patrick's Hospital	Procedure	- Arrythmia

ED Visit Dates	Location	Type	Diagnoses
04/18/2016	Henry Medical Center	Emergency	- Shortness of Breath
03/04/2016	Wallace Memorial Hospital	Emergency	- Fever, unspecified
12/21/2015	St. Patrick's Hospital	Emergency	- Medication side effect - Chest Pain
03/03/2015	Sisters of Mercy Centralia Hospital	Emergency	- Shortness of Breath

E.D. Visit Count (1 Yr.)	Visits
Sisters of Mercy Centralia Hospital	4
Henry Medical Center	37
Wallace Memorial Hospital	6
Total	47

Note: Visits indicate total known visits.

The above information is provided for the sole purpose of patient treatment. Use of this information beyond the terms of Data Sharing Memorandum of Understanding and License Agreement is prohibited. In certain cases not all visits may be represented. Consult the aforementioned facilities for additional information.
© Mon May 27 04:12:39 MDT 2016 Collective Medical Technologies, Inc. – Salt Lake City, UT – info@collectivemedicaltech.com

Sutter Health – Summit Campus Stats

	3 ED Visits in 30 Days		5 ED Visits in 12 Months	
Month	% of Visits	% of Patients	% of Visits	% of Patients
Jun-16	11.32%	8.14%	24.17%	19.54%
Jul-16	10.15%	6.96%	23.37%	19.21%
Aug-16	11.35%	8.23%	24.98%	20.47%
Sep-16	10.03%	8.05%	25.02%	21.68%
Oct-16	10.30%	7.97%	26.18%	22.18%
Nov-16	9.99%	8.07%	25.93%	22.59%
Dec-16	9.33%	7.03%	24.90%	21.05%
Jan-17	9.67%	7.67%	25.01%	21.70%

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CMT Roles

Name	Title	Role
Kyle Erb	Client Relations Manager	Implementation and Support
Gabe Waters	VP, Network Development	Region Support and Network Development
Michael Williams	Legal Counsel	Contracting, Legal
Lisa Hansen	Director, Accounting	Invoicing
Johnathan Bernston	IT Implementation	Security, Implementation, Interfaces, Development
Ben Zaniello	Chief Medical Officer	Executive Lead
Tory Neiwert	Director, Product	Product Customization, Development

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Clinical Consensus Group Roles

1. Committee Leadership (Drs. Berrol, Kanzaria, and Berrol)
   - Generally advocate and promote statewide PreManage Initiative and overall ED care coordination
   - Lead meeting agenda development
   - Identify potential committee members; encourage committee engagement

2. Committee Members
   - Attend meetings, follow through on assigned action-items
   - Champion PreManage initiative at respective organizations
   - Participate as "user" of PreManage (where possible) and provide feedback on experience
   - Respond to requests for information, feedback, guidance between meetings

3. Staff Support

   Primary [CMT]
   - Ongoing product/implementation support (see next slide)
   - develop meeting agendas
   - track action items; provide reminders
   - produce / distribute reports (e.g., Implementation Progress)

   Secondary
   - coordinate logistics on meeting location, schedule, agenda
   - gather information, feedback from stakeholder groups, report to Commtitee
   - distribute notices to member lists

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Clinical Consensus Group Composition

Name	Organization	Responsibility
		Clinical Consensus Group Co-Chair
		Clinical Consensus Group Co-Chair
		Clinical Consensus Group Member/IT Subcommittee Lead
		Clinical Consensus Group Member/Clinical Consensus Subcommittee Lead
		Clinical Consensus Group Member/Communications Subcommittee Lead
		Clinical Consensus Group Member/Staff Support
		Clinical Consensus Group Member
		Clinical Consensus Group Member
		Clinical Consensus Group Member
		Clinical Consensus Group Member
		Clinical Consensus Group Member
		Clinical Consensus Group Member
		Clinical Consensus Group Member
		Clinical Consensus Group Member

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Clinical Consensus Group Responsibilities (detail)

- Coordinate Implementation Efforts
- Develop Consensus on State-Wide Policies
- Lead Care Campaigns
- Public Stakeholder Coordination
- Evaluation of Effectiveness

Develop Consensus on State-Wide Policies

- What is the ED utilization focus for this region?
  - Washington: Patients 5 ED Visits in 12 months
  - Massachusetts: Patients with 6 ED Visits in 6 months
- Any other efforts?
  - Oregon: Focus on the material that belongs in the Care Recommendation and consistency in the location of case manager information

Coordinate Implementation Efforts

- Publicity and communication effort
- Advise on trouble-shooting efforts as challenges are encountered
- Encourage uptake and implementation efforts at your own organization as well as neighboring organizations
- Discuss Priority projects by region

Lead Care Campaigns

- Care Campaigns are areas of region-wide care collaboration that would benefit from committee leadership and shared action, often disease-specific
- Care Campaign Possibilities (with examples of specific goals):
  - Opioid Rx Reduction (drive more pain contracts into Edie)
  - Behavioral Health (partner with behavioral health clinics for post ED follow up)
  - Congestive Heart Failure Case Management (develop shared care protocol for admits with CHF)
  - Pediatric Asthma (region wide campaign about site of service, i.e. primary care > ED for reduction of acute attacks)

Public Stakeholder Coordination

- Common initial focus: Potential Prescription Drug Monitoring Program (PDMP) Integration
  - Create (or support existing) committee to lead effort
  - Report progress and action items for PDMP integration

Washington PDMP Report

Rx Details (6 Mo.)

Fill Date	Drug Description	Qty	Prescriber	CS	MED
2015-02-18	HYDROCODONE-ACETAMINOPHEN 7.5-325	30	John Smith, MD	3	60.0
2015-01-31	HYDROCODONE-ACETAMINOPHEN 7.5-325	30	John Smith, MD	3	60.0
2015-01-10	HYDROCODONE-ACETAMINOPHEN 7.5-325	15	John Smith, MD	3	60.0
2014-12-18	HYDROCODONE-ACETAMINOPHEN 7.5-325	30	John Smith, MD	3	60.0
2014-11-29	HYDROCODONE-ACETAMINOPHEN 5.0-250	30	John Smith, MD	3	60.0
2014-10-31	HYDROCODONE-ACETAMINOPHEN 5.0-250	30	John Smith, MD	3	60.0
2014-10-02	HYDROCODONE-ACETAMINOPHEN 5.0-250	30	John Smith, MD	3	60.0

Total 1

Rx Summary (12 Mo.)	Count
CS II-V Rx	0
CS-II Rx	0
Quantity Dispensed	480
Unique Prescribers	2
Unique Pharmacies	1
Benzos	1
Opioids	20
Long Acting Opioids	2

EXAMPLE

Evaluation of Effectiveness

- What goals will you want to look at in order to measure success?
  - In Oregon, basic utilization reports are created for key meetings where the committee reviews information such as Care Recommendations provided by entity
  - What other data could be provided in order to measure results of Northern California's initiatives?

Public Stakeholder Coordination

- Decide PDMP Criteria for Notifications

Washington PDMP Criteria:

1. More than three (3) prescribers within 12 months
2. More than four (4) controlled substance II-V prescriptions within 12 months
3. More than two (2) controlled substance II-V prescriptions within last 40 days
4. Any prescription for Methadone, Suboxone, fentanyl transdermal, LA morphine, and LA oxycodone within last 6 months
5. Any overlapping prescriptions for narcotics (controlled substance II-V) and benzodiazepines within last 6 months
6. More than 100 average MED/day prescribed within last 40 days

EXAMPLE

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Progress Report: Network

#	Hospital	Status
1	Alameda - Alameda	Implementing
2	Alameda - Highland	Live
3	Alameda - John George Psych - EDIE	Live
4	Alameda - San Leandro	Live
5	Chinese Hospital	Implementing July '17
6	CHOMP	Live
7	Fairchild	Live
8	San Francisco General	Live. Implementing to EMR now.
9	St. Joes - Petaluma Valley Hospital	Implementing
10	St. Joes - Queen of the Valley Medical Center	Implementing
11	St. Joes - Redwood Memorial Hospital	Implementing
12	St. Joes - Santa Rosa Memorial Hospital	Implementing
13	St. Joes - St. Joseph Hospital, Eureka	Implementing
14	Sutter - Alta Bates Summit - Berkeley	Live
15	Sutter - Alta Bates Summit - Oakland	Live
16	Sutter - CPMC - California West	Implementing. April '17 ETA
17	Sutter - CPMC - Davies	Implementing. April '17 ETA
18	Sutter - CPMC - Pacific	Implementing. April '17 ETA
19	Sutter - CPMC - St. Luke's	Implementing. April '17 ETA
20	Sutter - Delta	Live
21	Sutter - Eden	Live
22	Sutter - Medical Center of Sacramento	Implementing. April '17 ETA
23	Sutter - Memorial Med - Modesto	Implementing. April '17 ETA
24	Sutter - Mills-Peninsula	Implementing. April '17 ETA
25	Sutter - Solano Medical Center	Implementing. April '17 ETA
26	UCSF Parnassus	Implementing. Feb 14th ETA
27	UCSF Mission Bay	Implementing. Feb 14th ETA

High-level legal conclusions & outputs

Conclusions

- **HIPAA & Patient Consent**:
  - The HIPAA Privacy Rule allows hospitals, payers, and clinics to disclose PHI for "treatment", "payment", "health care operations", and "public health" activities without patient consent / authorization
  - CA state law is consistent with this HIPAA Privacy Rule TPO disclosure framework
  - PreManage ED (a/k/a "Edie") / PreManage Primary can operate on "opt out" basis (i.e., default is to share patient info unless patient "opts out")

- **Sensitive Information ("SI")**:
  - Some categories of PHI are subject to extra privacy restrictions (usually via additional patient consent requirements)
  - Examples:
    - psychotherapy notes (HIPAA)
    - substance abuse treatment information (42 CFR Part 2)
    - HIV/STD test results (CA state law)
    - information from mental health facilities (CA state law)
  - PreManage employs conservative compliance approach:
    (1) most SI is excluded from coming into PreManage by technical and/or policy controls; and
    (2) in limited cases where SI does come in to PreManage, technology restricts access to appropriate clinicians

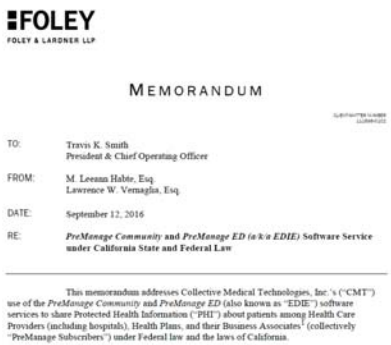
CMT Obtained 3rd Party Legal Opinion re EDIE & PreManage compliance with CA and Federal privacy rules

Objectives

- Confirm EDIE & PreManage compliance with both federal (HIPAA/42 CFR Part 2) and CA privacy statutes + regulations
- Focus on common legal questions
  - HIPAA
  - Patient consent
  - Sensitive information sharing in CA

Approach

- CMT has provided 3rd party legal opinion by Foley & Lardner, LLP:
  - Los Angeles office of nationally recognized law firm with expertise in healthcare privacy and security law
- Process for new hospitals, payers, clinics:
  - Provide internal legal counsel / privacy officer / HIM manager with Foley Legal Opinion for their review
  - Review form of Master Subscription Agreement and PreManage Service Order Form
  - Set up call with CMT: Travis Smith (President/COO, JD/MPH), Michael Williams (Corporate Counsel, JD) to discuss any open questions re the legal opinion, general privacy/security related questions, and negotiate terms of legal agreements.



FOLEY
FOLEY & LARDNER LLP

MEMORANDUM

TO: Travis K. Smith
President & Chief Operating Officer

FROM: M. Leeann Habte, Esq.
Lawrence W. Vernaglia, Esq.

DATE: September 12, 2016

RE: *PreManage Community* and *PreManage ED (a/k/a EDIE)* Software Service under California State and Federal Law

This memorandum addresses Collective Medical Technologies, Inc.'s ("CMT") use of the *PreManage Community* and *PreManage ED* (also known as "EDIE") software services to share Protected Health Information ("PHI") about patients among Health Care Providers (including hospitals), Health Plans, and their Business Associates[1] (collectively "PreManage Subscribers") under Federal law and the laws of California.

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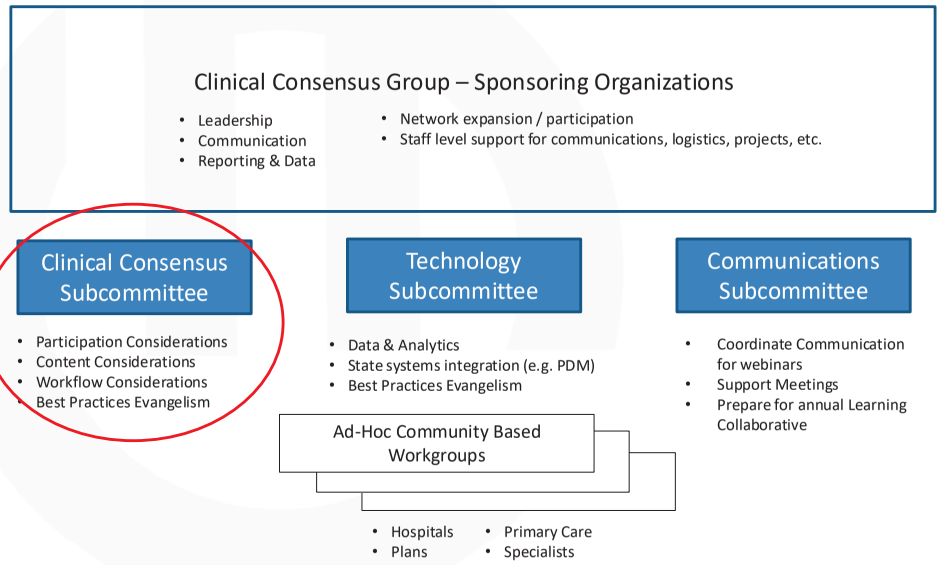
Structure



Example of Clinical Consensus Committee (early) Roadmap

1. Roles/Responsibilities of Committee
2. Notification Design and Review of Notification Data
3. Care Recommendation Communication Design and Training
4. Care Campaign prioritization, design, training
5. Ongoing review and modifications

Clinical Consensus Subcommittee will design/propagate best practice complex patient care guidelines

Participation Considerations

- Ensure broadly-representative functional participation: ED ACEP providers, case managers, social workers, chief nurses; consider plan case managers, county / state health stakeholders
- Ensure broadly-representative geographic (rural and urban; varying locations) and health system (independent, regional, statewide) participation
- Staff support from CMT and 1-2 Sponsoring Organizations; appoint rotating committee chair to drive agenda

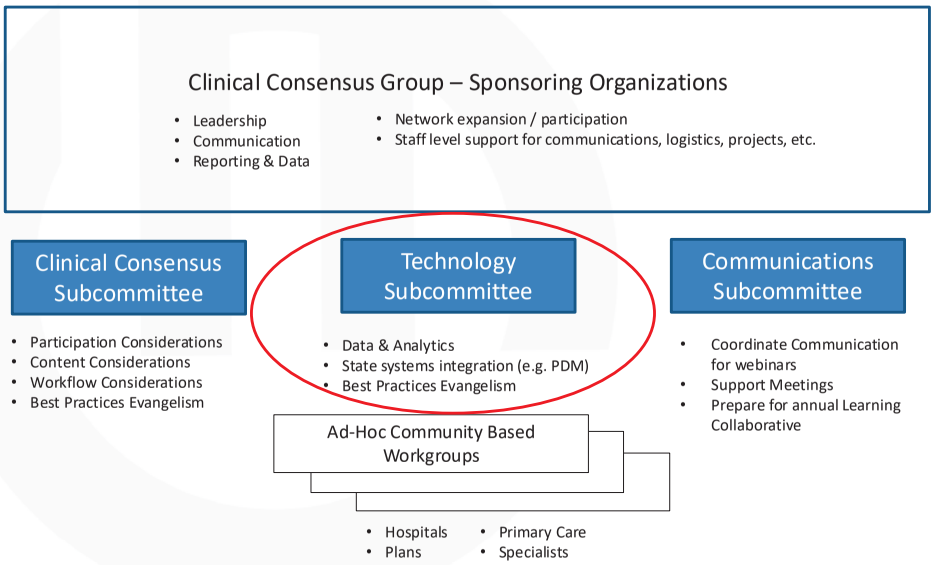
Content Considerations

- **Clinical collaboration**
  - Develop model clinical workflows, policies, and procedures across all hospitals to promote uniformity between emergency departments for consistent patient care
    - Patient education, consistently messages and delivered
    - Patient care plans shared broadly as living documents, irrespective of health system
    - Narcotic guidelines, tracked and managed within PreManage ED
    - Prescription monitoring: consider integrating push-based Rx alerts within PreManage ED
    - Provider feedback, broadly collected, analyzed, and disseminated
    - Identify and actively manage high utilizers through shared information and collaboration
- **Performance evaluation**
  - Develop statewide ED quality scorecards
  - Determine best sources and presentation opportunity of such data

Workflow Considerations

- Broadly solicit feedback and gain support for guidelines using individual relationships,
- CMT staff available as needed to support CCG, respond to PreManage operational questions, share best practices from other geographies, etc.

Structure



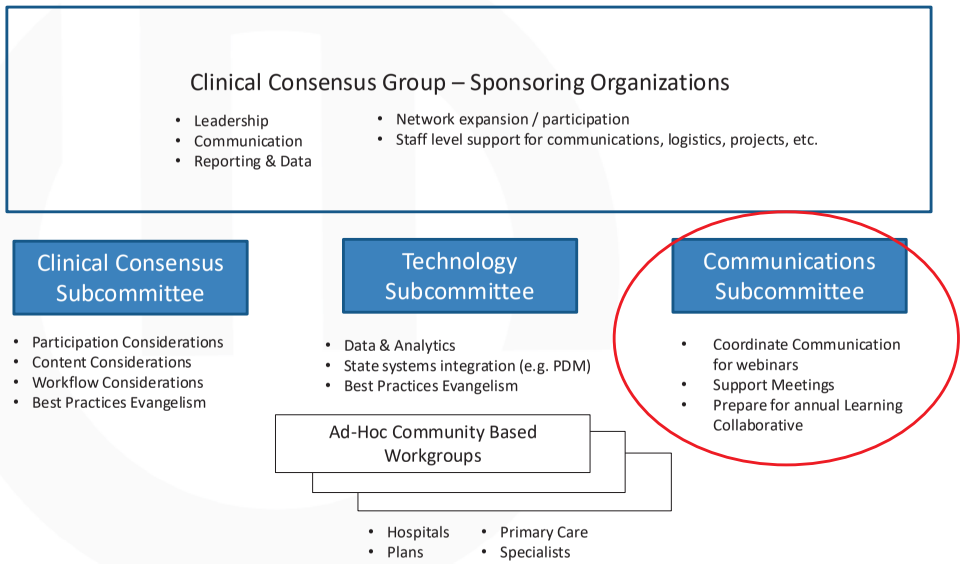
Technology Subcommittee will provide reporting & analytics, facilitate connectivity to state systems, and ensure proper use of data.

Data & Analytics	• Approve and coordinate the addition of new statewide data-elements, the addition of notifications or workflows for new care settings, and standardization of EHR interface policies or approaches (to the extent there is benefit to the users). • Ensure transparency for hospitals by tracking and reporting Edie data report requests and their disposition. Including the name of the organization(s), purpose, data and data description, to all hospital data owners.
Facilitate State System Integration	• Identify state systems and data repositories that should be connected to the Edie initiative (e.g. PDMP); facilitate plans to incorporate state systems and data repositories into the Edie initiative • Identify legal, policy, regulatory, and technical hurdles that may / will hinder the goals & objectives of the Edie initiative and VHLC • Facilitate integration of data from across state borders, as appropriate and feasible • Ensure participation and access to information is available to all stakeholders (e.g. community based organizations)
Best Practices	• Provide guidance and oversight related to patient privacy & consent • Identify standardized integration patterns, best practice, approaches, and opportunities for re-use for stakeholder on-boarding to the Edie initiative • Ensure adequate controls are in place related to data security

Communications Subcommittee will coordinate meetings, provide timely communication, and plan the Regional Learning Collaborative

Coordinate Meetings	• Work on securing a time and location for meetings that is convenient for committee members • Prepare agenda and send for review to the Co-Chairs • Send out and follow up on action items for each of the events.
Communication	• Work with CMT to organize all outgoing communication both for committee members as well as PreManage users • Discuss communication methods and timeline: PreManage announcements, newsletter, website, emails, etc. • Keep an accurate and updated contact list for PreManage users and committee members
Learning Collaborative Planning	• Plan and prepare for annual Learning Collaborative • Review with larger committee for discussion topics • Invite speakers • Create, distribute agenda and manage registration

Structure



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Next Steps

- Discuss other possible invitees of the next CCG.
- Plan next Clinical Consensus Group meeting
  - Make decisions on the region's focus for notifications
  - Work on selecting key metrics to review and report on for meetings
- Deep Dive Follow up (By Request)

CMT Support

CRM: Onboarding, Training and Client Relations Support	Kyle Erb Client Relations Manager Kyle.erb@collectivemedicaltech.com 801-810-2292
IT and Technical Support	Johnathan Bernston Implementation Engineer Johnathan.bernston@collectivemedicaltech.com 801-713-4446
Strategic and Tactical Support for State/Regional Efforts	Gabe Waters Vide President, Network Development Gabe.waters@collectivemedicaltech.com 801-376-7321
Executive Sponsor	Ben Zaniello MD MPH Chief Medical Officer, Vice President of Product baz@collectivemedicaltech.com 917-617-0563

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

August 30, 2017

TO: CHA EMS/T Committee

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: EDIE Outcomes

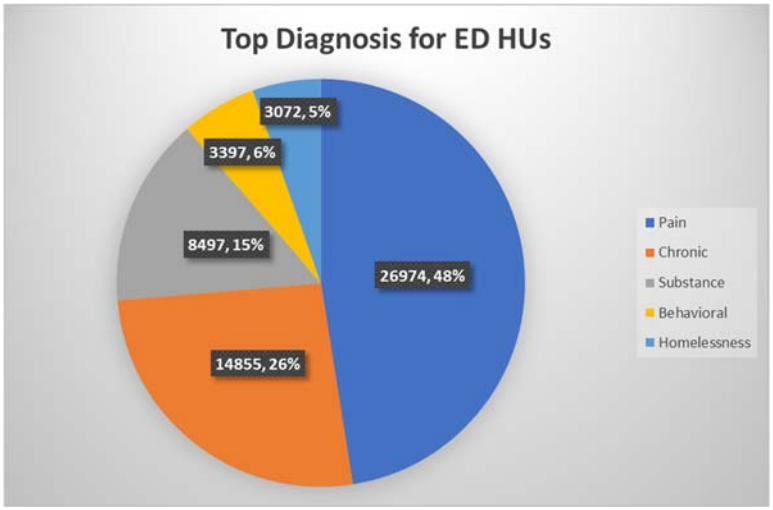
Dr. Casey Grover at Community Hospital of the Monterey Peninsula is the longest user of EDIE (18 months) in California and studied 150 of their frequent ED visits or "recurrent visitors" for a year with the following outcomes:

158 EDRVP (Emergency Department Recurrent Visitor Program) patients	Review of their ED and hospital visits 1 year before and 1 year after they were enrolled in the EDRVP.
EDRVP saved:	-$5,834,275 in ED and hospital charges -446 days of ED and inpatient bed time
EDRVP reduced:	- ED visits by 49% - Hospital admissions by 39% - CTs by 41% - Ultrasounds by 52% - X-rays by 38% - Blood work by 47%

Fifty hospitals across California are actively using the EDIE technology. Early data on those hospitals participating in the Northern California ED Consensus group (approximately 20 hospitals) showed:

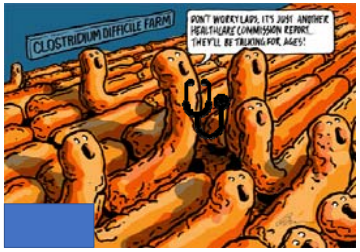
NorCal Total ED Visits	High Utilizer Visits at NorCal Hospitals	% of Visits by High Utilizers
404,898	110,755	27.3%

Distinct Patients	High Utilizers	% of Patients
232,368	18,875	8.1%



An important component of ECSI's planned research and fact-finding, is measuring emergency department utilization data to determine drivers of high utilization. Having the technology readily available and used by hospitals is a positive development and we look forward to incorporating this technology as the main vehicle of a sound researched based ECSI ED systems assessment. Dr. Maria Raven (UCSF) and Dr. Hemal Kanzaria (ZSFG) have agreed to be ECSI independent data researchers and are presently working on a small study between both their facilities to evaluate the EDIE system to assure its reliability as a valid research tool.

California Hospital Association
EMS/Trauma Committee
June 7, 2017



Carla E. Schneider, RN, MSN, CEN, MICN

1

All About Clostridium Difficile (C-diff)

- C-diff bacteria causes an infection that creates inflammation of the colon
- S/S: fever, loss of appetite, nausea, watery diarrhea, abd pain & tenderness
- In the U.S., care of C-diff places a burden on healthcare system, with cost in access of $3.2 billion/yr.
- CDC's most recent figure for C-diff associated deaths is growing, & survey completed in 2011 reflected over 500,000 infections and over 29,300 deaths/yr.
- Patients with C-diff can shed spores even when not having symptoms
- C-diff spores shed in stool & without necessary hygiene precautions, spores transfer to hands and finally surfaces
- handwashing with soap and water is the only way to prevent spread as c diff is resistant to hand gel & spores can live on inanimate surfaces for up to 30-60 days

(Fernanda, 2015)

2

Why Focus on Prevention by EMS Providers?

- Often patients have compromised immune systems, example include: young children, the elderly, patients with cancer, & victims of serious injuries including burns (Augustine, 2013)
- 65% of all residents from long term care facilities have a multidrug resistant organism, like MRSA or C-diff (Facility Guidance, 2015)
- The spores transferred to surfaces can survive outside the body for months and are highly resistant to cleaning agents (Fernanda, 2015)
- Use of appropriate cleaning agents for equipment between patients will prevent both EMS providers and patients from health care associated infection (Augustine, 2013)
- Stopping the spread of multi-drug resistant organisms saves lives

3

Review of Pre-Hospital Infection Prevention Policies; Both County Accredited and Private EMT/Paramedics

Excerpts:

When EMT's are dispatched or come into contact with C-diff …de-con gurney with PDI Sani-Cloth Bleach Germicidal Disposable Wipe (Shoreline)

Ambulance service providers shall be required to demonstrate satisfactory compliance with all infectious disease, blood- born and airborne pathogen control plans as required by federal and state regulations (OCEMS Policy #720.60)

"…generally we use an alcohol based wipe to clean them but when there is known C-diff we try to use bleach wipes however those are not always available to us. I would say that it is **NOT** common practice for bleach to be used during clean up on every patient with diarrhea." (Costa Mesa Firefighter)

…Common sense, experience, and a common basis of practices and informational controls are the best allies in keeping exposures to a minimum. The policies in this section should be viewed as guidelines, where individual personnel are aware of all areas of concern and approach each situation with informed caution and sense. (CMFD, Standard Operating Procedures)

4

Consider the Following Recommendations for EMS Providers:

- Review of C-diff , including risk of healthcare associated infections among patients and health-care providers (Fleming,2009)
- Update policies to reflect the use of an EPA registered sporicidal cleaning solutions for equipment between patients (http://www/epa.gov/sites/production/files/2017)
- Education and training on use of sporicidal solutions for disinfecting equipment, based on manufacturers recommendations including use of personal protective equipment (Fleming, 2009)

5

REFERENCES

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Augustine, J., Infectious exposure in EMS: The dirty business of keeping clean. *EMS 1 News.* Retrieved from: https://www.ems1.com/health-and-wellness/articles/1440871-Infectious-exposure-in-EMS-The-dirty-business-of-keeping-clean

Facility Guidance for Control of Carbapenem-resistant Enterobacteriaceae (2015) retrieved from: https://www.cdc.gov/hai/research/cdc-mdro-project.html

6

Margaret c. diff. John c. diff. Randall c. diff. Sol c. diff.
Kathleen c. diff. Aini c. diff. Rex c. diff. Paul c. diff.
Blenda c. diff. Arden c. diff.

First do no harm…

Donald c. diff. Duane c. diff. Xiying c. diff.
Michael c. diff. Joseph c. diff. Guip c. diff.
Dorothy c. diff. Patricia c. diff. Delia c. diff. Kathleen c. diff.

Tonia, 42

C.diff.

My battle with C. diff began in January 2015 after taking three doses of Clindamycin prophylactically. I may have picked up the spore during a stay in the critical care unit or while visiting a family member in the ICU. I may have even picked it up while grocery shopping. I will never know.

It is now the end of August as I'm writing this story. I am not sure if my battle is over. When I was first diagnosed, I was admitted to the hospital and started on Vancomycin. A week after finishing the Vancomycin, my symptoms returned and I was instead put on Flagyl. In February, I had to have emergency surgery for multiple bowel obstructions; this required antibiotics. A week after surgery, the C. diff was back. I was again put on Vancomycin, and needed to be hospitalized three more times.

In April, the doctor said, "Stop the meds and let's see what happens." After following these instructions, I was admitted two times for pancreatitis (most likely caused by all of the Vancomycin). In July, I tested positive again, and I was again admitted due to severe side effects of the Vancomycin. I was just tested again yesterday due to some symptoms, but the test was negative.

I struggle daily with stomach pain, fatigue, food intolerance, and a level of anxiety I have never experienced before in my life. This is a horrible infection and a true cure cannot come soon enough. No one should have to suffer through this, or lose their life, or the life of a loved one to this wretched bacterium. Something needs to be done, and very, very soon.

Judy, 72yo

C.diff.

Our mom went to the hospital when she was having difficulty breathing. She was admitted for a lung infection and treated with antibiotics for 8 days. Our family was not prepared for the torment that the following months would bring.

She began to experience uncontrollable diarrhea which resulted in severe dehydration and was later diagnosed with c.diff. We knew little about it but learned very quickly. It became second nature for our family to put on protective gowns and gloves before visiting her room.

She received a prolonged course of powerful antibiotics by mouth and enemas. When those didn't work, the Doctors recommended colon removal surgery. She lost so much weight and eventually had to have a feeding tube inserted. Being confined to the hospital and debilitated with C. diff was excruciating for our mother. It deprived her from the thing she loved the most, time with her kids and grand kids.

We lost her just six months after it all began. She was the matriarch of our family. We hope that in telling her story we can bring awareness to this devastating condition.

STATE OF CALIFORNIA – HEALTH AND HUMAN SERVICES AGENCY
EDMUND G. BROWN JR., *Governor*

CALIFORNIA EMERGENCY MEDICAL SERVICES AUTHORITY
10901 GOLD CENTER DRIVE, SUITE 400
RANCHO CORDOVA, CA 95670
(916) 322-4336 FAX (916) 324-2875

October 14, 2016

Secretary of the Senate
State Capitol, Room 3044
Sacramento, CA 95814

Dear Secretary:

Health and Safety Code § 1797.98b mandates the Emergency Medical Services (EMS) Authority to annually compile and forward a summary of each county's Maddy EMS Fund report.

The EMS Authority has collected Maddy EMS Fund reports from 50 counties, and has developed the enclosed Maddy EMS Fund Statewide Report Summary for Fiscal Year 2014/2015. The EMS Authority cannot certify the accuracy of the submitted reports, as the county data are self-reported.

The EMS Authority looks forward to working with counties to provide a standardized reporting template and instructions to improve future compliance, as well as the quality of data received.

The EMS Authority hopes this report will evolve to meet the needs of the Legislature and its committees. Should you have any questions, please contact the EMS Authority's Office of Legislation at (916) 431-3715.

Sincerely,

Howard Backer, MD, MPH, FACEP
Director

Enclosure

cc: Office of Legislative Counsel
Chief Clerk of the Assembly

Maddy Emergency Medical Services Fund

Statewide Report Summary FY 2014/2015

Emergency Medical Services Authority
California Health and Human Services Agency

EMSA #R002-2016
October 2016

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EMSA #R002-2016
October 2016

MADDY EMS FUND
STATEWIDE REPORT SUMMARY
FISCAL YEAR 2014/2015

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MADDY EMS FUND
STATEWIDE REPORT SUMMARY
FISCAL YEAR 2014/2015

EXECUTIVE SUMMARY

Health and Safety Code (HSC) § 1797.98a authorizes counties to establish a Maddy EMS Fund, through adoption of a resolution by the board of supervisors, to reimburse physicians/surgeons and hospitals for the cost of uncompensated emergency care and for discretionary EMS purposes. The Maddy EMS Fund is administered by each county, except when a county elects to have the state administer its medically indigent services program, and then the county may also elect to have its Maddy EMS Fund administered by the state. Additionally, HSC § 1797.98a(e) authorizes counties to establish a Richie's Fund, as part of the Maddy EMS Fund, to provide funding for pediatric trauma centers throughout the county. If no pediatric trauma centers exist, the funding must be used to improve access to, coordinating pediatric trauma and emergency services in the county. The expenditure of the Richie's Fund is limited to reimbursement to physicians/surgeons and hospitals for the cost of uncompensated emergency care.

The Maddy EMS Fund is funded through revenues generated from local penalty assessments on fines and forfeitures for various criminal offenses and motor vehicle violations (Government Code [GC] § 76000 and GC § 76104), including a portion of traffic school fees (Vehicle Code [VC] § 42007), collected by the courts and forwarded to the counties. The Richie's Fund is funded through revenues generated from local penalty assessments on fines and forfeitures for various criminal offenses and motor vehicle violations (GC § 76000.5), including a portion of traffic school fees (VC § 42007), collected by the courts and forwarded to the counties for deposit into the Maddy EMS Fund.

Currently, 50 counties (86%) have established the Maddy EMS Fund, and 31 (53%) of these counties have established the Richie's Fund. The 2014/2015 Fiscal Year (FY) data received from the counties is not detailed enough to calculate with precision. The Maddy EMS Fund balance reported at the beginning of the 2014/2015 FY was $33.6 million. This amount, in addition to the revenue deposited ($77.6 million) into the Maddy EMS Fund for the 2014/2015 FY provides for a combined total balance of $111.2 million. The 2014/2015 FY distributions totaled $80 million. The distributions are as follows:

- County Administration Cost - 9.9% ($7.7 million)
- Physicians/Surgeons - 51% ($39.6 million)
- Hospitals - 18.3% ($14.3 million)
- Discretionary EMS Purposes - 15.2% ($11.8 million)
- Richie's Fund - 8.0% ($6.2 million)
- Reserve - 0.5% ($388,400)

Following the above distributions, the counties reported a balance of $36.1 million of undistributed funds.

HISTORY AND BACKGROUND

In 1987, the Legislature concluded that EMS providers, including physicians/surgeons and hospitals, as part of a requirement to provide emergency medical care to all patients regardless of their ability to pay, "bore higher costs for their services but often received only partial or no payment from patients."[1] The legislature enacted a series of laws to compensate physicians/surgeons and hospitals for patients who cannot pay for their medical care. Senator Ken Maddy authored the first of these bills in 1987. The legislature enacted Senate Bill (SB) 12, Maddy (Chapter 1240, Statutes of 1987), allowing each county to establish, finance, and administer an EMS Fund, later known as the Maddy EMS Fund, which authorized a penalty assessment of $1 per $10 on applicable fines, penalties, and forfeitures (GC § 76000).

The bill was subsequently amended by SB 612, Maddy (Chapter 945, Statutes of 1988), in which the penalty assessment was doubled to $2 per $10 on applicable fines, penalties, and forfeitures.

As a result of a restructuring of penalty assessments for trial courts funding in 1991, the Maddy EMS Fund deposit methodology (GC § 76104) was revised by SB 939, Monteith (Chapter 674, Statutes of 1999). If the fund was established prior to July 1, 1991, then the amount deposited into the Maddy EMS Fund is based upon the actual amount collected and deposited in the Maddy EMS Fund for the1990/1991 FY, plus a maximum of 10% growth per year, if any. For counties implementing the penalty assessment after the 1990/1991 FY, up to 28% of the total revenue collected from penalty assessments under GC § 76000 may be set aside.

Legislation enacted by SB 623, Speier (Chapter 679, Statutes of 1999), requires a portion of fees collected from people attending traffic violator schools to be deposited into the Maddy EMS Fund, unless counties had already committed the fund to finance debt serviced related to capital projects before January 1, 2000 (VC § 42007).

In 2003, an audit was conducted by the Bureau of State Audits that detailed the status of county Maddy EMS Funds at that point in time. The County EMS Funds audit can be accessed through the California State Auditor's website or directly through the following link: https://www.bsa.ca.gov/pdfs/reports/2003-101.pdf.

Legislation enacted by SB 476, Florez (Chapter 707, Statutes of 2003), permits each county to maintain a reserve of up to 15% of the amount reimbursable to physicians/surgeons and hospitals, and allows reserves of any amount that is distributed for discretionary EMS purposes. When the physicians/surgeons balances

[1] *County Emergency Medical Services Funds: Despite Their Efforts to Properly Administer the Funds, Some Counties Have Yet to Reach Full Compliance With State Laws,* California State Auditor, Bureau of State Audits, Sacramento, California, March 2004, 2003-101, p.5.

exceed the permitted reserve, a county must proportionally distribute the excess to physicians/surgeons submitting claims during the year (HSC § 1797.98a(d)).

The HSC § 1797.98a was later amended by SB 1773, Alarcon (Chapter 841, Statutes of 2006), adding an additional penalty assessment of $2 per $10 on applicable fines, penalties, and forfeitures, and modifying the purpose and distribution by requiring 15% of the funds to be expended for pediatric trauma care, with a sunset date of December 31, 2013 (GC § 76000.5). The authorization for the additional penalty assessment and purpose and distribution was extended by SB 191, Padilla (Chapter 600, Statutes of 2013), through January 1, 2017, and again by SB 867, Roth (Chapter 147, Statutes of 2016), allowing counties to continue to collect for the Richie's Fund until January 1, 2027.

DISCUSSION

There are four distinct phases in administering the Maddy EMS Fund:

1. Collection of Penalty Assessments
2. Deposits into the Maddy EMS Fund
3. Distribution of Revenue
4. Expenditure of Funds

Phase 1 – Collections of Penalty Assessments

The courts are responsible for collecting fines, penalties, and forfeitures. A portion of the revenue is forwarded to the county based upon the specific revenue sources described in GC § 76000, GC § 76000.5, and VC § 42007.

Phase 2 – Deposits into the Maddy EMS Fund

The county is responsible for depositing the proper amounts into the Maddy EMS Fund. For the counties implementing the provisions of HSC § 1797.98a, utilizing penalty assessments from both GC § 76000 and GC § 76000.5, the total revenue from penalty assessments that should be deposited into the Maddy EMS Fund is as follows:

- Fund growth as calculated from FY 1990/1991 or up to 28% of the fund collected under GC § 76000, using the methodology as described in GC § 76104.

- Penalty assessment of $2 per $10 of fines, penalties, and forfeitures collected under GC § 76000.

- Penalty assessment of $2 per $10 of fines, penalties, and forfeitures collected under GC § 76000.5.

- A portion of fees from penalty assessments from Traffic Violator School under VC § 42007.

Phase 3 – Distribution of Revenue

Revenue is distributed for specific uses established in law including the county administration cost, reimbursement to physician/surgeons and hospitals for the cost of uncompensated care, and for discretionary EMS purposes. If the county has elected to establish a Richie's Fund pursuant to GC § 76000.5, then a separate distribution designation must also be established (HSC § 1797.98a(e)).

Revenue from GC § 76000 for the Maddy EMS Fund is distributed in the following manner:

Maddy EMS Fund - GC § 76000 Revenue Distribution Categories and Methodology
10% - County Administration Cost - First 10% of the money collected, or the actual administrative costs, whichever is lower, is distributed to the county to administer the county's Maddy EMS Fund.
The remaining 90% of the revenues is distributed as follows:
58% - Physicians/Surgeons - Payments to physicians/surgeons providing services to patients who have no insurance coverage or are otherwise unable to pay for emergency room visits. (Reimbursement is limited to up to 50% of the claims.)
25% - Hospitals - Payments only to hospitals providing disproportionate trauma and emergency medical care services.
17% - Discretionary EMS Purposes - Payments made for other EMS purposes, as determined by each county.

Revenue from GC § 76000.5 for the Richie's Fund is distributed in the following manner:

Richie's Fund – GC § 76000.5 Revenue Distribution Categories and Methodology
10% - County Administration Cost - First 10% of the money collected, or the actual administrative costs, whichever is lower, is distributed to the county to administer the county's Maddy EMS Fund.
15% - Richie's Fund - 15% of the money collected is distributed to the Richie's Fund. This fund provides funding for all pediatric trauma centers throughout the county. For counties without a pediatric trauma center, funding is available for improving access to, and coordinating, pediatric trauma and emergency services in the county, with preference given to hospitals specializing in services to children.

The remaining 75% of the revenues is distributed as follows:
58% - Physicians/Surgeons - Payments to physicians/surgeons providing services to patients who have no insurance coverage or are otherwise unable to pay for emergency room visits. (Reimbursement is limited to up to 50% of the claims.)
25% - Hospitals - Payments only to hospitals providing disproportionate trauma and emergency medical care services.
17% - Discretionary EMS Purposes - Payments made for other EMS purposes, as determined by each county.

Phase 4 – Expenditure of Funds

The expenditure of the funds is subject to the provisions of HSC § 1797.98a. Any interest accrued for physicians/surgeons, hospitals, discretionary EMS purposes, and for the Richie's Fund, as well as any remaining balances for these distribution designations, remains in that specified distribution designation. The intent of the statute is to have a simplified, cost-efficient system of administration so that the maximum amount of funds may be utilized to reimburse physicians/surgeons and for discretionary EMS purposes (HSC § 1797.98e(a)).

Physicians/surgeons receive reimbursement for emergency services provided, except those physicians/surgeons employed by county hospitals, in general acute care hospitals that provide basic, comprehensive, or standby emergency services up to the time the patient is stabilized. Any physician/surgeon may be reimbursed for up to 50% of the amount claimed for the initial cycle of reimbursements made annually by the administering agency in a given year. All funds remaining at the end of the FY in excess of any reserve held and rolled over to the next year must be distributed proportionally, based on the dollar amount of claims submitted and paid to all physicians/surgeons who submitted qualifying claims during that year.

Reimbursement of claims for emergency services provided to patients by any physician/surgeon shall be limited to services provided to a patient who does not have health insurance coverage for emergency services and care, cannot afford to pay for those services, and for whom payment will not be made by a third party. A county must adopt a fee schedule and reimbursement methodology to establish a uniform reasonable level of reimbursement from the county's Maddy EMS Fund for reimbursable services.

Hospitals may receive funding only if they provide disproportionate trauma and emergency medical care services. Reimbursement may be made directly or on a claims basis at the county's discretion.

Discretionary EMS purposes as determined by each county may be reimbursed, including, but not limited to, local EMS agency funding or the funding of regional poison

control centers. Funding may be used for purchasing equipment and for capital projects only to the extent that these expenditures support the provision of emergency services.

If a county has established a Richie's Fund, it must be utilized to provide funding for all pediatric trauma centers throughout the county, both publicly and privately owned and operated. The expenditure of money is limited to reimbursement to physicians/surgeons, and to hospitals for patients who do not make payment for emergency care services in hospitals up to the point of stabilization, or to hospitals for expanding the services provided to pediatric trauma patients at trauma centers and other hospitals providing care to pediatric trauma patients, or at pediatric trauma centers, including the purchase of equipment. Local EMS agencies may conduct a needs assessment of pediatric trauma services in the county to distribute these expenditures. Counties that do not maintain a pediatric trauma center may utilize the money deposited into the fund to improve access to, and coordination of, pediatric trauma and emergency services in the county, with preference for funding given to hospitals that specialize in services to children, and physicians/surgeons who provide emergency care for children.

REPORT METHODOLOGY

Each county establishing a Maddy EMS Fund must annually report to the EMS Authority on the implementation and status of the fund on April 15 of each year for the immediately preceding FY. The EMS Authority requests the reports from the counties, compiles the information and develops a summary of each county's report, and forwards the summary to the appropriate policy and fiscal committees of the Legislature.[2]

The EMS Authority cannot certify the accuracy of the submitted reports, as they are self-reported by the counties based on various report data received from the courts and county records. Therefore, the collected and deposited amounts identified by statute on the county submitted reports may not be a clear representation of the amounts available in the Maddy EMS Fund.

Additionally, 40 counties established their Maddy EMS Fund prior to July 1, 1991. Restrictions are in place to limit the counties' annual growth of deposits to the Maddy EMS Fund. GC § 76104 states that a county with an EMS Fund established prior to June 1, 1991, must limit the annual growth in deposits to the EMS Fund from Maddy revenues to no more than 10 percent annually, based on the amount of growth in the county's share of penalty assessments collected by the court. As noted in the State Auditor's report, counties were unaware of this provision and did not track the initial 1990/1991 deposits, and have not tracked the level of growth in the fund on an annual basis, if any. In the absence of individual data from each county, it is unclear if any conclusions can be made regarding the calculation of revenues that should be included in Maddy EMS Fund revenues. Given various local interpretations of GC § 76104, Maddy revenue deposits and distribution vary among counties.

[2] HSC § 1797.98b, (Amended by SB 1465, Committee on Health, [Chapter 442, Statutes of 2014]).

DATA SUMMARY

For the 2014/2015 FY, penalty assessment revenues of $77,641,371.53 were deposited into the Maddy EMS Fund and $80,018,368.16 was distributed for the county administration cost, physicians/surgeons, hospitals, discretionary EMS purposes, and for the Richie's Fund. Because the fund is continuously appropriated locally, fund balances on an accrual basis are used to supplement reimbursement levels on an annual basis. Actual reimbursements were $53,601,931.76 to physicians/surgeons for the 2014/2015 FY.

The accounting mechanisms and workflow used at the county level differ in their methodology and tracking ability. Revenue sources are intermingled for the purposes of tracking and reporting. Therefore, the information reported is highly variable and county specific. Because the data received from the counties does not possess enough specificity to calculate with precision, it is difficult to draw conclusions from the data.

From the gross revenue deposited ($77,641,371.53) into the Maddy EMS Fund for the 2014/2015 FY, the administrative cost was 9.9% ($7.7 million), the amount to physicians/surgeons was 51% ($39.6 million), the amount to hospitals was 18.3% ($14.3 million), and the amount for discretionary EMS purposes was 15.2% ($11.8 million). The Richie's Fund received 8.0% of the total amount available in the Maddy EMS Fund, or 44.8% of the amount received under GC § 76000.5 for purposes of HSC § 1797.98a(e). The counties also maintained a Reserve of 0.5% ($388,400).

Below is a statewide summary of the county totals for the establishment of a Maddy EMS Fund and Richie's Fund, and the reported funds collected, deposited, and distributed given the limitations noted above.

Table 1

Establishment of a Maddy EMS Fund/Richie's Fund		
Category	**Maddy EMS Fund**	**Richie's Fund**
Counties with an Established Fund[3]	50 (86%)	31 (53%)
Counties without an Established Fund	8 (14%)	27 (47%)

[3] Based upon previous information, 40 counties had established an EMS Fund prior to FY 1990/1991.

Table 2

Collections/Deposits during FY2014/15		
Category	**Total Amounts Collected by County[4]**	**Total Amounts Deposited into the Maddy EMS Fund**
Government Code § 76000	$51,254,323.61	$11,760,300.48
Government Code § 76000.5	$27,731,493.99	$24,755,821.29
Government Code § 76000.5 (HSC § 1797.98a(e))	$16,908,913.77	$13,921,685.32
Government Code § 76104	$21,319,700.73	$19,496,621.74
Vehicle Code § 42007(e)	$11,246,474.50	$7,706,942.70
TOTAL	**$128,460,906.60**	**$77,641,371.53**

Table 3

Distributions during FY2014/15	
Category	**Total Amount**
County Administration Cost	$7,720,224.64
Physicians/Surgeons	$39,595,677.47
Hospitals	$14,256,405.90
Discretionary EMS Purposes	$11,819,902.26
Richie's Fund	$6,237,743.87
County Reserve[5]	$388,414.02
TOTAL	**$80,018,368.16**

The counties reported a balance of undistributed funds at the end of the 2014/2015 FY following the above distributions that totals $36,138,105.89. The fund balance at the beginning of the FY was $33,627,866.88. This represents an increase in the total fund balance of $2.5 million (7.4%). The counties did not provide individual fund balances for each specified distribution designation. The EMS Authority has no information on how and when the remaining funds will be distributed by the counties. Typically this balance would represent a continuous collection and appropriation from year-to-year.

[4] Existing law allows for the collection of fines and forfeitures, and penalty assessments for uses other than the Maddy EMS Fund and Richie's Fund. Therefore, the deposit of funds into Maddy EMS Fund will be a portion of the total amounts collected by the Courts as defined in statute. The reports submitted by the county may not be a clear representation of the actual amounts available.

[5] The Reserve amount reported by the counties is not a statutorily-defined distribution category. Instead, reserve calculations should be limited to the specific distribution designation and managed separately as noted in HSC § 1797.98(b)(4).

Table 4

EMS Fund Balances as of June 30, 2015	
Category	**Total Amount**
County Administration Cost	Not Available
Physicians/Surgeons	Not Available
Hospitals	Not Available
Discretionary EMS Purposes	Not Available
Richie's Fund	Not Available
County Reserve	Not Available
TOTAL	**$36,138,105.89**

CONCLUSION

The EMS Authority is providing this Statewide Maddy EMS Fund Report Summary pursuant to HSC § 1797.98b, which became effective on January 1, 2015. However, there are limitations in the information available and a detailed analysis of the statewide nature of the Maddy EMS Fund could be unreliable.

Subsequent to the collection of the Maddy EMS Fund data, the EMS Authority discovered that county processes vary widely, specifically with regard to the collection and reporting of funds and the calculation of the growth limitation of deposits into the Maddy EMS Fund as noted in GC § 76104. These deficiencies were also noted in a 2003 audit conducted by the Bureau of State Audits.[6] The 2003 audit revealed that more than 24 counties were unaware of the growth limitation, and as a result, did not track the information required to calculate the limitation. *"It is possible that some counties deposited more revenues than allowed into their EMS Funds, but due to the lack of clarity in the law and the lack of all necessary information in county records, we could not quantify the impact of this issue."* The audit also found that the reporting format the counties use does not require any explanations on the differences between the remaining balance of the prior year and the beginning balance of the following year being reported, and the audit recommended that consideration should be given to revise the reporting format to account for the variation in reported information.

Based on the inconsistencies identified, the EMS Authority has concluded that the data provided in the submitted reports reflects the varied interpretation among county implementation of statute governing the Maddy EMS Fund. As a result, there is variation in the data quality. The EMS Authority looks forward to working with counties to standardize the interpretation of existing statutes to improve the data received in future reporting.

[6] *County Emergency Medical Services Funds: Despite Their Efforts to Properly Administer the Funds, Some Counties Have Yet to Reach Full Compliance With State Laws*, California State Auditor, Bureau of State Audits, Sacramento, California, March 2004, 2003-101, p.13-28.

The EMS Authority also recognizes that coverage expansions under the Affordable Care Act may have an impact on the Maddy EMS Fund; however, at this point in time, the EMS Authority is uncertain of the impact.

FUTURE REPORTING

The EMS Authority will provide technical assistance to the Maddy EMS Fund administrators to enable a more consistent interpretation of existing statutes and maintenance of reporting standards.

The EMS Authority will work with counties to revise the reporting format currently used to report Maddy EMS Fund information to improve the data collection and analysis of how these funds are used. This revised format will be available for use for the 2017/2018 FY data collection.

The EMS Authority will also revise existing reporting instructions to include how to calculate the allowable amount of growth in Maddy EMS Fund revenues from year-to-year, including which revenue sources to include and the proper distribution of funds. This effort is in response to requests from counties for technical assistance.

STATEWIDE COLLECTIONS

AND

DISTRIBUTIONS

Maddy Emergency Medical Services Fund
Statewide Collections and Distributions
FY 2014/2015

County	Establishment of Funds		Beginning Balance of Maddy Fund as of 1st day of Fiscal Year	Total Fines/ Forfeitures Collected by County	Penalty Assessments Collected & Deposited into Maddy EMS Fund by Statute										Total Maddy Funds Available for Distribution
					GC § 76000		GC § 76000.5		GC § 76000.5 (H&SC § 1797.98a(e))		GC § 76104		VC § 42007(e)		
	Maddy Fund	Richie's Fund			Collected	Deposited	Collected	Deposited	Collected	Deposited	Collected	Deposited	Collected	Deposited	
Alameda	Yes	Yes	$ 7,580,704.21	$ 3,982,607.00	$ -	$ -	$ 1,965,718.30	$ 1,965,718.30	$ 2,016,888.70	$ 2,016,888.70	$ -	$ -	$ -	$ -	$ 11,563,311.21
Alpine	Yes	No	$ -	$ 47,717.40	$ -	$ -	$ 47,717.40	$ 47,717.40	$ -	$ -	$ -	$ -	$ -	$ -	$ 47,717.40
Amador	Yes	No	$ 242,379.89	$ 162,106.54	$ -	$ -	$ -	$ -	$ -	$ -	$ 46,387.15	$ 47,403.99	$ -	$ -	$ 289,783.85
Butte	Yes	No	$ 21,528.54	$ 681,883.21	$ -	$ -	$ -	$ -	$ 245,627.61	$ 245,627.61	$ -	$ -	$ -	$ -	$ 269,287.81
Calaveras	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Colusa	Yes	Yes	$ 219,130.94	$ 366,959.51	$ -	$ -	$ 167,260.13	$ 158,912.40	$ -	$ -	$ -	$ -	$ -	$ -	$ 378,043.34
Contra Costa	Yes	Yes	$ 20,622.32	$ 4,244,581.30	$ 9,019,753.44	$ 848,986.44	$ 733,638.06	$ 717,283.63	$ 99,212.71	$ 99,212.71	$ -	$ -	$ 3,576,394.07	$ 547,103.04	$ 2,233,208.14
Del Norte	Yes	Yes	$ 24,923.71	$ -	$ -	$ -	$ -	$ -	$ 55,515.28	$ 55,515.28	$ 54,481.55	$ 54,481.55	$ -	$ -	$ 134,920.54
El Dorado	Yes	Yes	$ 330,788.69	$ 375,925.11	$ 194,173.36	$ 194,173.36	$ -	$ -	$ 178,751.75	$ 178,751.75	$ -	$ -	$ -	$ -	$ 703,713.80
Fresno	Yes	No	$ 2,137,656.00	$ 1,199,686.98	$ -	$ -	$ 916,898.00	$ 916,898.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,054,554.00
Glenn	Yes	No	$ 176,193.19	$ 70,815.78	$ 70,815.78	$ 71,984.25	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 248,177.44
Humboldt	Yes	Yes	$ 165,034.37	$ 364,775.41	$ 206,518.57	$ 206,518.57	$ -	$ -	$ 156,619.58	$ 159,619.58	$ -	$ -	$ -	$ -	$ 528,172.52
Imperial	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Inyo	Yes	Yes	$ 383,157.86	$ 622,178.85	$ -	$ -	$ 96,771.22	$ 96,771.22	Unknown	Unknown	$ 97,697.24	$ 97,697.24	$ -	$ -	$ 577,626.32
Kern	Yes	Yes	$ 1,094,538.54	$ 57,731,031.00	$ -	$ -	$ -	$ -	$ 196,947.10	$ 196,947.10	$ 1,497,909.52	$ 1,497,909.52	$ -	$ -	$ 2,789,395.16
Kings	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Lake	Yes	Yes	$ 44,151.67	Unknown*	$ 26,266.09	$ 26,084.06	$ -	$ -	$ 26,248.13	$ 26,125.74	$ -	$ -	$ 3,379.04	$ 3,379.04	$ 123,492.23
Lassen	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Los Angeles	Yes	Yes	$ 3,575,519.94	$ 44,393,629.84	$ 21,752,889.82	$ -	$ 7,477,541.90	$ 7,477,541.90	$ 1,319,633.21	$ 1,319,633.21	$ 8,701,151.45	$ 8,701,151.45	$ 5,895,701.40	$ 5,445,270.47	$ 26,519,116.97
Madera	Yes	No	$ 466,473.65	$ 182,461.71	$ 182,461.71	$ 182,461.71	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 648,935.36
Marin	Yes	Yes	$ 118,948.00	$ 771,535.88	$ -	$ -	$ -	$ -	$ 402,286.62	$ 402,286.62	$ 369,249.27	$ 369,249.27	$ -	$ -	$ 890,483.80
Mariposa	Yes	No	$ 234,943.45	$ 22,854.22	$ 11,929.90	$ 11,929.90	$ 8,638.90	$ 8,638.90	$ -	$ -	$ 2,285.42	$ 2,285.42	$ -	$ -	$ 257,797.60
Mendocino	Yes	Yes	$ 154,394.58	$ 237,256.48	$ 100,125.55	$ 100,125.55	$ -	$ -	$ 137,130.93	$ 137,130.93	$ -	$ -	$ -	$ -	$ 391,651.06
Merced	Yes	Yes	$ 270,925.40	$ 11,255,809.60	$ 803,994.95	$ 85,284.18	$ -	$ -	$ 3,733,673.88	$ 339,424.88	$ 3,200,700.47	$ 290,972.77	$ -	$ -	$ 986,607.23
Modoc	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Mono	Yes	No	$ 129,003.57	$ 68,282.55	$ 167,105.37	$ 41,876.61	$ -	$ -	$ -	$ -	$ 26,166.00	$ 26,166.00	$ -	$ -	$ 197,046.18
Monterey	Yes	No	$ 526,874.90	$ 911,525.41	$ -	$ -	$ 911,525.41	$ 911,525.41	$ -	$ -	$ -	$ -	$ -	$ -	$ 1,438,400.31
Napa	Yes	Yes	$ 111,433.00	$ 440,851.00	$ 219,677.00	$ 219,677.00	$ -	$ -	$ 221,174.00	$ 221,174.00	$ -	$ -	$ -	$ -	$ 552,284.00
Nevada	Yes	No	$ 140,617.18	$ 168,610.27	$ -	$ -	$ -	$ -	$ -	$ -	$ 168,610.27	$ 168,610.27	$ -	$ -	$ 309,227.45
Orange	Yes	Yes	$ 434,070.68	$ 11,961,126.36	$ 7,704,835.93	$ 3,498,876.60	$ 4,256,290.43	$ 3,002,812.90	$ -	$ 638,443.56	$ -	$ 1,331,671.33	$ -	$ -	$ 8,905,875.07

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* - Total deposit to MF (Lake: $123,492.23) (San Mateo: $2,266,148.86)

Maddy Emergency Medical Services Fund
Statewide Collections and Distributions
FY 2014/2015

County	Establishment of Funds		Beginning Balance of Maddy Fund as of 1st day of Fiscal Year	Total Fines/ Forfeitures Collected by County	Penalty Assessments Collected & Deposited into Maddy EMS Fund by Statute										Total Maddy Funds Available for Distribution
					GC § 76000		GC § 76000.5		GC § 76000.5 (H&SC § 1797.98a(e))		GC § 76104		VC § 42007(e)		
	Maddy Fund	Richie's Fund			Collected	Deposited	Collected	Deposited	Collected	Deposited	Collected	Deposited	Collected	Deposited	
Placer	Yes	Yes	$ 18,681.00	$ 711,803.00	$ -	$ -	$ 359,682.00	$ 359,682.00	$ 352,121.00	$ 352,121.00	$ -	$ -	$ -	$ -	$ 730,484.00
Plumas	Yes	No	$ 53.94	$ 29,257.30	$ -	$ -	$ 29,044.39	$ 29,044.36	$ -	$ -	$ 21,077.79	$ 21,077.79	$ -	$ -	$ 50,176.09
Riverside	Yes	Yes	$ -	$ 5,807,784.66	$ -	$ -	$ 2,912,789.00	$ 2,912,789.00	$ 2,894,995.66	$ 2,894,995.66	$ -	$ -	$ -	$ -	$ 5,807,784.66
Sacramento	Yes	No	$ -	$ 54,700,165.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 1,036,317.00	$ 1,017,768.00	$ 592,535.00	$ 592,535.00	$ 1,610,303.00
San Benito	Yes	Yes	$ 267,434.42	$ 141,956.21	$ 73,132.72	$ 73,132.72	$ -	$ -	$ 68,823.49	$ 68,823.49	$ -	$ -	$ -	$ -	$ 409,390.63
San Bernardino	Yes	Yes	$ 1,568.80	$ 3,907,043.70	$ -	$ -	$ -	$ -	$ 1,911,108.78	$ 1,911,108.78	$ 1,995,934.92	$ 1,995,934.92	$ -	$ -	$ 3,908,612.50
San Diego	Yes	Yes	$ 1,695,180.98	$ 28,573,590.53	$ 7,588,268.25	$ 3,128,950.00	$ 1,906,276.24	$ 1,902,819.00	$ 297,511.32	$ 296,973.00	$ 2,203,787.56	$ 2,199,792.00	$ 106,999.00	$ 106,999.00	$ 9,335,253.24
San Francisco	Yes	Yes	$ 1,340,016.00	$ 1,577,051.00	$ 793,142.00	$ 793,142.00	$ 675,009.00	$ 675,009.00	$ 108,900.00	$ 108,900.00	$ -	$ -	$ -	$ -	$ 2,917,067.00
San Joaquin	Yes	No	MD	$ 380,353.32	MD	MD	MD	MD	MD	MD	MD	MD	MD	MD	$ 380,353.32
San Luis Obispo	Yes	Yes	$ 301,789.38	$ 8,469,117.52	$ 338,478.57	$ 338,478.57	$ 383,010.76	$ 383,010.76	$ 58,499.13	$ 58,499.13	$ -	$ -	$ 100,548.39	$ 100,548.39	$ 1,182,326.23
San Mateo	Yes	Yes	$ 2,906,887.00	Unknown*	Unknown	Unknown	Unknown	Unknown	Unknown	$ 151,527.86	Unknown	Unknown	Unknown	Unknown	$ 5,173,035.86
Santa Barbara	Yes	Yes	$ 756,428.00	$ 21,603,705.66	$ 83,896.00	$ 41,948.00	$ 2,000,920.00	$ 400,184.00	$ 353,100.00	$ 70,620.00	$ 284,814.00	$ 142,407.00	$ -	$ -	$ 1,411,587.00
Santa Clara	Yes	No	$ 35,210.50	$ 2,091,536.03	$ 375,770.55	$ 375,770.55	$ 1,715,765.48	$ 1,715,765.48	$ -	$ -	$ -	$ -	$ -	$ -	$ 2,126,746.53
Santa Cruz	Yes	Yes	MD	$ 211,935.51	MD	MD	MD	MD	MD	MD	MD	MD	MD	MD	$ 610,002.09
Shasta	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Sierra	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Siskiyou	Yes	No	$ 181,887.73	$ 181,887.73	$ -	$ -	$ 142,320.69	$ 142,320.69	$ -	$ -	$ -	$ -	$ -	$ -	$ 324,208.42
Solano	Yes	No	$ 227,439.94	$ 848,561.92	$ -	$ -	$ -	$ -	$ -	$ -	$ 305,389.73	$ 305,389.73	$ -	$ -	$ 532,829.67
Sonoma	Yes	Yes	$ 580,414.00	$ 1,103,785.55	$ 1,017,986.64	$ 1,017,986.64	$ -	$ -	$ 85,798.91	$ 85,798.91	$ -	$ -	$ -	$ -	$ 1,684,199.55
Stanislaus	Yes	Yes	$ 552,717.00	$ 823,524.00	$ -	$ -	$ -	$ -	$ 139,283.00	$ 139,283.00	$ -	$ -	$ 688,132.00	$ 688,132.00	$ 1,380,132.00
Sutter	Yes	No	$ 623,506.26	$ 124,737.94	$ -	$ -	$ -	$ -	$ -	$ -	$ 124,737.94	$ 124,737.94	$ -	$ -	$ 748,244.20
Tehama	No	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Trinity	Yes	No	$ 64,891.50	$ 21,338.93	$ 21,338.93	$ 21,338.93	$ -	$ -	$ -	$ -	$ -	$ -	$ 35,018.80	$ -	$ 86,230.43
Tulare	Yes	Yes	$ 4,752.53	$ 7,712,352.99	$ 273,196.04	$ 253,008.40	$ -	$ -	$ 711,198.06	$ 647,750.14	$ -	$ -	$ -	$ -	$ 900,758.54
Tuolumne	Yes	No	$ 2,755.84	$ 78,749.79	$ 78,749.79	$ 78,749.79	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 81,505.63
Ventura	Yes	Yes	$ 2,148,666.51	$ 2,384,027.19	$ -	$ -	$ 932,456.84	$ 839,157.10	$ 393,394.35	$ 354,032.11	$ 810,409.20	$ 729,321.30	$ 247,766.80	$ 222,975.76	$ 4,294,152.78
Yolo	Yes	Yes	$ 3,185,828.00	$ 1,130,817.13	$ 149,816.65	$ 149,816.65	$ -	$ -	$ 728,196.48	$ 728,196.48	$ 252,804.00	$ 252,804.00	$ -	$ -	$ 4,316,645.13
Yuba	Yes	Yes	$ 127,743.27	$ 228,284.18	$ -	$ -	$ 92,219.84	$ 92,219.84	$ 16,274.09	$ 16,274.09	$ 119,790.25	$ 119,790.25	$ -	$ -	$ 356,027.45
Totals			$ 33,627,866.88	$ 283,107,578.20	$ 51,254,323.61	$ 11,760,300.48	$ 27,731,493.99	$ 24,755,821.29	$ 16,908,913.77	$ 13,921,685.32	$ 21,319,700.73	$ 19,496,621.74	$ 11,246,474.50	$ 7,706,942.70	$ 114,396,884.74

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Unknown = Court/county breakdown not available
* - Total deposit to MF (Lake: $123,492.23) (San Mateo: $2,266,148.86)

Maddy Emergency Medical Services Fund
Statewide Collections and Distributions
FY 2014/2015

County	Distribution of Maddy EMS Funds by Category						Total Maddy Funds Available at end of FY	Reimbursements							
								Physicians/Surgeons				Hospitals			
	County Administration Cost	County Reserve	Physicians/ Surgeons	Hospitals	EMS	Richie's Fund		Available Funds	Total Allowable Claims Submitted	Total Allowable Claims Reimbursed	% of Claims Reimbursed	Available Funds	Total Allowable Claims Submitted	Total Allowable Claims Reimbursed	% of Claims Reimbursed
Alameda	$ 383,056.40	$ -	$ 2,000,428.86	$ 244,999.99	$ 585,135.18	$ 1,000,000.00	$ 7,349,690.78	$ 3,723,232.41	$ 3,675,800.00	$ 2,076,827.00	57%	$ 3,796,038.07	N/A	N/A	N/A
Alpine	$ -	$ -	$ -	$ -	$ 47,717.40	N/A	$ -	$ -	$ -	$ -	0%	$ -	N/A	N/A	N/A
Amador	$ 4,362.02	$ -	$ 37,070.82	$ -	$ 6,268.01	N/A	$ 242,083.00	$ 64,799.31	$ 287,083.62	$ 37,070.82	13%	$ 126,513.20	N/A	N/A	N/A
Butte	$ 24,781.04	$ -	$ 129,357.03	$ 55,757.35	$ 37,914.99	N/A	$ 21,477.40	$ 129,357.03	$ 517,175.10	$ 129,357.03	25%	$ 55,757.35	$ 2,354,289.56	$ 55,757.35	2%
Calaveras	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Colusa	$ 15,703.64	$ -	$ 50,461.07	$ 30,000.00	$ 36,609.14	$ -	$ 245,269.49	$ 166,935.07	$ 207,420.00	$ 50,461.07	24%	$ 96,375.18	N/A	N/A	N/A
Contra Costa	$ 137,844.16	$ -	$ 1,017,485.81	$ 310,148.70	$ 210,901.10	$ -	$ 556,828.37	$ 1,103,463.56	$ 1,047,460.04	$ 1,047,460.04	100%	$ 475,615.75	N/A	N/A	N/A
Del Norte	$ 5,470.40	$ -	$ 60,754.86	$ -	$ 8,382.33	$ 55,515.28	$ 4,797.67	$ 96,004.29	$ 1,116,951.00	$ 96,004.29	9%	$ -	N/A	N/A	N/A
El Dorado	$ -	$ -	$ 185,745.81	$ 80,062.85	$ 58,191.44	$ 30,000.00	$ 349,713.70	$ 185,745.80	$ 185,745.80	$ 185,745.80	100%	$ 80,062.85	$ 80,062.85	$ 80,062.85	100%
Fresno	$ 86,011.00	$ -	$ 1,081,473.00	$ 231,782.00	$ 90,911.00	N/A	$ 1,564,377.00	$ 2,288,553.00	$ 20,378,584.00	$ 1,081,473.00	5%	$ 421,427.00	N/A	N/A	N/A
Glenn	$ 7,081.58	$ -	$ 37,920.54	$ 16,060.79	$ 10,921.34	N/A	$ 176,193.19	$ 37,920.54	$ 62,867.50	$ 37,920.54	60%	$ 16,060.79	N/A	N/A	N/A
Humboldt	$ 36,422.42	$ -	$ 426.26	$ -	$ -	$ 144,446.25	$ 325,733.96	$ 159,016.85	$ 683.00	$ 426.26	62%	$ 68,358.01	N/A	N/A	N/A
Imperial	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Inyo	$ 27,113.00	$ -	$ 195,175.59	$ 85,882.46	$ 51,533.55	Unknown	$ 217,921.72	$ 195,175.59	$ 195,175.59	$ 195,175.59	100%	$ 85,882.46	$ 85,882.46	$ 85,882.46	100%
Kern	$ 169,959.17	$ -	$ 771,475.43	$ 397,984.93	$ 255,015.39	$ 29,542.07	$ 1,165,418.17	$ 870,052.48	$ 771,475.43	$ 771,475.43	100%	$ 375,022.62	N/A	N/A	N/A
Kings	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Lake	$ 12,854.20	$ -	$ 86,786.74	$ -	$ 18,131.86	$ 8,766.94	$ 41,104.16	$ 86,786.74	$ 1,670,362.00	$ 86,786.74	5%	$ 25,652.81	$ -	$ -	0%
Lassen	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Los Angeles	$ 2,294,359.69	$ -	$ 10,755,332.75	$ 3,370,904.00	$ 3,216,234.15	$ 1,730,212.68	$ 5,152,073.73	$ 11,031,332.72	$ 61,206,194.70	$ 10,755,332.72	18%	$ 9,977,190.41	$ 3,370,904.00	$ 3,370,904.00	100%
Madera	$ 25,492.00	$ 39,187.92	$ 105,367.29	$ 45,887.95	$ 137,950.00	N/A	$ 295,050.20	$ 105,367.29	$ 1,580,420.80	$ 1,580,420.80	100%	$ 45,887.95	N/A	N/A	N/A
Marin	$ 77,153.59	$ -	$ 368,339.83	$ 158,509.83	$ 107,786.68	$ 44,530.12	$ 134,163.81	$ 446,241.94	$ 1,220,438.00	$ 368,339.83	30%	$ 158,509.83	N/A	N/A	N/A
Mariposa	$ 2,000.00	$ -	$ 70,000.00	$ 4,000.00	$ -	N/A	$ 181,797.67	$ 236,785.77	$ 70,000.00	$ 70,000.00	100%	$ 5,896.45	$ 1,701,113.00	$ 4,000.00	0%
Mendocino	$ 23,950.76	$ 32,695.79	$ 111,774.44	$ 48,195.34	$ -	$ 20,640.15	$ 154,394.58	$ 111,774.45	$ 197,578.22	$ 111,774.45	57%	$ 48,195.34	$ 99,890.68	$ 48,195.34	48%
Merced	$ 36,876.36	$ -	$ 327,810.18	$ 85,137.65	$ 147,623.59	$ 46,348.77	$ 342,810.68	$ 400,249.60	$ 3,742,783.00	$ 3,742,873.00	100%	$ 145,804.41	N/A	N/A	N/A
Modoc	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Mono	$ -	$ -	$ 91,443.16	$ 25,099.82	$ 15,765.15	$ -	$ 64,738.05	$ 99,726.95	$ 194,720.00	$ 91,443.16	47%	$ 42,985.75	$ 949,343.89	$ 25,099.82	3%
Monterey	$ 91,152.54	$ -	$ 570,441.54	$ 205,093.22	$ 139,463.39	N/A	$ 432,249.62	$ 1,438,400.31	$ 1,140,882.00	$ 570,441.54	50%	$ 1,438,400.31	N/A	N/A	N/A
Napa	$ 44,085.00	$ 68,211.00	$ 222,500.00	$ 100,380.00	$ -	$ 29,858.00	$ 87,250.00	$ 255,694.00	$ 247,684.00	$ 247,684.00	100%	$ 100,380.00	N/A	N/A	N/A
Nevada	$ 1,005.31	$ -	$ 85,391.08	$ 39,475.45	$ 60,835.00	N/A	$ 122,520.61	$ 85,391.08	$ 302,775.00	$ 85,391.08	28%	$ 39,475.45	$ 2,255,259.37	$ 39,475.45	2%
Orange	$ 317,380.27	$ -	$ 4,236,456.68	$ 1,934,289.90	$ 1,741,107.44	$ 628,048.44	$ 48,592.25	$ 4,238,286.19	$ 10,262,963.03	$ 10,262,963.03	100%	$ 2,609,101.17	N/A	N/A	N/A

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Maddy Emergency Medical Services Fund
Statewide Collections and Distributions
FY 2014/2015

County	Distribution of Maddy EMS Funds by Category						Total Maddy Funds Available at end of FY	Reimbursements							
								Physicians/Surgeons				Hospitals			
	County Administration Cost	County Reserve	Physicians/ Surgeons	Hospitals	EMS	Richie's Fund		Available Funds	Total Allowable Claims Submitted	Total Allowable Claims Reimbursed	% of Claims Reimbursed	Available Funds	Total Allowable Claims Submitted	Total Allowable Claims Reimbursed	% of Claims Reimbursed
Placer	$ 7,324.84	$ 161,903.77	$ 353,265.18	$ 9,024.32	$ 116,231.06	$ 28,366.00	$ 54,368.83	$ 381,631.00	$ 1,013,170.85	$ 381,631.00	38%	$ 170,928.09	$ 115,198.00	$ 9,024.00	8%
Plumas	$ 4,013.38	$ -	$ 26,769.27	$ 11,538.48	$ 7,846.16	N/A	$ 8.80	$ 26,769.27	$ 174,935.06	$ 26,769.27	15%	$ 11,538.48	$ 529,509.10	$ 11,537.80	2%
Riverside	$ 580,778.47	$ -	$ 2,779,798.97	$ 1,198,189.21	$ 814,768.66	$ 434,249.35	$ -	$ 2,779,798.97	$ 2,779,798.97	$ 2,779,798.97	100%	$ 1,632,438.56	N/A	N/A	N/A
Sacramento	$ 161,030.00	$ -	$ 808,188.00	$ 362,318.00	$ 246,376.00	N/A	$ 32,391.00	$ 840,578.00	$ 11,087,726.00	$ 808,188.00	7%	$ 362,318.00	N/A	N/A	N/A
San Benito	$ 14,195.61	$ -	$ 51,179.03	$ 13,451.27	$ 20,139.80	$ 25,878.30	$ 284,546.62	$ 281,113.05	$ 51,179.03	$ 51,179.03	100%	$ 36,431.21	N/A	N/A	N/A
San Bernardino	$ 390,861.28	$ -	$ 1,890,594.15	$ 814,911.19	$ 554,139.68	$ 258,106.20	$ -	$ 2,040,262.28	$ 1,707,194.71	$ 1,707,194.71	100%	$ 880,939.36	N/A	N/A	N/A
San Diego	$ 764,412.00	$ -	$ 3,818,022.00	$ 1,645,811.00	$ 1,118,326.52	$ 298,458.00	$ 1,690,706.72	$ 3,835,522.30	$ 34,822,756.66	$ 3,763,885.56	11%	$ 1,643,751.75	N/A	N/A	N/A
San Francisco	$ 158,227.00	$ 27,442.00	$ 607,002.00	$ 290,938.00	$ 191,330.00	$ 99,000.00	$ 1,543,128.00	$ 634,444.00	$ 634,444.00	$ 634,444.00	100%	$ 290,938.00	N/A	N/A	N/A
San Joaquin	$ -	MD	$ 202,191.38	$ -	$ -	N/A	$ 1,909,507.61	$ 250,863.18	$ 5,023,597.70	MD	MD	MD	MD	MD	MD
San Luis Obispo	$ 49,095.52	$ -	$ 399,409.15	$ 149,096.53	$ 131,517.23	$ 49,105.67	$ 404,102.13	$ 492,625.71	$ 2,042,378.00	$ 492,625.71	24%	$ 222,681.57	N/A	N/A	N/A
San Mateo	$ 438,865.00	$ -	$ 1,163,297.00	$ 503,378.00	$ 235,156.00	$ 150,000.00	$ 2,682,339.86	$ 1,163,297.00	$ 4,240,615.00	$ 1,163,297.00	27%	$ 503,378.00	N/A	N/A	N/A
Santa Barbara	$ 53,850.00	$ -	$ 326,221.00	$ 125,288.00	$ 86,997.00	$ -	$ 819,231.00	$ 401,045.00	$ 5,655,720.00	$ 326,221.00	6%	$ 213,855.00	$ 1,947,276.00	$ 125,288.00	6%
Santa Clara	$ 130,416.41	$ -	$ 1,255,529.61	$ 440,952.68	$ 299,847.83	N/A	$ -	$ 1,255,529.61	$ 23,605,743.25	$ 1,255,529.61	5%	$ 440,952.68	N/A	N/A	N/A
Santa Cruz	$ -	MD	$ 189,114.62	$ 148,875.00	$ -	MD	$ 272,012.47	$ (85,698.68)	$ 2,263,509.00	MD	MD	$ 151,132.46	MD	MD	MD
Shasta	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Sierra	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Siskiyou	$ 11,216.81	$ -	$ 41,741.30	$ 26,103.80	$ 26,529.09	N/A	$ 218,617.42	$ 165,469.03	$ 173,340.39	$ 41,741.30	24%	$ 77,700.19	$ 358,864.06	$ 9,292.92	3%
Solano	$ 28,309.28	$ -	$ 158,677.45	$ -	$ 46,508.91	N/A	$ 299,334.03	$ 158,677.45	$ 6,229,429.33	$ 158,677.42	3%	$ 224,290.60	$ -	$ -	0%
Sonoma	$ 102,657.65	$ 30,407.23	$ 486,109.51	$ 209,529.97	$ 112,073.15	$ 43,473.00	$ 699,949.04	$ 486,109.51	$ 3,988,195.00	$ 3,988,195.00	100%	$ 200,734.25	N/A	N/A	N/A
Stanislaus	$ 259,002.00	$ -	$ 572,797.00	$ 148,923.00	$ -	$ 160,888.00	$ 238,522.00	$ 759,856.00	$ 14,749,027.00	$ 422,013.00	3%	$ 359,207.00	$ 5,789,896.00	$ 202,884.00	4%
Sutter	$ 13,136.76	$ -	$ 61,218.35	$ 28,063.80	$ 20,099.24	N/A	$ 625,726.05	$ 129,966.16	$ 767,896.00	$ 61,218.35	8%	$ 28,063.80	N/A	N/A	N/A
Tehama	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Trinity	$ 2,133.89	$ 11,656.41	$ 54.82	$ 4,745.53	$ 2,099.60	N/A	$ 65,540.18	$ 61,565.60	$ -	$ -	0%	$ 4,745.53	$ 4,745.53	$ 4,745.53	100%
Tulare	$ 72,328.16	$ -	$ 425,274.31	$ 183,307.89	$ 119,528.34	$ 99,951.35	$ 5,121.02	$ 500,840.31	$ 453,590.59	$ 453,590.59	100%	$ 202,649.91	$ 2,603,260.91	$ 197,704.79	8%
Tuolumne	$ 8,135.00	$ -	$ 42,464.17	$ 18,303.00	$ 12,446.00	N/A	$ 157.46	$ 42,544.00	$ 228,670.00	$ 42,464.00	19%	$ 18,338.00	N/A	N/A	N/A
Ventura	$ 630,588.00	$ -	$ 1,041,154.78	$ 454,005.00	$ 632,597.86	$ 161,040.00	$ 1,374,767.14	$ 1,041,154.78	$ 2,874,565.41	$ 1,041,154.78	36%	$ 454,005.00	N/A	N/A	N/A
Yolo	$ 1,557.00	$ -	$ 201,527.00	$ -	$ -	$ 642,199.78	$ 3,471,361.35	$ 618,053.00	$ 2,257,824.00	$ 201,527.00	9%	$ 2,459,304.00	$ 642,499.78	$ 642,199.78	100%
Yuba	$ 13,976.03	$ 16,909.90	$ 94,658.65	$ -	$ 40,946.00	$ 19,119.52	$ 170,417.35	$ 170,037.03	$ 441,940.93	$ 117,739.24	27%	$ 84,594.61	$ -	$ -	0%
Totals	$ 7,720,224.64	$ 388,414.02	$ 39,595,677.47	$ 14,256,405.90	$ 11,819,902.26	$ 6,237,743.87	$36,138,105.89	$ 45,988,346.53	$ 237,550,468.71	$ 53,601,931.76	47%	$ 30,909,509.21	$ 22,887,995.19	$ 4,912,054.09	31%

MD = Missing data on report
^ = Old form used
N/A = No fund established and/or hospital funds not dispersed on claims basis
Unknown = Court/county breakdown not available
* - Total deposit to MF (Lake: $123,492.23) (San Mateo: $2,266,148.86)

COUNTY CONTACTS

Maddy EMS Fund – County Contact List

County	*Agency*	*Maddy EMS Fund*	*Richie's Fund*	*Primary Contact Name*	*Email*	*Phone*	*Address*
Alameda	Public Health	x	x	Binh Cao, Director	binh.cao@acgov.org	(510) 267-8068	1000 San Leandro Blvd., Ste. 200 San Leandro, CA 94577
Alpine	Finance	x	None	Janet Dutcher, CGFM, CPA, Assistant CAO to Budget/Finance	jdutcher@alpinecountyca.gov	(530) 694-1307	P. O. Box 266 Markleeville, CA 96120
Amador	Health and Human Services	x	None	James Foley, Director	jfoley@amadorgov.org	(209) 223-6625	18077 Conductor Blvd., Ste. 400 Sutter Creek, CA 95685
Butte	Public Health	x	None	Jodi Nicholas, Fiscal Manager	jnicholas@buttecounty.net	(530) 538-7581	202 Mira Loma Dr. Oroville, CA 95965
Calaveras	Health and Human Services	None	None	Mary Sawicki, Director	msawicki@co.calaveras.ca.us	(209) 754-6445	509 East Saint Charles St. San Andreas, CA 95249
Colusa	Health and Human Services	x	x	Bonnie Davies, Director	bdavies@colusadhhs.org	(530) 458-0266	251 East Webster St. Colusa, CA 95932
Contra Costa	Health Services	x	x	Patrick Godley, COO/CFO	patrick.godley@hsd.cccounty.us	(925) 957-5405	50 Douglas Dr., Ste. 310-C Martinez, CA 94553
Del Norte	Health and Human Services	x	x	Sei Thao, Fiscal Manager	SThao@co.del-norte.ca.us	(707) 464-0860 ext. 2564	455 K St. Crescent City, CA 95531
El Dorado	EMS	x	x	Richard Todd, EMS Administrator	richard.todd@edcgov.us	(530) 621-2758	2900 Fair Lane Ct. Placerville, CA 95667
Fresno	Public Health	x	None	Evelyn Reimer, Business Manager	ereimer@co.fresno.ca.us	(559) 600-6438	P.O. Box 11867 Fresno, CA 93775
Glenn	Tax Collector	x	None	Humberto Medina, Assistant Director of Finance	hmedina@countyofglenn.net	(530) 934-6476	516 West Sycamore St. Willows, CA 95988
Humboldt	Health and Human Services	x	x	Olivia Wilder, Budget Specialist	owilder@humboldt.ca.us.gov	(707) 441-5435	529 I Street, Eureka, CA 95501
Imperial	EMS	None	None	Christopher Herring, EMS Administrator	christopherherring@co.imperial.ca.us	(442) 265-1364	935 Broadway Ave. El Centro, CA 92243
Inyo	Health and Human Services	x	x	Jean Turner, Director	jturner@inyocounty.us	(760) 873-3305	163 May St. Bishop, CA 93514
Kern	EMS	x	x	Edward Hill, EMS Director	hille@co.kern.ca.us	(661) 321-3000	1800 Mount Vernon Ave. Bakersfield, CA 93306
Kings		None	None				

Maddy EMS Fund – County Contact List

Lake	Health Service	x	x	Cindy Silva-Brackett	Cindy.silva-brackett@lakecountyca.gov	(707) 263-1090 ext. 151	922 Bevins Ct. Lakeport, CA 95453
Lassen	Health and Social Services	None	None	Melody Brawley, Director	mbrawley@co.lassen.ca.us	(530) 251-8134	1445 Paul Bunyan Rd. Susanville, CA 96130
Los Angeles	EMS	x	x	Cathy Chidester, EMS Director	cchidester@dhs.lacounty.gov	(562) 347-1604	10100 Pioneer Blvd., Ste. 200 Santa Fe Springs, CA 90670
Madera	Public Health	x	None	Mary George-Solorio, Fiscal Manager	mary.solorio@co.madera.ca.gov	(559) 675-7893	14215 Road 28 Madera, CA 93638
Marin	Health and Human Services	x	x	Kam Lam, Accountant I	klam@marincounty.org	(415) 473-2739	20 North San Pedro Rd. San Rafael, CA 94903
Mariposa	Health	x	None	Diane Robarge, Accountant II	drobarge@mariposacounty.org	(209) 966-3686 ext. 116	5085 Bullion St. / P.O. Box 5 Mariposa, CA 95338
Mendocino	Health and Social Services	x	x	Mary Alice Willeford	willeform@co.mendocino.ca.us	(707) 472-2374	1120 South Dora St. Ukiah, CA 95482
Merced	Public Health	x	x	Karl Stahlhut, Staff Services Analyst	kstahlhut@co.merced.ca.us	(209) 381-1271	260 East 15th St. Merced, CA 95341
Modoc		None	None	Chester Robertson, CAO	cao@co.modoc.ca.us	(530) 233-7660	204 South Court St., Ste. 100 Alturas, CA 96101
Mono	Public Health	x	None	Lynda Salcido, Interim Administrative Officer	lsalcido@mono.ca.gov	(760) 924-1830	P.O. Box 3329, Mammoth Lakes, CA 93546
Monterey	EMS	x	None	Mike Petrie, EMS Director	PetrieM@co.monterey.ca.us	(831) 883-7555	1441 Shilling Pl. Salinas, CA 93901
Napa	Public Health	x	x	Karina Gallegos-Ruiz, Fiscal Analyst	karina.gallegos-ruiz@countyofnapa.org	(707) 253-6099	2261 Elm St, Bldg. K Napa, CA 94559
Nevada	Health and Human Services	x	None	Jill Blake, Director	public.health@co.nevada.ca.us	(530) 265-1450	950 Maidu Ave. Nevada City, CA 95959
Orange	Health Care Agency	x	x	Melissa Tober, Special Projects Manager	mtober@ochca.com	(714) 834-5891	405 West 5th St, Rm 710 Santa Ana, CA 92701
Placer	Health and Human Services	x	x	Jeffrey Brown, Director	jbrown@placer.ca.gov	(530) 886-1870	P.O. Box 20400 Auburn, CA 95604
Plumas	Treasurer - Tax Collector	x	None	Julie White, Treasure/Tax Collector Administrator	juliewhite@countyofplumas.com	(530) 283-6410	P.O. Box 176 Quincy, CA 95971

Maddy EMS Fund – County Contact List

Riverside	EMS Agency	x	x	Bruce Barton, EMS Administrator	bbarton@rivcocha.org	(951) 358-5029	4210 Riverwalk Way, Ste. 300 Riverside, CA 92505
Sacramento	Health and Human Services	x	None	Maryann Luke, Fiscal Services Chief	LukeM@SacCounty.net	(916) 875-1976	7001-A East Pkwy, Ste. 1100 F Sacramento, CA 95823
San Benito	Office of Emergency Services	x	x	Kevin O'Neill, Director	koneill@cosb.us	(831) 636-4168	439 Fourth St. Hollister, CA 95023
San Bernardino	EMS	x	x	Tom Lynch, EMS Administrator	tom.lynch@cao.sbcounty.gov	(909) 388-5830	1425 South 'D' St. San Bernardino, CA 92415
San Diego	Health and Human Services	x	x	Nick Macchione, FACHE, Director	nick.macchione@sdcounty.ca.gov	(619) 285-6502	6255 Mission Gorge Rd MS S-555 San Diego, CA 92120
San Francisco	Public Health	x	x	Josh Nossiter, Director of Finance & Operations	joshua.nossiter@sfdph.org	(415) 558-4037	30 Van Ness Ave., Ste. 260 San Francisco, CA 94102
San Joaquin	EMS	x	None	Dan Burch, EMS Administrator	dburch@sjgov.org	(209) 468-2827	P.O. Box 220 French Camp, CA 95231
San Luis Obispo	Public Health	x	x	Michael Taylor, Accountant	mtaylor@co.slo.ca.us	(805) 781-4876	2180 Johnson Ave. San Luis Obispo, CA 93401
San Mateo	Health	x	x	Michael Leach, EMS Performance Measure Analyst	mleach@smcgov.org	(650) 573-3768	225 37th Ave San Mateo, CA 94403
Santa Barbara	EMS	x	x	John Eaglesham, EMS Director	john.eaglesham@sbcphd.org	(805) 681-5274	300 North San Antonio Rd. Santa Barbara, CA 93110
Santa Clara	Health and Hospital System	x	None	Jackie Lowther, EMS Director	jackie.lowther@hhs.sccgov.org	(408) 792-1350	751 South Bascom Ave. San Jose, CA 95128
Santa Cruz	Health Services Agency	x	x	Giang Nguyen, RN, MSN, Director	giang.nguyen@co.santa-cruz.ca.us	(831) 454-4000	1000 Emeline Ave., Bldg. D Santa Cruz, CA 95060
Shasta		None	None	Donnell Ewert, Director	dewert@co.shasta.ca.us	(530) 229-8400	2650 Breslauer Way Redding, CA 96001
Sierra		None	None	Darden Bynum, Director	darden.bynum@sierracounty.ca.gov	(530) 993-6700	202 Front St. / P.O. Box 7 Loyalton, CA 96118
Siskiyou	Public Health	x	None	Terri Funk, Director	tfunk@co.siskiyou.ca.us	(530) 841-2140	818 South Main St. Yreka, CA 96097
Solano	Health and Social Services	x	None	Connie Pettersen, Policy and Financial Manager	clpettersen@solanocounty.com	(707) 784-8524	275 Beck Ave MS 5-220 Fairfield, CA 94533

Maddy EMS Fund – County Contact List

Sonoma	Health Services	x	x	Rachel Sweet, Accountant II	rachel.sweet@sonoma-county.org	(707) 565-4898	3324 Chanate Rd. Santa Rosa, CA 95404
Stanislaus	Health Services	x	x	Maria Blanco, Manager	mblanco@schsa.org	(209) 525-4802	830 Scenic Dr. / P.O. Box 3271 Modesto, CA 95353
Sutter	Human Services	x	None	Ed Smith, Interim Director	pgivans@co.sutter.ca.us	(530) 822-7215	1445 Veterans Memorial Cir. Yuba City, CA 95993
Tehama		None	None				
Trinity	Auditor Controller's Office	x	None	Christine Gaffney, Accountant I	cgaffney@trinitycounty.org	(530) 623-8382	11 Court St., Rm 230 / P.O. Box 1613 Weaverville, CA 96093
Tulare	Public Health	x	x	Melinda Gann, Accountant	MGann@tularehhsa.org	(559) 624-8435	5957 South Mooney Blvd. Visalia, CA 93277
Tuolumne	Auditor-Controller's Office	x	None	Jessica Tucker, Senior Accountant	jtucker@co.tuolumne.ca.us	(209) 533-6593	2 South Green St. Sonora, CA 95370
Ventura	EMS	x	x	Steve Carroll, EMS Administrator	steve.carroll@ventura.org	(805) 981-5305	2220 East Gonzales Rd, Suite 200 Oxnard, CA 93036
Yolo	EMS	x	x	Kristin Weivoda, EMS Administrator	kweivoda@yolocounty.org	(530) 666-8671	137 North Cottonwood St., Ste. 2601 Woodland, CA 95695
Yuba	Health and Human Services	x	x	Jennifer Vasquez, Director	jvasquez@co.yuba.ca.us	(530) 749-6358	5730 Packard Ave. / P.O. Box 2320 Marysville, CA 95901

REPORT SUBMITTAL BY COUNTY

(EMSA 801)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Alameda County

Fiscal Year Reported: FY14-15 **Date Submitted:** 03/03/2016

A. FINES AND FORFEITURES COLLECTED (Note: A1 reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 3,982,607.00
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	1,965,718.30	$ 1,965,718.30
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	2,016,888.70	$ 2,016,888.70
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	3,982,607.00	$ 3,982,607.00

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 3,982,607.00
   If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Alameda County Public Health Department
   Contact: Binh Cao Telephone: 510-267-8054
   Title: Administrative Services Director Email: binh.cao@acgov.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Alameda County Public Health Department
   Contact: Binh Cao Telephone: 510-267-8054
   Title: Administrative Services Director Email: binh.cao@acgov.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** ***(Note: Include interest earned)*** $ 7,580,704.21
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** ***(Note: Data from A3)*** $ 3,982,607.00
3. **Total Maddy EMS Funds available for disbursement.** ***(Note: B1 + B2)*** $ 11,563,311.21
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 383,056.40
b. Other Emergency Medical Services* Discretionary	$ 585,135.18
c. Hospitals	$ 244,999.89
d. Physicians/Surgeons	$ 2,000,426.86
e. ~~Reserve~~ Richie Fund	$ 1,000,000.00
f. Totals	$ 4,213,620.43

5. **Maddy EMS Fund disbursements during fiscal year being reported.** ***(Note: Data from B4f)*** $ 4,213,620.43
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** ***(Note: B3 - B5)*** $ 7,349,690.78
   If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Alameda County

Fiscal Year Reported: FY14-15 **Date Submitted:** 03/03/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 12/09/2008

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 3,723,232.41
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	34,564	$ 15,162,453.00	100%
b. Allowable Claims Submitted	28,286	$ 3,676,800.00	82%
c. Allowable Claims Reimbursed	28,286	$ 2,076,827.00	100%

This is slightly different from actual disbursement 4 The difference is due to reimbursement payments from physicians / hospitals.

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Alameda County Public Health Department
Contact: Binh Cao Telephone: 510-267-8054
Title: Administrative Services Director Email: binh.cao@acgov.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 3,796,038.07
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Alameda County Public Health Department
Contact: Binh Cao Telephone: 510-267-8054
Title: Administrative Services Director Email: binh.cao@acgov.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Alpine County

Fiscal Year Reported: 2014/2015 **Date Submitted:** 02/22/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 47,717.40
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	$ 47,717.40	$ 47,717.40
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 47,717.40	$ 47,717.40

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 47,717.40 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Alpine County Superior Courts
   Contact: Annie Long Telephone: 530-694-2213
   Title: Court Executive Officer Email: along@alpine.courts.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Alpine County
   Contact: Janet Dutcher Telephone: 530-694-2284
   Title: Assistant CAO to Budget & Finance Email: jdutcher@alpinecountyca.gov

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)*
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 47,717.40
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 47,717.40 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	
b. Other Emergency Medical Services*	$ 47,717.40
c. Hospitals	
d. Physicians/Surgeons	
e. Reserve	
f. Totals	$ 47,717.40 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 47,717.40
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 0.00 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Alpine County

Fiscal Year Reported: 2014/2015 **Date Submitted:** 02/22/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.**
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

3. **Please confirm the following required documents are attached to this report:**
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity:
Contact: Telephone:
Title: Email:

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.**
2. **Are funds disbursed to hospitals on a claims basis?** ***(Note: If no, go to E4.)*** ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: N/A
Contact: Telephone:
Title: Email:

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: AMADOR

Fiscal Year Reported: 2014/2015 **Date Submitted:** 4/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 162,106.54

2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited	
a. Government Code Section 76000	$ -	$ -	
b. Government Code Section 76000.5	$ -	$ -	
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ -	$ -	
d. Government Code Section 76104	$ 46,387.15	$ 47,403.99	Includes interest
e. Vehicle Code Section 42007 (e)	$ -	$ -	
f. Totals	$ 46,387.15	$ 47,403.99	

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 47,403.99 ✓

** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**

Entity: Amador County Superior Court
Contact: Rob Klotz — Telephone: 209-257-2681
Title: Amador Superior Court CEO — Email: rklotz@amadorcourt.org

5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**

Entity: Amador County Auditor
Contact: Tacy Oneto Rouen — Telephone: 209-223-6363
Title: Auditor — Email: trouen@amadorgov.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 242,379.86
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 47,403.99
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 289,783.85 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 4,362.02
b. Other Emergency Medical Services*	$ 6,268.01
c. Hospitals	$ -
d. Physicians/Surgeons	$ 37,070.82
e. Reserve	$ -
f. Totals	$ 47,700.85 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 47,700.85 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 242,083.00 ✓

** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: AMADOR

Fiscal Year Reported: 2014/2015 **Date Submitted:** 4/15/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ☐ Yes ☑ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** **$ 64,799.31**
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	72	$ 287,083.62	100%
b. Allowable Claims Submitted	72	$ 287,083.62	100%
c. Allowable Claims Reimbursed	72	$ 37,070.82	100%

3. **Please confirm the following required documents are attached to this report:**

☐ Descriptions of the physician and surgeon claim payment methodologies
☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Amador County Public Health
Contact: Debbie Staniford Telephone: 209-223-6407
Title: Admin & Fiscal Supervisor Email: dstaniford@amadorgov.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** **$ 126,513.20**
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ☐ Yes ☑ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	0	$ -	
b. Allowable Claims Submitted	0	$ -	
c. Allowable Claims Reimbursed	0	$ -	

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Amador County Public Health
Contact: Debbie Staniford Telephone: 209-223-6407
Title: Admin & Fiscal Supervisor Email: dstaniford@amadorgov.org

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Butte

Fiscal Year Reported: 2014-15 Date Submitted: 4/4/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 681,883.21
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$ -	$ -
b. Government Code Section 76000.5	$ -	$ -
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 245,627.61	$ 245,627.61
d. Government Code Section 76104	$ -	$ -
e. Vehicle Code Section 42007 (e)	$ -	$ -
f. Totals	$ 245,627.61	$ 245,627.61

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 245,627.61
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
   Entity: Superior Courst of California, County of Butte
   Contact: Jarrod Orr Telephone: 530-532-7208
   Title: Deputy Court Executive Officer Email: jorr@buttecourt.ca.gov
5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
   Entity: Butte County Auditor Controller Office
   Contact: Annie Liu Telephone: 530-538-6676
   Title: Manager, Governmental Accounting Email: aliu@buttecounty.net

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 21,528.54
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 247,759.27
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 269,287.81
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 24,781.04
b. Other Emergency Medical Services*	$ 37,914.99
c. Hospitals	$ 55,757.35
d. Physicians/Surgeons	$ 129,357.03
e. Reserve	$ -
f. Totals	$ 247,810.41

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 247,810.41
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 21,477.40
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Butte

Fiscal Year Reported: 2014-15 **Date Submitted:** 4/4/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ☐ Yes ☑ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 129,357.03
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number		Amount	% Claims
a. Claims Submitted	1,210	$	531,509.10	100%
b. Allowable Claims Submitted	1,205	$	517,175.10	100%
c. Allowable Claims Reimbursed	1,205	$	129,357.03	100%

3. **Please confirm the following required documents are attached to this report:**
   - ☑ Descriptions of the physician and surgeon claim payment methodologies
   - ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
   - ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
   - ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
   - ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c
4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**
   Entity: Butte County Public Health Department
   Contact: Elizabeth Heckathorn Telephone: 530-538-2166
   Title: Supervisor, Administrative Analyst Email: eheckathorn@buttecounty.net

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 55,757.35
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ☑ Yes ☐ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number		Amount	% Claims
a. Claims Submitted	940	$	2,354,289.56	100%
b. Allowable Claims Submitted	940	$	2,354,289.56	100%
c. Allowable Claims Reimbursed	940	$	55,757.35	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**
   Entity: Butte County Public Health Department
   Contact: Elizabeth Heckathorn Telephone: 530-538-2166
   Title: Supervisor, Administrative Analyst Email: eheckathorn@buttecounty.net

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: COLUSA

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/25/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 366,959.51
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 167,260.13	$ 158,912.40
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 167,260.13	$ 158,912.40

$0 for Richies for FY 14/15.

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 158,912.40
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: COLUSA COUNTY SUPERIOR COURT
   Contact: CYNTHIA OTERO Telephone: (530) 458-0687
   Title: COURT ACCOUNTANT Email: CYNTHIA.OTERO@COLUSA.COURTS.CA.GOV
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: COLUSA COUNTY AUDITOR-CONTROLLER
   Contact: MARGARET VAN WARMERDAM Telephone: (530) 458-0404
   Title: ACCOUNTANT Email: MVANWARMERDAM@COUNTYOFCOLUSA.COM

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 219,130.94
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 158,912.40
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 378,043.34
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 15,703.64
b. Other Emergency Medical Services*	$ 36,609.14
c. Hospitals	$ 30,000.00
d. Physicians/Surgeons	$ 50,461.07
e. ~~Reserve~~ Richie's Fund	$ 0.00
f. Totals	$ 132,773.85

None for FY 14/15

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 132,773.85
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 245,269.49
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: COLUSA

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/25/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 08/12/2014

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 166,935.07
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	349	$ 207,420.00	100%
b. Allowable Claims Submitted	349	$ 207,420.00	100%
c. Allowable Claims Reimbursed	349	$ 50,461.07	100%

3. **Please confirm the following required documents are attached to this report:**
- [x] Descriptions of the physician and surgeon claim payment methodologies
- [x] Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- [x] Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- [x] Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- [x] Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: COLUSA COUNTY HEALTH & HUMAN SERVICES
Contact: CHRISTINE FUSARO Telephone: (530) 458-0870
Title: STAFF SERVICES MANAGER Email: CFUSARO@COLUSADHHS.ORG

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 96,375.18
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: COLUSA COUNTY HEALTH & HUMAN SERVICES
Contact: CHRISTINE FUSARO Telephone: (530)458-0870
Title: STAFF SERVICES MANAGER Email: CFUSARO@COLUSADHHS.ORG

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: CONTRA COSTA COUNTY

Fiscal Year Reported: FISCAL YEAR 2014-2015 Date Submitted: April 15, 2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 4,244,581.30
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$ 9,019,753.44	$ 848,986.44
b. Government Code Section 76000.5 733,638.06	$ ~~832,850.77~~	$ ~~816,496.34~~ 717,283.63
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 99,212.71	$ 99,212.71
d. Government Code Section 76104	$ -	$ -
e. Vehicle Code Section 42007 (e)	$ 3,576,394.07	$ 547,103.04
f. Totals	$ 13,428,998.28	$ 2,212,585.82 ✓

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 2,212,585.82 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
   Entity: Contra Costa Superior Court
   Contact: Fae Li — Telephone: (925) 957-5608
   Title: Senior Financial Services Manager — Email: FLI@CONTRACOSTA.COURTS.CA.GOV
5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
   Entity: Contra Costa Health Services Department
   Contact: PATRICK GODLEY — Telephone: (925) 957-5405
   Title: CCC HSD COO/CFO — Email: PATRICK.GODLEY@HSD.CCCOUNTY.US

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 20,622.32
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 2,212,585.82 ✓
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 2,233,208.14 ✓
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 137,844.16
b. Other Emergency Medical Services*	$ 210,901.10
c. Hospitals	$ 310,148.70
d. Physicians/Surgeons	$ 1,017,485.81
e. ~~Reserve~~ Richie's Fund	$ Ø
f. Totals	$ 1,676,379.77 ✓

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 1,676,379.77 ✓
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 556,828.37 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: CONTRA COSTA COUNTY

Fiscal Year Reported: FISCAL YEAR 2014-2015 **Date Submitted:** April 15, 2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ☑ Yes ☐ No
2. **If yes, what date was the fund established?** 01/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 1,103,463.56
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	16,177	$ 2,384,187.76	100%
b. Allowable Claims Submitted	16,138	$ 1,047,460.04	100%
c. Allowable Claims Reimbursed	16,138	$ 1,047,460.04	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Contra Costa Health Services
Contact: PATRICK GODLEY Telephone: (925) 957-5405
Title: CCC HSD COO/CFO Email: PATRICK.GODLEY@HSD.CCCOUNTY.US

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 475,615.75
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ☐ Yes ☑ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted		$ -	
b. Allowable Claims Submitted		$ -	
c. Allowable Claims Reimbursed		$ -	

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Contra Costa Health Services
Contact: PATRICK GODLEY Telephone: (925) 957-5405
Title: CCC HSD COO/CFO Email: PATRICK.GODLEY@HSD.CCCOUNTY.US

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: DEL NORTE COUNTY

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/12/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 0.00
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 55,515.28	$ 55,515.28
d. Government Code Section 76104	$ 54,481.55	$ 54,481.55
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 109,996.83	$ 109,996.83 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 109,996.83 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: DEL NORTE COUNTY
   Contact: GRETCHEN STUHR Telephone: 707-464-7208
   Title: COUNTY COUNSEL Email: GStuhr@co.del-norte.ca.us
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: DEL NORTE COUNTY
   Contact: CLINTON SCHAAD Telephone: 707-464-7202
   Title: AUDITOR-CONTROLLER Email: CSchaad@co.del-norte.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 24,923.71
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 109,996.83 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 134,920.54 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	~~$ 11,021.94~~ $5,470.40
b. Other Emergency Medical Services*	~~$ 20,086.64~~ $8,382.33
c. Hospitals	
d. Physicians/Surgeons	~~$ 80,084.29~~ $60,754.86
e. ~~Reserve~~ Richie's Fund	~~$ 0.00~~ $55,515.28
f. Totals	$ 130,122.87 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 130,122.87 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 4,797.67 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: DEL NORTE COUNTY

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/12/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 06/26/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 96,004.29
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	2,449	$ 1,116,951.00	100%
b. Allowable Claims Submitted	2,449	$ 1,116,951.00	100%
c. Allowable Claims Reimbursed	2,449	$ 96,004.29	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: MORGAN HILL EMERGENCY GROUP
Contact: DELILAH T. ORREGO Telephone: 628-447-0296
Title: EMS/INSURANCE CODER Email: DELILAH@EMERGENCYGROUPSOFFICE.COM

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.**
2. **Are funds disbursed to hospitals on a claims basis?** ***(Note: If no, go to E4.)*** ( ) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity:
Contact: Telephone:
Title: Email:

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: El Dorado County

Fiscal Year Reported: July 1, 2014 through June 30, 2015 **Date Submitted:** 03/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. **$ 372,925.11**
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$ 194,173.36	$ 194,173.36
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 178,751.75	$ 178,751.75
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 372,925.11 ✓	$ 372,925.11 ✓

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* **$ 372,925.11** ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
   Entity: El Dorado County Superior Court
   Contact: Amy Wong — Telephone: 530-621-7420
   Title: Accountant — Email: awong@eldoradocourt.org
5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
   Entity: El Dorado County Health & Human Services
   Contact: Pamela Selko — Telephone: 530-295-6814
   Title: Accountant II — Email: pamela.selko@edcgov.us

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* **$ 330,788.69**
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* **$ 372,925.11** ✓
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* **$ 703,713.80** ✓
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 0.00
b. Other Emergency Medical Services*	$ 58,191.44
c. Hospitals	$ 80,082.85
d. Physicians/Surgeons	$ 185,745.81
e. ~~Reserve~~ Richie's Fund	$ 30,000.00
f. Totals	$ 354,000.10 ✓

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* **$ 354,000.10** ✓
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* **$ 349,713.70** ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Reviewed by YCK 3/16/16

3/21/16

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: El Dorado County

Fiscal Year Reported: July 1, 2014 through June 30, 2015 **Date Submitted:** 03/15/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 07/17/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 185,745.80
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	3,418	$ 2,107,954.35	100%
b. Allowable Claims Submitted	3,418	$ 185,745.80	100%
c. Allowable Claims Reimbursed	3,418	$ 185,745.80	100%

3. **Please confirm the following required documents are attached to this report:**

A ☑ Descriptions of the physician and surgeon claim payment methodologies
B ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
C ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
D ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98c
E ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: El Dorado County Health & Human Servies
Contact: Lori Walker Telephone: 530-295-6907
Title: Chief Fiscal Officer Email: lori.walker@edcgov.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 80,062.85
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* (●) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	348	$ 878,219.65	100%
b. Allowable Claims Submitted	348	$ 80,062.85	100%
c. Allowable Claims Reimbursed	348	$ 80,062.85	100%

4 4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: El Dorado Health & Human Services
Contact: Lori Walker Telephone: 530-295-6907
Title: Chief Fiscal Officer Email: lori.walker@edcgov.us

Reviewed by YCK 3/16/16

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)
Page 1 of 2

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Fresno County

Fiscal Year Reported: FY 2014-15 Date Submitted: 05/12/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. 1,199,686.98 ~~$ 0.00~~

2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	$ 916,898.00	$ 916,898.00
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (c)		
f. Totals	$ 916,898.00	$ 916,898.00

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 916,898.00
** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
Entity: Fresno County Superior Court
Contact: Fay Woo Telephone: (559) 457-2165
Title: Accountant II Email: fwoo@fresno.courts.ca.gov

5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
Entity: Fresno County Department of Public Health
Contact: Evelyn Reimer Telephone: (559) 600-6438
Title: Public Health Business Manager Email: ereimer@co.fresno.ca.us

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 2,137,656.00
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 916,898.00
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* ~~$ 916,898.00~~ 3,054,554
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 86,011.00
b. Other Emergency Medical Services*	$ 90,911.00
c. Hospitals	$ 231,782.00
d. Physicians/Surgeons	$ 1,081,473.00
e. Reserve	
f. Totals	$ 1,490,177.00

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 1,490,177.00
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* ~~$ 573,279.00~~ 1,564,377
** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Fresno County

Fiscal Year Reported: FY 2014-15 **Date Submitted:** 05/12/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 2,288,553.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	78,003	$ 21,841,232.00	100%
b. Allowable Claims Submitted	72,995	$ 20,378,584.00	95%
c. Allowable Claims Reimbursed	72,995	$ 1,081,473.00	100%

3. **Please confirm the following required documents are attached to this report:**
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Fresno County Department of Public Health
Contact: Evelyn Reimer Telephone: (559) 600-6438
Title: Public Health Business Manager Email: ereimer@co.fresno.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 421,427.00
2. **Are funds disbursed to hospitals on a claims basis?** ***(Note: If no, go to E4.)*** ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Fresno County Department of Public Health
Contact: Evelyn Reimer, Public Health Business Manager Telephone: (559) 600-6438
Title: Public Health Business Manager Email: ereimer@co.fresno.ca.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: County of Glenn

Fiscal Year Reported: Fiscal Year Ending on June 30, 2015 **Date Submitted:** 04/14/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 70,815.78
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 70,815.78	$ 71,984.25
b. Government Code Section 76000.5	$ 0.00	$ 0.00
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 0.00	$ 0.00
d. Government Code Section 76104	$ 0.00	$ 0.00
e. Vehicle Code Section 42007 (e)	$ 0.00	$ 0.00
f. Totals	$ 70,815.78 ✓	$ 71,984.25 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 71,984.25 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Glenn County Superior Court
   Contact: Kevin Harrigan — Telephone: (530) 934-6382
   Title: Court Executive Officer — Email: kharrigan@glenncourt.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: County of Glenn
   Contact: Susan Storz — Telephone: (530) 934-6476
   Title: Account Clerk Supervisor — Email: sstorz@countyofglenn.net

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 176,193.19
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 71,984.25 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 248,177.44 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 7,081.58
b. Other Emergency Medical Services*	$ 10,921.34
c. Hospitals	$ 16,060.79
d. Physicians/Surgeons	$ 37,920.54
e. Reserve	$ 0.00
f. Totals	$ 71,984.25 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 71,984.25 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 176,193.19 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: County of Glenn

Fiscal Year Reported: Fiscal Year Ending on June 30, 2015 **Date Submitted:** 04/14/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 37,920.54
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	2	$ 125,735.00	100%
b. Allowable Claims Submitted	2	$ 62,867.50	100%
c. Allowable Claims Reimbursed	2	$ 37,920.54	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: County of Glenn
Contact: Humberto Medina
Title: Assistant Director of Finance
Telephone: (530) 934-6476
Email: hmedina@countyofglenn.net

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 16,060.79
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: County of Glenn
Contact: Humberto Medina
Title: Assistant Director of Finance
Telephone: (530) 934-6476
Email: hmedina@countyofglenn.net

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Humboldt

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/20/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated court(s))

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 364,775.41
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 206,518.57	$ 206,518.57
b. Government Code Section 76000.5	$ 156,619.58	$ 156,619.58
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 363,138.15 ✓	$ 363,138.15 ✓

Richie

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 363,138.15 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Courts of California, County of Humboldt
   Contact: Telephone: 707-445-7256
   Title: Email:
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: County of Humboldt, Auditor's Office
   Contact: Charlotte Merkel Telephone: 707-476-2456
   Title: Sr Accountant/Auditor Email: cmerkel@co.humboldt.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 165,034.37
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 363,138.15 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 528,172.52 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 36,422.42
b. Other Emergency Medical Services*	144,446.25 ~~$ 165,569.88~~
c. Hospitals	$ 0.00
d. Physicians/Surgeons	$ 426.26
e. Reserve	$ 0.00
f. Totals	$ 202,438.56 ✓

B. Other EMS
Richie- $21,143.63

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 202,438.56
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 325,733.96 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Humboldt

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/20/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 06/26/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 159,016.85
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	7	$ 1,366.00	100%
b. Allowable Claims Submitted	7	$ 683.00	100%
c. Allowable Claims Reimbursed	7	$ 426.26	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: County of Humboldt, Public Health
Contact: Olivia Wilder Telephone: 707-441-5435
Title: Budget Specialist Email: owilder@co.humboldt.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 68,358.01
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted		$ 0.00	0%
b. Allowable Claims Submitted		$ 0.00	0%
c. Allowable Claims Reimbursed		$ 0.00	0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: County of Humboldt, Public Health
Contact: Olivia Wilder Telephone: 707-441-5435
Title: Budget Specialist Email: owilder@co.humboldt.ca.us

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Inyo

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/06/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 622,178.85
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	$ 96,771.22	$ 96,771.22
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104	$ 97,697.24	$ 97,697.24
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 194,468.46 ✓	$ 194,468.46 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 194,468.46 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Court of California, County of Inyo
   Contact: Danielle Sexton Telephone: 760-872-4730
   Title: Court Finance Manager Email: danielle.sexton@inyocourt.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Superior Court of California, County of Inyo
   Contact: Danielle Sexton Telephone: 760-872-4730
   Title: Court Finance Manager Email: danielle.sexton@inyocourt.ca.gov

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 383,157.86
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 194,468.46 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 577,626.32 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 27,113.00
b. Other Emergency Medical Services*	$ 51,533.55
c. Hospitals	$ 85,882.46
d. Physicians/Surgeons	$ 195,175.59
e. Reserve	
f. Totals	$ 359,704.60 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 359,704.60
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 217,921.72 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Inyo

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/06/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** ☒ Yes ○ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 195,175.59
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted		$ 257,639.23	0%
b. Allowable Claims Submitted		$ 195,175.59	0%
c. Allowable Claims Reimbursed		$ 195,175.59	0%

3. **Please confirm the following required documents are attached to this report:**
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Inyo County Health & Human Services
Contact: Melissa Best-Baker Telephone: 760-878-0232
Title: Senior Management Analyst Email: mbestbaker@inyocounty.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 85,882.46
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ◉ Yes ○ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted		$ 1,697,726.93	0%
b. Allowable Claims Submitted		$ 85,882.46	0%
c. Allowable Claims Reimbursed		$ 85,882.46	0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Inyo County Health & Human Services
Contact: Melissa Best-Baker Telephone: 760-878-0232
Title: Senior Management Analyst Email: mbestbaker@inyocounty.us

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Kern County

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/07/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 57,731,031.00
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 0.00	$ 0.00
b. Government Code Section 76000.5	$ 196,947.10	$ 196,947.10
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 0.00	$ 0.00
d. Government Code Section 76104	$ 1,497,909.52	$ 1,497,909.52
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 1,694,856.62 ✓	$ 1,694,856.62 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 1,694,856.62
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Court of California, County of Kern, Metropolitan Division
   Contact: Gina Fisher — Telephone: (661) 868-4668
   Title: Fiscal Officer — Email: Gina.Fisher@kern.courts.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Kern County Public Health Services Department EMS Division
   Contact: Edward Hill — Telephone: (661) 321-3000
   Title: EMS Director — Email: hille@co.kern.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 1,094,538.54
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 1,694,856.62 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 2,789,395.16 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 169,959.17
b. Other Emergency Medical Services*	$ 255,015.39
c. Hospitals	~~$ 427,627.00~~ 397,984.93
d. Physicians/Surgeons	$ 771,475.43
e. ~~Reserve~~ Richie's Fund	~~$ 0.00~~ 29,542.07
f. Totals	$ 1,623,976.99 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 1,623,976.99 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 1,165,418.17 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Kern County

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/07/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 02/01/2015

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 870,052.48
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	21,675	$ 2,220,831.63	100%
b. Allowable Claims Submitted	21,675	$ 771,475.43	100%
c. Allowable Claims Reimbursed	21,675	$ 771,475.43	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Kern County Public Health Services Department EMS Division
Contact: Edward Hill Telephone: (661) 321-3000
Title: EMS Director Email: hille@co.kern.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 375,022.62
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Kern County Public Health Services Department EMS Division
Contact: Edward Hill Telephone: (661) 321-300
Title: EMS Director Email: hille@co.kern.ca.us

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Lake

Fiscal Year Reported: 07/01/2014 - 6/30/2015 **Date Submitted:** 6/28/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** unknown
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 26,266.09	$ 26,084.06
b. Government Code Section 76000.5	$ -	$ -
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 26,248.13	$ 26,125.74
d. Government Code Section 76104	$ -	$ -
e. Vehicle Code Section 42007 (e)	$ 3,379.04	$ 3,379.04
f. Totals	$ 55,893.26	$ 55,588.84

There are other sources that contribute to the collections/deposits that have not been accounted for, which is why the total deposit (line A2f) varies from the grand total deposit (line 3).

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 123,492.23

** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Multiple entities that collect and deposit the funds. Do not have a single source contact.
   Contact: Telephone:
   Title: Email:

5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Multiple entities that collect, deposit and distrubute these funds. Do not have a single source contact.
   Contact: Telephone:
   Title: Email:

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 44,151.67
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 123,492.23
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 167,643.90
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 12,854.20
b. Other Emergency Medical Services*	$ 18,131.86
c. Hospitals	$ -
d. Physicians/Surgeons	$ 86,786.74
e. Reserve	$ -
f. Richie's Fund	$ 8,766.94
g. Totals	$ 126,539.74

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 126,539.74
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 41,104.16

** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Lake

Fiscal Year Reported: 07/01/2014 - 6/30/2015 **Date Submitted:** 6/28/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ☑ Yes ☐ No
2. **If yes, what date was the fund established?** 07/01/07

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 86,786.74
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	3,327	$ 2,035,752.00	100%
b. Allowable Claims Submitted	2,679	$ 1,670,362.00	81%
c. Allowable Claims Reimbursed	2,679	$ 86,786.74	100%

3. **Please confirm the following required documents are attached to this report:**
   - ☑ Descriptions of the physician and surgeon claim payment methodologies
   - ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
   - ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
   - ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
   - ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c
4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: County of Lake, Health Services
Contact: Cindy Silva-Brackett or Denise Pomeroy Telephone: 707-263-1090
Title: Accountant II or Deputy Director, Health Services Administration Email: cindy.silva-brackett@lakecountyca.gov denise.pomeroy@lakecountyca.gov

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 25,652.81
2. **Are funds disbursed to hospitals on a claims basis?** ***(Note: If no, go to E4.)*** ☑ Yes ☐ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	0	$ -	0%
b. Allowable Claims Submitted	0	$ -	0%
c. Allowable Claims Reimbursed	0	$ -	0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: County of Lake, Health Services
Contact: Cindy Silva-Brackett or Denise Pomeroy Telephone: 707-263-1090
Title: Accountant II or Deputy Director, Health Services Administration Email: cindy.silva-brackett@lakecountyca.gov or denise.pomeroy@lakecountyca.gov

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EMERGENCY MEDICAL SERVICES AUTHORITY
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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: LOS ANGELES COUNTY

Fiscal Year Reported: FY 2014 - 2015 Date Submitted: 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 44,393,629.84

2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	21,753,889.82 ~~$ 36,454,041.27~~	~~$ 8,701,151.45~~ 0
b. Government Code Section 76000.5	$ 7,477,541.90	$ 7,477,541.90
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 1,319,633.21	$ 1,319,633.21
d. Government Code Section 76104	8,701,151.45 ~~$ 4,451,390.00~~	~~$ 0.00~~ 8,701,151.45
e. Vehicle Code Section 42007 (e) → 42007	$ 5,895,701.40	$ 5,445,270.47
f. Totals	45,146,917.78 ~~$ 49,698,307.78~~	$ 22,943,597.03 ✓

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 22,943,597.03 ✓
** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
Entity: LOS ANGELES SUPERIOR COURT - REVENUE MANAGEMENT
Contact: SYLVIA CORRAL Telephone: 213-633-0087
Title: FINANCE ADMINISTRATOR Email: SCorral@lacourt.org

5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
Entity: LOS ANGELES SUPERIOR COURT - REVENUE MANAGEMENT
Contact: SYLVIA CORRAL Telephone: 213-633-0087
Title: FINANCE ADMINISTRATOR Email: SCorral@lacourt.org

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 3,575,519.94
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 22,943,597.03 ✓
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 26,519,116.97 ✓
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements	
a. Administration	$ 2,294,359.69	
b. Other Emergency Medical Services*	$ 3,216,234.15	
c. Hospitals	$ 3,370,904.00	
d. Physicians/Surgeons	$ 10,755,332.72	← Estimated payments
e. ~~Reserve~~ Richie's Fund	$ 1,730,212.68	← Estimated for Richie's Fund Pmt.
f. Totals	$ 21,367,043.24 ✓	

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 21,367,043.24 ✓
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 5,152,073.73 ✓
** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: LOS ANGELES COUNTY

Fiscal Year Reported: FY 2014 - 2015 **Date Submitted:** 04/15/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ◉ Yes ○ No
2. **If yes, what date was the fund established?** 04/01/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 11,031,332.72
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	308,496	$ 85,792,738.00	100%
b. Allowable Claims Submitted	220,087	$ 61,206,194.70	71%
c. Allowable Claims Reimbursed	220,087	$ 10,755,332.72	100%

← Estimated clms, amt. and %.

3. **Please confirm the following required documents are attached to this report:**
- ☒ Descriptions of the physician and surgeon claim payment methodologies
- ☒ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☒ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☒ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☒ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: DEPT OF HEALTH SERVICES - EMERGENCY MEDICAL SERVICES AGENCY (EMS)
Contact: CATHY CHIDESTER Telephone: 562-347-1604
Title: EMS DIRECTOR Email: cchidester@dhs.lacounty.gov

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 9,977,190.41
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ◉ Yes ○ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	410	$ 3,370,904.00	100%
b. Allowable Claims Submitted	410	$ 3,370,904.00	100%
c. Allowable Claims Reimbursed	410	$ 3,370,904.00	100%

← Excludes Richie's Fund Payment

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: DEPT OF HEALTH SERVICES - EMERGENCY MEDICAL SERVICES AGENCY (EMS)
Contact: CATHY CHIDESTER Telephone: 562-347-1604
Title: EMS DIRECTOR Email: cchidester@dhs.lacounty.gov

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Madera

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $182,461.71
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$182,461.71	$ 182,461.71
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 0.00	$ 182,461.71 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 182,461.71 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Madera Courts-Finance Division
   Contact: Tracy Callaway — Telephone: (559) 416-5513
   Title: Chief Financial Officer — Email: tracy.callaway@madera.courts.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Madera County Public Health Department
   Contact: Rebecca Yanez — Telephone: (559) 675-7893
   Title: Administrative Analyst — Email: rebecca.yanez@co.madera.ca.gov

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 466,473.65
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 182,461.71 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 648,935.36 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 25,492.00
b. Other Emergency Medical Services*	$ 137,950.00
c. Hospitals	$ 45,887.95
d. Physicians/Surgeons	$ 105,367.29
e. Reserve	$ 39,187.92
f. Totals	$ 353,885.16 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 353,885.16 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 295,050.20 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Madera

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/15/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 105,367.29
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	2,635	$ 1,571,540.80	100%
b. Allowable Claims Submitted	2,633	$ 1,580,420.80	100%
c. Allowable Claims Reimbursed	2,633	$ 1,580,420.80	100%

3. **Please confirm the following required documents are attached to this report:**
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Madera County Public Health Department
Contact: Rebecca Yanez Telephone: (559) 675-7893
Title: Administrative Analyst Email: rebecca.yanez@co.madera.ca.gov

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 45,887.95
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Madera County Public Health Department
Contact: Rebecca Yanez Telephone: (559) 675-7893
Title: Administrative Analyst Email: rebecca.yanez@co.madera.ca.gov

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: MARIN

Fiscal Year Reported: FY2014-2015 REVISED **Date Submitted:** 05/06/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State-operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** 771,535.88
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 402,286.62	$ 402,286.62
d. Government Code Section 76104	$ 369,249.27	$ 369,249.27
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 771,535.88	$ 771,535.88

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 771,535.88
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity:
   Contact: Telephone:
   Title: Email:
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity:
   Contact: Telephone:
   Title: Email:

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 118,948.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 771,535.88
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 890,483.88
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 77,153.59
b. Other Emergency Medical Services*	$ 107,786.68
c. Hospitals	$ 158,509.83
d. Physicians/Surgeons	$ 368,339.83 **
e. ~~Reserve~~ Pediatric Trauma	$ 44,530.12
f. Totals	$ 756,320.07

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 756,320.07
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* (See Attachment I) $ 134,163.81
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

** d. Physicians/Surgeons amounts included $15,485.15 REFUND from the Physicians/Surgeons.

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: MARIN

Fiscal Year Reported: FY2014-2015 REVISED

Date Submitted: 05/06/2016

C. RICHIE'S FUND

1. Has the reporting entity established a Richie Fund? (●) Yes ( ) No
2. If yes, what date was the fund established? 01/01/2008

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $ 446,241.94
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	3,221	$ 1,459,486.00	100%
b. Allowable Claims Submitted	2,714	$ 1,220,438.00	84%
c. Allowable Claims Reimbursed	2,714	$ 368,339.83	100%

3. Please confirm the following required documents are attached to this report: (Please See Attachment II)

- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity: Marin County - Dept of Health and Human Services - Office of Finance
Contact: La Valda Marshall
Title: Assistant CFO
Telephone: (415) 473-6936
Email: lmarshall@marincounty.org

E. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 158,509.83
2. Are funds disbursed to hospitals on a claims basis? *(Note: If no, go to E4.)* ( ) Yes (●) No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report. (Please See Attachment III)
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity: Marin County - Dept of Health and Human Services - Office of Finance
Contact: La Valda Marshall
Title: Assistant CFO
Telephone: (415) 473-6936
Email: lmarshall@marincounty.org

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Mariposa

Fiscal Year Reported: FY 2014-2015 **Date Submitted:** 04/14/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 22,854.22
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 11,929.90	$ 11,929.90
b. Government Code Section 76000.5	8,638.90 ~~$ 3,496.70~~	~~$ 3,496.70~~ 8,638.90
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	~~$ 5,142.20~~	~~$ 5,142.20~~
d. Government Code Section 76104	$ 2,285.42	$ 2,285.42
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 22,854.22 ✓	$ 22,854.22 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 22,854.22 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Mariposa County Public Health Department
   Contact: Diane Robarge — Telephone: (209) 966-3689 Ext #11
   Title: Accountant — Email: drobarge@mariposacounty.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Mariposa County Public Health Department
   Contact: Diane Robarge — Telephone: (209) 966-3689 Ext #116
   Title: Accountant — Email: drobarge@mariposacounty.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 234,943.45
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 22,854.22 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 257,797.67 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 2,000.00
b. Other Emergency Medical Services*	
c. Hospitals	$ 4,000.00
d. Physicians/Surgeons	$ 70,000.00
e. Reserve	
f. Totals	$ 76,000.00 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 76,000.00 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 181,797.67 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Mariposa

Fiscal Year Reported: FY 2014-2015 **Date Submitted:** 04/14/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $236,785.77
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	248	$ 75,628.00	100%
b. Allowable Claims Submitted	228	$ 70,000.00	92%
c. Allowable Claims Reimbursed	228	$ 70,000.00	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Mariposa County Public Health Department
Contact: Diane Robarge Telephone: (209) 966-3689 Ext #116
Title: Accountant Email: drobarge@mariposacounty.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 5,896.45
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ◉ Yes ○ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	4	$ 1,701,113.00	100%
b. Allowable Claims Submitted	4	$ 1,701,113.00	100%
c. Allowable Claims Reimbursed	4	$ 4,000.00	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Mariposa County Public Health Department
Contact: Diane Robarge Telephone: (209) 966-3689 Ext #116
Title: Accountant Email: drobarge@mariposacounty.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Mendocino

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State-operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 237,256.48
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	100,125.55	$ 100,125.55
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	137,130.93	$ 137,130.93
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	237,256.48	$ 237,256.48 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 237,256.48 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Mendocino County Court Collections
   Contact: Cathy Harpe Telephone: (707) 234-6847
   Title: Deputy Treasurer Tax Collector Email: harpec@co.mendocino.ca.us
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Mendocino County Court Collections
   Contact: Cathy Harpe Telephone: (707) 234-6847
   Title: Deputy Treasurer Tax Collector Email: harpec@co.mendocino.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 154,394.58
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 237,256.48 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 391,651.06 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 23,950.76
b. ~~Other Emergency Medical Services~~* Richters Fund	20,640.15
c. Hospitals	$ 48,195.34
d. Physicians/Surgeons	$ 111,774.44
e. Reserve	~~$ 59,335.94~~ 32,695.79
f. Totals	$ 237,256.48 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 237,256.48 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 154,394.58 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Mendocino

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/15/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 03/31/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 111,774.45
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	506	$ 197,578.22	100%
b. Allowable Claims Submitted	506	$ 197,578.22	100%
c. Allowable Claims Reimbursed	506	$ 111,774.45	100%

3. **Please confirm the following required documents are attached to this report:**
- [x] Descriptions of the physician and surgeon claim payment methodologies
- [ ] Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- [ ] Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- [ ] Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- [ ] Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Mendocino County HHSA, Public Health Fiscal
Contact: Mary Alice Willeford Telephone: (707) 472-2374
Title: Administrative Services Manager Email: willefom@co.mendocino.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 48,195.34
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* (●) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	22	$ 99,890.68	100%
b. Allowable Claims Submitted	22	$ 99,890.68	100%
c. Allowable Claims Reimbursed	22	$ 48,195.34	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Mendocino County HHSA, Public Health Fiscal
Contact: Mary Alice Willeford Telephone: (707) 472-2374
Title: Administrative Services Manager Email: willefom@co.mendocino.ca.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Merced County

Fiscal Year Reported: 7/1/2014-6/30/2015 **Date Submitted:** 03/10/2016

A. FINES AND FORFEITURES COLLECTED (Note: All reported to County by State-operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 11,255,809.60
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 803,994.95	$ 85,284.18
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 3,733,673.88	$ 339,424.88
d. Government Code Section 76104	$ 3,200,700.47	$ 290,972.77
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 7,738,369.30 ✓	$ 715,681.83 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 715,681.83
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Merced County Auditor-Controller's Office
   Contact: Lisa Cardell-Presto, CPA — Telephone: (209)385-7511
   Title: Auditor-Controller — Email: lcardella-presto@co.merced.ca.us
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Merced County Department of Public Health
   Contact: Karl Stahlhut — Telephone: (209)381-1271
   Title: Fiscal Manager — Email: kstahlhut@co.merced.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 270,925.40
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 715,681.83 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 986,607.23 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 96,876.36
b. Other Emergency Medical Services*	$ 147,623.59
c. Hospitals	$ 85,137.65
d. Physicians/Surgeons	~~$ 374,158.05~~ 327,810.18
e. ~~Reserve~~ Richie's Fund	46,348.77
f. Totals	$ 643,796.65 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 643,796.65 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 342,810.68 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Merced County

Fiscal Year Reported: 7/1/2014-6/30/2015 **Date Submitted:** 03/10/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 10/30/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 400,249.60
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	7,035	$ 3,772,132.00	100%
b. Allowable Claims Submitted	6,994	$ 3,742,783.00	99%
c. Allowable Claims Reimbursed	6,994	$ 3,742,873.00	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Merced County Department of Public Health
Contact: Karl Stahlhut
Title: Fiscal Manager
Telephone: (209)381-1271
Email: kstahlhut@co..merced.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 145,804.41
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Merced County Department of Public Health
Contact: Karl Stahlhut
Title: Fiscal Manager
Telephone: (209)381-1271
Email: kstahlhut@co..merced.ca.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Mono

Fiscal Year Reported: 2014-15 Date Submitted: 7/11/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 68,282.55
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$ 167,105.37	$ 41,876.61
b. Government Code Section 76000.5	$ -	$ -
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ -	$ -
d. Government Code Section 76104	$ 26,166.00	$ 26,166.00
e. Vehicle Code Section 42007 (e)	$ -	$ -
f. Totals	$ 193,271.37	$ 68,042.61

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 68,042.61
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
   Entity: Mono County Superior Court
   Contact: Hector Gonzalez Telephone: 760.924.5444
   Title: CEO Email:
5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
   Entity: Mono County Finance Department
   Contact: Stephanie Butters Telephone: 760.932.5496
   Title: Auditor-Controller Email: sbutters@mono.ca.gov

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 129,003.57
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 68,042.61
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 197,046.18
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ -
b. Other Emergency Medical Services*	$ 15,765.15
c. Hospitals	$ 25,099.82
d. Physicians/Surgeons	$ 91,443.16
e. Reserve	$ -
f. Richie's Fund	$ -
g. Totals	$ 132,308.13

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 132,308.13
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 64,738.05
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Mono

Fiscal Year Reported: 2014-15 Date Submitted: 7/11/2016

C. RICHIE'S FUND

1. Has the reporting entity established a Richie Fund? ☐ Yes ☑ No
2. If yes, what date was the fund established?

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $ 99,726.95
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	151	$ 194,720.00	100%
b. Allowable Claims Submitted	151	$ 194,720.00	100%
c. Allowable Claims Reimbursed	71	$ 91,443.16	47%

3. Please confirm the following required documents are attached to this report:
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity: Mono County Public Health Dept.
Contact: Kimberly Bunn Telephone: 760.932.5587
Title: Public Health Fiscal & Administrative Officer Email: kbunn@mono.ca.gov

E. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 42,985.75
2. Are funds disbursed to hospitals on a claims basis? *(Note: If no, go to E4.)* ☑ Yes ☐ No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	151	$ 949,343.89	100%
b. Allowable Claims Submitted	151	$ 949,343.89	100%
c. Allowable Claims Reimbursed	5	$ 25,099.82	3%

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity: Mono County Public Health Dept.
Contact: Kimberly Bunn Telephone: 760.932.5587
Title: Public Health Fiscal & Administrative Officer Email: kbunn@mono.ca.gov

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)
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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: MONTEREY

Fiscal Year Reported: 2014-2015 **Date Submitted:** 05/03/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 911,525.41
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 911,525.41	$ 911,525.41
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 911,525.41	$ 911,525.41

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 911,525.41
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: SUPERIOR COURT OF C ALIFORNIA, COUNTY OF MONTEREY
   Contact: LENA BELNAS Telephone: 831-755-5619
   Title: ACCOUNTANT AUDITOR III Email: lena.belnas@monterey.courts.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: MONTEREY COUNTY EMERGENCY MEDICAL SERVICES
   Contact: TERESA RIOS Telephone: 831-783-7082
   Title: MANAGEMENT ANALYST III Email: riost@co.monterey.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 526,874.90
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 911,525.41
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 1,438,400.31
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 91,152.54
b. Other Emergency Medical Services*	$ 139,463.39
c. Hospitals	$ 205,093.22
d. Physicians/Surgeons	$ 570,441.54
e. Reserve	
f. Totals	$ 1,006,150.69

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 1,006,150.69
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 432,249.62
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: MONTEREY

Fiscal Year Reported: 2014-2015 **Date Submitted:** 05/03/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 1,438,400.31
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	12,655	$ 1,192,691.09	100%
b. Allowable Claims Submitted	12,289	$ 1,140,882.00	97%
c. Allowable Claims Reimbursed	12,289	$ 570,441.54	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: MONTEREY COUNTY EMERGENCY MEDICAL SERVICES
Contact: TERESA RIOS Telephone: 831-783-7082
Title: MANAGEMENT ANALYST III Email: riost@co.monterey.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 1,438,400.31
2. **Are funds disbursed to hospitals on a claims basis?** ***(Note: If no, go to E4.)*** ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: MONTEREY COUNTY EMERGENCY MEDICAL SERVICEWS
Contact: TERESA RIOS Telephone: 831-783-7082
Title: MANAGEMENT ANALYST III Email: riost@co.monterey.ca.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
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Page 1 of 2

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Napa County

Fiscal Year Reported: 2014-2015 Date Submitted: 04/11/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State-operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 440,851.00

2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000 Maddy	$ 219,677.00	$ 219,677.00
b. Government Code Section 76000.5 SB1773	$ 221,174.00	$ 221,174.00
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 440,851.00 ✓	$ 440,851.00 ✓

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 440,851.00 ✓
** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
Entity: Napa County HHSA-Fiscal Division
Contact: Karina Gallegos-Ruiz Telephone: 707.253.4718
Title: Staff Analyst Email: Karina.Gallegos-Ruiz@countyofnapa.org

5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
Entity: Napa County HHSA-Fiscal Division
Contact: Karina Gallegos-Ruiz Telephone: 707.253.4718
Title: Staff Analyst Email: Karina.Gallegos-Ruiz@countyofnapa.org

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 111,433.00
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 440,851.00 ✓
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 552,284.00 ✓
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 44,085.00
b. ~~Other Emergency Medical Services*~~ Richie's Fund	$ 29,858.00
c. Hospitals	$ 100,380.00
d. Physicians/Surgeons	$ 222,500.00
e. Reserve	$ 68,211.00
f. Totals	$ 465,034.00 ✓

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 465,034.00 ✓
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 87,250.00 ✓
** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Napa County

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/11/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** ◉ Yes ○ No
2. **If yes, what date was the fund established?** 07/01/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 255,694.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	3,930	$ 309,076.00	100%
b. Allowable Claims Submitted	3,901	$ 247,684.00	99%
c. Allowable Claims Reimbursed	3,901	$ 247,684.00	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Fiscal-Napa County
Contact: Karina Gallegos-Ruiz
Title: Fiscal Staff Analyst
Telephone: 707.253.4718
Email: Karina.Gallegos-Ruiz@countyofnapa.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 100,360.00
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed		$ 100,360.00	0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Fiscal-Napa County
Contact: Karina Gallegos-Ruiz
Title: Fiscal Staff Analyst
Telephone: 707.253.4718
Email: Karina.Gallegos-Ruiz-@countyofnapa.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: NEVADA

Fiscal Year Reported: FY 14/15 **Date Submitted:** 05/23/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 168,610.27
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104	$ 168,610.27	$ 168,610.27
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 168,610.27	$ 168,610.27

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 168,610.27
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Nevada County Courts
   Contact: Sarah Trudo Telephone: (530) 265-1311
   Title: Email: Sarah.Trudo@nevadacountycourts.com
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: same as above
   Contact: Telephone:
   Title: Email:

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 140,617.18
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 168,610.27
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 309,227.45
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 1,005.31
b. Other Emergency Medical Services*	$ 60,835.00
c. Hospitals	$ 39,475.45
d. Physicians/Surgeons	$ 85,391.08
e. Reserve	$ 0.00
f. Totals	$ 186,706.84

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 186,706.84
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 122,520.61
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: NEVADA

Fiscal Year Reported: FY 14/15 **Date Submitted:** 05/23/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 85,391.08
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	5,080	$ 302,775.00	100%
b. Allowable Claims Submitted	5,080	$ 302,775.00	100%
c. Allowable Claims Reimbursed	5,080	$ 85,391.08	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Nevada County Public Health Department
Contact: James Kraywinkel Telephone: (530) 470-2415
Title: Accountant Email: James.Kraywinkel@co.nevada.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 39,475.45
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ◉ Yes ○ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	2,359	$ 2,255,259.37	100%
b. Allowable Claims Submitted	2,359	$ 2,255,259.37	100%
c. Allowable Claims Reimbursed	2,359	$ 39,475.45	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Nevada County Public Health
Contact: James Kraywinkel Telephone: (530) 470-2415
Title: Accountant Email: James.Kraywinkel@co.nevada.ca.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

County: Orange County

Fiscal Year Reported: FY 2014-15 **Date Submitted:** 04/15/2016

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 11,961,126.36
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	7,704,835.93 ~~$ 3,498,876.80~~	$ 3,498,876.80
b. Government Code Section 76000.5	4,256,290.43 ~~$ 3,002,812.90~~	$ 3,002,812.90
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	0 ~~$ 638,443.56~~	$ 638,443.56
d. Government Code Section 76104	~~$ 1,331,671.33~~	$ 1,331,671.33
e. Vehicle Code Section 42007 (e)	$ 0.00	$ 0.00
f. Totals	11,961,126.36 ~~$ 8,471,804.39~~	$ 8,471,804.39

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 8,471,804.39
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
   Entity: Orange County Superior Court
   Contact: Solange Beckes — Telephone: 657-622-7548
   Title: Financial Services Manager — Email: sbeckes@occourts.org
5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
   Entity: Orange County Auditor Controller
   Contact: Anabelle Garcia — Telephone: 714-834-2481
   Title: Manager, Cost, Revenue & Budget — Email: anabelle.garcia@ac.ocgov.com

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)*	$ 434,070.68
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)*	$ 8,471,804.39
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)*	$ 8,905,875.07

4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements	
a. Administration	$ 317,380.27	
b. Other Emergency Medical Services*	$ 1,741,107.44	
c. Hospitals	~~$ 2,362,338.43~~	1,934,289.99
d. Physicians/Surgeons	$ 4,236,456.88	
e. Reserve- Richie's Fund	~~$ 0.00~~	628,048.44
f. Totals	$ 8,857,282.82	

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)*	$ 8,857,282.82
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)*	$ 48,592.25

** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (h) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Orange County

Fiscal Year Reported: FY 2014-15 **Date Submitted:** 04/15/2016

RICHIE FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 02/01/2006

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 4,238,286.19
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	88,343	$ 45,447,295.01	100%
b. Allowable Claims Submitted	84,933	$ 10,262,963.03	96%
c. Allowable Claims Reimbursed	84,933	$ 10,262,963.03	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98c
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Orange County Health Care Agency
Contact: Melissa Tober
Title: Manager, Special Projects
Telephone: 714-834-5891
Email: mtober@ochca.com

REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 2,609,101.17
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Orange County Health Care Agency
Contact: Melissa Tober
Title: Manager, Special Projects
Telephone: 714-834-5891
Email: mtober@ochca.com

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: PLACER

Fiscal Year Reported: JULY 1,2014-JUNE 30, 2015 **Date Submitted:** 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State-operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** ~~$ 10,983,076.00~~
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.** 711,803.00

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	$ 359,682.00	$ 359,682.00
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 352,121.00	$ 352,121.00
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 711,803.00 ✓	$ 711,803.00 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 711,803.00 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: PLACER COUNTY COURTS
   Contact: SUE RAWLIN Telephone: 916-408-6000
   Title: SUPERVISING COURT SERVICES CLERK Email: SRAWLIN@PLACERCO.ORG
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: PLACER COUNTY AUDITORS OFFICE
   Contact: LYNN YOSHIDA Telephone: 530-889-4166
   Title: MANAGING ACCOUNTANT AUDITOR Email: LYOSHIDA@PLACER.CA.GOV

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 18,681.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 711,803.00 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 730,484.00 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 7,324.84
b. Other Emergency Medical Services*	$ 116,231.06
c. Hospitals	$ 9,024.32
d. Physicians/Surgeons	~~$ 381,631.18~~ 353,265.18
e. Reserve	$ 161,903.77
f. Totals	$ 676,115.17 ✓

f. $28,366 (Riches)

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 676,115.17 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 54,368.83 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: PLACER

Fiscal Year Reported: JULY 1,2014-JUNE 30, 2015 **Date Submitted:** 04/15/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 09/18/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 381,631.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	10,017	$ 4,119,282.00	100%
b. Allowable Claims Submitted	10,017	$ 1,013,170.85	100%
c. Allowable Claims Reimbursed	10,017	$ 381,631.00	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Placer County
Contact: STAN HAPAK Telephone: 530-745-3144
Title: ADMINISTRATIVE & FISCAL OPERATIONS MANAGE Email: SHAPAK@PLACER.CA.GOV

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 170,928.09
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* (●) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	132	$ 230,396.00	100%
b. Allowable Claims Submitted	132	$ 115,198.00	100%
c. Allowable Claims Reimbursed	132	$ 9,024.00	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Placer County
Contact: STAN HAPAK Telephone: 530-745-3144
Title: ADMINISTRATIVE & FISCAL OPERATIONS MANAGER Email: SHAPAK@PLACER.CA.GOV

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Plumas

Fiscal Year Reported: 2014-15 **Date Submitted:** 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to Courts by State-operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 29,257.30
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	$ 29,044.39	$ 29,044.36
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104	$ 21,077.79	$ 21,077.79
e. Vehicle Code Section 42007 (c)		
f. Totals	$ 50,122.18	$ 50,122.15

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 50,122.15
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: County of Plumas
   Contact: Julie White — Telephone: 530-283-6410
   Title: Treasurer/Tax Collector — Email: juliewhite@county ofplumas.com
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: County of Plumas
   Contact: Roberta Allen — Telephone: 530-283-6246
   Title: Auditor/Controller — Email: robertaallen@countyofplumas.com

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 53.94
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 50,122.15
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 50,176.09
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 4,013.36
b. Other Emergency Medical Services*	$ 7,846.16
c. Hospitals	$ 11,538.48
d. Physicians/Surgeons	$ 26,769.27
e. Reserve	
f. Totals	$ 50,167.29

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 50,167.29
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* # 8.80 ~~$ 29,053.15~~
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Plumas

Fiscal Year Reported: 2014-15 Date Submitted: 04/15/2016

C. RICHIE'S FUND

1. Has the reporting entity established a Richie Fund? ○ Yes ◉ No
2. If yes, what date was the fund established?

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $ 26,769.27
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	328	$ 174,935.06	100%
b. Allowable Claims Submitted	327	$ 174,935.06	100%
c. Allowable Claims Reimbursed	327	$ 26,769.27	100%

3. Please confirm the following required documents are attached to this report:
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity: Northern California EMS, Inc
Contact: Kathy Van Donge Telephone: 530-229-3979
Title: Admin Assistant Email: kvandonge@norcalems.org

E. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 11,538.48
2. Are funds disbursed to hospitals on a claims basis? *(Note: If no, go to E4.)* ◉ Yes ○ No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	328	$ 529,509.10	100%
b. Allowable Claims Submitted	328	$ 529,609.10	100%
c. Allowable Claims Reimbursed	328	$ 11,537.80	100%

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity: Northern California EMS, Inc
Contact: Kathy Van Donge Telephone: 530-229-3979
Title: Admin Assistant Email: kvandonge@norcalems.org

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: County of Riverside

Fiscal Year Reported: 2014 / 2015 **Date Submitted:** 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 5,807,784.66
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	2,912,789 ~~$ 5,807,784.66~~	~~$ 5,807,784.66~~ 2,912,789
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	2,894,995.66	2,894,995.66
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 5,807,784.66 ✓	$ 5,807,784.66 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 5,807,784.66 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Emergency management Department
   Contact: Nadine Hays Telephone: 951-358-7111
   Title: Administrative Services Supervisor Email: NAHays@rivcocha.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Riverside County Foundation Medical
   Contact: Teresa Herrera Telephone: 951-686-3342 x 304
   Title: Budgets Email: THerrera@rfasi.com

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 0.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 5,807,784.66 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 5,807,784.66 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 580,778.47
b. Other Emergency Medical Services*	$ 814,768.66
c. Hospitals	~~$ 1,632,438.56~~ 1,198,189.21
d. Physicians/Surgeons	$ 2,779,798.97
e. ~~Reserve~~ Richie's Ped. Trauma	434,249.35
f. Totals	$ 5,807,784.66 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 5,807,784.66 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 0.00 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: County of Riverside

Fiscal Year Reported: 2014 / 2015 **Date Submitted:** 04/15/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 2,779,798.97
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	70,891	$ 18,082,948.26	100%
b. Allowable Claims Submitted	64,820	$ 2,779,798.97	91%
c. Allowable Claims Reimbursed		2,779,798.97	100%

3. **Please confirm the following required documents are attached to this report:**
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Riverside County Foundation Medical
Contact: Teresa Herrera
Title: Budgets
Telephone: 951-686-3342 x 304
Email: THerrera@rfasi.com

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 1,632,438.56
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Riverside County Foundation Medica
Contact: Teresa Herrera
Title: Budgets
Telephone: 951-686-3342 x 304
Email: THerrera@rfasi.com

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Sacramento

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/18/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State-operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 54,700,165.00
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 0.00	$ 0.00
b. Government Code Section 76000.5	$ 0.00	$ 0.00
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 0.00	$ 0.00
d. Government Code Section 76104	$ 1,036,317.00	$ 1,017,768.00
e. Vehicle Code Section 42007 (e)	$ 592,535.00	$ 592,535.00
f. Totals	$ 1,628,852.00 ✓	$ 1,610,303.00 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 1,610,303.00 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Court of California, County of Sacramento
   Contact: Cassie Wolter — Telephone: (916) 874-8013
   Title: Budget Analyst — Email: WolterC@saccourt.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: County of Sacramento - Department of Health and Human Services
   Contact: Maryann Luke — Telephone: (916) 875-1976
   Title: Chief of Fiscal — Email: LukeM@saccounty.net

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 0.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 1,610,303.00 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 1,610,303.00 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 161,030.00
b. Other Emergency Medical Services*	$ 246,376.00
c. Hospitals	$ 362,316.00
d. Physicians/Surgeons	$ 808,188.00
e. Reserve	$ 0.00
f. Totals	$ 1,577,912.00 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 1,577,912.00
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 32,391.00 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Sacramento

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/18/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 840,578.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	69,686	$ 11,194,512.00	100%
b. Allowable Claims Submitted	69,276	$ 11,067,726.00	99%
c. Allowable Claims Reimbursed	69,276	$ 808,186.00	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: County of Sacramento - Department of Health and Human Services
Contact: Maryann Luke
Title: Chief of Fiscal
Telephone: (916) 875-1976
Email: LukeM@saccounty.net

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 362,318.00
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	0	$ 0.00	0%
b. Allowable Claims Submitted	0	$ 0.00	0%
c. Allowable Claims Reimbursed	0	$ 0.00	0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: County of Sacramento - Department of Health and Human Services
Contact: Maryann Luke
Title: Chief of Fiscal
Telephone: (916) 875-1976
Email: LukeM@saccounty.net

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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Benito County

Fiscal Year Reported: 2014/2015 Date Submitted: 4/1/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 141,956.21

2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$ 73,132.72	$ 73,132.72
b. Government Code Section 76000.5	$ -	$ -
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 68,823.49	$ 68,823.49
d. Government Code Section 76104	$ -	$ -
e. Vehicle Code Section 42007 (e)	$ -	$ -
f. Totals	$ 141,956.21	$ 141,956.21

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 141,956.21
** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
Entity: Superior Courts of California
Contact: Gil Solorio Telephone: 831-636-4057
Title: Court Executive Officer Email:

5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
Entity: Superior Courts of California
Contact: Gil Solorio Telephone: 831-636-4057
Title: Court Executive Officer Email:

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 267,434.42
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 141,956.21
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 409,390.63
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 14,195.61
b. Other Emergency Medical Services*	$ 20,139.80
c. Hospitals	$ 13,451.27
d. Physicians/Surgeons	$ 51,179.03
e. Reserve	
f. Richie's Fund	$ 25,878.30
g. Totals	$ 124,844.01

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 124,844.01
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 284,546.62
** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Benito County

Fiscal Year Reported: 2014/2015 Date Submitted: 4/1/2016

C. RICHIE's FUND

1. Has the reporting entity established a Richie Fund? ☑ Yes ☐ No
2. If yes, what date was the fund established? 03/01/00

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $ 281,113.05
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	1,211	$ 51,179.03	100%
b. Allowable Claims Submitted	1,211	$ 51,179.03	100%
c. Allowable Claims Reimbursed	1,211	$ 51,179.03	100%

3. Please confirm the following required documents are attached to this report:
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity: San Benito County EMS
Contact: Kevin O'Neill Telephone: 831-636-4168
Title: EMS Administrator Email: koneill@cosb.us

E. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 36,431.21
2. Are funds disbursed to hospitals on a claims basis? *(Note: If no, go to E4.)* ☐ Yes ☑ No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted		$ -	
b. Allowable Claims Submitted		$ -	
c. Allowable Claims Reimbursed		$ -	

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity: San Benito County EMS
Contact: Kevin O'Neill Telephone: 831-636-4168
Title: EMS Administrator Email: koneill@cosb.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Bernardino

Fiscal Year Reported: 2014/2015 **Date Submitted:** 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State-operated Courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 3,907,043.70
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 1,911,108.78	$ 1,911,108.78
d. Government Code Section 76104	$ 1,995,934.92	$ 1,995,934.92
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 3,907,043.70 ✓	$ 3,907,043.70 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 3,907,043.70 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Court of San Bernardino County
   Contact: Robert E. Fleshman — Telephone: (909) 708-8744
   Title: Chief Financial Officer — Email: RFleshman@sb-court.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Arrowhead Regional Medical Center
   Contact: Frank Arambula — Telephone: (909) 580-6170
   Title: Chief Financial Officer — Email: ArambulaF@armc.sbcounty.gov

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 1,568.80
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 3,907,043.70 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 3,908,612.50 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration * 1a	$ 390,861.28
b. Other Emergency Medical Services*	$ 554,139.68
c. Hospitals	$ 814,911.19
d. Physicians/Surgeons	$ 1,890,594.15
e. Reserve/Richie Fund	$ 258,106.20
f. Totals	$ 3,908,612.50 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 3,908,612.50 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 0.00 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Bernardino

Fiscal Year Reported: 2014/2015 **Date Submitted:** 04/15/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 01/08/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 2,040,262.26
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	96,651	$ 1,766,321.69	100%
b. Allowable Claims Submitted	93,517	$ 1,707,194.71	97%
c. Allowable Claims Reimbursed	93,517	$ 1,707,194.71	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Risk Management
Contact: Rafael Viteri
Title: Deputy Director
Telephone: (909) 386-8730
Email: RViteri@riskmgmt.sbcounty.gov

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 880,939.36
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Arrowhead Regional Medical Center
Contact: Frank Arambula
Title: Chief Financial Officer
Telephone: (909 580-6150
Email: ArambulaF@armc.sbcounty.gov

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: SAN DIEGO

Fiscal Year Reported: 2014 - 2015 Date Submitted: 4/29/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State-operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 28,573,590.53

2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited	Without Interest
a. Government Code Section 76000	$ 7,588,268.25	$ 3,128,950.00	
b. Government Code Section 76000.5	$ 1,906,276.24	$ 1,902,819.00	
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 297,511.32	$ 296,973.00	Richie Fund Only
d. Government Code Section 76104	$ 2,203,787.56	$ 2,199,792.00	
e. Vehicle Code Section 42007 (e)	106,999	$ 106,999.00	
f. Totals	~~$ 11,995,843.37~~ 12,102,842.37	$ 7,635,533.00	

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 7,635,533.00

** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.

Entity: San Diego Superior Court
Contact: Jeffrey Gately Telephone: (619) 450-7205
Title: Chief Financial Officer Email: Jeffrey.Gately@sdcourt.ca.gov

5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.

Entity: County of San Diego Emergency Medical Services
Contact: Marlene Goldstein Telephone: (619) 285-6533
Title: Admin Analyst III Email: Marlene.Goldstein@sdcounty.ca.gov

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 1,695,180.98
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 7,635,533.00
   INTEREST $ 4,539.26
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 9,335,253.24
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 764,412.00
b. Other Emergency Medical Services*	$ 1,118,326.52
c. Hospitals	$ 1,645,811.00
d. Physicians/Surgeons	$ 3,818,022.00
e. Richie Fund	$ 298,458.00
f. Totals	$ 7,645,029.52

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 7,645,029.52
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 1,690,223.72

** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Reimbursement to category b → $ 483.00
Please see attached for description of other medical services $ 1,690,706.72

C. RICHIE'S FUND

1. Has the reporting entity established a Richie Fund? ☑ Yes ☐ No
2. If yes, what date was the fund established? 2008

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $ 3,835,522.30
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	132,801	$ 65,147,726.31	100%
b. Allowable Claims Submitted	74,903	$ 34,822,756.66	56%
c. Allowable Claims Reimbursed	74,903	$ 3,763,885.56	100%

3. Please confirm the following required documents are attached to this report:

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: SAN DIEGO

Fiscal Year Reported: 2014 - 2015 Date Submitted: 4/29/2016

- ☑ Descriptions of the physician and surgeon claim payment methodologies PES Program Handbook attached
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund PES Program Handbook attached
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies County met with representatives from Palomar, Sharp, Grossmont, and Scripps Health to review program.
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e HHSA responds to and meets with physicians and related groups concerning payment methodology and distribution.
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (c) of Section 1797.98c 67%-25% of Medi-Cal Fee Schedule

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity:	Americhoice - United Healthcare		
Contact:	Chris Andreasen	Telephone:	888-595-6547
Title:	Director of Operations	Email:	chris-andreasen@uhc.com
Entity:	County of San Diego - Eligibility Operations		
Contact:	Jeannie Hufford	Telephone:	(619) 338-2751
Title:	Chief, Eligibility Contracts & Finance	Email:	Jeannie.Hufford@sdcounty.ca.gov

II. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 1,643,751.75
2. Are funds disbursed to hospitals on a claims basis? *(Note: If no, go to E4.)* ☐ Yes ☑ No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted		$ -	
b. Allowable Claims Submitted		$ -	
c. Allowable Claims Reimbursed		$ -	

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report. *Please see attached for description of the methodology*

5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity:	County of San Diego Emergency Medical Services		
Contact:	Marlene Goldstein	Telephone:	(619) 285-6533
Title:	Admin Analyst III	Email:	Marlene.Goldstein@sdcounty.ca.gov

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: City and County of San Francisco

Fiscal Year Reported: 2014-15 **Date Submitted:** 7/1/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 1,577,051.00
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000 (SB 12)	$ 793,142.00	$ 793,142.00
b. Government Code Section 76000.5 (SB 1773) 675,009	$ ~~783,909.00~~	$ ~~783,909.00~~ 675,009
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 108,900	$ 108,900
d. Government Code Section 76104	$ -	$ -
e. Vehicle Code Section 42007 (e)	$ -	$ -
f. Totals	$ 1,577,051.00	$ 1,577,051.00

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 1,577,051.00
   If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Court of San Francisco, Traffic Division
   Contact: Sue Wong Telephone: 415-551-5757
   Title: CFO Email: suewong@sftc.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: San Francisco Department of Public Health Finance Section
   Contact: Harvey Fong Telephone: (415) 554-2885
   Title: Principal Accountant Email: Harvey.fong@sfdph.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** ***(Note: Include interest earned)*** $ 1,340,016.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** ***(Note: Data from A3)*** $ 1,577,051.00
3. **Total Maddy EMS Funds available for disbursement.** ***(Note: B1 + B2)*** $ 2,917,067.00
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 158,227.00
b. Other Emergency Medical Services*	$ 191,330.00
c. Hospitals	$ 290,938.00
d. Physicians/Surgeons	$ 607,002.00
e. Reserve	$ 27,442.00
f. Richie's Fund	$ 99,000.00
g. Totals	$ 1,373,939.00

5. **Maddy EMS Fund disbursements during fiscal year being reported.** ***(Note: Data from B4f)*** $ 1,373,939.00
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** ***(Note: B3 - B5)*** $ 1,543,128.00
   If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: City and County of San Francisco

Fiscal Year Reported: 2014-15 **Date Submitted:** 7/1/2016

subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: City and County of San Francisco

Fiscal Year Reported: 2014-15 **Date Submitted:** 7/1/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** ☑ Yes ☐ No
2. **If yes, what date was the fund established?** 7/12/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 634,444.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	29,876	$ 9,467,502.00	100%
b. Allowable Claims Submitted	21,744	$ 634,444.00	73%
c. Allowable Claims Reimbursed	21,744	$ 634,444.00	100%

3. **Please confirm the following required documents are attached to this report:**
   - ☑ Descriptions of the physician and surgeon claim payment methodologies
   - ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
   - ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
   - ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
   - ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c
4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**
   Entity: AmeriChoice (United Health Care)
   Contact: Chris Andreasen Telephone: 858-658-8729
   Title: Director of Operations Email: chris_andreasen@uhc.com

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 290,938.00
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ☐ Yes ☑ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted		$ -	
b. Allowable Claims Submitted		$ -	
c. Allowable Claims Reimbursed		$ -	

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**
   Entity: AmeriChoice (United Health Care)
   Contact: Chris Andreasen Telephone: 858-658-8729
   Title: Director of Operations Email: chris_andreasen@uhc.com

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: City and County of San Francisco

Fiscal Year Reported: 2014-15 **Date Submitted:** 7/1/2016

Annual Maddy Fund Report to the Legislature
Emergency Medical Services Fund

Please type or print responses clearly

County Reporting San Joaquin County

Maddy Fund Administrator Dan Burch, EMS Administrator
Name Title

Telephone 209-468-6818

E-mail dburch@sjgov.org

Court Contact Julian Flores, Fiscal Services Technician
Name Title

Telephone 209-992-5477

Email jflores@sjcourts.org

Date Report Submitted 5/18/16

Fiscal Year Reporting Period 2014-2015

*1.	Total amount of fines and forfeitures collected.	$ 380,353.32
*2.	Total amount penalty assessments collected.	$ not separated from above
3.	Total amount deposited into the EMS Fund.	$ 380,353.32
4.	Total amount of all allowable physician claims submitted.	$ 5,023,597.70
5.	Number of physician claims paid.	10,093
6.	Based on the County's uniform fee schedule, at what percentage were physician claims paid in the "initial" payment?	4.02 %
7.	Based on the County's uniform fee schedule, at what percentage were physician claims paid in a second payment (if a second payment was made in accordance with H&S Code Section 1797.98a.(d)?	0 %
8.	If your payment methodology requires the submission of claims by hospitals, what was the amount of those claims?	$ 0
	Percentage of claims paid	No claims submitted

☐ Does not apply – hospital funds not distributed on a claims basis. Please refer to attached policy & procedures.

Account	Beginning Fund Balance	Deposits	Disbursements	Remaining Fund Balance
Physician (58%)	250,863.18	199,132.44	202,191.38	247,804.24
Hospitals (25%)	151,132.46	86,348.48	0	237,480.94
EMS Purposes (17%)	1,211,666.87	61,558.06	0	1,273,224.93
Administration	112,637.16	38,360.34	0	150,997.50
TOTAL	$1,726,299.67	$385,399.32	$202,191.38	$1,909,507.61

Attach 1) copies of all policies, procedures, and any regulatory actions your county uses to administer the fund, 2) a description of the county's methodology for paying physicians and hospitals from the fund, and 3) the name(s) of physician and hospital administrator organizations, or the name(s) of specific physicians and hospital administrators, the county contacted to review the county's claims payment methodologies.

*Note: As reported to counties by state operated courts

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Luis Obispo

Fiscal Year Reported: FY 2014-15 **Date Submitted:** 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 8,469,117.52
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 338,478.57	$ 338,478.57
b. Government Code Section 76000.5	$ 383,010.76	$ 383,010.76
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 58,499.13	$ 58,499.13
d. Government Code Section 76104	$ 0.00	$ 0.00
e. Vehicle Code Section 42007 (e)	$ 100,548.39	$ 100,548.39
f. Totals	$ 880,536.85 ✓	$ 880,536.85 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 880,536.85 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Court of California, County of San Luis Obispo
   Contact: Michelle Frazier — Telephone: 805-781-5417
   Title: Court Fiscal Director — Email: michelle.frazier@slo.courts.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: County of San Luis Obispo, Auditor-Controller's Office
   Contact: Karen Magill-Pang — Telephone: 805-781-5181
   Title: Accounting Technician — Email: kmagillpang@co.slo.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 301,789.38
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 880,536.85 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 1,182,326.23 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 49,095.52
b. Other Emergency Medical Services*	$ 131,517.23
c. Hospitals	~~$ 172,207.95~~ 149,096.53
d. Physicians/Surgeons	~~$ 426,403.40~~ 399,409.15
e. ~~Reserve~~ Richie's Fund	49,105.67
f. Totals	$ 778,224.10 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 778,224.10 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 404,102.13 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Luis Obispo

Fiscal Year Reported: FY 2014-15 **Date Submitted:** 04/15/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 04/01/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 492,625.71
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	3,445	$ 2,092,213.00	100%
b. Allowable Claims Submitted	3,402	$ 2,042,378.00	99%
c. Allowable Claims Reimbursed	3,402	$ 492,625.71	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: County of San Luis Obispo, Health Agency
Contact: Michael Taylor Telephone: 805-781-4876
Title: Accountant Email: mtaylor@co.slo.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 222,681.57
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: County of San Luis Obispo, Health Agency
Contact: Michael Taylor Telephone: 805-781-4876
Title: Accountant Email: mtaylor@co.slo.ca.us

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Mateo County

Fiscal Year Reported: July 1, 2014- June 30, 2015 (Qtr 2014C, 2014D, 2015A, 2015B) **Date Submitted:** 02/22/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** Unknown
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	Unknown	Unknown
b. Government Code Section 76000.5	Unknown	Unknown
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	Unknown	Unknown $151,527.86
d. Government Code Section 76104	Unknown	Unknown
e. Vehicle Code Section 42007 (e)	Unknown	Unknown
f. Totals	Unknown	~~$2,114,621.00~~

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $2266,148.86 ~~$2,114,621.00~~
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: San Mateo County Superior Court
   Contact: Mona Hall — Telephone: (650) 599-1531
   Title: Director of Finance, Superior Court — Email: mhall@sanmateocourt.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: San Mateo County Accounting
   Contact: Imelda Baumgard — Telephone: 650-573-2374
   Title: Accounting Manager — Email: mbaumgard@smcgov.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 2,906,887.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* 2266148.86 ~~$2,114,621.00~~
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* ~~$ 2,340,696.00~~ 5,173,035.86
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 438,865.00
b. Other Emergency Medical Services*	$ 235,156.00
c. Hospitals	$ 503,378.00
d. Physicians/Surgeons	$ 1,163,297.00
e. Reserve ~~Richie's Fund~~	$150,000 $ 0.00
f. Totals	~~$ 2,340,696.00~~

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $2,490696 ~~$2,340,696.00~~
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* ~~$ 2,707,549.00~~ 2,682,339.86
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: San Mateo County

Fiscal Year Reported: July 1, 2014- June 30, 2015 (Qtr 2014C, 2014D, 2015A, 2015B) **Date Submitted:** 02/22/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 1999

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 1,163,297.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	9,124	$ 4,240,615.00	100%
b. Allowable Claims Submitted	9,057	$ 4,240,615.00	99%
c. Allowable Claims Reimbursed	9,057	$ 1,163,297.00	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies http://smchealth.org/sites/default/files/docs/675197805Guidelines_121905.pdf
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: San Mateo County EMS Agency
Contact: Michael Leach
Title: Performance Measurement Analyst
Telephone: 650-573-3768
Email: mleach@smcgov.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 503,378.00
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed		$ 503,378.00	0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**

5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: San Mateo County EMS Agency
Contact: Michael Leach
Title: Performance Measurement Analyst
Telephone: 650-573-3768
Email: mleach@smcgov.org

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Santa Barbara

Fiscal Year Reported: 2014-2015 **Date Submitted:** 06/28/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $21,603,705.66
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected**	Deposited
a. Government Code Section 76000	$ 83,896.00	$ 41,948.00
b. Government Code Section 76000.5	2,000,920	400,184
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	353,100 ~~$ 2,354,920.00~~	70,620 ~~$ 470,804.00~~
d. Government Code Section 76104	$ 284,814.00	$ 142,407.00
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 2,722,730.00	$ 655,159.00

*** Note: The EMS fines, forfeitures, and penalties is an estimated amount based on the amount deposited ($655,159) to the EMS trust fund. The estimated total EMS fines & forfeitures and penalties collected is the amount deposited divided by the fraction of dollars as described in the legislation.*

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 655,159.00
   **** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.***
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Santa Barbara Superior Court
   Contact: Tim Upton Telephone: 805-882-4677
   Title: Supervising Accountant Email: tupton@sbcourts.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Santa Barbara County EMS Agency
   Contact: John Eaglesham Telephone: 805-681-5394
   Title: EMS Agency Director Email: john.eaglesham@sbcphd.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** ***(Note: Include interest earned)*** $ 756,428.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** ***(Note: Data from A3)*** $ 655,159.00
3. **Total Maddy EMS Funds available for disbursement.** ***(Note: B1 + B2)*** $ 1,411,587.00
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 53,850.00
b. Other Emergency Medical Services*	$ 86,997.00
c. Hospitals	$ 125,288.00
d. Physicians/Surgeons	$ 326,221.00
e. ~~Reserve~~ Richie's Fund	Ø
f. Totals	$ 592,356.00

5. **Maddy EMS Fund disbursements during fiscal year being reported.** ***(Note: Data from B4f)*** $ 592,356.00
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** ***(Note: B3 - B5)*** $ 819,231.00
   **** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.***
   **distributed to EMS Agency to partially fund trauma manager, medical CQI coordinator and medical director.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Santa Barbara

Fiscal Year Reported: 2014-2015 **Date Submitted:** 06/28/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 01/01/2009

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 401,045.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	%Claims
a. Claims Submitted	17,482	$ 6,996,555.00	100%
b. Allowable Claims Submitted	14,412	$ 5,655,720.00	82%
c. Allowable Claims Reimbursed	14,412	$ 326,221.00	100%

3. **Please confirm the following required documents are attached to this report:**
- [x] Descriptions of the physician and surgeon claim payment methodologies
- [x] Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- [x] Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- [x] Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- [x] Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Santa Barbara County EMS Agency
Contact: John Eaglesham Telephone: 805-681-5394
Title: EMS Agency Director Email: john.eaglesham@sbcphd.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 213,855.00
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* (●) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	%Claims
a. Claims Submitted	3,052	$ 2,870,229.00	100%
b. Allowable Claims Submitted	2,464	$ 1,947,276.00	81%
c. Allowable Claims Reimbursed	2,464	$ 125,268.00	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Santa Barbara County EMS Agency
Contact: John Eaglesham Telephone: 805-681-5394
Title: EMS Agency Director Email: john.eaglesham@sbcphd.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: County of Santa Clara

Fiscal Year Reported: FY 2015 **Date Submitted:** 04/21/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 2,091,536.03
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 375,770.55	$ 375,770.55
b. Government Code Section 76000.5	$ 1,715,765.48	$ 1,715,765.48
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 2,091,536.03	$ 2,091,536.03

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 2,091,536.03
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Superior Court, County of Santa Clara
   Contact: Stephanie Gomez Telephone: 408-882-2871
   Title: Director, Finance Email: sgomez@scscourt.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: County of Santa Clara
   Contact: Marilou Mutuc Telephone: 408-299-5249
   Title: Accountant Email: marilou.mutuc@fin.sccgov.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 35,210.50
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 2,091,536.03
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 2,126,746.53
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 130,416.41
b. Other Emergency Medical Services*	$ 299,847.83
c. Hospitals	$ 440,952.68
d. Physicians/Surgeons	$ 1,255,529.61
e. Reserve	$ 0.00
f. Totals	$ 2,126,746.53

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 2,126,746.53
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 0.00
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: County of Santa Clara

Fiscal Year Reported: FY 2015 **Date Submitted:** 04/21/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 1,255,529.61
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	77,419	$ 23,771,484.25	100%
b. Allowable Claims Submitted	68,120	$ 23,605,743.25	88%
c. Allowable Claims Reimbursed	68,120	$ 1,255,529.61	100%

3. **Please confirm the following required documents are attached to this report:**
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Santa Clara Valley Health and Hospital System , Finance Dept.
Contact: Pearly Epp Telephone: 408-885-6889
Title: Maddy Funds Administrator Email: pearly.epp@hhs.sccgov.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 440,952.68
2. **Are funds disbursed to hospitals on a claims basis?** ***(Note: If no, go to E4.)*** ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Santa Clara Valley Health and Hospital System
Contact: Pearly Epp Telephone: 408-885-6889
Title: Maddy Funds Administrator Email: pearly.epp@hhs.sccgov.org

Annual Maddy Fund Report to the Legislature
Emergency Medical Services Fund

Please type or print responses clearly

County Reporting **Santa Cruz**

Maddy Fund Administrator **Michael Beaton** (Name) **Director of Admin** (Title)

Telephone **(831) 454-4449**

E-mail beatonm@co.santa-cruz.ca.us

Date Report Submitted **11/06/15**

Fiscal Year Reporting Period **2014-15**

*1.	Total amount of fines and forfeitures collected.	* includes penalties	211,935.51
*2.	Total amount penalty assessments collected.	interest	160.33
3.	Total amount deposited into the EMS Fund.		212,095.84
4.	Total amount of all allowable physician claims submitted.		2,263,509.00
5.	Number of physician claims paid.		4,630
6.	Based on the County's uniform fee schedule, at what percentage were physician claims paid in the "initial" payment?		13.45%
7.	Based on the County's uniform fee schedule, at what percentage were physician claims paid in a second payment (if a second payment was made in accordance with H&S Code Section 1797.98a.(d)?		na
8.	If your payment methodology requires the submission of claims by hospitals, what was the amount of those claims?		na
	Percentage of claims paid		na

☒ Does not apply – hospital funds not distributed on a claims basis. Please refer to attached policy & procedures.

Account	Beginning Fund Balance	Deposits	Disbursements	Remaining Fund Balance
Physician (52.20%)	(85,698.38)	212,051.83	189,114.62	(62,761.17)
Hospitals (22.5%)	219,268.31	95,679.86	148,875.00	166,073.17
EMS Purposes (15.3%)	74,148.95	58,633.72	0.00	132,782.67
Administration (10.0%)	7,012.69	28,905.11	0.00	35,917.80
TOTAL	214,731.57	395,270.52	337,989.62	272,012.47

Attach 1) copies of all policies, procedures, and any regulatory actions your county uses to administer the fund, 2) a description of the county's methodology for paying physicians and hospitals from the fund, and 3) the name(s) of physician and hospital administrator organizations, or the name(s) of specific physicians and hospital administrators, the county contacted to review the county's claims payment methodologies.

*Note: As identifed by deposits into Trust Fund

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: SISKIYOU

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/22/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated court(s))

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 181,887.73
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 142,320.69	$ 142,320.69
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 142,320.69	$ 142,320.69

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 142,320.69
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: COUNTY OF SISKYOU / AUDITOR - CONTROLLER
   Contact: JENNIE EBEJER Telephone: 530-842-8030
   Title: AUDITOR-CONTROLLER Email: JEBEJER@CO.SISKIYOU.CA.US
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: COUNTY OF SISKIYOU / PUBLIC HEALTH DIVISION
   Contact: DAWN WALTON Telephone: 530-841-2149
   Title: DEPARTMENT FISCAL OFFICER Email: DWALTON@CO.SISKIYOU.CA.US

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 181,887.73
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 142,320.69
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 324,208.42
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 11,216.81
b. Other Emergency Medical Services*	$ 26,529.09
c. Hospitals	$ 26,103.80
d. Physicians/Surgeons	$ 41,741.30
e. Reserve	
f. Totals	$ 105,591.00

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 105,591.00
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 218,617.42
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: SISKIYOU

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/22/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 165,469.03
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	1,662	$ 184,595.14	100%
b. Allowable Claims Submitted	1,020	$ 173,340.39	61%
c. Allowable Claims Reimbursed	1,020	$ 41,741.30	100%

3. **Please confirm the following required documents are attached to this report:**
- ☐ Descriptions of the physician and surgeon claim payment methodologies
- ☐ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☐ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: COUNTY OF SISKYOU / PUBLIC HEALTH DIVISION
Contact: DAWN WALTON Telephone: 530/841-2149
Title: DEPARTMENT FISCAL OFFICER Email: DWALTON@CO.SISKIYOU.CA.US

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 77,700.19
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ◉ Yes ○ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	474	$ 512,290.76	100%
b. Allowable Claims Submitted	200	$ 358,864.06	42%
c. Allowable Claims Reimbursed	200	$ 9,292.92	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: COUNTY OF SISKYOU / PUBLIC HEALTH DIVISION
Contact: DAWN WALTON Telephone: 530/841-2149
Title: DEPARTMENT FISCAL OFFICER Email: DWALTON@CO.SISKIYOU.CA.US

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Solano County

Fiscal Year Reported: FY 2014- 2015 **Date Submitted:** 04/13/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 848,561.92
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104	305,389.73 ~~$ 40,182.41~~	$ 305,389.73
e. Vehicle Code Section 42007 (e)		
f. Totals	305,389.73 ~~$ 40,182.41~~ ✓	$ 305,389.73 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 305,389.73 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Solano Superior Court/ Solano County Probation Department
   Contact: Liliana Chavez/ Lennette Maniaul — Telephone: 707-207-7479/ 707-784-7626
   Title: Court Accountant/ Admin Services Manager — Email: LGRebisz@solano.courts.ca.gov/ LManiaul@SolanoCounty.com
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Solano Superior Court/ Solano County Probation Department
   Contact: Liliana Chavez/ Lennette Maniaul — Telephone: 707-207-7479/ 707-784-7626
   Title: Court Accountant/ Admin Services Manager — Email: LGRebisz@solano.courts.ca.gov/ LManioul@SolanoCounty.com

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 227,439.94
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 305,389.73 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 532,829.67 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 28,309.28
b. Other Emergency Medical Services*	$ 46,508.91
c. Hospitals	$ 0.00
d. Physicians/Surgeons	$ 158,677.45
e. Reserve	$ 0.00
f. Totals	$ 233,495.64 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 233,495.64 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 299,334.03 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Solano County

Fiscal Year Reported: FY 2014- 2015 **Date Submitted:** 04/13/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 158,677.45
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	9,219	$ 6,289,274.65	100%
b. Allowable Claims Submitted	9,030	$ 6,229,429.33	98%
c. Allowable Claims Reimbursed	9,030	$ 158,677.42	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: County of Solano- Health and Social Services
Contact: Sally Wright Telephone: 707-784-8508
Title: Staff Analyst Email: SAWright@solanocounty.com

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 224,290.60
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ◉ Yes ○ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	0	$ 0.00	0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: County of Solano -Health and Social Services
Contact: Sally Wright Telephone: 707-784-8508
Title: Staff Analyst Email: SAWright@solanocounty.com

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Sonoma

Fiscal Year Reported: 14/15 **Date Submitted:** 06/06/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** 1,103,785.55 ~~$ 1,017,986.64~~

2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 1,017,986.64	$ 1,017,986.64
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	85,798.91	85,798.91
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals 1,103,785.55	~~$ 1,017,986.64~~	~~$ 1,017,986.64~~ 1,103,785.55

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** ~~$ 1,017,986.64~~
** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**

Entity: Sonoma County Courts
Contact: Linda Walker Telephone: 707-521-6507
Title: Court Financial Email: lwalker@sonomacountycourt.org

5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**

Entity: Sonoma County Department of Health Services
Contact: Rachel Sweet Telephone: 707-565-4898
Title: Accountant II Email: rachel.sweet@sonoma-county.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 580,414.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* 1,103,785.55 ~~$ 1,017,986.64~~
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* 1,684,199.55 ~~$ 1,598,400.64~~
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 102,657.65
b. Other Emergency Medical Services*	$ 112,073.15
c. Hospitals	$ 209,529.97
d. Physicians/Surgeons	$ 486,109.51
e. Reserve	$ 30,407.23
f. ~~Totals~~ Pediatric Trauma 43,473	~~$ 940,777.51~~

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* 984,250.51 ~~$ 940,777.51~~
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* 699,949.04 ~~$ 657,623.13~~

** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Sonoma

Fiscal Year Reported: 14/15 **Date Submitted:** 06/06/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 01/01/2008

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 486,109.51
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	9,007	$ 3,988,195.00	100%
b. Allowable Claims Submitted	9,007	$ 3,988,195.00	100%
c. Allowable Claims Reimbursed	9,007	$ 3,988,195.00	100%

3. **Please confirm the following required documents are attached to this report:**
- [x] Descriptions of the physician and surgeon claim payment methodologies
- [x] Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- [x] Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- [x] Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- [x] Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Sonoma County Department of Health Services
Contact: Rachel Sweet Telephone: 707-565-4898
Title: Accountant Email: rachel.sweet@sonoma-county.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 200,734.25
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ( ) Yes (●) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Sonoma County Coastal Valley EMS
Contact: Joanne Chapman Telephone: 707-565-6506
Title: EMS Coordinator Email: joannechapman@sonoma-county.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Stanislaus County

Fiscal Year Reported: 2014-2015 **Date Submitted:**

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 823,524.00
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 139,283.00	$ 139,283.00
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)	$ 688,132.00	$ 688,132.00
f. Totals	$ 827,415.00 ✓	$ 827,415.00 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 827,415.00 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Stanislaus County Auditor Controller's Office
   Contact: Jillian Echavarria — Telephone: (209 525-6598
   Title: Accountant II — Email: echavarria@stancounty.com
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Stanislaus County Health Services Agency
   Contact: Maria Blanco — Telephone: (209) 558-4802
   Title: Manager III — Email: mblanco@schsa.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 552,717.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 827,415.00 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 1,380,132.00 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 259,002.00
b. Other Emergency Medical Services*	
c. Hospitals	$ 148,923.00
d. Pbysicians/Surgeons	$ 572,797.00
e. ~~Reserve~~ Richie distribution	$ 160,888.00
f. Totals	$ 1,141,610.00 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 1,141,610.00 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 238,522.00 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Stanislaus County

Fiscal Year Reported: 2014-2015 **Date Submitted:**

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 03/20/2007

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 759,856.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	27,296	$ 14,749,027.00	100%
b. Allowable Claims Submitted	27,296	$ 14,749,027.00	100%
c. Allowable Claims Reimbursed	27,061	$ 422,013.00	99%

3. **Please confirm the following required documents are attached to this report:**
- [x] Descriptions of the physician and surgeon claim payment methodologies
- [x] Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- [ ] Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- [ ] Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- [x] Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Stanislaus Foundation for Medical and Dental Care
Contact: Joanne Chipponeri Telephone: (209) 527-1704
Title: Chief Executive Officer Email: fmc@stanislausmedicalsociety.com

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 359,207.00
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* (●) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	445	$ 5,907,273.00	100%
b. Allowable Claims Submitted	443	$ 5,789,896.00	100%
c. Allowable Claims Reimbursed	443	$ 202,884.00	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Stanislaus County Health Services Agency
Contact: Maria Blanco Telephone: (209) 558-4802
Title: Manager III Email: mblanco@schsa.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Sutter County

Fiscal Year Reported: 2014-15 **Date Submitted:** 03/25/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 124,737.94
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104	$ 124,737.94	$ 124,737.94
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 124,737.94 ✓	$ 124,737.94 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 124,737.94 ✓
   If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Sutter County Superior Court
   Contact: Brenda Cummings — Telephone: (530) 822-3340
   Title: Fiscal Manager — Email: bcummings@suttercourts.com
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Sutter County Auditor Controller
   Contact: Ronda Putman — Telephone: (530) 822-7127
   Title: Assistant Auditor Controller — Email: rputman@co.sutter.ca.us

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 623,506.26
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 124,737.94 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 748,244.20 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 13,136.76
b. Other Emergency Medical Services*	$ 20,099.24
c. Hospitals	$ 28,063.80
d. Physicians/Surgeons	$ 61,218.35
e. Reserve	
f. Totals	$ 122,518.15 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 122,518.15 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 625,726.05 ✓
   If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Sutter County

Fiscal Year Reported: 2014-15 **Date Submitted:** 03/25/2016

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** ○ Yes ◉ No
2. **If yes, what date was the fund established?**

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 129,966.16
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	1,602	$ 767,896.00	100%
b. Allowable Claims Submitted	1,602	$ 767,896.00	100%
c. Allowable Claims Reimbursed	1,602	$ 61,218.35	100%

3. **Please confirm the following required documents are attached to this report:**
- ☑ Descriptions of the physician and surgeon claim payment methodologies
- ☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Sutter County Human Services - Health Division
Contact: Pamela Givans Telephone: (530) 822-7215
Title: Administrative Services Officer Email: pgivans@co.sutter.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 28,063.80
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* ○ Yes ◉ No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	0	$ 0.00	0%
b. Allowable Claims Submitted	0	$ 0.00	0%
c. Allowable Claims Reimbursed	0	$ 0.00	0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Sutter County Human Services - Health Division
Contact: Pamela Givans Telephone: (530) 822-7215
Title: Administrative Services Officer Email: pgivans@co.sutter.ca.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: TRINITY COUNTY

Fiscal Year Reported: 2014-2015 Date Submitted: 04/15/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 21,338.93
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$ 21,338.93	$ 21,338.93
b. Government Code Section 76000.5	$ 0.00	$ 0.00
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 0.00	$ 0.00
d. Government Code Section 76104	$ 0.00	$ 0.00
e. Vehicle Code Section 42007 (e)	$ 35,018.80	$ 0.00
f. Totals	$ 56,357.73	$ 21,338.93

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 21,338.93
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
   Entity: Trinity Superior Court
   Contact: Gary Sandal Telephone: 530-623-8355
   Title: HR & Technology Analyst Email: gsandahl@trinitycounty.org
5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
   Entity: Trinity County Auditor-Controller
   Contact: Christine Gaffney Telephone: 530-623-8362
   Title: Accountant I Email: cgaffney@trinitycounty.org

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 64,891.50
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 21,338.93
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 86,230.43
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 2,133.89
b. Other Emergency Medical Services*	$ 2,099.60
c. Hospitals	$ 4,745.53
d. Physicians/Surgeons	$ 54.82
e. Reserve	$ 11,656.41
f. Totals	$ 20,690.25

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 20,690.25
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 65,540.18
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

65540.18

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: TRINITY COUNTY

Fiscal Year Reported: 2014-2015 Date Submitted: 04/15/2016

C. RICHIE's FUND

1. Has the reporting entity established a Richie Fund? ○ Yes ◉ No
2. If yes, what date was the fund established?

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $ 61,565.60
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	0	$ 0.00	0%
b. Allowable Claims Submitted	0	$ 0.00	0%
c. Allowable Claims Reimbursed	0	$ 0.00	0%

3. Please confirm the following required documents are attached to this report:

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity: Trinity County Auditor-Controllor
Contact: Christine Gaffney Telephone: 530-623-8382
Title: Accountant I Email: cgaffney@trinitycounty.org

E. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 4,745.53
2. Are funds disbursed to hospitals on a claims basis? *(Note: If no, go to E4.)* ◉ Yes ○ No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	1	$ 4,745.53	100%
b. Allowable Claims Submitted	1	$ 4,745.53	100%
c. Allowable Claims Reimbursed	1	$ 4,745.53	100%

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity: Trinity County Auditor-Controllor
Contact: Christine Gaffney Telephone: 530-623-8382
Title: Accountant I Email: cgaffney@trinitycounty.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA #21 (Rev. 10/2015)
Page 1 of 2

Maddy Emergency Medical Services (EMS) Fund Report

County: Tulare County

Fiscal Year Reported: 2014 - 2015 Date Submitted:

A. Penalty Assessments Collected and Deposited in Maddy EMS Fund

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$	$
b. Government Code Section 76000.5	$	$
c. Government Code Section 76000.10 for purposes of subdivision (b) of Health and Safety Code Section 1797.98a	$	$
d. Government Code Section 76104	$	$
e. Vehicle Code Section 42007 (a)	$	$
f. Totals	$	$

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $
*If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.

4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.

Entity:	Tulare County Probation	/	Tulare County Superior Court		
Contact:	Sheryl Pecharich	/	Cherie Ferreira	Telephone:	( ) -
Title:	Program Analyst Supervisor	/	Accountant III	Email:	

5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.

Entity:	Tulare County Probation	/	Tulare County Superior Court		
Contact:	Sheryl Pecharich	/	Cherie Ferreira	Telephone:	( ) -
Title:	Program Analyst Supervisor	/	Accountant III	Email:	

B. Maddy EMS Fund

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. (Note: Include interest earned) $
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. (Note: Data from A3) $
3. Total Maddy EMS Funds available for disbursement. (Note: B1 + B2) $
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$
b. Other Emergency Medical Services*	$ 119,538.24
c. Uniforms	$ 123,307.89
d. Physicians/Surgeons	$ 425,274.31
e. Reserve Funds	$
f. Totals	$

5. Maddy EMS Fund disbursements during fiscal year being reported. (Note: Data from B4) $
6. Maddy EMS Fund balance on last day of the fiscal year being reported. (Note: B3 - B5) $
*If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (3) of subdivision (b) of Section 1797.98a, please attach a description of each of these services to this report.

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Tulare County

Fiscal Year Reported: 2011 - 2012 **Date Submitted:** [illegible]

A. MADDY EMS FUND

1. Has the reporting entity established a Maddy Fund? ◉ Yes ○ No
2. If yes, what date was the fund established? [illegible]

B. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. [illegible]
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	5,891	$ [illegible]	100%
b. Allowable Claims Submitted	5,891	$ [illegible]	100%
c. Allowable Claims Reimbursed	5,891	$ [illegible]	100%

3. Please confirm the following required documents are attached to this report.
- ☑ Description of the physician and surgeon claims payment methodologies
- ☑ Summary of the policies, procedures, and regulatory action taken to implement and administer the fund
- ☑ Name(s) of physician and hospital administrative organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- ☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- ☑ Identification of the fee schedule used by the county pursuant to subdivision (c) of Section 1797.98c

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity: Tulare County Health & Human Services
Contact: Dena Allen Telephone: [illegible]
Title: Administrative Services Officer II Email: [illegible]@tularehhsa.org

C. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ [illegible]
2. Are funds disbursed to hospitals on a claims basis? (Note: If no, go to C4.) ◉ Yes ○ No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	438	$ [illegible]	100%
b. Allowable Claims Submitted	438	$ [illegible]	100%
c. Allowable Claims Reimbursed	438	$ [illegible]	100%

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity: Tulare County Health & Human Services
Contact: Dena Allen Telephone: [illegible]
Title: Administrative Services Officer II Email: [illegible]@tularehhsa.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Tuolumne

Fiscal Year Reported: 2014-2015 **Date Submitted:** 04/14/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. 78,749.79 ~~$ 0.00~~
2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.

Statute	Collected	Deposited
a. Government Code Section 76000	$ 78,749.79	$ 78,749.79
b. Government Code Section 76000.5		
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a		
d. Government Code Section 76104		
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 78,749.79	$ 78,749.79

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 78,749.79
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.
   Entity: County of Tuolumne
   Contact: Michelle Ronning — Telephone: 209-533-5547
   Title: Revenue Recovery Manager — Email: mronning@co.tuolumne.ca.us
5. Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.
   Entity: Superior Court of Tuolumne County
   Contact: Shelley Walker — Telephone: 209-533-6928
   Title: Court Fiscal Manager — Email: shelley@tuolumne.courts.ca.gov

B. MADDY EMS FUND

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. *(Note: Include interest earned)* $ 2,755.84
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. *(Note: Data from A3)* $ 78,749.79
3. Total Maddy EMS Funds available for disbursement. *(Note: B1 + B2)* $ 81,505.63
4. For each category listed enter disbursements during the fiscal year being reported.

Category	Disbursements
a. Administration	$ 8,135.00
b. Other Emergency Medical Services*	$ 12,446.00
c. Hospitals	$ 18,303.00
d. Physicians/Surgeons	$ 42,464.17
e. Reserve	
f. Totals	$ 81,348.17

5. Maddy EMS Fund disbursements during fiscal year being reported. *(Note: Data from B4f)* $ 81,348.17
6. Maddy EMS Fund balance on last day of the fiscal year being reported. *(Note: B3 - B5)* $ 157.46
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Tuolumne

Fiscal Year Reported: 2014-2015 Date Submitted: 04/14/2016

C. RICHIE's FUND

1. Has the reporting entity established a Richie Fund? ○ Yes ◉ No
2. If yes, what date was the fund established?

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $ 42,544.00
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	1,044	$ 393,450.00	100%
b. Allowable Claims Submitted	987	$ 228,670.00	95%
c. Allowable Claims Reimbursed	987	$ 42,464.00	100%

3. Please confirm the following required documents are attached to this report:

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☐ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☐ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.

Entity: County of Tuolumne
Contact: Jessica Tucker Telephone: 209-533-6593
Title: Assistant Auditor-Controller Email: jtucker@co.tuolumne.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 18,338.00
2. Are funds disbursed to hospitals on a claims basis? *(Note: If no, go to E4.)* ○ Yes ◉ No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.

Entity: County of Tuolumne
Contact: Jessica Tucker Telephone: 209-533-6593
Title: Assistant Auditor-Controller Email: jtucker@co.tuolumne.ca.us

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
EMSA 801 (Rev. 10-2015)

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: VENTURA COUNTY
Fiscal Year Reported: FY 2014-15 Date Submitted: 3/31/2016

A FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter total amount of fines and forfeitures collected by County during the fiscal year being reported. $ 2,384,027.19

2. Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	$ 932,456.84	$ 839,157.10
c. Government Code Section 76000.5 for purposes subdivision € of Health and Safety Code Section 1797.98a	$ 393,394.35	$ 354,032.11
d. Government Code Section 76104	$ 810,409.20	$ 729,321.30
e. Vehicle Code Section 42007 (e)	$ 247,766.80	$ 222,975.76
f. Totals	$ 2,384,027.19 ✓	$ 2,145,486.27 ✓

3. Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.* $ 2,145,486.27 ✓
**If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*

4. **Etner contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
Entity: VENTURA SUPERIOR COURT
Contact: RICHARD CABRAL *Telephone:* (805) 289-8881
Title: DIRECTOR OF FINANCE, PLANNING & COLLEC *Email:* richard.cabral@ventura.courts.ca.gov

5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund**
Entity: VENTURA COUNTY EMERGENCY MED SRV
Contact: STEVE CARROLL *Telephone:* (805)981-5305
Title: EMS ADMINISTRATOR *Email:* steve.carroll@ventura.org

A FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. Enter Maddy EMS Fund balance as of first day of fiscal year being reported. (Note: Include interest earned) $ 2,148,666.51
2. Penalty assessments deposited into Maddy EMS fund during fiscal year being reported. (Note: Data from A3) $ 2,145,486.27 ✓
3. Total Maddy EMS Funds available for disbursement. (Note: B1 + B2) $ 4,294,152.78 ✓
4. For each category listed enter disbursements during the fiscal year being reported

Category	Disbursements
a. Administration	630,588.00
b. Other Emergency Medical Services	~~793,637.86~~ 632,597.86
c. Hospitals	454,005.00
d. Physicians/Surgeons	1,041,154.78
e. ~~Reserve~~ Richie's Fund	161,040.00 ✓
f. Totals	2,919,385.64 ✓

5. Maddy EMS Funds disbursements during fiscal year being reported. (Note: Data frp, B4f) $ 2,919,385.64 ✓
6. Maddy EMS Fund balance on last day of fiscal year being reported. (Note: B3 - B5) $ 1,374,767.14 ✓

**If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report*

**4 (b) - Is $161,040 Pediatric Trauma plus $632,597.86 fo Leasehold Improvements cost.

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: VENTURA COUNTY
Fiscal Year Reported: FY 2014-15 Date Submitted: 3/30/2016

C. RICHIE'S FUND

1. Has the reporting entity established a Richie Fund? (X) Yes ( ) No
2. If Yes, what date was the fund established? 7/1/2012

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported. $1,041,154.78
2. Enter data on claims submitted and paid during the fiscal year being reported.

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	15128	$8,278,298.51	100%
b. Allowable Claims Submitted	23894	$2,874,565.41	84%
c. Allowable Claims Reimbursed	23894	$1,041,154.78	84%

3. **Please confirm the following required documentations are attached to this report:**
(X) Description of the physician and surgeon claim payment methodologies
(X) Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
(X) Name(s) of physician and hospital administrator organizations, or names of specific physician/surgeons and hospital administrators, the county contact to review claims payment methodologies
(X) Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
(X) Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c
4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**
Entity: *American Insurance Administrators*
Contact: *Manaz Billimoria* *Telephone:* *(562)463-5044*
Title: *PROGRAM ADMINISTRATOR* *Email:* manaz@mapinc.com

E. REIMBURSEMENT TO HOSPITALS

1. Enter available funding to be disbursed during the fiscal year being reported. $ 454,005.00
2. Are funds disbursed to hospitals on a claims basis? (Note: If no, go to E4.) ( ) Yes (X) No
3. Enter data on claims submitted and reimbursements during the fiscal year being reported.

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			
b. Allowable Claims Submitted			
c. Allowable Claims Reimbursed			

4. Please attach a description of the methodology used to disburse money to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of section 1797.98a to this report. **Exhibit A**
5. Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals
Entity: *Ventura County HCA/PUB Agency*
Contact: *Eloisa Delgado* *Telephone:* *(805) 981-5265*
Title: *Accounting Officer IV* *Email:* eloisa.delgado@ventura.org

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Yolo

Fiscal Year Reported: 2014-15 **Date Submitted:** 02/10/2016

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 1,130,817.13
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000	$ 149,816.65	$ 149,816.65
b. Government Code Section 76000.5	$ 0.00	$ 0.00
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 728,196.48	$ 728,196.48
d. Government Code Section 76104	$ 252,804.00	$ 252,804.00
e. Vehicle Code Section 42007 (e)	$ 0.00	$ 0.00
f. Totals	$ 1,130,817.13 ✓	$ 1,130,817.13 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 1,130,817.13 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Yolo Superior Courts
   Contact: Leanne Sweeney Telephone: 530-406-6700
   Title: Court Financial Officer Email: lsweeney@yolo.courts.ca.gov
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: County of Yolo, Department of Financial Services
   Contact: Mark Krummenaker Telephone: 530-666-8212
   Title: Accounting Manager Email: mkrummenaker@yolocounty.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 3,185,828.00
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 1,130,817.13 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 4,316,645.13 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements
a. Administration	$ 1,557.00
b. Other Emergency Medical Services*	$ 0.00
c. ~~Hospitals~~ Rape's Fund	$ 642,199.78
d. Physicians/Surgeons	$ 201,527.00
e. Reserve	$ 0.00
f. Totals	$ 845,283.78 ✓

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 845,283.78 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 3,471,361.35 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Yolo

Fiscal Year Reported: 2014-15 **Date Submitted:** 02/10/2016

C. RICHIE'S FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 09/30/2006

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 618,053.00
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	6,971	$ 2,257,824.00	100%
b. Allowable Claims Submitted	6,971	$ 2,257,824.00	100%
c. Allowable Claims Reimbursed	6,971	$ 201,527.00	100%

3. **Please confirm the following required documents are attached to this report:**
- [x] Descriptions of the physician and surgeon claim payment methodologies
- [x] Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
- [ ] Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
- [ ] Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
- [x] Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: County of Yolo HHSA
Contact: John Buzolich Telephone: 530-666-8689
Title: Fiscal Administrative Officer Email: jbuzolich@yolocounty.org

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 2,459,304.00
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* (●) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted	7	$ 642,199.78	100%
b. Allowable Claims Submitted	7	$ 642,199.78	100%
c. Allowable Claims Reimbursed	7	$ 642,199.78	100%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: County of Yolo HHSA
Contact: John Buzolich Telephone: 530-666-8689
Title: Fiscal Administrative Officer Email: jbuzolich@yolocounty.org

STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY
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Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Yuba County Health and Human Services

Fiscal Year Reported: 2014-2015 **Date Submitted:** 4/8/16

A. FINES AND FORFEITURES COLLECTED (Note: As reported to County by State operated courts)

1. **Enter total amount of fines and forfeitures collected by County during the fiscal year being reported.** $ 228,284.18
2. **Enter total amount of penalty assessments collected by County and penalty assessments deposited into the Maddy EMS Fund, by individual statute, during the fiscal year being reported.**

Statute	Collected	Deposited
a. Government Code Section 76000		
b. Government Code Section 76000.5	$ 92,219.84	$ 92,219.84
c. Government Code Section 76000.5 for purposes of subdivision (e) of Health and Safety Code Section 1797.98a	$ 16,274.09	$ 16,274.09
d. Government Code Section 76104	$ 119,790.25	$ 119,790.25
e. Vehicle Code Section 42007 (e)		
f. Totals	$ 228,284.18 ✓	$ 228,284.18 ✓

3. **Total penalty assessments deposited into Maddy EMS Fund during fiscal year being reported.*** $ 228,284.18 ✓
   ** If no monies were deposited during the fiscal year being reported, please attach the reason(s) to this report.*
4. **Enter contact information of individual or entity responsible for collection of fines, forfeitures, and penalties.**
   Entity: Yuba Courts
   Contact: Renee Danielson Telephone: 530-749-7611
   Title: Court Division Manager Email: rdanielson@yubacourts.org
5. **Enter contact information of individual or entity responsible for distribution of penalty assessments into the EMS Fund.**
   Entity: Yuba Courts
   Contact: Renee Danielson Telephone: 530-749-7611
   Title: Court Division Manager Email: rdanielson@yubacourts.org

B. MADDY EMS FUND

1. **Enter Maddy EMS Fund balance as of first day of fiscal year being reported.** *(Note: Include interest earned)* $ 127,743.27
2. **Penalty assessments deposited into Maddy EMS fund during fiscal year being reported.** *(Note: Data from A3)* $ 228,284.18 ✓
3. **Total Maddy EMS Funds available for disbursement.** *(Note: B1 + B2)* $ 356,027.45 ✓
4. **For each category listed enter disbursements during the fiscal year being reported.**

Category	Disbursements	
a. Administration	~~$ 15,227.52~~	$ 13,976.03
b. Other Emergency Medical Services*	$ 40,946.00	
c. ~~Hospitals~~ Richie's Fund	~~$ 0.00~~	$ 19,119.52
d. Physicians/Surgeons	~~$ 112,626.00~~	$ 94,658.65
e. Reserve	$ 16,909.90	
f. Totals	$ 185,610.10 ✓	

5. **Maddy EMS Fund disbursements during fiscal year being reported.** *(Note: Data from B4f)* $ 185,610.10 ✓
6. **Maddy EMS Fund balance on last day of the fiscal year being reported.** *(Note: B3 - B5)* $ 170,417.35 ✓
   ** If funds were disbursed for other emergency medical services, pursuant to subparagraph (C) of paragraph (5) of subdivision (b) of Section 1797.98a, please attach a description of each of those services to this report.*

Maddy Emergency Medical Services (EMS) Fund Report

REPORTING ENTITY

County: Yuba County Health and Human Services

Fiscal Year Reported: 2014-2015 **Date Submitted:** 4/8/16

C. RICHIE's FUND

1. **Has the reporting entity established a Richie Fund?** (●) Yes ( ) No
2. **If yes, what date was the fund established?** 03/26/1990

D. REIMBURSEMENT TO PHYSICIANS/SURGEONS

1. **Enter available funding to be disbursed to physicians and surgeons during the fiscal year being reported.** $ 170,037.03
2. **Enter data on claims submitted and paid during the fiscal year being reported.**

Physicians/Surgeons Claims	Number	Amount	% Claims
a. Claims Submitted	1,181	$ 441,940.93	100%
b. Allowable Claims Submitted	1,181	$ 441,940.93	100%
c. Allowable Claims Reimbursed	1,181	$ 117,739.24	100%

3. **Please confirm the following required documents are attached to this report:**

☑ Descriptions of the physician and surgeon claim payment methodologies
☑ Statement of the policies, procedures, and regulatory action taken to implement and administer the fund
☑ Name(s) of physician and hospital administrator organizations, or names of specific physicians/surgeons and hospital administrators, the county contacted to review claims payment methodologies
☑ Description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e
☑ Identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c

4. **Enter information of individual or entity responsible for distribution of funding to physicians/surgeons.**

Entity: Yuba County Health and Human Services
Contact: Jennifer Vasquez
Title: Director
Telephone: 530-749-6358
Email: plee@co.yuba.ca.us

E. REIMBURSEMENT TO HOSPITALS

1. **Enter available funding to be disbursed during the fiscal year being reported.** $ 84,594.61
2. **Are funds disbursed to hospitals on a claims basis?** *(Note: If no, go to E4.)* (●) Yes ( ) No
3. **Enter data on claims submitted and reimbursements during the fiscal year being reported.**

Hospital Claims	Number	Amount	% Claims
a. Claims Submitted			0%
b. Allowable Claims Submitted			0%
c. Allowable Claims Reimbursed			0%

4. **Please attach a description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a to this report.**
5. **Enter contact information individual or entity responsible for distribution of Maddy EMS Funds to hospitals.**

Entity: Yuba County Health and Human Services
Contact: Jennifer Vasquez
Title: Director
Telephone: 530-749-6358
Email: plee@co.yuba.ca.us

RELEVANT STATE CODE SECTIONS

1797.98a. (a) The fund provided for in this chapter shall be known as the Maddy Emergency Medical Services (EMS) Fund.

(b) (1) Each county may establish an emergency medical services fund, upon the adoption of a resolution by the board of supervisors. The moneys in the fund shall be available for the reimbursements required by this chapter. The fund shall be administered by each county, except that a county electing to have the state administer its medically indigent services program may also elect to have its emergency medical services fund administered by the state.

(2) Costs of administering the fund shall be reimbursed by the fund in an amount that does not exceed the actual administrative costs or 10 percent of the amount of the fund, whichever amount is lower.

(3) All interest earned on moneys in the fund shall be deposited in the fund for disbursement as specified in this section.

(4) Each administering agency may maintain a reserve of up to 15 percent of the amount in the portions of the fund reimbursable to physicians and surgeons, pursuant to subparagraph (A) of, and to hospitals, pursuant to subparagraph (B) of, paragraph (5). Each administering agency may maintain a reserve of any amount in the portion of the fund that is distributed for other emergency medical services purposes as determined by each county, pursuant to subparagraph (C) of paragraph (5).

(5) The amount in the fund, reduced by the amount for administration and the reserve, shall be utilized to reimburse physicians and surgeons and hospitals for patients who do not make payment for emergency medical services and for other emergency medical services purposes as determined by each county according to the following schedule:

(A) Fifty-eight percent of the balance of the fund shall be distributed to physicians and surgeons for emergency services provided by all physicians and surgeons, except those physicians and surgeons employed by county hospitals, in general acute care hospitals that provide basic, comprehensive, or standby emergency services pursuant to paragraph (3) or (5) of subdivision (f) of Section 1797.98e up to the time the patient is stabilized.

(B) Twenty-five percent of the fund shall be distributed only to hospitals providing disproportionate trauma and emergency medical care services.

(C) Seventeen percent of the fund shall be distributed for other emergency medical services purposes as determined by each county, including, but not limited to, the funding of regional poison control centers. Funding may be used for purchasing

equipment and for capital projects only to the extent that these expenditures support the provision of emergency services and are consistent with the intent of this chapter.

(c) The source of the moneys in the fund shall be the penalty assessment made for this purpose, as provided in Section 76000 of the Government Code.

(d) Any physician and surgeon may be reimbursed for up to 50 percent of the amount claimed pursuant to subdivision (a) of Section 1797.98c for the initial cycle of reimbursements made by the administering agency in a given year, pursuant to Section 1797.98e. All funds remaining at the end of the fiscal year in excess of any reserve held and rolled over to the next year pursuant to paragraph (4) of subdivision (b) shall be distributed proportionally, based on the dollar amount of claims submitted and paid to all physicians and surgeons who submitted qualifying claims during that year.

(e) Of the money deposited into the fund pursuant to Section 76000.5 of the Government Code, 15 percent shall be utilized to provide funding for all pediatric trauma centers throughout the county, both publicly and privately owned and operated. The expenditure of money shall be limited to reimbursement to physicians and surgeons, and to hospitals for patients who do not make payment for emergency care services in hospitals up to the point of stabilization, or to hospitals for expanding the services provided to pediatric trauma patients at trauma centers and other hospitals providing care to pediatric trauma patients, or at pediatric trauma centers, including the purchase of equipment. Local emergency medical services (EMS) agencies may conduct a needs assessment of pediatric trauma services in the county to allocate these expenditures. Counties that do not maintain a pediatric trauma center shall utilize the money deposited into the fund pursuant to Section 76000.5 of the Government Code to improve access to, and coordination of, pediatric trauma and emergency services in the county, with preference for funding given to hospitals that specialize in services to children, and physicians and surgeons who provide emergency care for children. Funds spent for the purposes of this section, shall be known as Richie's Fund. This subdivision shall remain in effect until January 1, 2017, and shall have no force or effect on or after that date, unless a later enacted statute, that is chaptered before January 1, 2017, deletes or extends that date.

(f) Costs of administering money deposited into the fund pursuant to Section 76000.5 of the Government Code shall be reimbursed from the money collected in an amount that does not exceed the actual administrative costs or 10 percent of the money collected, whichever amount is lower. This subdivision shall remain in effect until January 1, 2017, and shall have no force or effect on or after that date, unless a later enacted statute, that is chaptered before January 1, 2017, deletes or extends that date.

(Amended by Stats. 2013, Ch. 600, Sec. 2. (SB 191) Effective January 1, 2014.)

State of California

HEALTH AND SAFETY CODE

Section 1797.98b

1797.98b. (a) Each county establishing a fund, on January 1, 1989, and on each April 15 thereafter, shall report to the authority on the implementation and status of the Emergency Medical Services Fund. Notwithstanding Section 10231.5 of the Government Code, the authority shall compile and forward a summary of each county's report to the appropriate policy and fiscal committees of the Legislature. Each county report, and the summary compiled by the authority, shall cover the immediately preceding fiscal year, and shall include, but not be limited to, all of the following:

(1) The total amount of fines and forfeitures collected, the total amount of penalty assessments collected, and the total amount of penalty assessments deposited into the Emergency Medical Services Fund, or, if no moneys were deposited into the fund, the reason or reasons for the lack of deposits. The total amounts of penalty assessments shall be listed on the basis of each statute that provides the authority for the penalty assessment, including Sections 76000, 76000.5, and 76104 of the Government Code, and Section 42007 of the Vehicle Code.

(2) The amount of penalty assessment funds collected under Section 76000.5 of the Government Code that are used for the purposes of subdivision (e) of Section 1797.98a.

(3) The fund balance and the amount of moneys disbursed under the program to physicians and surgeons, for hospitals, and for other emergency medical services purposes, and the amount of money disbursed for actual administrative costs. If funds were disbursed for other emergency medical services, the report shall provide a description of each of those services.

(4) The number of claims paid to physicians and surgeons, and the percentage of claims paid, based on the uniform fee schedule, as adopted by the county.

(5) The amount of moneys available to be disbursed to physicians and surgeons, descriptions of the physician and surgeon claims payment methodologies, the dollar amount of the total allowable claims submitted, and the percentage at which those claims were reimbursed.

(6) A statement of the policies, procedures, and regulatory action taken to implement and run the program under this chapter.

(7) The name of the physician and surgeon and hospital administrator organization, or names of specific physicians and surgeons and hospital administrators, contacted to review claims payment methodologies.

(8) A description of the process used to solicit input from physicians and surgeons and hospitals to review payment distribution methodology as described in subdivision (a) of Section 1797.98e.

(9) An identification of the fee schedule used by the county pursuant to subdivision (e) of Section 1797.98c.

(10) (A) A description of the methodology used to disburse moneys to hospitals pursuant to subparagraph (B) of paragraph (5) of subdivision (b) of Section 1797.98a.

(B) The amount of moneys available to be disbursed to hospitals.

(C) If moneys are disbursed to hospitals on a claims basis, the dollar amount of the total allowable claims submitted and the percentage at which those claims were reimbursed to hospitals.

(11) The name and contact information of the entity responsible for each of the following:

(A) Collection of fines, forfeitures, and penalties.

(B) Distribution of penalty assessments into the Emergency Medical Services Fund.

(C) Distribution of moneys to physicians and surgeons.

(b) (1) Each county, upon request, shall make available to any member of the public the report provided to the authority under subdivision (a).

(2) Each county, upon request, shall make available to any member of the public a listing of physicians and surgeons and hospitals that have received reimbursement from the Emergency Medical Services Fund and the amount of the reimbursement they have received. This listing shall be compiled on a semiannual basis.

(Amended by Stats. 2014, Ch. 442, Sec. 5. (SB 1465) Effective September 18, 2014.)

State of California

HEALTH AND SAFETY CODE

Section 1797.98c

1797.98c. (a) Physicians and surgeons wishing to be reimbursed shall submit their claims for emergency services provided to patients who do not make any payment for services and for whom no responsible third party makes any payment.

(b) If, after receiving payment from the fund, a physician and surgeon is reimbursed by a patient or a responsible third party, the physician and surgeon shall do one of the following:

(1) Notify the administering agency, and, after notification, the administering agency shall reduce the physician and surgeon's future payment of claims from the fund. In the event there is not a subsequent submission of a claim for reimbursement within one year, the physician and surgeon shall reimburse the fund in an amount equal to the amount collected from the patient or third-party payer, but not more than the amount of reimbursement received from the fund.

(2) Notify the administering agency of the payment and reimburse the fund in an amount equal to the amount collected from the patient or third-party payer, but not more than the amount of the reimbursement received from the fund for that patient's care.

(c) Reimbursement of claims for emergency services provided to patients by any physician and surgeon shall be limited to services provided to a patient who does not have health insurance coverage for emergency services and care, cannot afford to pay for those services, and for whom payment will not be made through any private coverage or by any program funded in whole or in part by the federal government, with the exception of claims submitted for reimbursement through Section 1011 of the federal Medicare Prescription Drug, Improvement and Modernization Act of 2003, and where all of the following conditions have been met:

(1) The physician and surgeon has inquired if there is a responsible third-party source of payment.

(2) The physician and surgeon has billed for payment of services.

(3) Either of the following:

(A) At least three months have passed from the date the physician and surgeon billed the patient or responsible third party, during which time the physician and surgeon has made two attempts to obtain reimbursement and has not received reimbursement for any portion of the amount billed.

(B) The physician and surgeon has received actual notification from the patient or responsible third party that no payment will be made for the services rendered by the physician and surgeon.

(4) The physician and surgeon has stopped any current, and waives any future, collection efforts to obtain reimbursement from the patient, upon receipt of moneys from the fund.

(d) A listing of patient names shall accompany a physician and surgeon's submission, and those names shall be given full confidentiality protections by the administering agency.

(e) Notwithstanding any other restriction on reimbursement, a county shall adopt a fee schedule and reimbursement methodology to establish a uniform reasonable level of reimbursement from the county's emergency medical services fund for reimbursable services.

(f) For the purposes of submission and reimbursement of physician and surgeon claims, the administering agency shall adopt and use the current version of the Physicians' Current Procedural Terminology, published by the American Medical Association, or a similar procedural terminology reference.

(g) Each administering agency of a fund under this chapter shall make all reasonable efforts to notify physicians and surgeons who provide, or are likely to provide, emergency services in the county as to the availability of the fund and the process by which to submit a claim against the fund. The administering agency may satisfy this requirement by sending materials that provide information about the fund and the process to submit a claim against the fund to local medical societies, hospitals, emergency rooms, or other organizations, including materials that are prepared to be posted in visible locations.

(Amended by Stats. 2005, Ch. 671, Sec. 3. Effective January 1, 2006.)

State of California

HEALTH AND SAFETY CODE

Section 1797.98e

1797.98e. (a) It is the intent of the Legislature that a simplified, cost-efficient system of administration of this chapter be developed so that the maximum amount of funds may be utilized to reimburse physicians and surgeons and for other emergency medical services purposes. The administering agency shall select an administering officer and shall establish procedures and time schedules for the submission and processing of proposed reimbursement requests submitted by physicians and surgeons. The schedule shall provide for disbursements of moneys in the Emergency Medical Services Fund on at least a quarterly basis to applicants who have submitted accurate and complete data for payment. When the administering agency determines that claims for payment for physician and surgeon services are of sufficient numbers and amounts that, if paid, the claims would exceed the total amount of funds available for payment, the administering agency shall fairly prorate, without preference, payments to each claimant at a level less than the maximum payment level. Each administering agency may encumber sufficient funds during one fiscal year to reimburse claimants for losses incurred during that fiscal year for which claims will not be received until after the fiscal year. The administering agency may, as necessary, request records and documentation to support the amounts of reimbursement requested by physicians and surgeons and the administering agency may review and audit the records for accuracy. Reimbursements requested and reimbursements made that are not supported by records may be denied to, and recouped from, physicians and surgeons. Physicians and surgeons found to submit requests for reimbursement that are inaccurate or unsupported by records may be excluded from submitting future requests for reimbursement. The administering officer shall not give preferential treatment to any facility, physician and surgeon, or category of physician and surgeon and shall not engage in practices that constitute a conflict of interest by favoring a facility or physician and surgeon with which the administering officer has an operational or financial relationship. A hospital administrator of a hospital owned or operated by a county of a population of 250,000 or more as of January 1, 1991, or a person under the direct supervision of that person, shall not be the administering officer. The board of supervisors of a county or any other county agency may serve as the administering officer. The administering officer shall solicit input from physicians and surgeons and hospitals to review payment distribution methodologies to ensure fair and timely payments. This requirement may be fulfilled through the establishment of an advisory committee with representatives comprised of local physicians and surgeons and hospital administrators. In order to reduce the county's administrative burden, the administering officer may instead request an existing board, commission, or local medical society, or physicians and

surgeons and hospital administrators, representative of the local community, to provide input and make recommendations on payment distribution methodologies.

(b) Each provider of health services that receives payment under this chapter shall keep and maintain records of the services rendered, the person to whom rendered, the date, and any additional information the administering agency may, by regulation, require, for a period of three years from the date the service was provided. The administering agency shall not require any additional information from a physician and surgeon providing emergency medical services that is not available in the patient record maintained by the entity listed in subdivision (f) where the emergency medical services are provided, nor shall the administering agency require a physician and surgeon to make eligibility determinations.

(c) During normal working hours, the administering agency may make any inspection and examination of a hospital's or physician and surgeon's books and records needed to carry out this chapter. A provider who has knowingly submitted a false request for reimbursement shall be guilty of civil fraud.

(d) Nothing in this chapter shall prevent a physician and surgeon from utilizing an agent who furnishes billing and collection services to the physician and surgeon to submit claims or receive payment for claims.

(e) All payments from the fund pursuant to Section 1797.98c to physicians and surgeons shall be limited to physicians and surgeons who, in person, provide onsite services in a clinical setting, including, but not limited to, radiology and pathology settings.

(f) All payments from the fund shall be limited to claims for care rendered by physicians and surgeons to patients who are initially medically screened, evaluated, treated, or stabilized in any of the following:

(1) A basic or comprehensive emergency department of a licensed general acute care hospital.

(2) A site that was approved by a county prior to January 1, 1990, as a paramedic receiving station for the treatment of emergency patients.

(3) A standby emergency department that was in existence on January 1, 1989, in a hospital specified in Section 124840.

(4) For the 1991–92 fiscal year and each fiscal year thereafter, a facility which contracted prior to January 1, 1990, with the National Park Service to provide emergency medical services.

(5) A standby emergency room in existence on January 1, 2007, in a hospital located in Los Angeles County that meets all of the following requirements:

(A) The requirements of subdivision (m) of Section 70413 and Sections 70415 and 70417 of Title 22 of the California Code of Regulations.

(B) Reported at least 18,000 emergency department patient encounters to the Office of Statewide Health Planning and Development in 2007 and continues to report at least 18,000 emergency department patient encounters to the Office of Statewide Health Planning and Development in each year thereafter.

(C) A hospital with a standby emergency department meeting the requirements of this paragraph shall do both of the following:

(i) Annually provide the State Department of Public Health and the local emergency medical services agency with certification that it meets the requirements of subparagraph (A). The department shall confirm the hospital's compliance with subparagraph (A).

(ii) Annually provide to the State Department of Public Health and the local emergency medical services agency the emergency department patient encounters it reports to the Office of Statewide Health Planning and Development to establish that it meets the requirement of subparagraph (B).

(g) Payments shall be made only for emergency medical services provided on the calendar day on which emergency medical services are first provided and on the immediately following two calendar days.

(h) Notwithstanding subdivision (g), if it is necessary to transfer the patient to a second facility providing a higher level of care for the treatment of the emergency condition, reimbursement shall be available for services provided at the facility to which the patient was transferred on the calendar day of transfer and on the immediately following two calendar days.

(i) Payment shall be made for medical screening examinations required by law to determine whether an emergency condition exists, notwithstanding the determination after the examination that a medical emergency does not exist. Payment shall not be denied solely because a patient was not admitted to an acute care facility. Payment shall be made for services to an inpatient only when the inpatient has been admitted to a hospital from an entity specified in subdivision (f).

(j) The administering agency shall compile a quarterly and yearend summary of reimbursements paid to facilities and physicians and surgeons. The summary shall include, but shall not be limited to, the total number of claims submitted by physicians and surgeons in aggregate from each facility and the amount paid to each physician and surgeon. The administering agency shall provide copies of the summary and forms and instructions relating to making claims for reimbursement to the public, and may charge a fee not to exceed the reasonable costs of duplication.

(k) Each county shall establish an equitable and efficient mechanism for resolving disputes relating to claims for reimbursements from the fund. The mechanism shall include a requirement that disputes be submitted either to binding arbitration conducted pursuant to arbitration procedures set forth in Chapter 3 (commencing with Section 1282) and Chapter 4 (commencing with Section 1285) of Part 3 of Title 9 of the Code of Civil Procedure, or to a local medical society for resolution by neutral parties.

(*l*) Physicians and surgeons shall be eligible to receive payment for patient care services provided by, or in conjunction with, a properly credentialed nurse practitioner or physician's assistant for care rendered under the direct supervision of a physician and surgeon who is present in the facility where the patient is being treated and who is available for immediate consultation. Payment shall be limited to those claims that are substantiated by a medical record and that have been reviewed and countersigned

by the supervising physician and surgeon in accordance with regulations established for the supervision of nurse practitioners and physician assistants in California.

(Amended by Stats. 2008, Ch. 288, Sec. 2. Effective January 1, 2009.)

State of California

HEALTH AND SAFETY CODE

Section 1797.98f

1797.98f. Notwithstanding any other provision of this chapter, an emergency physician and surgeon, or an emergency physician group, with a gross billings arrangement with a hospital shall be entitled to receive reimbursement from the Emergency Medical Services Fund for services provided in that hospital, if all of the following conditions are met:

(a) The services are provided in a basic or comprehensive general acute care hospital emergency department, or in a standby emergency department in a small and rural hospital as defined in Section 124840.

(b) The physician and surgeon is not an employee of the hospital.

(c) All provisions of Section 1797.98c are satisfied, except that payment to the emergency physician and surgeon, or an emergency physician group, by a hospital pursuant to a gross billings arrangement shall not be interpreted to mean that payment for a patient is made by a responsible third party.

(d) Reimbursement from the Emergency Medical Services Fund is sought by the hospital or the hospital's designee, as the billing and collection agent for the emergency physician and surgeon, or an emergency physician group.

For purposes of this section, a "gross billings arrangement" is an arrangement whereby a hospital serves as the billing and collection agent for the emergency physician and surgeon, or an emergency physician group, and pays the emergency physician and surgeon, or emergency physician group, a percentage of the emergency physician and surgeon's or group's gross billings for all patients.

(Amended by Stats. 1998, Ch. 1016, Sec. 3. Effective January 1, 1999.)

State of California

HEALTH AND SAFETY CODE

Section 1797.98g

1797.98g. The moneys contained in an Emergency Medical Services Fund, other than moneys contained in a Physician Services Account within the fund pursuant to Section 16952 of the Welfare and Institutions Code, shall not be subject to Article 3.5 (commencing with Section 16951) of Chapter 5 of Part 4.7 of Division 9 of the Welfare and Institutions Code.

(Added by Stats. 1991, Ch. 1169, Sec. 4.)

State of California

GOVERNMENT CODE

Section 76000

76000. (a) (1) Except as otherwise provided elsewhere in this section, in each county there shall be levied an additional penalty in the amount of seven dollars ($7) for every ten dollars ($10), or part of ten dollars ($10), upon every fine, penalty, or forfeiture imposed and collected by the courts for all criminal offenses, including all offenses involving a violation of the Vehicle Code or any local ordinance adopted pursuant to the Vehicle Code.

(2) This additional penalty shall be collected together with and in the same manner as the amounts established by Section 1464 of the Penal Code. These moneys shall be taken from fines and forfeitures deposited with the county treasurer prior to any division pursuant to Section 1463 of the Penal Code. The county treasurer shall deposit those amounts specified by the board of supervisors by resolution in one or more of the funds established pursuant to this chapter. However, deposits to these funds shall continue through whatever period of time is necessary to repay any borrowings made by the county on or before January 1, 1991, to pay for construction provided for in this chapter.

(3) This additional penalty does not apply to the following:

(A) Any restitution fine.

(B) Any penalty authorized by Section 1464 of the Penal Code or this chapter.

(C) Any parking offense subject to Article 3 (commencing with Section 40200) of Chapter 1 of Division 17 of the Vehicle Code.

(D) The state surcharge authorized by Section 1465.7 of the Penal Code.

(b) In each authorized county, provided that the board of supervisors has adopted a resolution stating that the implementation of this subdivision is necessary to the county for the purposes authorized, with respect to each authorized fund established pursuant to Section 76100 or 76101, for every parking offense where a parking penalty, fine, or forfeiture is imposed, an added penalty of two dollars and fifty cents ($2.50) shall be included in the total penalty, fine, or forfeiture. Except as provided in subdivision (c), for each parking case collected in the courts of the county, the county treasurer shall place in each authorized fund two dollars and fifty cents ($2.50). These moneys shall be taken from fines and forfeitures deposited with the county treasurer prior to any division pursuant to Section 1462.3 or 1463.009 of the Penal Code. The judges of the county shall increase the bail schedule amounts as appropriate to reflect the added penalty provided for by this section. In those cities, districts, or other issuing agencies which elect to accept parking penalties, and otherwise process parking violations pursuant to Article 3 (commencing with Section 40200) of Chapter 1 of Division 17 of the Vehicle Code, that city, district, or issuing agency shall observe

the increased bail amounts as established by the court reflecting the added penalty provided for by this section. Each agency which elects to process parking violations shall pay to the county treasurer two dollars and fifty cents ($2.50) for each fund for each parking penalty collected on each violation which is not filed in court. Those payments to the county treasurer shall be made monthly, and the county treasurer shall deposit all those sums in the authorized fund. No issuing agency shall be required to contribute revenues to any fund in excess of those revenues generated from the surcharges established in the resolution adopted pursuant to this chapter, except as otherwise agreed upon by the local governmental entities involved.

(c) The county treasurer shall deposit one dollar ($1) of every two dollars and fifty cents ($2.50) collected pursuant to subdivision (b) into the general fund of the county.

(d) The authority to impose the two-dollar-and-fifty-cent ($2.50) penalty authorized by subdivision (b) shall be reduced to one dollar ($1) as of the date of transfer of responsibility for facilities from the county to the Judicial Council pursuant to Article 3 (commencing with Section 70321) of Chapter 5.1, except as money is needed to pay for construction provided for in Section 76100 and undertaken prior to the transfer of responsibility for facilities from the county to the Judicial Council.

(e) The seven-dollar ($7) additional penalty authorized by subdivision (a) shall be reduced in each county by the additional penalty amount assessed by the county for the local courthouse construction fund established by Section 76100 as of January 1, 1998, when the money in that fund is transferred to the state under Section 70402. The amount each county shall charge as an additional penalty under this section shall be as follows:

Alameda	$5.00	Marin	$5.00	San Luis Obispo	$5.00
Alpine	$5.00	Mariposa	$2.50	San Mateo	$4.75
Amador	$5.00	Mendocino	$7.00	Santa Barbara	$3.50
Butte	$7.00	Merced	$4.75	Santa Clara	$5.50
Calaveras	$3.00	Modoc	$3.50	Santa Cruz	$7.00
Colusa	$6.00	Mono	$4.00	Shasta	$3.50
Contra Costa	$5.00	Monterey	$5.00	Sierra	$7.00
Del Norte	$7.00	Napa	$3.00	Siskiyou	$5.00
El Dorado	$5.00	Nevada	$4.75	Solano	$5.00
Fresno	$7.00	Orange	$5.29	Sonoma	$5.00
Glenn	$4.00	Placer	$4.75	Stanislaus	$5.00
Humboldt	$5.00	Plumas	$7.00	Sutter	$6.00
Imperial	$6.00	Riverside	$4.60	Tehama	$7.00
Inyo	$4.00	Sacramento	$5.00	Trinity	$4.50
Kern	$7.00	San Benito	$5.00	Tulare	$5.00
Kings	$7.00	San Bernardino	$5.00	Tuolumne	$7.00
Lake	$7.00	San Diego	$7.00	Ventura	$5.00
Lassen	$2.00	San Francisco	$6.99	Yolo	$7.00
Los Angeles	$5.00	San Joaquin	$3.75	Yuba	$3.00

Madera	$7.00				

(Amended by Stats. 2010, Ch. 720, Sec. 26. (SB 857) Effective October 19, 2010.)

State of California

GOVERNMENT CODE

Section 76000.5

76000.5. (a) (1) Except as otherwise provided in this section, for purposes of supporting emergency medical services pursuant to Chapter 2.5 (commencing with Section 1797.98a) of Division 2.5 of the Health and Safety Code, in addition to the penalties set forth in Section 76000, the county board of supervisors may elect to levy an additional penalty in the amount of two dollars ($2) for every ten dollars ($10), or part of ten dollars ($10), upon every fine, penalty, or forfeiture imposed and collected by the courts for all criminal offenses, including violations of Division 9 (commencing with Section 23000) of the Business and Professions Code relating to the control of alcoholic beverages, and all offenses involving a violation of the Vehicle Code or a local ordinance adopted pursuant to the Vehicle Code. This penalty shall be collected together with and in the same manner as the amounts established by Section 1464 of the Penal Code.

(2) This additional penalty does not apply to the following:

(A) A restitution fine.

(B) A penalty authorized by Section 1464 of the Penal Code or this chapter.

(C) A parking offense subject to Article 3 (commencing with Section 40200) of Chapter 1 of Division 17 of the Vehicle Code.

(D) The state surcharge authorized by Section 1465.7 of the Penal Code.

(b) Funds shall be collected pursuant to subdivision (a) only if the county board of supervisors provides that the increased penalties do not offset or reduce the funding of other programs from other sources, but that these additional revenues result in increased funding to those programs.

(c) Moneys collected pursuant to subdivision (a) shall be taken from fines and forfeitures deposited with the county treasurer prior to any division pursuant to Section 1463 of the Penal Code.

(d) Funds collected pursuant to this section shall be deposited into the Maddy Emergency Medical Services (EMS) Fund established pursuant to Section 1797.98a of the Health and Safety Code.

(e) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.

(Amended by Stats. 2013, Ch. 600, Sec. 1. (SB 191) Effective January 1, 2014. Repealed as of January 1, 2017, by its own provisions.)

State of California

GOVERNMENT CODE

Section 76104

76104. (a) For purposes of supporting emergency medical services pursuant to Chapter 2.5 (commencing with Section 1797.98a) of Division 2.5 of the Health and Safety Code, the board of supervisors of any county which established in the county treasury an Emergency Medical Services Fund prior to June 1, 1991, shall continue that fund using penalty revenues pursuant to Section 76000 as specified in the resolution or resolutions adopted by the board of supervisors prior to June 1, 1991, to create that fund. Except as provided in subdivision (d), the amount deposited in that fund shall be at and shall not exceed the corresponding amount for the 1990–91 fiscal year, plus a percentage representing the growth, if any, in the fines and forfeitures collected in comparison with the 1990–91 fiscal year, not to exceed 10 percent per fiscal year.

(b) For any county which established an Emergency Medical Services Fund prior to June 1, 1991, and for which that fund has not received deposits for 12 full months of collections of the penalty, the 1990–91 fiscal year shall be computed by projecting actual collection experience to produce an estimated annual amount.

(c) The board of supervisors of a county that has not established an Emergency Medical Services Fund prior to July 1, 1991, may set aside up to 28 percent of the total revenue from the penalty established pursuant to Section 76000 in the county treasury for purposes of supporting emergency medical services pursuant to Chapter 2.5 (commencing with Section 1797.98a) of Division 2.5 of the Health and Safety Code.

(d) Notwithstanding any other provision of law, in complying with this section, a county shall not be required to contribute an amount in excess of the receipts of the penalty assessment authorized for this purpose.

(e) The fund moneys shall be held by the county treasurer separate from any funds subject to transfer or division pursuant to Section 1463 of the Penal Code. The moneys of the Emergency Medical Services Fund shall be payable only for the purposes specified in Chapter 2.5 (commencing with Section 1797.98a) of Division 2.5 of the Health and Safety Code.

(Amended by Stats. 1999, Ch. 674, Sec. 1. Effective January 1, 2000.)

State of California

VEHICLE CODE

Section 42007

42007. (a) (1) The clerk of the court shall collect a fee from every person who is ordered or permitted to attend a traffic violator school pursuant to Section 41501 or 42005 in an amount equal to the total bail set forth for the eligible offense on the uniform countywide bail schedule. As used in this subdivision, "total bail" means the amount established pursuant to Section 1269b of the Penal Code in accordance with the Uniform Bail and Penalty Schedule adopted by the Judicial Council, including all assessments, surcharges, and penalty amounts. Where multiple offenses are charged in a single notice to appear, the "total bail" is the amount applicable for the greater of the qualifying offenses. However, the court may determine a lesser fee under this subdivision upon a showing that the defendant is unable to pay the full amount.

The fee shall not include the cost, or any part thereof, of traffic safety instruction offered by a traffic violator school.

(2) The clerk may accept from a defendant who is ordered or permitted to attend traffic violator school a payment of at least 10 percent of the fee required by paragraph (1) upon filing a written agreement by the defendant to pay the remainder of the fee according to an installment payment schedule of no more than 90 days as agreed upon with the court. The Judicial Council shall prescribe the form of the agreement for payment of the fee in installments. When the defendant signs the Judicial Council form for payment of the fee in installments, the court shall continue the case to the date in the agreement to complete payment of the fee and submit the certificate of completion of traffic violator school to the court. The clerk shall collect a fee of up to thirty-five dollars ($35) to cover administrative and clerical costs for processing an installment payment of the traffic violator school fee under this paragraph.

(3) If a defendant fails to make an installment payment of the fee according to an installment agreement, the court may convert the fee to bail, declare it forfeited, and report the forfeiture as a conviction under Section 1803. The court may also charge a failure to pay under Section 40508 and impose a civil assessment as provided in Section 1214.1 of the Penal Code or issue an arrest warrant for a failure to pay. For the purposes of reporting a conviction under this subdivision to the department under Section 1803, the date that the court declares the bail forfeited shall be reported as the date of conviction.

(b) Revenues derived from the fee collected under this section shall be deposited in accordance with Section 68084 of the Government Code in the general fund of the county and, as may be applicable, distributed as follows:

(1) In any county in which a fund is established pursuant to Section 76100 or 76101 of the Government Code, the sum of one dollar ($1) for each fund so established shall be deposited with the county treasurer and placed in that fund.

(2) In any county that has established a Maddy Emergency Medical Services Fund pursuant to Section 1797.98a of the Health and Safety Code, an amount equal to the sum of each two dollars ($2) for every seven dollars ($7) that would have been collected pursuant to Section 76000 of the Government Code and, commencing January 1, 2009, an amount equal to the sum of each two dollars ($2) for every ten dollars ($10) that would have been collected pursuant to Section 76000.5 of the Government Code with respect to those counties to which that section is applicable shall be deposited in that fund. Nothing in the act that added this paragraph shall be interpreted in a manner that would result in either of the following:

(A) The utilization of penalty assessment funds that had been set aside, on or before January 1, 2000, to finance debt service on a capital facility that existed before January 1, 2000.

(B) The reduction of the availability of penalty assessment revenues that had been pledged, on or before January 1, 2000, as a means of financing a facility which was approved by a county board of supervisors, but on January 1, 2000, is not under construction.

(3) The amount of the fee that is attributable to Section 70372 of the Government Code shall be transferred pursuant to subdivision (f) of that section.

(c) For fees resulting from city arrests, an amount equal to the amount of base fines that would have been deposited in the treasury of the appropriate city pursuant to paragraph (3) of subdivision (b) of Section 1463.001 of the Penal Code shall be deposited in the treasury of the appropriate city.

(d) The clerk of the court, in a county that offers traffic school shall include in any courtesy notice mailed to a defendant for an offense that qualifies for traffic school attendance the following statement:

NOTICE: If you are eligible and decide not to attend traffic school your automobile insurance may be adversely affected. For drivers with a noncommercial driver's license, one conviction in any 18-month period will be held confidential and not show on your driving record if you complete a traffic violator school program. For drivers with a commercial driver's license, one conviction in any 18-month period will show on your driving record without a violation point if you complete a traffic violator school program.

(e) Notwithstanding any other provision of law, a county that has established a Maddy Emergency Medical Services Fund pursuant to Section 1797.98a of the Health and Safety Code shall not be held liable for having deposited into the fund, prior to January 1, 2009, an amount equal to two dollars ($2) for every ten dollars ($10) that

would have been collected pursuant to Section 76000.5 of the Government Code from revenues derived from traffic violator school fees collected pursuant to this section.

(Amended by Stats. 2013, Ch. 523, Sec. 31. (SB 788) Effective January 1, 2014.)

State of California

PENAL CODE

Section 1464

1464. (a) (1) Subject to Chapter 12 (commencing with Section 76000) of Title 8 of the Government Code, and except as otherwise provided in this section, there shall be levied a state penalty in the amount of ten dollars ($10) for every ten dollars ($10), or part of ten dollars ($10), upon every fine, penalty, or forfeiture imposed and collected by the courts for all criminal offenses, including all offenses, except parking offenses as defined in subdivision (i) of Section 1463, involving a violation of a section of the Vehicle Code or any local ordinance adopted pursuant to the Vehicle Code.

(2) Any bail schedule adopted pursuant to Section 1269b or bail schedule adopted by the Judicial Council pursuant to Section 40310 of the Vehicle Code may include the necessary amount to pay the penalties established by this section and Chapter 12 (commencing with Section 76000) of Title 8 of the Government Code, and the surcharge authorized by Section 1465.7, for all matters where a personal appearance is not mandatory and the bail is posted primarily to guarantee payment of the fine.

(3) The penalty imposed by this section does not apply to the following:

(A) Any restitution fine.

(B) Any penalty authorized by Chapter 12 (commencing with Section 76000) of Title 8 of the Government Code.

(C) Any parking offense subject to Article 3 (commencing with Section 40200) of Chapter 1 of Division 17 of the Vehicle Code.

(D) The state surcharge authorized by Section 1465.7.

(b) Where multiple offenses are involved, the state penalty shall be based upon the total fine or bail for each case. When a fine is suspended, in whole or in part, the state penalty shall be reduced in proportion to the suspension.

(c) When any deposited bail is made for an offense to which this section applies, and for which a court appearance is not mandatory, the person making the deposit shall also deposit a sufficient amount to include the state penalty prescribed by this section for forfeited bail. If bail is returned, the state penalty paid thereon pursuant to this section shall also be returned.

(d) In any case where a person convicted of any offense, to which this section applies, is in prison until the fine is satisfied, the judge may waive all or any part of the state penalty, the payment of which would work a hardship on the person convicted or his or her immediate family.

(e) After a determination by the court of the amount due, the clerk of the court shall collect the penalty and transmit it to the county treasury. The portion thereof attributable to Chapter 12 (commencing with Section 76000) of Title 8 of the

Government Code shall be deposited in the appropriate county fund and 70 percent of the balance shall then be transmitted to the State Treasury, to be deposited in the State Penalty Fund, which is hereby created, and 30 percent to remain on deposit in the county general fund. The transmission to the State Treasury shall be carried out in the same manner as fines collected for the state by a county.

(f) The moneys so deposited in the State Penalty Fund shall be distributed as follows:

(1) Once a month there shall be transferred into the Fish and Game Preservation Fund an amount equal to 0.33 percent of the state penalty funds deposited in the State Penalty Fund during the preceding month, except that the total amount shall not be less than the state penalty levied on fines or forfeitures for violation of state laws relating to the protection or propagation of fish and game. These moneys shall be used for the education or training of department employees which fulfills a need consistent with the objectives of the Department of Fish and Game.

(2) Once a month there shall be transferred into the Restitution Fund an amount equal to 32.02 percent of the state penalty funds deposited in the State Penalty Fund during the preceding month. Those funds shall be made available in accordance with Section 13967 of the Government Code.

(3) Once a month there shall be transferred into the Peace Officers' Training Fund an amount equal to 23.99 percent of the state penalty funds deposited in the State Penalty Fund during the preceding month.

(4) Once a month there shall be transferred into the Driver Training Penalty Assessment Fund an amount equal to 25.70 percent of the state penalty funds deposited in the State Penalty Fund during the preceding month.

(5) Once a month there shall be transferred into the Corrections Training Fund an amount equal to 7.88 percent of the state penalty funds deposited in the State Penalty Fund during the preceding month. Money in the Corrections Training Fund is not continuously appropriated and shall be appropriated in the Budget Act.

(6) Once a month there shall be transferred into the Local Public Prosecutors and Public Defenders Training Fund established pursuant to Section 11503 an amount equal to 0.78 percent of the state penalty funds deposited in the State Penalty Fund during the preceding month. The amount so transferred shall not exceed the sum of eight hundred fifty thousand dollars ($850,000) in any fiscal year. The remainder in excess of eight hundred fifty thousand dollars ($850,000) shall be transferred to the Restitution Fund.

(7) Once a month there shall be transferred into the Victim-Witness Assistance Fund an amount equal to 8.64 percent of the state penalty funds deposited in the State Penalty Fund during the preceding month.

(8) (A) Once a month there shall be transferred into the Traumatic Brain Injury Fund, created pursuant to Section 4358 of the Welfare and Institutions Code, an amount equal to 0.66 percent of the state penalty funds deposited into the State Penalty Fund during the preceding month. However, the amount of funds transferred into the Traumatic Brain Injury Fund for the 1996–97 fiscal year shall not exceed the amount of five hundred thousand dollars ($500,000). Thereafter, funds shall be transferred

pursuant to the requirements of this section. Notwithstanding any other provision of law, the funds transferred into the Traumatic Brain Injury Fund for the 1997–98, 1998–99, and 1999–2000 fiscal years, may be expended by the State Department of Mental Health, in the current fiscal year or a subsequent fiscal year, to provide additional funding to the existing projects funded by the Traumatic Brain Injury Fund, to support new projects, or to do both.

(B) Any moneys deposited in the State Penalty Fund attributable to the assessments made pursuant to subdivision (i) of Section 27315 of the Vehicle Code on or after the date that Chapter 6.6 (commencing with Section 5564) of Part 1 of Division 5 of the Welfare and Institutions Code is repealed shall be utilized in accordance with paragraphs (1) to (8), inclusive, of this subdivision.

(Amended by Stats. 2007, Ch. 302, Sec. 17. Effective January 1, 2008.)

1463. All fines and forfeitures imposed and collected for crimes shall be distributed in accordance with Section 1463.001.

The following definitions shall apply to terms used in this chapter:

(a) "Arrest" means any law enforcement action, including issuance of a notice to appear or notice of violation, which results in a criminal charge.

(b) "City" includes any city, city and county, district, including any enterprise special district, community service district, or community service area engaged in police protection activities as reported to the Controller for inclusion in the 1989–90 edition of the Financial Transactions Report Concerning Special Districts under the heading of Police Protection and Public Safety, authority, or other local agency (other than a county) which employs persons authorized to make arrests or to issue notices to appear or notices of violation which may be filed in court.

(c) "City arrest" means an arrest by an employee of a city, or by a California Highway Patrol officer within the limits of a city.

(d) "County" means the county in which the arrest took place.

(e) "County arrest" means an arrest by a California Highway Patrol officer outside the limits of a city, or any arrest by a county officer or by any other state officer.

(f) "Court" means the superior court or a juvenile forum established under Section 257 of the Welfare and Institutions Code, in which the case arising from the arrest is filed.

(g) "Division of moneys" means an allocation of base fine proceeds between agencies as required by statute, including, but not limited to, Sections 1463.003, 1463.9, 1463.23, and 1463.26 of this code, Sections 13001, 13002, and 13003 of the Fish and Game Code, and Section 11502 of the Health and Safety Code.

(h) "Offense" means any infraction, misdemeanor, or felony, and any act by a juvenile leading to an order to pay a financial sanction by reason of the act being defined as an infraction, misdemeanor, or felony, whether defined in this or any other code, except any parking offense as defined in subdivision (i).

(i) "Parking offense" means any offense charged pursuant to Article 3 (commencing with Section 40200) of Chapter 1 of Division 17 of the Vehicle Code, including registration and equipment offenses included on a notice of parking violation.

(j) "Penalty allocation" means the deposit of a specified part of moneys to offset designated processing costs, as provided by Section 1463.16 of this code and by Section 68090.8 of the Government Code.

(k) “Total parking penalty” means the total sum to be collected for a parking offense, whether as fine, forfeiture of bail, or payment of penalty to the Department of Motor Vehicles (DMV). It may include the following components:

(1) The base parking penalty as established pursuant to Section 40203.5 of the Vehicle Code.

(2) The DMV fees added upon the placement of a hold pursuant to Section 40220 of the Vehicle Code.

(3) The surcharges required by Section 76000 of the Government Code.

(4) The notice penalty added to the base parking penalty when a notice of delinquent parking violations is given.

(*l*) “Total fine or forfeiture” means the total sum to be collected upon a conviction, or the total amount of bail forfeited or deposited as cash bail subject to forfeiture. It may include, but is not limited to, the following components as specified for the particular offense:

(1) The “base fine” upon which the state penalty and additional county penalty is calculated.

(2) The “county penalty” required by Section 76000 of the Government Code.

(3) The “DNA penalty” required by Sections 76104.6 and 76104.7 of the Government Code.

(4) The “emergency medical services penalty” authorized by Section 76000.5 of the Government Code.

(5) The “service charge” permitted by Section 853.7 of the Penal Code and Section 40508.5 of the Vehicle Code.

(6) The “special penalty” dedicated for blood alcohol analysis, alcohol program services, traumatic brain injury research, and similar purposes.

(7) The “state penalty” required by Section 1464.

(Amended by Stats. 2007, Ch. 302, Sec. 16. Effective January 1, 2008.)

CA AB 263

AUTHOR: Rodriguez [D]
TITLE: Emergency Medical Services Workers: Working Conditions
INTRODUCED: 01/31/2017
LAST AMEND: 06/21/2017
DISPOSITION: Pending
LOCATION: Senate Appropriations Committee
SUMMARY:

Relates to the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act. Requires an employer that provides emergency medical services as part of an emergency medical services system or plan to authorize and permit its employees to take prescribed rest periods. Requires a specified report concerning violent incidents involving EMS providers. Specifies application of these provisions to employers that are air carriers.

STATUS:

07/10/2017 In SENATE Committee on APPROPRIATIONS: To Suspense File.

INDEX: 35, 57
ISSUES: BJ, GBS*
LOBBYIST: CD, KAS*
POSITION: F, X

CA AB 340

AUTHOR: Arambula [D]
TITLE: Early and Periodic Screening, Diagnosis, and Treatment
INTRODUCED: 02/07/2017
DISPOSITION: Pending
LOCATION: Senate Appropriations Committee
SUMMARY:

Requires that screening services under a specified Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program include screening for trauma. Requires the adoption of tools and protocols for screening children for trauma.

STATUS:

08/21/2017 In SENATE Committee on APPROPRIATIONS: To Suspense File.

INDEX: 35, 65
ISSUES: AK*, DBR, SL
LOBBYIST: AH, BG*
POSITION: F

CA AB 437

AUTHOR: Rodriguez [D]
TITLE: At-Risk Persons: First Responders
INTRODUCED: 02/13/2017
LAST AMEND: 04/26/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Requires the Attorney General to establish and maintain within the Violent Crime Information Center a Voluntary Online At-Risk Community Network for purposes of providing information to first responders in order to prevent harmful interactions between first responders and seniors or persons with disabilities. Provides for broadcast of a Be on the Lookout bulletin within its jurisdiction under circumstances upon which a person in the network is missing or needs assistance.

STATUS:

05/26/2017 In ASSEMBLY Committee on APPROPRIATIONS: Not heard.

INDEX: 31, 35
ISSUES: BJ, SL*
LOBBYIST: AH*, CD
POSITION: F

CA AB 451

AUTHOR: Arambula [D]
TITLE: Health Facilities: Emergency Services and Care
INTRODUCED: 02/13/2017
LAST AMEND: 07/05/2017
DISPOSITION: Pending
LOCATION: Senate Appropriations Committee
SUMMARY:

Specifies that a psychiatric unit within a genera acute care hospital, a psychiatric health facility, or an acute psychiatric hospital is required to provide emergency services to care to treat a person with a psychiatric emergency medical condition who has been accepted by the facility if the facility has appropriate facilities and qualified personnel. Makes conforming changed to related provisions.

STATUS:

08/21/2017 In SENATE Committee on APPROPRIATIONS: To Suspense File.

INDEX: 35, 77
ISSUES: BJ, SL*
LOBBYIST: AH*, CD
POSITION: N/A, X

CA AB 545

AUTHOR: Bigelow [R]
TITLE: Joint Powers Agreements: County of El Dorado
INTRODUCED: 02/13/2017
ENACTED: 07/24/2017
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 124
SUMMARY:

Authorizes a private, nonprofit hospital in the County of El Dorado to enter into a joint powers agreement with a public agency. Prohibits nonprofit hospitals and public agencies participating in the agreement from reducing or eliminating any emergency services without a public hearing.

STATUS:

07/24/2017 Signed by GOVERNOR.
07/24/2017 Chaptered by Secretary of State. Chapter No. 124

INDEX: 15, 35
ISSUES: AM, PW*
LOBBYIST: CD*, KAS
POSITION: F

CA AB 583

AUTHOR: Wood [D]
TITLE: Emergency Medical Air Transportation
INTRODUCED: 02/14/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee

SUMMARY:

Extends the dates of the Emergency Medical Air Transportation Act so that the assessment of the penalties will terminate January 1, 2028, and any moneys unexpended and unencumbered in the Emergency Medical Air Transportation Act Fund on June 30, 2029, will transfer to the Federal Fund. Extends the operation of the Emergency Medical Air Transportation Act.

STATUS:

05/26/2017	In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.

INDEX:	35
ISSUES:	BJ
LOBBYIST:	CD
POSITION:	S, X

CA AB 735

AUTHOR:	Maienschein [R]
TITLE:	Swimming Pools: Public Safety
INTRODUCED:	02/15/2017
LAST AMEND:	05/26/2017
DISPOSITION:	Pending
LOCATION:	Senate Appropriations Committee

SUMMARY:

Requires public swimming pools that are required to provide lifeguard services and that charge a direct fee to provide an Automated External Defibrillator during pool operations. Requires the State Department of Education, in consultation with the State Department of Public Health, to issue best practices guidelines related to pool safety at K-12 schools.

STATUS:

07/10/2017	In SENATE Committee on APPROPRIATIONS: To Suspense File.

INDEX:	35
ISSUES:	BJ
LOBBYIST:	CD
POSITION:	F

CA AB 820

AUTHOR:	Gipson [D]
TITLE:	Emergency Medical Services Authority: Task Force
INTRODUCED:	02/15/2017
LAST AMEND:	03/23/2017
DISPOSITION:	Pending
LOCATION:	Assembly Health Committee

SUMMARY:

Authorizes the Emergency Medical Services Authority to establish a task force to develop a report evaluating alternative destinations to a general acute care hospital for first responders to transport a patient who may be a danger to himself, herself, or others or gravely disabled as a result of a mental health disorder. Requires the report to be published on the authority's Internet Web site.

STATUS:

03/23/2017	To ASSEMBLY Committee on HEALTH.
03/23/2017	From ASSEMBLY Committee on HEALTH with author's amendments.
03/23/2017	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

	INDEX:	35
	ISSUES:	BJ
	LOBBYIST:	CD
	POSITION:	S, X

CA AB 909	**AUTHOR:**	Steinorth [R]
	TITLE:	Emergency Response: Trauma Kits
	INTRODUCED:	02/16/2017
	LAST AMEND:	05/02/2017
	DISPOSITION:	Pending
	LOCATION:	Assembly Appropriations Committee

SUMMARY:

Requires a person or entity that supplies a trauma kit to provide the acquirer with all information governing the use and maintenance of the kit. Applies specific exemptions from civil liability to a lay rescuer or person who renders emergency care or treatment by the use of a trauma kit and to a person or entity that provides emergency first aid, trauma, or similar training in the use of a trauma kit to a person who renders emergency care.

STATUS:

06/20/2017	In ASSEMBLY. Coauthors revised.
INDEX:	35
ISSUES:	BJ*, LR
LOBBYIST:	CD
POSITION:	F

CA AB 1116	**AUTHOR:**	Grayson [D]
	TITLE:	Peer Support and Crisis Referral Services Act
	INTRODUCED:	02/17/2017
	LAST AMEND:	07/18/2017
	DISPOSITION:	Pending
	LOCATION:	Senate Appropriations Committee

SUMMARY:

Creates the Peer Support and Crisis Referral Services Act. Defines peer support team as a local critical incident response team composed of individuals from the emergency services professions and other fields who have completed a training course developed by certain emergency agencies. Establishes a privilege for communications between emergency service personnel and peer support team members or staff of a crisis hotline or referral service. Relates to liability for team members.

STATUS:

08/21/2017	In SENATE Committee on APPROPRIATIONS: To Suspense File.
INDEX:	31, 35
ISSUES:	BJ, CLH*
LOBBYIST:	CD, KAS*
POSITION:	F

CA AB 1204	**AUTHOR:**	Mayes [R]
	TITLE:	Public Health: Emergency Prescriptions
	INTRODUCED:	02/17/2017
	LAST AMEND:	03/28/2017
	DISPOSITION:	Pending
	LOCATION:	Assembly Health Committee

SUMMARY:

Authorizes a licensed physician to prescribe a one-month supply of a life-saving medication to a patient to be stored for the use of that patient in case of a natural disaster or other emergency.

STATUS:

03/28/2017	From ASSEMBLY Committee on HEALTH with author's amendments.
03/28/2017	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX: 35
ISSUES: BJ
LOBBYIST: CD
POSITION: F

CA AB 1650

AUTHOR: Maienschein [R]
TITLE: Emergency Medical Services: Paramedicine
INTRODUCED: 02/17/2017
LAST AMEND: 04/20/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee

SUMMARY:

Creates the Community Paramedic Program in the Emergency Medical Services Authority to provide specified services, such as case management services and linkage to nonemergency services for frequent EMS system users, through local community paramedic programs. Requires the authority to develop criteria to qualify services for participation in the program, develop an application process for local EMS agencies seeking to participate in the program, and to review and approve applications for participation.

STATUS:

05/10/2017	In ASSEMBLY Committee on APPROPRIATIONS: To Suspense File.

INDEX: 35
ISSUES: BJ
LOBBYIST: CD
POSITION: S, X

CA SB 398

AUTHOR: Monning [D]
TITLE: Acquired Brain Trauma
INTRODUCED: 02/15/2017
LAST AMEND: 04/06/2017
DISPOSITION: Pending
LOCATION: Assembly Human Services Committee

SUMMARY:

Relates to a program of services for persons with acquired traumatic brain injury. Makes that program operative indefinitely. Requires the Department of Rehabilitation to pursue all sources of funding and by authorizing the department to require that service providers meet specified program and operational certification standards in order to receive ongoing funding.

STATUS:

06/20/2017	From ASSEMBLY Committee on HEALTH: Do pass to Committee on HUMAN SERVICES. (15-0)

INDEX: 35, 65
ISSUES: AK*, AO, DBR

LOBBYIST: BG*, CD
POSITION: F

CA SB 432

AUTHOR: Pan [D]
TITLE: Emergency Medical Services
INTRODUCED: 02/15/2017
LAST AMEND: 07/12/2017
DISPOSITION: Pending
FILE: 177
LOCATION: Assembly Consent Calendar - Second Legislative Day
SUMMARY:

Requires a health facility to give a certain notice immediately to a designated officer upon determining that the person to whom prehospital emergency medical care personnel provided emergency medical or rescue services is diagnosed as being afflicted with a specified disease or condition and to give notice to the county health officer with the name and telephone number of the personnel. Requires at alternative notification if this information has not been provided to the facility.

STATUS:

07/20/2017 In ASSEMBLY. Read second time. To Consent Calendar.
INDEX: 35
ISSUES: BJ*, LR, SL
LOBBYIST: CD
POSITION: S, X

CA SB 687

AUTHOR: Skinner [D]
TITLE: Health Facilities: Emergency Services: Attorney General
INTRODUCED: 02/17/2017
LAST AMEND: 07/13/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Applies existing notice and consent requirements to a nonprofit corporation that operates or controls a health facility plans to sell, transfer, lease or otherwise dispose of the assets resulting from the reduction or elimination of emergency medical services provided at a licensed emergency center after the consent of the Attorney General. Prohibits the Department of Public Health from licensing a stand-alone emergency room or freestanding emergency center that is not part of a general acute care hospital.

STATUS:

08/23/2017 In ASSEMBLY Committee on APPROPRIATIONS: To Suspense File.
INDEX: 24, 35
ISSUES: AM*, LR, SL
LOBBYIST: CD, KAS*
POSITION: O, X

CA SB 792

AUTHOR: Wilk [R]
TITLE: Local Government: Measure B Oversight Commission
INTRODUCED: 02/17/2017
LAST AMEND: 05/26/2017
DISPOSITION: Pending
LOCATION: Assembly Local Government Committee

SUMMARY:

Requires the County of Los Angeles to establish the Measure B Oversight Commission and requires a certain report regarding the County of Los Angeles trauma network and the special tax levied on all improved parcels in the County to provide funding for the Countywide System of Trauma Centers, Emergency Medical Services, and Bioterrorism Response. Requires the posting of certain information on an Internet Web site.

STATUS:

06/28/2017	In ASSEMBLY Committee on LOCAL GOVERNMENT: Heard, remains in Committee.
INDEX:	109, 35
ISSUES:	AM*, BJ
LOBBYIST:	BG*, KAS
POSITION:	F

Whole Person Care Pilots

Return to Medi-Cal 2020 Homepage

The overarching goal of the Whole Person Care (WPC) Pilots is the coordination of health, behavioral health, and social services, as applicable, in a patient-centered manner with the goals of improved beneficiary health and wellbeing through more efficient and effective use of resources. WPC Pilots will provide an option to a county, a city and county, a health or hospital authority, or a consortium of any of the above entities serving a county or region consisting of more than one county, or a health authority, to receive support to integrate care for a particularly vulnerable group of Medi-Cal beneficiaries who have been identified as high users of multiple systems and continue to have poor health outcomes. Through collaborative leadership and systematic coordination among public and private entities, WPC Pilot entities will identify target populations, share data between systems, coordinate care real time, and evaluate individual and population progress – all with the goal of providing comprehensive coordinated care for the beneficiary resulting in better health outcomes.

Stakeholder Engagement

CMS Approval of WPC City Amendment and Second Round of Pilot Applications

On June 1, 2017, the Centers for Medicare and Medicaid Services (CMS) approved an amendment to the Special Terms and Conditions of California's Medi-Cal 2020 Demonstration for the WPC pilots program. The technical amendment enables the State to accept applications from and designate a city to be a lead entity for the WPC Pilot Program.

CMS Approval Letter for Amendment

On June 8, 2017, CMS also approved the second round of WPC pilot applications. CMS find the applications from the specific counties and city to be in accordance with the Medi-Cal 2020 Demonstration Special Terms and Conditions (STCs) and approval protocols for the WPC program. The approved pilots are listed in CMS' approval letter below.

CMS Approval Letter for Second Round of Pilot Applications

Resources and Information

In 2016, DHCS completed a first round WPC application process and approved 18 lead entities to operate WPC pilots. In early 2017, DHCS conducted a second application process to expand current pilots and/or approve additional entities to operate WPC pilots.

General Information

- Current Medi-Cal 2020 Special Terms & Conditions - Refer to STCs 110-126 [pages 80-88] for information relevant to WPC
  - Attachment GG - WPC Reporting and Evaluation: Mid-year and annual reporting requirements and evaluation process
  - Attachment HH - WPC Pilot Requirements and Application Process: Application submission and review process, pilot funding, termination process, and WPC Learning Collaboratives
  - Attachment MM - WPC Pilot Requirements and Metrics: Performance metrics (universal and variant), incorporation of Plan-Do-Study-Act (PDSA), and reporting requirements
  - CMS Approval Letter of Attachments GG, HH, MM, and the Application Criteria (May 13, 2016)
  - CMS Approval Letter of Attachment MM: Pilot Requirements and Metrics (October 21, 2016)
- Frequently Asked Questions and Answers (Updated February 22, 2017)
- Comparison of Whole Person Care (WPC) Pilots, Health Homes Program (HHP), Coordinated Care Initiative (CCI), and Public Hospital Redesign and Incentives in Medi-Cal (PRIME)
- Whole Person Care Pilot Overview
- Whole Person Care Pilot Applications Statistics - Approved Pilots
- Approved Whole Person Care Pilot Applications - First Round

Application Resources

- Whole Person Care Pilot Application - Second Round (Revised January 13, 2017)
- Whole Person Care Pilot - Legacy Lead Entity Pilot Expansion Instructions - Second Round (January 13, 2017)
- Whole Person Care Pilot Application
- Whole Person Care Agreement Template
- Application Timeline - First Round (Revised April 11, 2016)
- Letter of Intent Instructions (Revised March 29, 2016 and due close of business on April 8, 2016)
- Letter of Intent Submissions
- List of Whole Person Care Pilot Applicants - First Round

Budget Information

- Budget Instructions - Second Round (Revised January 13, 2017)
- Budget Instructions - First Round
- Budget Summary Template* - Second Round New Applicants
- Budget Summary Template Sample* - Second Round New Applicants
- Budget Summary Template* - First Round and Second Round Expansion Pilots
- Budget Summary Template Sample* - First Round

**Please note that the Budget Summary Templates and Samples are ADA-compliant documents, which have limited functionality due to certain modifications. Please send a request to the WPC Program Inbox at 1115WholePersonCare@dhcs.ca.gov to receive the fully-functional version of the template and sample.*

Past Stakeholder Webinars

- January 27, 2017 - WPC Application and Budget Webinar - Second Round New Applicants
- June 3, 2016 Budget Webinar Presentation - First Round
- May 19, 2016 WPC Application Webinar Presentation - First Round
- March 22, 2016 WPC Webinar Presentation

Additional Resources

- CMS Housing Guidance
- CMS Jail/Incarceration Guidance

Contact Us

Please direct your comments, questions or suggestions regarding the Whole Person Care Pilots to the following email address: 1115WholePersonCare@dhcs.ca.gov

Last modified on: 7/10/2017 11:39 AM

HC HARBAGE CONSULTING

The California Whole Person Care Pilot Program: County Partnerships to Improve the Health of Medi-Cal Beneficiaries

Prepared by Lucy Pagel, Tanya Schwartz and Jennifer Ryan
with support from The California Endowment
February 2017

Introduction

The California Whole Person Care (WPC) Pilot program is designed to coordinate health, behavioral health, and social services in order to improve the health outcomes of Medi-Cal beneficiaries who are high utilizers of the health care system. Through collaboration and coordination among county agencies, health plans, providers, and other entities, the WPC Pilots are designing and developing the infrastructure and processes to integrate and improve care for vulnerable populations.

The five-year program, approved in December 2015 as part of the Medi-Cal 2020 waiver, will provide up to $3 billion to support the Pilots – $1.5 billion of federal Medicaid matching funds and $1.5 billion from local funds provided through intergovernmental transfers (IGTs). Reimbursement is not provided for services already covered by Medi-Cal.

Summary of Approved WPC Pilots

To participate in the WPC Pilot program, Pilot lead entities (usually a county government) submitted an application to the Department of Health Care Services (DHCS) that outlined their approach to key design components of the program. While the waiver established minimum standards for participation, applicants had some flexibility to propose strategies that would best meet the needs of their local communities. The first round of WPC Pilot applications were due in July 2016.

In November 2016, DHCS approved 18 WPC Pilot applications (see Appendix A), accounting for nearly $2.4 billion of the $3 billion in total available funding for the WPC Pilot program. Because the state did not allocate all of the available funding in the first round, DHCS is providing a second opportunity to apply to participate in the WPC Pilot program. The second round of WPC funding is available to entities that did not apply during the first round, as well as Pilots that were approved in the first round that would like to expand their programs. The second round of WPC applications are due in March 2017 and awards are expected to be announced in the summer of 2017.

Figure 1: WPC Pilot Locations and Size

Target Populations

The Medi-Cal 2020 waiver listed populations that WPC Pilots could target, but permitted Pilots to identify additional populations in their applications. Nearly all of the approved WPC Pilots will target: 1) high utilizers with repeated incidents of avoidable Emergency Department use, hospital admissions or nursing facility placement; and 2) individuals who are homeless or at-risk of homelessness. Figure 2 lists the number of Pilots by target population.

Figure 2: WPC Pilot Target Populations

Target Population	# of Pilots
High utilizers with repeated incidents of avoidable Emergency Department (ED) use, hospital admissions, or nursing facility placement	15 Pilots
Individuals who are homeless/at-risk for homelessness	14 Pilots
Individuals with mental health and/or substance use disorder (SUD) conditions	8 Pilots
Individuals recently released from institutions (e.g. hospital, jail, Institutions for Mental Diseases (IMD), skilled nursing facility)	7 Pilots
High utilizers with two or more chronic conditions	3 Pilots

** WPC Pilots may target more than one population.*

WPC Pilot Themes

Although the WPC lead entities have flexibility in designing interventions to address local needs, many Pilots share similar elements: 1) Supporting the homeless population; 2) Enhancing care coordination; and 3) Sharing patient data across providers. Below are descriptions of these key themes across the Pilots and highlighted examples of individual WPC Pilot strategies.

Supporting the Homeless Population

Fourteen WPC Pilots are targeting Medi-Cal beneficiaries who are homeless or at-risk of homelessness, populations that typically have more frequent ED usage and inpatient hospital stays and lack the resources to maintain stable housing. Pilots will support this population by enhancing care coordination efforts and providing a range of housing support services.

Targeted Care Coordination and Wrap-Around Services

The WPC Pilots are providing targeted care coordination and wrap-around services to ensure that homeless beneficiaries receive ongoing care, particularly following acute illnesses and ED visits. The WPC Pilots have innovative plans to provide coordinated and sustainable care for this population. Figure 3 outlines examples of the types of interventions the Pilots are implementing to reduce the effects and occurrence of homelessness.

Figure 3: Examples - WPC Pilot Enhanced Care Coordination and Wrap-Around Services

Intervention	Key Components
Recuperative Care Services	• Short-term residential care for those recovering from an acute illness or injury • Assistance with activities of daily living • Linkages to health, mental health and substance use disorder services • Coordination with permanent housing providers
Sobering Centers	• Medical triage, wound dressing changes, rehydration service • Bedding during recovery • Linkages to health, mental health, and substance use disorder services
Mobile Teams/Service Integration Teams	• Mobile vans bring teams to meet the beneficiary where they are located • Linkages to health, social, and homeless care support services • Staffed by a variety of providers including: nurse practitioners, behavioral health specialists, substance abuse specialists, probation officers and others
Peer Support Specialists	• Specialists who model recovery, offer advice on housing, conduct outreach, and connect beneficiaries to case management

Housing Support Interventions

In order to address the ongoing health and housing needs of homeless beneficiaries, many WPC Pilots are implementing programs to connect individuals to sustainable housing. These programs vary, but typically include providing beneficiaries with a variety of housing navigation services including: 1) placing beneficiaries in safe housing; 2) working with landlords to protect them from risks involved with housing the population; and 3) working with both parties to maintain the beneficiary's housing situation once it is established.

WPC Pilot Spotlight: Alameda County Health Care Services Agency - Housing-Related Services

Alameda County has a comprehensive plan to help WPC Pilot participants find and maintain stable housing. The table below outlines key components of these services.

Service	Key Components
Housing and Tenancy Sustaining Services	• Assistance identifying safe and affordable housing, linking beneficiaries to permanent housing, and providing move-in assistance (security deposits, furniture, etc.) • Residency retention services including: household management, landlord relations coaching, dispute resolution, housing recertification, linkages to services, and updating housing support and crisis plans
Skilled Nursing Facility Housing Transitions Program	• Intensive housing navigation services for beneficiaries transitioning out of a Skilled Nursing Facility and into more independent community settings
Street Outreach	• Expanded outreach to link all unsheltered chronically homeless individuals to care
Community Living Facilities Quality Improvement	• Create a database of existing units, including information on quality and availability • Create and enforce housing standards; certify housing as clean and safe • Provide consultation, education, and training to operators, residents, and the community
Housing Education and Legal Assistance Program	• Create a legal services unit dedicated to housing • Toll-free number for Medi-Cal beneficiaries with housing access or retention problems • Housing education workshops

WPC Pilot Spotlight: Los Angeles County - Homeless Care Support Services

Los Angeles County is implementing a number of projects focused on helping homeless beneficiaries, including through the Homeless Care Support Services (HCSS) program. HCSS provides beneficiaries with comprehensive wrap-around services to improve their health, achieve housing sustainability, and decrease the use of high-cost services. Beneficiaries are connected to permanent housing opportunities and receive rent subsidies either through Section 8 federal funding or through the county's flexible housing pool funds. The HCSS program provides three levels of services depending on the beneficiary's needs:

Tier 1: Bridge

- Services provided 24 hours a day, seven days a week
- Targeted at beneficiaries who have just come off the streets, are least connected to services, and are most likely to have unmanaged health and behavioral health conditions

Tier 2: High Acuity

- Provided to beneficiaries during their first 12 months in permanent housing.
- Targeted at beneficiaries who have just come off the streets, are least connected to services
- Each Case Manager is assigned to 20 beneficiaries to help them:
  - Obtain identification cards, birth certificates, and other documents
  - Navigate housing identification and procurement processes
  - Develop relationships with health providers
  - Manage their health conditions
  - Learn life skills (e.g. meal prep, personal finances)

Tier 3: Low Acuity

- Provided to beneficiaries after living in permanent housing for 12 months, if evaluated as appropriate
- Each case manager is assigned to 40 beneficiaries
- Moderate case management provided based on beneficiary's need

Enhanced Care Coordination and Care Management

Many WPC Pilots are providing enhanced care coordination and care management services, particularly for beneficiaries with multiple chronic conditions, mental health disorders and/or substance use disorders, and those recently released from an institution (e.g. jail/prison, or Institutions for Mental Diseases).

WPC Pilot Spotlight: San Diego County Health and Human Services Agency - Service Integration Teams and Customized Care Management Module

San Diego County is using "Service Integration Teams" (SITs) and advanced information technology (see below) to address and coordinate beneficiaries' housing, health, and social service needs. Each of the twelve SITs includes a social worker and peer support specialist with access to a shared staff of two registered nurses, four housing navigators, and a project manager. The SITS provide services to beneficiaries for up to two years, altering the intensity of services based on beneficiary need.

Enrollment and Service Timeline

Phase	Time Period	Services
1	1-3 months prior to enrollment	Intensive outreach and engagement resulting in enrollment
2	1-3 months after enrollment	Intensive housing navigation, care coordination and development of Comprehensive Care Plan (CCP)
3	4-9 months after enrollment	Continued care coordination, monitoring of CCP, housing supports and tenancy sustaining services
4	10-15 months after enrollment	Moderate care coordination
5	16-27 months after enrollment	Lower level care coordination and follow-up

Advanced Information Technology through ConnectWellSD:

- ConnectWellSD links data from 9 systems to provide a comprehensive service profile for each beneficiary
- SITs will use a customized care management module in ConnectWellSD to:
  - Enhance data sharing among multiple systems, including health, housing, and social services;
  - Support care coordination; and
  - Receive "real time" information on emergency department visits and hospital admissions via the county's health information exchange, San Diego Health Connect.

The care coordination efforts involve assessing beneficiaries to determine their health, behavioral health, substance use disorder (SUD) and social service needs and developing care plans to guide treatment. Some WPC Pilots are developing care teams of providers and social service representatives to provide comprehensive support. Additionally, some Pilots are tailoring the type and intensity of services based on the needs of target populations (e.g. individuals recently released from incarceration) or according to the beneficiary's progress.

WPC Pilot Spotlight: Kern Medical Center- Streamlining Transitions Back into the Community

Kern County is using enhanced care coordination to help beneficiaries recently released from incarceration transition back into the community. Key components include:

- Provision of services up to 90 days following release from incarceration;
- A health care clinic established within the jail to provide beneficiaries who have been presumptively determined eligible for Medi-Cal prior to release with a wellness check, drugs prescribed while incarcerated and a discharge plan based off a health assessment;
- A post-incarceration liaison is assigned to the care team 90 days after their release;
- Life skills transition classes; and
- Enrollment in ongoing care coordination services.

Enhanced Care Coordination – Behavioral Health

Under the WPC program, many Pilots are implementing projects focused on expanding and increasing access to resources for those with SUDs and behavioral health disorders. Through the use of navigation teams, integration with primary care, and mobile outreach and response teams, Pilots plan to identify, engage, and treat this population in a comprehensive manner.

WPC Pilot Spotlight: San Joaquin County Health Care Services Agency- Behavioral Health Navigation Teams

San Joaquin County will use both Navigation Teams and Mobile Crisis Response Teams to ensure that beneficiaries with behavioral health disorders receive timely, appropriate, and comprehensive care.

Role of Navigation Teams

- Help beneficiaries address non-clinical barriers to care (e.g. transportation, housing);
- Develop linkages with community resources;
- Collaborate with Mobile Crisis Response Teams;
- Link beneficiaries to WPC services including post-crisis follow-up and stabilization;
- Work to re-engage beneficiaries who do not follow-up with care; and
- Provide ongoing support for the duration of individuals' enrollment in the WPC Pilot.

Role of Mobile Crisis Response Teams

- Conduct on-site mental health assessments, interventions, and treatment evaluations;
- Work to reduce incarceration of beneficiaries who are suffering from a mental health crisis; and
- Refer beneficiaries to WPC participating entities and community partners.

Data Sharing Across Providers

The WPC Pilot program requires Pilots to develop data collection and data sharing capabilities across participating entities, including with their partner managed care plan(s) (MCPs). MCPs will provide the lead entity with basic client information to identify the patient population eligible for the WPC program. MCPs can request information that is available within the data system, such as utilization and enrollment figures and can schedule regular comprehensive reports on services provided.

All 18 Pilots are using the WPC funding to expand their existing data sharing frameworks, with the goal of developing data systems that enable a beneficiary's health care providers, care coordinators, and social service providers to share data and communicate effectively. Below is a summary of the types of data projects that are being implemented under the WPC program:

- 12 Pilots will create a Health Information Exchange (HIE);
- 11 Pilots will implement patient population software;
- 9 Pilots will host a data warehouse;
- 7 Pilots will collect real-time data;
- 7 Pilots will utilize case management software;
- 6 Pilots will share real-time data; and
- 3 Pilots will develop entirely new data sharing systems.

WPC Pilot Spotlight:
San Francisco Department of Public Health - Multi-Agency Care Coordination System (MACCS)

The MACCS includes a data sharing platform, a multi-agency universal assessment tool, and enhanced care coordination capabilities. This system will leverage learnings from their current integrated system and expand its reach, depth and utility to enable the San Francisco Department of Public Health and its partner entities to:

- Establish a data sharing platform that can be used as both a real-time mobile care management tool that links information across city agencies, community based organizations, and disciplines and an integrated data system for analysis and monitoring;
- Develop and implement a multi-agency universal assessment tool to evaluate the needs of each homeless San Franciscan;
- Strengthen care coordination by stratifying the population based on risk and prioritizing those with the greatest needs for the most intensive interventions; and
- Provide a foundation for a citywide Navigation System, which will align shelter and housing resources, including wraparound services and create system-wide priorities and data to match people in need with the appropriate housing intervention.

WPC Pilot Payments

Pilots will receive payments from DHCS based on their approved budgets, assuming they achieve the WPC goals and metrics outlined in their approved application.

- In the first year, the WPC Pilots are focused on infrastructure development. Pilots received payment for submitting their applications and reporting baseline data.

- In years two through five, the Pilots will be focused on providing services, implementing interventions, achieving metrics, and providing incentive payments. Pilots must submit mid-year and annual reports to DHCS and will receive payment based on achieving the metrics outlined in their application.

Each WPC Pilot lead entity chose the financing structure that will be used to pay for the interventions in their county, including fee-for-service (FFS), per member per month (PMPM) bundles, pay for reporting, pay for outcomes, and incentive based payments. In most cases, Pilots will use PMPM bundles to pay for care coordination services. Each PMPM is calculated based on the expected cost of a typical beneficiary who will receive services under the Pilot. Pilots typically use a FFS structure for 'one-time' services, such as those provided at sobering centers. Payments for reporting, outcomes, and incentives are designed to encourage the Pilots to achieve the goals of WPC and provide them with funding to support quality improvement activities and data sharing.

Incentive Payments

Some Pilots chose to place a larger portion of their budgets into incentive payments, which means they will only receive these payments if they achieve the goals established in the application. Smaller Pilots were less likely to take on this risk, often due to the uncertainty of achieving metrics with smaller populations. These Pilots placed more of their budgets into reporting measures, making it more likely they will receive the full payments.

Both Los Angeles County and Santa Clara County developed budgets in which the amount of funding they receive is tied to achieving established outcomes. These systems of payment are designed to hold the counties accountable for achieving the goals outlined in their applications, but also provide incentives for partial achievement, thereby encouraging the Pilots to continue to work toward their goals throughout the duration of the Pilot.

For example:

- **The Los Angeles County Department of Health Care Services** assigned a point total for each milestone incentive payment category in its budget: Timely Implementation, Physical Infrastructure Development, and IT/Quality Infrastructure Development. In order to receive full payment for a given category, the county must earn all of the points assigned to that category. If the county only earns some of the points in a category, they receive a proportionally lower payment for that category.

- **The Santa Clara Valley Health and Hospital System** established a tiered system of Pay for Outcome measures under which they will receive 100% of the incentive payment for fully meeting a given goal, 90% of the payment for meeting 90% of the goal, phasing down to 10% of the payment for meeting 10% of a goal.

Next Steps

The WPC Pilots are in the midst of developing the infrastructure and business relationships that will enable them to fully launch their programs. DHCS is continuing to provide guidance and technical assistance to the Pilots through regular communication and support, and DHCS is in the process of launching a Learning Collaborative to help ensure their successful implementation. DHCS opened a second round of WPC applications in January 2017. Applications are due in March 2017 and applicants are expected to be notified of DHCS decisions in the summer of 2017.

DHCS will work closely with Pilots to implement these innovative programs aimed at providing comprehensive, effective and efficient health care and social services support to improve the health and well-being of vulnerable Medi-Cal beneficiaries. The WPC Pilot program allows for targeted efforts, autonomy and innovation, and can serve as model for other states that are looking to incorporate community and social services to provide comprehensive support for their Medicaid beneficiaries.

Appendix A: Summary of Approved WPC Pilots

WPC Lead Entity	Target Population(s)	Estimated Number of Beneficiaries	Five-Year Budget
Alameda County Health Care Services Agency	• Homeless, at-risk of homelessness • High-risk, high-utilizers • Medically complex	20,000	$283,453,400
Contra Costa Health Services	• High-risk, high-utilizers	52,500	$203,958,160

Kern Medical Center	• High-risk, high-utilizers with emphasis on:
	  ○ Homeless, at-risk of homelessness
	  ○ Release from incarceration
		2,000	$157,346,500

Los Angeles County Department of Health Services	• Homeless, at-risk of homelessness • Released from incarceration • Serious Mental Illness (SMI) and/or SUD • High-risk, high-utilizers	137,700	$900,000,000

Monterey County Health Department	• High-risk, high-utilizers and homeless, at-risk of homelessness and 3 or more of the following:
	  ○ Serious Mental Illness (SMI) and/or SUD
	  ○ Two or more chronic conditions
	  ○ Four or more Mental Health Unit admissions
	  ○ Three or more Emergency Department (ED) visits in six months
	  ○ Two or more hospital admissions in six months
	  ○ Five or more prescribed medications
		500	$26,834,630

Napa County	• Homeless, at-risk of homelessness with emphasis on:
	  ○ High-risk, high-utilizers
	  ○ Physical disability
	  ○ SMI and/or SUD
	  ○ Multiple chronic conditions
		800	$22,686,030

Orange County Health Care Agency	• High-risk, high-utilizers and homeless, at-risk of homelessness • SMI	8,098	$23,500,000
Placer County Health and Human Services Department	• High-risk, high-utilizers • SMI and/or SUD • Two or more chronic health conditions • Recent release from incarceration	450	$20,126,290
Riverside University Health System Behavioral Health	• Recent release from incarceration	38,000	$35,386,995

WPC Lead Entity	Target Population(s)	Estimated Number of Beneficiaries	Five-Year Budget
San Bernardino County Arrowhead Regional Medical Center	• High-risk, high-utilizers	2,000	$24,537,000

San Diego County Health and Human Services Agency	• High-risk, high-utilizers and:
	  ○ Homeless, at-risk of homelessness
	  ○ SMI, SUDs, or chronic physical health conditions
		1,049	$43,619,950

San Francisco Department of Public Health	• Homeless, at-risk homelessness with emphasis on: ○ High-risk, high-utilizers	10,720	$118,000,000
San Joaquin County Health Care Services Agency	• High-risk, high-utilizers • SMI and/or SUD • Homeless, at-risk of homelessness upon discharge from an institution	2,130	$17,500,000

San Mateo County Health System	• High-risk, high-utilizers with four or more ED visits in the past year. Emphasis on:
	  ○ SMI and/or SUD
	  ○ Homelessness
	  ○ Recent release from incarceration
		5,000	$165,367,710

Santa Clara Valley Health and Hospital System	• High-risk, high-utilizers and:
	  ○ Engaged in two or more systems of care
	  ○ In the top 5% of utilizers in the health system in the past year
		10,000	$225,715,295

Shasta County Health and Human Services Agency	• Homeless, at-risk of homelessness and: ○ Two or more ED visits in the last three months	600	$19,403,550

Solano County Health & Social Services	• High-Risk, high utilizers and:
	  ○ Avoidable ED use
	  ○ Two or more chronic conditions, with at least one SMI or SUD diagnosis
		250	$4,667,010

Ventura County Health Care Agency	• High-risk, high utilizers	2,000	$97,837,690

Who We Are

About Us

Who We Are

What We Do (https://www.chcs.org/about-us/what-we-do/)

Our Core Tenets (https://www.chcs.org/about-us/our-core-tenets/)

History and Funders (https://www.chcs.org/history-funders/)

Staff (https://www.chcs.org/staff/)

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Cultural Humility: A Key Element of Trauma-Informed Care (https://www.chcs.org/cultural-humility-key-element-trauma-informed-care/)

Key Ingredients for Making Trauma-Informed Care a Standard of Care (https://www.chcs.org/key-ingredients-making-trauma-informed-care-standard-care/)

Putting Medicaid Capacity Building into Action (https://www.chcs.org/putting-medicaid-capacity-building-action/)

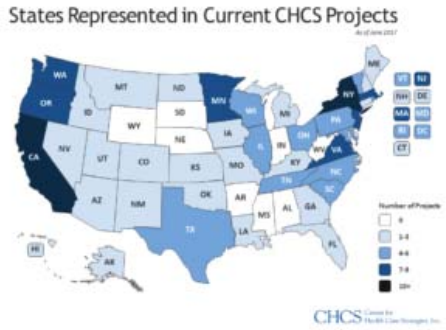
The Evolution of Shared Savings Payment Methodologies for Medicaid Accountable Care Organizations (https://www.chcs.org/evolution-shared-savings-payment-methodologies-medicaid-accountable-care-organizations/)

A nonprofit policy center dedicated to improving the health of low-income Americans.

Since 1995, the Center for Health Care Strategies (CHCS) has partnered with nearly every state in the country to promote innovations in publicly financed health care, especially for individuals with complex, high-cost needs. Its work brings together state and federal agencies, health plans, providers, and consumer groups to advance models of organizing, financing, and delivering health care services. In so doing, it has developed both

a birds-eye view and a ground-level feel for the nation's health care delivery system for low-income Americans and a unique perspective on how to generate systems-level change within Medicaid and across public and private payers.

(http://www.chcs.org/media/CHCS-Participation-Map_060817.png)



As a nonpartisan organization, CHCS facilitates problem-solving exchanges and peer learning among a diverse range of health care stakeholders to improve access, integrate fragmented services, reduce avoidable expenditures, and link payment with quality. CHCS' technical assistance and training activities, supported primarily by philanthropic and federal funding, are organized under three core priorities:

- **Health Care Access** (/topics/health-care-coverage-and-access/): Helping states make the most out of coverage opportunities to provide high-quality and cost-effective services for low-income Americans.
- **Delivery System and Payment Reform** (/topics/financingdelivery-systempayment-reform/): Supporting states in designing and implementing comprehensive, statewide multi-payer delivery system and payment reforms that reward value as opposed to volume and support improvements in population health.
- **Integrated Services for People with Complex Needs** (/topics/adults-with-complex-needs/): Advancing innovations in care for many of the nation's highest-need, highest-cost populations, including high-risk children and youth (/topics/children/); adults eligible for Medicare and Medicaid (/topics/medicare-medicaidlong-term-care/), including those with long-term care needs; and people with complex physical health, behavioral health, and social service needs.

CHCS also focuses on leadership and capacity building (/topics/medicaid-leadership/) to ensure that state leaders have the skills, expertise, and tools necessary to achieve Medicaid's potential as a national model for high-quality, cost-effective care.

At CHCS, we are fortunate to collaborate with mission-driven partners across the country to advance shared goals for better health. From policy concept through program implementation, our work is designed to help ensure that health reform's promise of coverage translates to high quality and cost-effective care.

Study Overview:

Out-of-hospital cardiac arrest (OHCA) is the most common cause of death from cardiac disease in adults in the United States. Among patients who are resuscitated and survive to hospital admission, survival to hospital discharge ranges from 14% to 42%. Treatment at ST segment elevation myocardial infarction (STEMI) centers, defined as hospitals that are capable of performing percutaneous coronary intervention at all times, is associated with both overall survival and survival with good neurologic recovery compared with treatment at non-STEMI centers. However, even among STEMI centers, rates of survival with good neurologic recovery ranged from 17% to 40% after adjusting for usual patient and hospital characteristics. These observations suggest that there are unknown features of hospitals and care delivery that affect the impact of therapeutic interventions. Differences in clinical care and organizational culture (e.g., teamwork, communication) may explain variation in outcomes within STEMI centers that are all capable of delivering the same interventions. The overarching goal of this research study is to develop a set of “best practices” for the care of patients resuscitated from OHCA.

Who? EMS medical directors, ED physicians, ED nurses, intensivists, ICU nurses, and interventional cardiologists from ~20 STEMI centers throughout California. Neither participants nor their hospitals will be identified in the study’s results.

What? One 45-minute telephone interview. Participants will be compensated for their time with a $100 Amazon gift card.

Why? To understand the aspects of clinical care and organizational culture (e.g., quality improvement, teamwork, communication) may affect outcomes for patients resuscitated from out-of-hospital cardiac arrest

When? Currently enrolling

How? Contact Ben Mooso (bamooso@ucdavis.edu / 916-734-5752) or Bryn Mumma (bemumma@ucdavis.edu / 916-734-1350)

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

August 30, 2017

TO: CHA EMS/Trauma Committee

FROM: Pat Blaisdell, VP Continuum of Care
Debby Rogers, VP Clinical Performance and Transformation

SUBJECT: Access to Post-Hospital Care/Discharge Delay

CHA member hospitals report significant difficulty securing appropriate post-hospital care for patients who no longer require a hospital level of care and may have specialized needs. As a result, these individuals may remain in hospital beds beyond the time required to treat their medical condition, often for extended periods. In order to assess the scope and impact of this problem, the CHA Case Management Committee developed a survey and queried committee member hospitals in a one-day, point-in-time survey in July 2016.

Background

Following a hospitalization for injury or illness, many patients require continued care either at home or in a specialized facility. A key role of hospital-based case managers and discharge planners is to work with patients and their families to identify an appropriate post-acute care setting, based on the individual's medical needs and available resources.

Some patients require continued specialized care that is provided in skilled nursing facilities (SNFs), Institute for Mental Disease (IMD), and/or residential treatment, but hospital personnel are unable to locate a facility that has the capability and capacity to accept the patient. In other cases, individuals may be able to go home or to another community setting with support, but the necessary reimbursement or ongoing care coordination may not be available.

Study Results

The CHA Case Management survey focused on patients whose patient discharge was delayed greater than seven days beyond what was deemed medically necessary. Seven days was selected as the determining timeframe to eliminate operational barriers that could briefly delay discharge, such as lack of available transportation.

Twenty acute care hospitals, representing 8% of California's hospital beds, participated in the survey. For a specific date in July, 2016, hospitals were asked to report:

- # of patients with > 7 excess hospital days

- Total # of excess days attributable to those patients
- Payer status
- Barrier(s) to discharge

The 20 hospitals reported:

- # of patients with > 7 excess hospital days: **78**
- Average delay: **52 days;** Median delay: **17 days**; Range: **10 – 399 days**
- **> 75%** were reported to require skilled nursing or custodial residential care
- Over half were **MediCal beneficiaries**

The most frequently reported barrier to transition was the presence of a behavioral or behavioral health issue. Additional barriers repoted included; patient/family disagreement with plan; homelessness; undocumented status; lacking capacity and unrepresented; presence of a tracheotomy; need for dialysis; high caregiver burden, including obesity; and age related issues. Many patients evidence multiple barriers.

If the incidence of delayed discharges for the reporting hospitals is characteristic across the state:

- On a daily basis **1,004** persons with > 7 excess days remain in hospital beds
- At an estimated cost of **$3.2 million/day, or $ 1.17 billion/year**
- Hospitals receive little to no reimbursement for these extra days or care, and often provide additional unreimbursed care to facilitate discharge.

Implications
Lengthy hospital stays have significant negative implications for individuals, including negative impact on medical and functional outcome and independence, a need for excess or unnecessary long term care or institutionalization, and deterioration of existing community support.

In hospitals, these excess stays divert costly and limited inpatient resources, resulting in delays in hospital admissions and ED crowding. Hospitals receive little to no reimbursement for these extra days or care, and often provide additional unreimbursed care to facilitate discharge, such as paying for necessary equipment or transportation, leasing SNF beds for timely access, or for care at a board and care facility.

Summary
Lack of access to post-hospital care is having a significant impact on hospital length of stay, and has serious implications for patients and hospitals alike. The impact of this issue extends far beyond a single care setting or provider type and will require sustained and comprehensive action and collaborative with other key stakeholders. CHA staff, in coordination with key CHA

specialty centers and commmittees is developing a preliminary action plan to include additional research, outreach to other key stakeholders, and development of policy and advocacy strategies and member education and support.

The most frequently reported barrier to transition was the presence of a behavioral or behavioral health issue. Additional barriers repoted included; patient/family disagreement. Homelessness, undocumented status, unrepresented and lacking capacity, presence of a tracheotomy, need for dialysis, hig h caregiver burden, including obesity, and age related issues. Many patients evidence multiple barriers.

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

August 30, 2017

TO: EMS/T Committee

FROM: BJ Bartleson, VP Nursing and Clinical Services

SUBJECT: NQF Draft Measures

The National Quality Forum (NQF) under contract with the Department of Health and Human Services develops care performance measures that are reviewed for healthcare measurement in the United States. These measures are used for payment and public reporting purposes particularly for quality improvement and value based initiatives. The NQF recently finalized a draft report on "Emergency Department Quality of Transitions of Care Measurement Framework" because there are few measures that address the content and quality of transitions of care for a medical condition into and out of the ED from a usual source of care or from various care settings (e.g., primary care providers or specialists, long term care hospitals, or skilled nursing facilities) and then who are discharged from the ED to their usual source of care. An NQF expert panel identified a set of priority measures and concepts that improve transitions for both patients and providers, promote structures and processes to link clinical and non-clinical settings more effectively, and measure outcomes to help monitor the development and implementation of systems to optimize transitions. The report also promotes short and long term changes that could be utilized to reduce care fragmentation and improve care coordination through enhancing ED transitions of care. This work is timely, for state wide review, as we implement the ECSI initiative and look to resources to guide our research agenda, best practices and performance measure development.

1215 K Street, Suite 800, Sacramento, CA 95814 · *Telephone:* 916.443.7401 · *Facsimile:* 916.552.7596 · www.calhospital.org

NATIONAL QUALITY FORUM

Emergency Department Quality of Transitions of Care Measurement Framework

DRAFT REPORT

May 26, 2017

This report is funded by the Department of Health and Human Services under contract HHSM-500-2012-00009I Task Order HHSM-500-T0025.

Content

Executive Summary

Emergency Department (ED) visits are often critical inflection points in a patient's health trajectory, making management and information transfers a critical component of quality and outcomes. Consequently, bidirectional information flows require attention as patients are transferred from outpatient providers to EDs; EDs to outpatient providers; within EDs and hospitals; and between EDs and other settings such as nursing homes, home health, rehabilitation, and prehospital providers. Improving the management of transitions of care into, out of, and within the ED has the potential to improve person-centered care, value, and reduce costs.

Either the lack of, or poor and/or incomplete, or unclear information transfer during ED transitions in care between providers and settings may lead to patient anxiety, uncertainty, avoidable resource utilization, or a worsening in the patient's condition and potential harm. Return visits to the ED within three days of a discharge are estimated at 8.2% nationally, and of those patients who had a revisit, 32% revisited a different institution.[1] Similarly, hospital to home transitions can also involve ED transitions in care as one in five Medicare beneficiaries discharged from the hospital are readmitted within 30 days – half of whom have not yet seen an outpatient doctor for follow-up.[2] Most of these readmissions occur through the ED. The variability in communication during transitions from one care setting to another may also contribute to confusion among clinicians about the patient's severity of condition and near-term care needs, duplicative tests, inconsistent patient monitoring, medication errors, delays in diagnosis, and lack of follow through on referrals. System failures may contribute to poor outcomes in patient safety, quality of care, and health outcomes.[3]

There are currently few measures that address the content and quality of transitions of care for a medical condition into and out of the ED, such as patients who visit the ED from a usual source of care or from various care settings (e.g., primary care providers or specialists, long-term care hospitals, or skilled nursing facilities) and then who are discharged from the ED to their usual source of care. To address this, the National Quality Forum (NQF) convened a multistakeholder Expert Panel to aid in the development of a quality performance measurement framework including priority measures and measure concepts and a set of guiding recommendations to aid in promoting improvement in the management of transitions of care into and out of the ED. This report summarizes the findings of the measurement framework and offers recommendations for measure implementation and measure development to address this important void.

The Panel assessed the state of quality measurement for ED transitions and identified a set of priority measures and concepts that: improve transitions for both patients and providers; promote structures and processes to link clinical and non-clinical settings more effectively; and measure outcomes to help monitor the development and implementation of systems to optimize transitions. In parallel, the Panel deliberated over ways to promote positive near and long-term changes, which were distilled into four high-impact area recommendations:

1. **Infrastructure and linkages**: The development of new infrastructure and linkages are needed to support ED transitions that are patient-centered. For example, hospitals will need

to make further investments in ED-based care managers, navigators, and social workers, and facilitate referrals to community health workers and healthcare coaches.

2. **Health information technology (HIT):** Enhancements are needed to HIT to support high quality ED transitions in care. For example, HIT should be developed to help support shared decision making between providers and patients during ED transitions in care.
3. **Payment models**: New payment models may facilitate quality improvement in ED transitions. For example, EDs and hospitals that move to global budgets rewarding hospitals for coordinated care may promote investment in ED transitions to reduce inefficient ED downstream use (e.g., unscheduled ED revisits).
4. **Research agenda:** Further research is needed to understand which patients are at highest risk for encountering problems with poor quality or poor outcomes related to ED transitions, and which interventions work best to reduce transition-related problems and improve outcomes. Stakeholders in ED transitions in care (i.e., providers, policymakers, researchers, and HIT vendors) should identify, develop, evaluate, and promulgate promising models for ED and community engagement.

These recommendations reinforce the well-recognized need to reduce care fragmentation and improve care coordination through enhancing ED transitions in care. Recommendations are not limited to any single health condition, organization type, or type of measure. They are intentionally broadly applicable to all entities that participate in transitions of care into and out of the ED.

Introduction

Care fragmentation across the healthcare system is increasingly a major quality issue, particularly as patients' transition between care settings.[4] Transitions of care are defined as the movement of patients between healthcare locations, providers, or different levels of care as their conditions and care needs change. During this transition process, there can be problems with communication among healthcare providers causing patients to experience conflicting care plans, duplication of services, and potentially experience medical errors or delays in care.[5] Fragmentation and its negative effects on the quality of patient care can be magnified in hospital-based ED care. ED care is delivered commonly at a critical juncture in a patient's health trajectory – an acute illness or injury – and the physicians and facility caring for the patient often have no prior relationship with the patient.[6]

EDs play a key role in healthcare delivery in the United States with more than 137 million visits in 2014, according to the Healthcare Cost and Utilization Project.[7] Over the past decade, visits to hospital-based EDs have consistently outpaced population growth. In the past several years, there have been expansions in the types of facilities patients can use for acute unscheduled care, including urgent care clinics, retail clinics, direct-to-consumer telemedicine, and freestanding EDs.[8] EDs also care for a wide variety of patients from neonates to the oldest old, and must provide medical screening examinations for all patients who present for care regardless of their willingness to pay according to The Emergency Medical Treatment and Labor Act (EMTALA).[9]

Care transitions into and out of the ED are challenged by the lack of interoperability in electronic health records (EHRs), the lack of standardization in information that is transferred to and from EDs before the patient arrives, while the patient is in the ED, or after the patient departs the ED for further outpatient or inpatient care.[10] These issues make transitions between providers around ED care particularly high-risk for patients, and prone to error and communication issues. Risks related to transitions are even higher when patient factors (e.g., older age and comorbid conditions) or condition-related factors (e.g., severity of illness or immediate treatment needs) increase the need for good communication between providers and with patients. Ensuring high quality transitions when patients are transferred into and out of EDs must be a high priority, with a close focus on high-risk patients. There are, however, many potential ways to optimize ED transitions in care that have been identified. Specifically, improving provider education around how to execute effective transitions, assessing provider performance on transitions in care, ensuring that EHR vendors produce useful transition tools, identifying specific data elements necessary for a high-quality ED transition as well as best practices have been proposed. However, to date, few of these have been broadly implemented in every ED.

The purpose of this Expert Panel was to identify existing measures and measure concepts for transitions in care into and out of the ED, to identify gaps to fill through measure development, and to create a conceptual model for measuring ED transitions. The overall goal of this effort is to use measurement to drive quality improvement and accountability for optimizing ED transitions for patients as well as reward providers and health systems that are able to consistently conduct high quality transitions into and out of the ED.

This project builds on prior work by NQF and others. For example, NQF has been actively working to improve performance measures for care coordination for the last ten years, which has validated the importance of multiple parties working together as a unified system to achieve positive outcomes for the patient. In addition, NQF's Measure Applications Partnership (MAP) has identified an initial Care Coordination Family of Measures related to the National Quality Strategy (NQS) priorities and high-impact conditions.[11] This Family of Measures include addressing avoidable admissions and readmissions, system infrastructure support, care transitions, communication, care planning, and patient surveys related to care coordination.

Prior work outside of NQF has also been done in ED transitions. In 2012, the American College of Emergency Physicians (ACEP) released the *Transitions of Care Task Force Report*.[12] The report issued recommendations to improve transitions of care to advance population health, patient experiences, and reduce costs to the system. One central recommendation to "identify the components of a minimum data set for all transitions," is a desire shared by this project's Panel.

Project Overview

Under a contract with the Department of Health and Human Services (HHS), NQF was tasked with developing a measurement framework and identifying measure concepts that focus on the quality of transitions of care into and out of the ED. There is a great need for measures that address the quality of transitions in care for patients with a wide range of medical conditions as well as ongoing social service needs. This framework is intended to serve as a foundation to address the current measure gaps and identify promising measure concepts to guide future measurement development. As a nonprofit, membership organization and a consensus-based entity, NQF brings together multistakeholder groups to reach consensus on critical issues to improve health and healthcare through quality measurement. A list of the members of the ED Quality of Transitions of Care Expert Panel and the NQF Staff can be found in Appendix B.

This project aims to identify ways to measure and improve patient transitions of care into and out of the ED, and ultimately make the process more patient-centered, while enhancing value and reducing cost. There are other types of important transitions of care that occur within an ED, such as ED physician to ED physician or ED physician to hospital handoffs for patients who are admitted. There are also transitions that occur when emergency medical services (EMS), the police, or the fire department respond to individuals who may or may not be transported to the ED. This project, however, focuses on the transitions of care into and out of the ED, with a particular emphasis on the role of follow-up care for the patient. After an ED visit, follow-up is a high-risk time where patients may experience important gaps in care that may result in missed diagnoses, and potentially avoidable healthcare utilization, such as return ED visits.[131415] Through a process of reviewing prior work in this area and convening a Panel to assess the current and future state of transition of care measures, this report was developed through:

1. A synthesis of evidence through an environmental scan for existing measures and measure concepts; conducted key informant interviews to provide additional expert insight on gaps in measures as well as ways that technology related to ED transitions is changing;
2. The development of a measurement framework to identify measure gaps and prioritize a list of existing measures and measure concepts for immediate use or further development;
3. The convening of a Panel through a series of webinars, in-person meetings, and conference calls; and
4. The identification of gaps in quality measurement based on the framework and environmental scan.

Synthesis of Findings and Definitions

NQF staff conducted a comprehensive environmental scan and review of evidence to inform the development of the ED Quality of Transitions of Care measurement framework. The environmental scan included a review of relevant measures and measure concepts, a literature review, and a series of key informant interviews. The methods used to conduct the scan and the identified relevant articles are included in Appendix A. These findings were synthesized and presented to the Panel in a series of webinars to further define the most important components of a quality transition into and out of the ED.

The primary purpose of the scan was to assist in the development of a measurement framework, and to identify an initial set of measures and measure concepts to be considered for inclusion in the framework. The scan included care transitions in other settings outside of the ED (e.g., hospital to primary care or home), care processes relevant to all care transitions (e.g., medication reconciliation), and target populations and/or conditions that are relevant to acute, unscheduled care.

The scan identified measures and measure concepts by searching trusted measure sources such as NQF's Quality Positioning System (QPS), Centers for Medicare and Medicaid Services' (CMS) Quality Measures Inventory, Agency for Healthcare Research and Quality's (AHRQ) National Quality Measures Clearinghouse, AHRQ's National Guidelines Clearinghouse, Health Indicators Warehouse, The Joint Commission, and previous NQF endorsement and framework projects. A total of 136 measures and 42 measure concepts were identified in the scan. NQF staff then sorted the list of measures by relevance: 29 measures were directly relevant to the ED, 30 measures were potentially relevant, 36 measures were indirectly relevant, and 41 measures were considered not relevant. For a full list of measures and measure concepts that were recommended by the Panel, refer to Appendix C.

The comprehensive literature review was conducted in January and February 2017 and referenced authoritative sources such as PubMed, JSTOR, and Academic Search Primer. Grey literature and web searches through Google identified additional presentations, programs, tools, and other documentation related to transitions of care. Over 250 academic journal abstracts were reviewed for relevance, as well as more than 200 grey literature sources. In addition, NQF staff conducted a series of key informant interviews to provide supplemental information specific to ED communications with EMS, technology considerations to support interoperable transitions of care systems, and considerations for long-term and post-acute care transitions into and out of the ED.

NQF staff categorized the findings from the entire environmental scan – the measure review, the literature review, and the key informant interviews – into the following topics that provided the foundation for the measurement framework.

Table 1. Findings from the Environmental Scan

Topic	**Examples**
Notable Care Transitions	Coleman's Care Transitions, Naylor's Bridging Nursing Support/Transitional Care Model, Project RED, Project BOOST, the

Interventions	GRACE Model, and the STAAR Initiative
Care Transitions Conceptual Models and Frameworks	Ideal Transition in Care (ITC Framework)[16], National Transitions of Care Coalition (NTOCC) Conceptual Model, NQF's Care Coordination Conceptual Framework, Conceptual Model for Episodes of Acute, Unscheduled Care[17], and Care Coordination Across Transitions in Care Settings[18]
Transition Quality	Whether the transition of care was safe, effective, patient-centered, efficient, and equitable.
Provider Information Exchange	Sending and receiving of information to support the transition. Examples of best practices to support the timely, salient, effective transfer of information.
Community Alignment	Community efforts and resources that may potentially support transitions of care.

The following definitions were used to support the synthesis of the findings:

- **Care Coordination** *is the deliberate organization of patient care activities between two or more participants (including patient) involved in a patient's care to facilitate the appropriate delivery of healthcare services.*
- **Patient and Family Centered Care** *is the extent to which care is provided to the patient, caregiver, and/or family, which is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.*
- **Community Services Setting** *refers to an array of services and supports delivered to a patient either at home or other integrated community setting that promotes the independence, health and well-being, self-determination, and community inclusion of a person of any age and health need.*

Measurement Framework, Measures, Concepts and Gaps

Process for Finalizing the Framework, Domains, Subdomains, and Measures/Concepts

Performance measurement is a mechanism for assessing healthcare quality, including whether care is safe, effective, patient-centered, timely, efficient, and equitable.[19] The primary purpose of the framework is to define a structure for measuring and evaluating the quality of transitions into and out of the ED. As such, the framework intentionally encompasses all of the different types of providers, patients, families and their caregivers, and community supports that interact with the ED and have the ability to influence quality in a transition of care. The framework also takes into account how these interactions change and are influenced by the patient's condition as well as the how the patient comes into the ED. The measurement framework is informed by the synthesis of the results of the environmental scan of measures and literature, key informant interviews, and feedback from the Panel. The framework is composed of a series of domains that articulate high-level ideas, and within each of those domains are subdomains that provide meaning to the domain by translating the high-level ideas into more measurable concrete actions, outcomes, and events. The framework's priority domains were identified and refined by the Panel, who provided additional granularity on what elements of the domain are essential to performance measurement and then translated those elements into subdomain topics.

During the development and refinement of the framework, the Panel drew from the following definitions:

1. An "episode of care" refers to the group of healthcare visits and other care delivered from the onset of a symptom to its resolution or development of a chronic condition.[20] Episodes of care may also include an exacerbation of an acute illness. During an episode of care that involves the ED, transitions in care occur as patients enter the ED (e.g., as a referral from an outpatient provider) and also occur as patients are discharged from the ED and their care transitions to non-ED providers (e.g., primary care physicians or specialists), or to community organizations (e.g., social services).
2. A "system of care" refers to the spectrum of settings in which services are delivered that are relevant to an episode of care (e.g., EDs, hospitals, skilled nursing facilities, home health agencies, and community organizations).
3. "High-risk transitions" into and out of the ED are characterized by three factors, alone or in combination:
    (1) The clinical condition/potential condition involved in the ED transition, which may include:
        i. A diagnosis that requires immediate treatment (e.g., sepsis, acute myocardial infarction, emergency surgery) or a potential diagnosis that requires immediate treatment (e.g., chest pain, potential ectopic pregnancy)
        ii. A diagnosis that requires defined follow-up/additional care (e.g., a new diagnosis of cancer, diabetes, or heart failure) or a potential diagnosis that requires defined follow-up/additional care (e.g., symptoms of unintentional weight loss that could represent cancer)

iii. The initiation of a high-risk medication (e.g., Rivaroxaban for the treatment of pulmonary embolus)

(2) Underlying comorbid conditions and age of the patient involved in the ED transition, which may include:
   i. Extremes of age (e.g., neonates)
   ii. The presence of chronic medical conditions (e.g., heart failure, diabetes, chronic obstructive pulmonary disease, cancer)
   iii. The presence of underlying mental illness (e.g., schizophrenia)

(3) The psycho-social-environmental circumstances of the patient involved in the ED transition in care, which may include:
   i. Compromised economic circumstances/lack of resources (e.g., poverty, lack of healthcare coverage)
   ii. Lack of or poor access to care (e.g., no primary care physician, required specialist does not take patients' health insurance)
   iii. Substance use disorders (e.g., alcoholism, opioid dependency)
   iv. An unsafe home or work environment (e.g., domestic violence)

Domains/Subdomains

The framework's domains are organized into four interrelated components that are essential to a quality transition of care: provider information exchange; patient, family, and caregiver information exchange; engagement of broader community; and achievement of outcomes. Each of the domains includes a definition and a series of subdomains. The domains are to be viewed as dynamic topic areas and not silos, the goal of the framework is to establish a common fabric in which the domains are threaded and cross-referenced throughout. An additional goal of the framework is to address relevant themes that may not be specified in the domains. For instance, the Panel identified care fragmentation as a contributing factor to poor quality transitions of care; consequently, the framework was developed in such a way to consider communication across all of the domains. The following table provides definitions for four domains and ten subdomains.

Table 2. ED Transitions in Care Measurement Framework: Domains and Subdomains

Domains and Definitions	**Subdomains and Definitions**
Provider Information Exchange: Communication and transfer of information between providers that occurs during transitions of care into and out of the Emergency Department.	• **Key Information Elements and Properties of its Transmission**: Key information includes the following: ○ Expected plan of care and anticipated contingencies ○ Chief complaint, history of present illness, working diagnosis, and reason for transfer ○ Patient acuity ○ Test results and procedures performed ○ Advanced directives

Domains and Definitions	Subdomains and Definitions
	○ Point of contact for family/caregiver status ○ Follow-up plan of care ○ Capacities and capabilities of the ED and outpatient setting to handle care ○ Contact information and specific requests about communication (e.g., return phone call) Depending on the nature of the transition, modes of the information transfer may be important. These may include modality (electronic, telephone, in-person), timeliness, efficiency, salience/parsimony, accuracy, feasibility, specific providers involved, and accessibility of the information. • **Care Coordination and Feedback:** This includes sharing accountability for collaborative care during the transition of care to transmit and receive key information in a manner appropriate to the nature of the transition. In addition, feedback needs to be provided across settings to improve care and care transitions.
Patient, Family, and Caregiver Information Exchange: Interactive bidirectional communication between patients (and their families, caregivers, or health proxies) and multidisciplinary healthcare team (e.g., case manager, nurse)	• **Key Information Elements and Properties of its Transmission**: There are two communication pathways for key information: 1). Healthcare team to patient ○ Diagnosis and cause(s) or potential cause(s) of condition ○ Expected short- and long-term course and treatment plan ○ Anticipated contingencies for possible symptom/condition evolution ○ Short-term and potentially long-term logistics of care ○ Diagnosis-specific and community-specific resources 2). Patient to healthcare team ○ Contact information for preferred and secondary point of contact ○ Contact information for care team (may include primary care physician, care manager, specialist, etc.) ○ Informed consent ○ Desires for follow-up care ○ Desires for sharing information ○ Advanced directives ○ Living will ○ Information about managing symptoms ○ Medication information ○ Any logistic barriers or facilitators of care that are relevant Modes of communication exchange may include verbal (e.g., in-person or telephone), digital (e.g., email, text, or video), written, fax, HIT (e.g., patient portal or EHR). Modality may be informed by an assessment of

Domains and Definitions	Subdomains and Definitions
	barriers. • **Effective Communication and Shared Decision Making:** Effective communication and shared decision making encompasses the assessment of patients' needs and verification that the patients' needs and preferences have been met. Effective communication will establish what (if any) potential barriers exist for patients to effectively receive communication about their health status and care. Potential barriers may include lack of insurance to access follow-up care, or medications, lack of social supports, or lack of health literacy. Meaningfully incorporating individuals' goals, values, and preferences into care planning requires respectful and compassionate conversations between providers and patients. These discussions should elicit patients' goals and values as well as encourage patients and caregivers to be partners in decision making.
Engagement of the Broader Community: The extent to which the broader community's organizations, services and information technology infrastructures are available and engaged to support a quality transition of care into and out of the ED. The community setting refers to an array of clinical and non-clinical services and supports the care delivered to a patient that promotes the independence, health and well-being, self-determination, and community inclusion of a person of any age and health need.	• **Connection and Alignment:** The identification, availability, and engagement of appropriate clinical and non-clinical community services that support a transition of care. This should include multi-directional communication to facilitate care coordination with the ability to leverage existing communication pathways and should include the sharing of a patient-centered care plan to better promote linkages among the broader community. • **Accessibility of Services:** Assessment of the availability of community supports and services that support transitions of care.
Achievement of Outcomes: The extent to which quality patient-centered ED transition of care outcomes occur across patient episodes of acute care within systems of care.	• **Healthcare Utilization & Costs:** Healthcare utilization may include ED visits, hospital admissions/readmissions, medications, procedures, testing, and transportation. Increased utilization and costs may occur due to poor transitions leading to duplicative care and additional investment of provider resources. Better patient transitions into and out of the ED have the potential to reduce cost and unnecessary utilization. Utilization and cost measures should be reported with

Domains and Definitions	Subdomains and Definitions
	quality measures. • **Provider Experience:** Assess the transition team members' experiences working within systems of care responsible for delivering coordinated care. Provider experience may also relate to resources within the broader community, and how specific resources may facilitate ED transitions or the lack of resources may make transitions more difficult. • **Patient/Family/Caregiver Experience:** The ways in which the patient, family, and caregiver experience care in a transition – may take into consideration level of respect and responsiveness to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions. • **Follow-up and Safety Outcomes:** During a transition in care, the extent to which there are institutional processes to ensure appropriate care during the ED visit and appropriate follow-up after the ED visit.

Provider Information Exchange

Provider information exchange is an essential component of an effective ED transition in care. When patients are referred to the ED for specific care and treatment or transition back to their outpatient providers, there is a variety of ways that providers communicate information with one another. For transitions into the ED, often the referring provider calls the ED with a brief verbal description of the patient, reason for referral along with clinical details, and contact information for communication after ED care is delivered. However, it is not uncommon for no such communication to happen. When no communication occurs, this can create confusion for the treating ED provider about the reason for referral, diagnostic concerns, and whether additional involvement in the patient's care is desired or expected. This can also create confusion with the patient as to what care should be delivered in the ED, what to expect, particularly if what was told to the patient before they arrived in the ED (i.e., a specific test would be performed or treatment given) does not happen. After ED care, many EDs provide verbal or written reports of information back to primary care or specialty providers; however, this does not occur consistently. There is frequently a request by the ED provider for follow-up within a specific time period (e.g., 2-3 days). However, it is sometimes not clear whether the primary care physician has the capacity to re-evaluate the patient within that period, or whether there are sufficient resources for ongoing management of the patient's condition. A major measure gap in this area is that provider information exchange is not standardized (specifically what information is transmitted), and information is sometimes not transmitted in a timely manner to the next provider or no information is transferred at all. Finally, it is sometimes unclear what providers need to do and in what period of time during an ED

transition, specifically while there is often the implicit expectation for shared accountability for care coordination, responsibilities for transitioning care may not be clear among providers. Ultimately, the Panel identified two subdomains for provider information exchange that are relevant to quality measurement: key information elements and properties of its transmission and care coordination and feedback.

Key Information Elements and Properties of Its Transmission

To optimize transitions, it is important that specific information be communicated between providers. Specific information communicated during a transition to the ED may differ from information communicated during a transition from the ED back to the outpatient environment. The Panel identified several key information elements that may be transmitted during ED transitions including:

- Expected plan of care and anticipated contingencies – When patients are being transferred into and out of the ED, it is important that expectations for specific care from the sending and receiving provider be communicated. This improves the quality of care as the sending provider may have more detailed or current information about the patient's condition. It is also important to describe anticipated contingencies; specifically, how the receiving provider may react to test results and what actions may occur as the patient's condition evolves.
- Chief complaint, history of present illness, reason for transfer, and working diagnosis – It is important to appropriately frame the precise reason for the transfer, which includes the chief complaint – or chief concern – for the transition between settings as well as a brief narrative history of the clinical context of the transfer, working diagnosis, and relevant comorbid conditions.
- Patient acuity – Communicating patient acuity is vital because there may be time-sensitive actions required when the patient arrives in the ED (e.g., early administration of antibiotics) or similarly, time-sensitive actions in an outpatient setting (e.g., stress testing to rule out acute coronary syndrome).
- Test results and procedures performed – Communicating objective data about test results and procedures performed is relevant to transitions both into and out of the ED.
- Advanced directives – Information on patient wishes is important and can often guide specific treatment pathways.
- Point of contact for family/caregiver status – Specific points of contact including contact information for caregivers and how they may be relevant for an ED transition in care is important.
- Follow-up plan of care – As patient's transition out of the ED, EDs should communicate explicit follow-up plans with the patient and receiving provider with clear contingencies as the patient's condition evolves.
- Capacities and capabilities of the ED and outpatient setting – Providers may share information about specific capabilities of an ED and hospital (i.e., available specialists, test or treatment availability), or capabilities of outpatient settings to implement a plan of care.

During transitions, information may be transmitted in a variety of ways across settings. Depending on the nature of the transition, modes of the transition are important and may include electronic,

telephone, or in-person communication. The clinical context of the transition should guide the mode of transmission. Oftentimes, information is not available in a timely way. Therefore, it is important for transition communication to occur so that information is available prior to the next visit. It is also important to consider the efficiency of how the information is transferred and how systems can facilitate transitions, particularly electronic systems. Today, few systems efficiently manage transitions across settings where providers can easily transmit, receive, and share in the care of patients as they transition into and out of the ED. Systems should be built to structure transition information in a way that easily identifies key information that the receiving provider should focus on (i.e., salient information) related to the transition. This should also be communicated in a way that minimizes provider burden in reviewing information; however, information needs to be complete and comprehensive. The accuracy of the information is vital as well as its accessibility by the receiving provider.

Care Coordination and Feedback

Providers need to coordinate care across settings and there should be shared accountability for specific actions across transitions in care. Currently, few systems facilitate care coordination into and out of the ED where it is clear what needs to be done, by whom, and when. The Panel discussed shared accountability not as a way to identify problems in transitions but rather as a way to frame transitions such that each party – the sending and receiving provider – has clear expectations for key information elements and properties of its transmission. That information transfer can be facilitated through design of technology and other ways to standardize ED transitions across settings. The Panel also agreed that it is important that systems be implemented to allow for feedback for care transitions on individual patients. For example, when a patient is transferred to the ED and specific care that was expected is not delivered (e.g., a lumbar puncture is not done to rule out meningitis) or when a patient is referred for a specific procedure as an outpatient (e.g., surgery) that is not delivered, it is important for that settings provider to receive feedback on individual patients so that all providers can learn about the capabilities of different settings and receive feedback on their medical decisions. Because many different types of providers with different training can be involved in ED transitions, feedback is important; particularly those that occur that may be optimized. Feedback is vital for continuous quality improvement.

Environmental Scan

In the environmental scan, the NQF team identified 24 existing quality measures for provider information exchange that varied with respect to their type (process, structure, and outcome) and whether they were directly, potentially, or indirectly related to provider communication. This included measures related to specific information being sent from the ED to longitudinal settings and vice versa, and from EDs to other facilities. Several metrics were indirectly related to ED transitions and were identified with the goal of modifying them to align more closely with ED transitions.

Existing measures that were thought to be relevant included seven measures around Emergency Transfer Communication (percentage of patients transferred to another healthcare facility where several information elements were transmitted within 60 minutes of transfer). Specific information elements included:

- Required information is communicated to the receiving facility prior to departure
- Entire vital signs record is communicated
- Medication information is communicated
- Patient information is communicated
- Physicians information is communicated
- Nursing information is communicated
- Procedures and test information is communicated

A full list of the seven relevant measures is in Appendix C.

Measure concepts and gaps in measurement

During the meeting, the Panel identified several measure concepts from existing measures as well as novel concepts. The measure concepts focused on how providers exchanged information with one another during ED care transitions, and focused in particular on high-risk populations, specifically those with a high-risk condition, high-risk comorbid conditions, or other factors such as socioeconomic status that reduced their access to care or was associated with poor health literacy. Specific concepts that were identified include:

- ED medication reconciliation performed with relevant providers for high-risk prescribing
- Transfer of specific information to relevant providers the next clinic day for high-risk ED discharges (two similar concepts were identified)
- Transfer of a transition of care document by emergency medical services at ED arrival
- Collaborative ED care plans for frequent ED users
- ED visit information available to other providers via health information exchange
- A feedback system for referring providers for specific cases potentially useful for quality improvement

The detailed list of measure concepts identified by the Panel is in Appendix C.

Along with the measure concepts, the Panel identified several gaps in measurement where potential concepts have yet to be explicitly identified. Specifically, the Panel determined a particularly important property of transitions in care was the transmission of advanced directive information, which affects whether patients are transferred (in the case of Physician Orders for Life-Sustaining Treatment (POLST), which define advanced directives) and whether patients receive care in the ED in line with their and their family's wishes. The Panel also identified measure gaps around the accuracy of the information that is sent and received during ED transitions in care. There were no specific quality metrics proposed for accuracy; however, the Panel suggested this could potentially be measured through structural measures of whether quality improvement processes are in place or through provider experience surveys.

Patient, Family, and Caregiver Information Exchange

Effective patient communication is core to a quality transition of care, and has been linked to improved patient outcomes and reduced readmissions.[21] Furthermore, the need for good communication is so

widely accepted that a patients experience with their healthcare is now linked to Medicare incentive payments.[22] However, despite these new priorities, ED transitions of care pose significant challenges to effective patient-centered communication. Specifically, the ED's role of providing acute unscheduled care typically includes an interaction with a patient that the ED provider has not seen before. These communication complexities are compounded by frequent interruptions to patient provider communications inside of the ED.[23] As such, the Panel defined quality patient information exchange to include key information relevant to the ED visit, communicated in an understandable way by the ED provider to the patient and caregiver, as well as communication of relevant information to other providers involved in continued care for the patient.

When transitioning out of the ED into other settings, patients, families and caregivers need to understand: the working diagnosis of their chief complaint; the expected clinical course of their condition in the short term, or what to do, where to go; and who to call if specific symptoms occur. Unfortunately, this information is not always consistently communicated. While information is often provided in discharge instructions to patients, many patients experience confusion about what care was delivered in the ED and the plan of care afterwards.[24] Due to these differences, individualized approaches to information exchange are needed to ensure patients fully comprehend their transition plan.

Within this domain, the Panel agreed on two subdomains that are critical when developing quality measures specific to information exchange and communication with patients, their families, or their caregivers:

1. **Key Information Elements and Properties of its Transmission**: Defined by either information shared by the healthcare team to a patient, or by information shared by the patient to the healthcare team. The focus of this subdomain is specific to information that specifically supports the patient in a transition of care.
2. **Effective Communication and Shared Decision Making**: During a patients' transition in care, the extent to which the communication they receive is effective and the opportunity for shared decision making is made available.

The environmental scan identified 15 measures and six concepts related to the domain of patient, family, and caregiver information exchange. In their review of the relevant measures and concepts, the Panel discussed limitations of existing measures, and articulated areas for advancement in measure development.

Current Measure Limitations and Gaps

The measures identified in the scan as potentially supporting patient information exchange were limited to specific settings or patient populations. For instance, actionable discharge instructions have been identified as a critical component to supporting quality transitions from the ED to home (or non-hospital facility); yet existing measures are narrowly focused on specific conditions, such as asthma or dementia. Further, the Panel recognized that existing measures focused on patients receiving transition information lack incentives to improve the quality of transition information; rather, the incentive is

merely aimed to encourage the sharing of information. The Panel agreed that providers should be incentivized to improve the quality of transition information, measuring quality by how well the information corresponds to the nature of the patient's condition, their immediate care needs, and resources needed to support their transition. In addition, existing measures in general did not address shared decision making or provider communication with the patient. While several measures developed to support CMS' Meaningful Use program focus on electronic access to health information (personal and general) were found to be relevant, the Panel stressed the need to consider new and innovative ways to incentivize communication of information in a manner that is understandable, relevant, and accessible to the patient.

Moving Beyond Accepted Process

The Panel identified several examples of processes in the existing measures relevant to the domain that are now covered through The Joint Commission's hospital accreditation guidance, or are generally accepted as common practice. For instance, review of the transition record with the patient upon discharge, or documentation of advanced care directives in the medical record are both widely implemented as standard practice. The Panel reiterated guidance for future quality measurement to focus on the assessment of information and how it is communicated to the patient. Specifically, quality measured by how well the transition record includes the necessary information to support patient needs. Several criteria were proposed by the Panel on how to assess the quality of information communicated to the patient:

- Clarity;
- Understandable instructions for next steps in care;
- Anticipated contingencies and specific steps to follow should changes occur; and
- Phone number for the patient to call post-discharge.

Other measure gaps identified by the Panel included an assessment of patients' potential barriers to a quality transition. For instance, an assessment may include availability of insurance (e.g., access to follow-up care or medications), availability of needed social supports, or the patient's health literacy status. One priority identified by the Panel is the need to measure whether conversations between providers and patients meaningfully incorporate the patient's goals, values, and preferences into a care plan through respectful and compassionate conversations. These discussions should elicit patients' goals and values as well as encourage patients and caregivers to be partners in shared decision making.

Concepts that could fill gaps

The Panel identified measure gaps in key information specifically for additional information to provide patients with a post-discharge source that may provide additional clarifications to discharge instructions and/or answer questions specific to their ED visit. In addition, the Panel noted that not all patients require the same level of information. Potential concepts to support gaps in the area of key information and its transmission and effective communication and shared decision making include:

- ED-based telephone number provided to the patient to clarify instructions, if needed

- Documentation of specific information provided to the patient and a discussion that accounts for patient preferences
- Follow-up appointment scheduled for patients without a designated primary care provider
- Discharge instructions provided in the patient's preferred language and appropriate literacy level while taking into account the patient's socioeconomic status
- Documentation of a designated healthcare point of contact for treatment planning that has been shared with available family or caregivers for non-verbal patients
- Shared decision making process

The detailed list of measure concepts identified by the Panel is in Appendix C.

Engagement of the Broader Community

Engaging the broader community, defined as both clinical and non-clinical supports, in transitions of care efforts can have a promising effect on a patient's health trajectory. Historically, however, supports for the patient have acted as silos rather than engaging and communicating as one system of care for the patient. With less than one percent of any given person's life spent inside the healthcare system, a vast majority of time is spent outside of the clinical care environment.[25] Having a better understanding of a patient's social needs and putting mechanisms in place to address those needs may reduce unnecessary healthcare utilization and costs. Unfortunately, determining which patients require community supports and ensuring those community supports are available when needed remains a challenge. This is particularly an issue in ED care, which serves as a safety net where complex circumstances arise for patients that intersect with law enforcement, social service agencies, housing, and other community resources.

The engagement of the broader community is defined as the extent to which the broader community's organizations, services, and information technology infrastructures are available and engaged to support a quality transition of care into and out of the ED. Additionally, the community setting refers to an array of clinical and non-clinical services that support care delivered to a patient promoting the independence, health and well-being, self-determination, and community inclusion of a person of any age and health need. The Panel discussed the importance of recognizing there are both clinical and non-clinical aspects to transitions in care that may need to involve not only clinical care providers but also other non-clinical resources in the community. Within this domain, the Panel agreed upon two subdomains that are critical when engaging the broader community:

1. **Connection and Alignment** is defined as the identification, availability, and engagement of appropriate clinical and non-clinical community services that support a transition of care. This should include multi-directional communication to facilitate care coordination with the ability to leverage existing communication pathways and should include the sharing of a patient centered care plan to better promote linkages among the broader community.
2. **Accessibility of Services** is defined as the assessment of the availability of community supports and services that support transitions of care.

The Panel deemed the subdomains as important because identifying and engaging available community services and supports (e.g., housing, food, and transportation) creates a system that works

collaboratively for the greater good of the patient. Additionally, ensuring that these services are accessible to the patients in need is essential to increasing healthy outcomes. Knowing what is available within each community will lead to a better understanding of potential community needs and gaps in care. The environmental scan identified 16 measures and seven measure concepts related to the domain of Engagement of the Broader Community. In reviewing the possibly relevant measures and concepts, the Panel discussed that a number of the measures did not specifically focus on the greater community's system of care and thus concluded that they did fit within this domain. Accordingly, the Panel focused considerable attention on measure concepts given the lack of focus on the broader community in the current measurement landscape.

The Panel's discussion around these two subdomains focused on three key themes leading to the development of measure concepts:

1. **Importance of Care Coordination Services**. The use of care managers, social workers, coordinators, or navigators within the ED is an important aspect of transitions of care. Having this service available provides the patient with someone who can assist them with scheduling follow-up appointments, connect them with community resources, and facilitate communication with payers, family members, or other members from the patient's care team. The Panel did note that, while care coordination services are intended to reduce fragmentation, they sometimes actually add to the already fragmented system. One example was provided of a woman who had fallen for the third time in six months and when offered a care manager, she refused stating that she already had five – two from her health plan, one from the hospital, one from the ED, and one from her primary care physician's office. Knowing who is on a patient's care team – whether it be a family member, caregiver, primary care physician, or care manager – can reduce fragmentation and ensure a more integrated health system focused on working together as one cohesive unit. The Panel also recognized that a measure concept focused on the idea of care coordination would not be practical if it applied to every person who came to the ED and instead proposed that such a measure would focus only on patients who were identified as high-risk.
2. **Utilizing and Knowing about Available Community Resources.** The Panel discussed assessing health and social needs (e.g., transportation, income, food) of patients who may be considered high-risk and connecting them with available community services. Being aware of needed services and focusing on meaningful linkages between the ED and the community should be a priority for both clinical and non-clinical organizations. A large part of the Panel's discussion also focused on accountability and who should be responsible for collecting and maintaining a list of available resources as well as making any necessary referrals. Two resources were discussed that could be a starting point for EDs as well as primary care physicians, specialists, etc. – Aunt Bertha and 2-1-1 San Diego. Aunt Bertha is a customizable platform for healthcare systems and social services that allows them to find and refer clients to a myriad of services based on a specific zip code.[26] Putting systems in place within the ED that use such services could be a starting point to ensure that a provider is connecting a patient with appropriate, nearby services. Related to this idea, the Panel discussed the concept of assessing high-risk patients who are at risk for a transition failure due to unmet needs. Developing a validated tool to track

patients' "high-risk score" over time and referring them to necessary community supports based on that score was something that the Panel agreed was aspirational, but something that could be considered for future measurement development.

3. **Bidirectional Communication.** Many health systems lack the infrastructure and incentives to develop systems that support bidirectional communication between clinical and non-clinical services, which makes closing the referral loop a constant barrier in a successful transition of care. The Panel discussion focused on the need for a system that allows a sending facility (e.g., the ED) to see that its referral to a community service (e.g., Meals on Wheels) was received to support better communication among clinical and non-clinical services. Subsequently, the Panel recommended one concept related to bidirectional communication. The Panel noted an initiative, the San Diego Community Information Exchange (CIE), which links the databases of organizations including housing and elder service agencies, paramedics, Meals on Wheels, and other similar organization who serve vulnerable populations.[27] This initiative is enhancing bidirectional communication across providers who serve the same clients and allows real time information to be shared, leading to better service delivery and positive community health and social outcomes.

Given the lack of current measures within this domain, the Panel focused on measure concepts that could fill noted gaps. The Panel also recognized that several of its identified concepts were quite aspirational and agreed that the gaps listed below are important but will require additional research to build the relevant evidence base, measure development and testing, and additional data sources and data sharing capabilities:

- Best practices around how to best close the referral loop between providers
- How to leverage payers in care coordination activities
- Challenges related to shared accountability between the ED and community organizations
- Determining whether repeat ED visits is the result of a failed system
- Privacy concerns when engaging community supports and services
- The importance of collecting information on the patient's care team at the time of transition

The detailed list of measure concepts identified by the Panel is in Appendix C.

Achievement of Outcomes

One of the key questions within healthcare is what is the outcome of any care provided? How did the health state of the patient change for the better or adversely? Process measures highlight whether services have been provided or documented, but outcome measures provide the results. Measuring outcomes in transitions of care is particularly problematic given that transitions occur across multiple settings. Early in its discussion, the Panel discussed the challenge of measurement as the patient moves from one setting (Point A) to the ED (Point B) and then back to the original setting or a different setting (Point C). While these three settings may be completely separate (e.g., have no relationship with one another), there is an implied 'system of care' as the patient moves from one setting to another and the goal is to be able to measure outcomes in each setting. The achievement of outcomes is the extent to which quality patient-centered ED transition of care outcomes occur across patient episodes of acute care within systems of care.

Outcomes of transitions in care need to be considered from different perspectives – the patient, the provider, the organization, and the payer. The four subdomains represent different types of outcomes to provide a more complete picture of the results of the healthcare provided during transitions of care. The Panel agreed with the four proposed subdomains:

1. **Healthcare Utilization and Costs:** Healthcare utilization may include ED visits, hospital admissions/readmissions, medications, procedures, testing, and transportation. Increased utilization and costs may occur due to poor transitions leading to duplicative care and additional investment of provider resources. Better patient transitions into and out of the ED have the potential to reduce cost and unnecessary utilization. Utilization and cost measures should be paired with quality measures.
2. **Provider Experience:** Assess the transition team members' experiences working within systems of care responsible for delivering coordinated care. Provider experience may also relate to resources within the broader community, and how specific resources may facilitate ED transitions or the lack of resources may make transitions more difficult.
3. **Patient/Family/Caregiver Experience:** The ways in which the patient, family, and caregiver experiences care in a transition – may take into consideration level of respect and responsiveness to individual patient preferences, needs, and values and ensuring that patient preferences and values guide all clinical decisions.
4. **Follow-up and Safety Outcomes:** During a transition in care, the extent to which there are institutional processes to ensure appropriate care during the ED visit and appropriate follow-up after the ED visit.

The environmental scan identified 16 measures and five measure concepts related to the achievement of outcomes domain. In reviewing the possibly relevant measures and concepts, the Panel discussed the limitations of existing measures, considerations related to the diverse patients transitioning through the ED, and the challenges of measuring follow-up. Additionally, the Panel focused considerable attention on measure concepts given the lack of outcome measures for transitions in care. During the Panel's discussions, the following key ideas were identified:

- **Overcoming the limitations of current measures:** Most of the suggested measures for the achievement of outcomes were developed for use in a single setting. The Panel discussed the idea of paired measures that would allow for the capture of activities in multiple settings, (e.g., documentation of needed follow-up by the ED and verification of any follow-up provided in the next setting). Paired measures would also encourage shared accountability, (i.e., all the providers in the patient's system of care would have specific responsibilities within their setting). The Panel also determined that some of the suggested measures were too narrow and should be re-purposed (e.g., re-specified) to be more broadly applicable. For example, most of the measures related to medication reconciliation were specified for a single setting or a subpopulation of patients. The Panel suggested that a more effective medication reconciliation measure would be one driven by a change in the patient's medications (e.g., when a medication is added, deleted, or has a change in dosage). Such a measure could be specified for a broad denominator of patients across a variety of settings. The provider information exchange domain also addressed medication reconciliation measures since these are typically process measures, not outcome measures.

- **Developing measures for high-risk patients:** EDs care for a wide variety of different types of patients, which affects the complexity of transitions in care. For example, patients may have complex medical needs, complex social needs, or both. The Panel agreed that measures or concepts should be able to accommodate a diverse set of patients (e.g., not every patient needs to be measured in the same way). In particular, the Panel identified patients at high risk of having a poor transition in care and patients who use the ED frequently as being two groups requiring special attention. The Panel recognized that high-risk patients and patients who use the ED frequently typically require additional time and resources, which may not always be available. Even while recognizing the challenges in ensuring an effective transition of care for these patients, the Panel agreed it was important for the ED to take initial steps in measurement that would enable the ED to become an even more effective partner within the system of care.
- **Patient follow-up including return visits to the ED:** In transitions of care, one of the important measures is whether the patient received any necessary follow-up after discharge. The Panel recommended two concepts for patient follow-up recognizing that there are multiple decision makers in follow-up. In sharing information with the next setting of care, the ED provider may include recommendations for follow-up. The provider seeing the patient in the next setting of care determines what specific follow-up care is needed and how continuing care should be delivered (e.g., visit, phone call, email). The patient also plays a role in follow-up based on the patient's understanding of what follow-up needs to occur and the patient's ability to access needed follow-up. The Panel also discussed the importance of distinguishing between scheduled and unscheduled return visits to the ED. A patient may be scheduled for a return visit to the ED for several reasons, such as for a wound check, if the ED provider cannot verify that the patient will receive needed follow-up (e.g., has no primary care provider), or if the ED or its associated organization can provide specialized care needed by the patient (e.g., Sickle Cell clinic). However, unscheduled return visits to the ED may signal a poor transition for the patient. Determining the reason for the unscheduled return visit will be critical, but will mean additional data collection from the patient who can provide needed information as to why the return visit occurred, (e.g., patient was uncertain as to what to do or to expect after leaving the ED previously or the patient was unable to access needed medications or services). With this additional information, it will be possible to develop interventions or strategies to improve transitions in care that can lead to better outcomes and reduced costs.

Concepts that could fill gaps

Given the lack of outcome measures for transitions in care, the Panel focused on measure concepts that could fill the measure gaps. The Panel also recognized that several of its identified concepts were quite aspirational and would potentially require research to build the evidence base, measure development and testing, and additional data sources and data sharing capabilities. Whenever possible, the Panel tried to identify either initial or intermediate measures that would help build a pathway to the more aspirational concepts. For example, better provider access to patient information may reduce duplicate testing. Potential concepts to support gaps in this area include:

- Reduction in duplicate testing
- Improved transitions for patients who are frequent users of the ED
- Provider experience with select aspects of transitions

- Patient experience during transitions of care
- Follow-up with patients after discharge from the ED
- Reduction in adverse drug events
- Return visits to the ED

The detailed list of measure concepts identified by the Panel is in Appendix C.

Common Themes

The Expert Panel identified a series of common themes across the four domains:

1. The importance of timely and effective communication across and between stakeholders,
2. The need to increase linkages between providers and other community resources to optimize transitions, and
3. The importance of finding outcomes that are proximally or directly related to ED transitions to monitor quality improvement efforts.

Two common themes emerged within the domains of *provider information exchange* and *patient information change*. First, it is vital that specific information elements be communicated during ED transitions in care, and second, all stakeholders should be accountable for healthcare decisions around ED transitions. Specific and complete information is important for the providers involved and for the patient in order to have a shared understanding of the patient's current condition and plans for care, the prior history and context of the condition, expectations for care, and communication. For this process to run smoothly, ideally a health information technology infrastructure would allow for information sharing with providers and patients as well as serve as the platform for shared accountability and decision making. The timing of information transfer between providers, patients, and the community was also a crosscutting theme. For the most effective care to be delivered, the entity caring for the patient should optimally have complete access to information. When information is not transferred or there are delays in transfer, the quality of the ED visit when patients are being referred in, and for the subsequent follow-up visits by either clinical or non-clinical providers are impacted. Therefore, providers need to transmit information such that the next provider (i.e., the ED, primary care provider, specialist, or community stakeholder) has a clear understanding of what is needed to best deliver continued care for the patient.

To optimize sharing of information outside of the ED, *engagement of the community* is vital. Because the ED is often a focus source of care within the community, this requires work by the ED and community stakeholders to collaborate to ensure that transitions into and out of the ED are optimized. Improving this process involves increasing the connectivity of the healthcare community and ensuring that EDs have complete and updated information about community resources and that the resources are available to the patient as needed.

Finally, the Panel recognized that ED transitions have the potential to enhance or reduce the quality of care and that focusing on both providers and patients on improving this process will lead to measurable *outcomes*. Measuring outcomes is a vital component to ED transitions and while it may be, for example,

difficult to link a specific safety outcome to transitions, several measurable outcomes are important, including healthcare utilization and costs, accessibility of follow-up, as well as clinical outcomes.

Priority Measures and Measure Concepts

The Panel engaged in a process of identifying and then prioritizing measures and measure concepts through an in-person meeting, a series of conference calls, and an online survey. The Panel initially assessed all of the measures, potential measure concepts, and existing measure gaps identified in the environmental scan. Panel members were then assigned to one domain to further evaluate the measures for elimination or to determine if additional measure concepts were needed.

A total of six measures and 24 measure concepts were submitted by the Panel to be considered for the prioritization exercise. Via an online survey, the Panel was asked to rank each of the final measures and measure concepts on their importance and feasibility. Importance was rated on a scale of one through five (1 as low, 3 as moderate, and 5 as high). When rating the importance of a measure or measure concept, the Panel considered:

1. The relevance to ED transitions of care;
2. Whether it is a high-priority area and to what extent it focuses on important or aspirational outcomes, is meaningful to the patient, or supports systemic/integrated view of care;
3. The impact of the measure as to whether it affects large/small numbers of patients, addresses a leading cause of morbidity/mortality, or contributes to inappropriate resource use; and
4. The likelihood that what is being measured will improve the quality of care during the transition.

Similarly, feasibility was rated on a scale of one through five (1 as not feasible, 3 as aspirational/potentially feasible in the future, and 5 as very feasible today). When rating the feasibility of a measure or measure concept, the Panel considered:

1. Availability and ease of capturing data;
2. Resource requirements including consideration for total cost of implementing the measure or education/training of the workforce; and
3. Organizational readiness to tackle the issue related to the measure or measure concept, including consideration for variability across organizations and how that affects readiness, capacity, adoption of quality improvement, and implementation of the measure or measure concept.

These criteria were selected because of their relevance to both prioritizations of existing measures and measure concepts for future development. NQF staff collected and analyzed the survey results.

Results

The prioritization results are based on a total of 15 responses representing two-thirds of the Panel. All of the measures and measure concepts received moderate (3) to high (5) scores for importance. The range of feasibility scores was more variable including not feasible or aspirational (2) to feasible today (5). The measures and measure concepts were then ranked by calculating the product of the average importance and feasibility scores. The distribution of the rank scores align with three implementation readiness areas: aspirational or long-term, mid-term, or feasible today.

Prioritization Findings

A combination of five measures and measure concepts ranked high in importance and feasibility and are recommended as ready for implementation today. These measures and concepts focus on:

- Provider communication (e.g., EMS, ED, other facilities);
- Patient-centered communication and discharge activities; and
- Community resource information to support transitions.

A total of 19 measures and measure concepts ranked moderate to high importance and moderate feasibility and are recommended as ready for implementation in the mid-term. The focus of these measures and concepts include:

- Care managers, coordinators, and navigator services in the ED;
- Improved discharge instructions with considerations for patient language, socioeconomic status, and contact information;
- Timeliness of information transfer to support high-risk transitions into and out of the ED; and
- Provider and patient experience with ED transitions in care.

Six measures and measure concepts ranked moderate to high importance and low feasibility and are recommended as aspirational measures for future development and implementation. These measures and concepts include:

- Reduction in duplicate testing based on payer level data;
- Improved transitions for frequent users of ED;
- Bidirectional communication between clinical and community resources; and
- Shared care plan between the patient, primary care provider, and ED for frequent ED users.

Prioritization Themes

As part of the measure ranking and prioritization exercise, the Panel also provided feedback on each of the measures and measure concepts in terms of importance and feasibility (see Appendix D for the prioritization results and feedback). This feedback mirrors the overall recommendations made by the Panel.

Expert Panel Recommendations: Priorities for ED Quality of Transitions of Care and Performance Measurement

Through a multistakeholder review process, the Panel assessed the state of quality measurement for ED transitions of care. The Panel identified measures and concepts that, today and in the future, may improve ED transitions by providers and make information more understandable to patients. The Panel also identified measures and concepts to promote new linkages between clinical and non-clinical settings and to make existing linkages more effective. Finally, the Panel recognized the importance of developing outcome measures to help monitor the implementation of systems to optimize ED transitions.

The Panel also developed recommendations to promote positive policy change. Similar to the prioritization process, the Panel identified steps that could be implemented today to improve ED transitions, as well as longer-term aspirational goals.

1. **EDs should expand infrastructure and increase linkages to support patient-centered ED transitions.**
    a. Hospitals should invest in ED-based care managers, navigators, and social workers, and facilitate linkages and referrals to community health workers and healthcare coaches. EDs are open 24-7; similarly, these services need to be available 24-7 when patients need them.
    b. ED-based systems should be available (e.g., a phone number or other communication system) to answer discharged patients' questions such as how to take new medications, or questions about the evolution of symptoms.
    c. EDs should have up-to-date, accurate information on available clinical providers for follow-up and for community resources. This information should be available to patients. Ideally, there should be a systematic collection of community resources by communities (e.g., the 2-1-1 system in San Diego).[28] ED-focused processes should also facilitate linkages and referrals to available clinical providers and community resources.

2. **Enhancements to health information technology (HIT) are required to support high quality ED transitions in care.**
    a. Health information exchanges are a public good and should be supported by public funding or by payers. An aspirational goal is a unified medical record stored in the cloud that clinical and non-clinical providers and patients can access.
    b. HIT should be developed to allow sharing of key information elements important to ED transitions between hospitals or health systems as well as between clinical and non-clinical providers. Data sharing includes adding standardized data fields to capture social determinants of health (e.g., homelessness, health literacy, and patient's preferred language).
    c. HIT should facilitate feedback about patients across systems of care – particularly when cases are useful for quality improvement – to promote a learning system.
    d. HIT should integrate information from multiple sources (e.g., pharmacy data, prescription drug monitoring programs, local clinics, other health systems).
    e. Similar to an admission/discharge/transfer alert system, HIT should allow care team members or the medical home to be alerted, when appropriate, when patients arrive or depart the ED. This notification system could also be controlled directly by patients.

f. HIT should be developed to support shared decision making between providers and patients during ED transitions. A good example is the Chest Pain Choice Trial, where a shared decision making tool lowered admission rates for ED patients with chest pain without compromising safety.[29]
g. HIT should be developed to overcome privacy concerns that can be barriers to information sharing between providers and community-based organizations. One facilitator would be a common consent form. Alternatively, health information exchanges or a unified medical record could allow patients to control their personal information.
h. Tools should be developed by ED providers and others to enhance a patients' understanding of their conditions. For example, information in the form of videos could help explain the evolution of common symptoms and how to handle specific issues as the condition evolves after ED discharge.

3. <u>New payment models may facilitate quality improvement in ED transitions.</u>

a. EDs, hospitals, and other entities (e.g., health plans, managed care) that move to global budgets/capitation to reward entities for coordinated care may promote investment in ED transitions. This has worked in integrated delivery systems.[30] These investments may improve the quality of ED transitions, by reducing inefficient ED downstream use (e.g., unscheduled ED revisits) and increasing necessary follow-up.
b. New payment models should be considered to reimburse providers using existing or new fee-for-services codes or for activities related to ED transitions.[31] For example, new reimbursement codes could be developed for ED-based observation units to provide more intensive care coordination services.[32] Consideration should also be given to reimbursing primary care providers and specialists for coordination efforts or for follow-up not involving an in-person visit. These additional payments may support the resources needed to deliver high quality ED transitions.
c. New payment models should also be considered with measurement at the community-level to promote linkages with EDs and information sharing.

4. <u>Research agenda</u>

a. Taxonomies are needed to support improved ED transitions in care for: 1) care-team to care-team communication, and 2) care-team to patient communication. Specifically, these taxonomies would create the information elements that should be shared with parameters describing recommended modalities and timing for information sharing.
b. Research is needed to understand which patients are at highest risk for encountering problems with poor quality or poor outcomes related to ED transitions, and which interventions work best to reduce transition-related problems as well as improve outcomes. Specifically, research is needed to identify ways that specific patients could be screened to identify unmet social service needs that may increase the risk of poor ED transitions.
c. Stakeholders in ED transitions in care (e.g., providers, policymakers, researchers, and HIT vendors) should identify, develop, evaluate and promulgate promising models for ED and community engagement including:
    i. Linkages between EDs and law enforcement, social services, legal support, housing, and other resources;

ii. Linkages to payer resources;
iii. Linkages between EDs and local clinical providers; and
iv. Linkages between EDs and mental health/substance use facilities.

d. Research should assess the cost-effectiveness as well as the health return on investment from the patient, provider, payer, and society perspectives for interventions to improve ED transitions.

Conclusion

Care fragmentation across the healthcare system leads to anxiety, ambiguity, avoidable resource utilization, and the potential worsening of a patient's condition. By identifying ways to ensure consistent, clear communication among providers, patients, and the broader community during ED transitions can lead to better person-centered care, value, and cost efficiency – all of which are positive and measureable health outcomes. Focusing efforts on better care coordination, collaborative care, and working together as a cohesive system will drive quality improvement and enhance the quality of transitions of care into and out of the ED.

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Appendix A: Methodology

NQF conducted a three-step approach to the synthesis of evidence and environmental scan that included: (1) a collection of information sources; (2) the review of information sources (e.g., extraction of measures, and measure concepts); and (3) key informant interviews. For this project, NQF defined measures and measure concepts as:

- A measure is a fully developed metric that includes detailed specifications and may have undergone scientific testing.
- A measure concept is an idea for a measure that includes a description of the measure, including planned target and population, but has not undergone testing.

Collection of Information Sources

NQF conducted a search for information sources such as measure repositories, literature, and programs used in ED transitions of care. NQF identified existing measures and searched through measure repositories such as the NQF Quality Positioning System, AHRQ's National Quality Measures Clearinghouse, AHRQ's Care Coordination Measures Database, National Guidelines Clearinghouse, American College of Emergency Physicians, Health Indicators Warehouse, CMS' measure inventory (e.g., Hospital Compare), The Joint Commission, and other previous NQF endorsement and framework projects. NQF staff also conducted the literature review portion of the environmental scan that included peer-reviewed research publications and grey literature. Databases for the literature review included PubMed, Google Scholar, and the Cochrane Collaboration. NQF staff conducted a targeted search within the literature databases using various combinations of keywords that derived from the domains and subdomains of the measurement framework (see Table 5).

Review of Information Sources

NQF staff conducted a literature review that met the inclusion and exclusion criteria outlined in Table 3.

Table 3. Inclusion/Exclusion Criteria for Literature Review

Included	**Excluded**
• Literature published after 2009 • Pertains to the quality of transitions of care into and out of the emergency department	• Published before 2009 and not current • Not available in English

Sources were sorted by relevance using the following criteria in Table 4.

Table 4. Relevance Criteria for Evidence, Measures, Measure Concepts, and Instruments

Relevance Criteria	**Definition**
Directly Relevant	• The evidence, measures, measure concepts, and/or instruments that directly impacts providers and patients by providing guidance on essential

	communication practices to support a quality transition.
Potentially Relevant	• The evidence, measures, measure concepts, and/or instruments that are directly relevant to the ED transitions but do not directly specifically support ED transitions.
Indirectly Relevant	• The evidence, measures, measure concepts, and/or instruments that are related to a transition in care without a clear, specific link to the ED.

The complete list of measures and measure concepts are displayed in Appendix C. NQF staff searched literature databases using combinations of keywords as shown in Table 5.

Table 5. Keywords

- Age
- Acute
- Acute care
- Care
- Care coordination
- Caregiver
- Communication
- Community
- Chief complaint
- Complaint
- Critical care
- Delivery of health care
- Discharge
- Discharge plan
- Electronic health record
- Elements
- Elements of transitions
- Emergency
- Emergency care
- Emergency department
- Emergency medical services
- Emergency service
- Geriatric
- Elderly
- Hand off(s)
- Health care
- Health home
- Health information technology
- High risk populations
- Home health
- Hospital
- Hospital emergency service
- Interoperability
- Long term care
- Medical services
- Patient
- Patient centered
- Patient-discharge
- Patient-reported outcomes
- Pediatric
- Population
- Point of care
- Provider
- Primary care
- Primary health care
- Referral
- Setting
- Skilled nursing facility
- Specialty
- Specialty care
- Transfer(s)
- Transition(s)
- Transition of care
- Unscheduled care

NQF staff identified 46 relevant articles from the literature review, which are listed below:

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Key Informant Interviews

The environmental scan also included interviewing key informants. NQF staff conducted the interviews to supplement the information and data provided by the Panel, the literature review, and the measure review. Information from the interviews provided additional expert insight on measure gaps as well as emerging measures. The interviews were conducted by using an interview guide with a standard set of questions related to ED quality of transitions of care. Key informants had familiarity with and experience in transitions of care, transition practices that improve provider knowledge of patients, and the improvement of patient outcomes due to higher quality transition. The list of key informants and the interview guide are in Table 6.

Table 6. List of Key Informants

Informant	**Relevant Experience**	**Organization**
Maria Brenny-Fitzpatrick, MSN, CNS, FNP-C, GNP-BC, APNP	Director of transitional care with experience in transition practices and care coordination through the use of standardized transition forms.	University of Wisconsin Health System
Daniel Ebbett	Familiarity with emergency medical services technology and key elements needed for a quality transition of care into and out of the ED.	MedStar

Informant	Relevant Experience	Organization
Carmen Gonzalez, MD	Experience with the use of a standardized handoff protocol into and out of the ED.	The University of Texas MD Anderson Cancer Center
Terrence O'Malley, MD	Expertise and knowledge on care coordination and transitions particularly from long-term post-acute care to the ED as well as interoperability.	Massachusetts General Hospital
Marjory Palladino, MSN, CRRN	Nursing Director with experience in the transfer of health information from Skilled Nursing Facilities to the ED.	Hartford Healthcare Senior Services-Southington Care Center

Key Informant Interview Guide

General Questions

1. What is your experience with measurement of transitions in care?
    a. If not formal measurement, are there standards or internal guidelines you use to support quality transitions?
    b. Best practices?
2. What do you see as the most important transitions in care that apply to the ED?
    a. From interviewees perspective, and other?
3. How are ED transitions different from other types of transitions in care?
    a. If you don't have experience with other types of transitions, how do you think they might be different?
4. What are the highest risk ED transitions/patients?
    a. Can you think where care could be improved?
    b. Are there other transitions (high risk or otherwise) that you can think of that warrant improvement?
5. What do you think are the best ways to measure the quality of ED transitions in care?
    a. What are the best outcomes of a transition?
    b. What do you think is the top priority when it comes to measuring ED transitions in care?
6. What are the best data sources for those measures?
    a. Or, how might you measure?
7. Are you aware of any best practices for ED transitions in care?
    a. In your organization, or elsewhere?
8. What are the most relevant pieces of information you need during a transition?
    a. Most relevant for the provider(s)?
    b. For the patient or caregiver?
9. How should transition information be shared with the patient?
    a. Are there considerations depending on the type of patient?

Appendix B: Expert Panel Roster and NQF Staff

Expert Panel Co-Chairs

Stephen Cantrill, MD, FACEP
Physician, Denver Health Medical Center, University of Colorado School of Medicine
Denver, Colorado

Janet Niles, RN, MS, CCM
President, Niles Associates, Inc.
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Expert Panel

Billie Bell, RN
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Professor-Emergency Medicine, University of Florida
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Jesse Pines, MD
Consultant

Marcia Wilson, PhD, MBA
Consultant

Appendix C: Measure Compendium

The measure compendium is a list of measures and measure concepts, which were deemed as relevant by the Panel, which address the quality transitions of care into and out of the ED.

#	Domain	Subdomain	Existing Measure or Concept	Title/Description
1	Provider Information Exchange	Key Information Elements and Properties of its Transmission	Concept	Medication reconciliation collaboratively performed in the ED and with the primary care physician (or relevant specialist) for high-risk prescribing in the ED.
2			Concept	The percentage of high-risk discharges from the ED where specific information elements are transferred to the primary care provider (or responsible specialist) by the next clinic day.
3			Concept	The percentage of high risk transitions to the ED where specific information elements are transferred to the ED from the referring facility or provider.
4			Concept	The proportion of EMS runs where a transition of care document or verbal report is provided to the ED at ED arrival.
5		Care Coordination and Feedback	Existing Measure	Emergency Transfer Communication: Percentage of patients transferred to another healthcare facility: where several information elements and transmitted within 60 minutes of transfer (NQF Measure #0291): 1) Required information is communicated to the receiving facility prior to departure 2) Entire vital signs record is communicated 3) Medication information is communicated 4) Patient information is communicated 5) Physicians information is communicated 6) Nursing information is communicated 7) Procedures and test

#	Domain	Subdomain	Existing Measure or Concept	Title/Description
				information is communicated
6			Concept	*The proportion of patients managed by a primary care physicians (or responsible specialist) who are frequent users of EDs (>=4 visits in a 12-month period) who have, (jointly when possible) created a care plan in collaboration with their primary care physician and the ED.
7			Concept	A structural measure as to whether hospitals provide data to and facilitate a portal for providers to be able to view ED visits and other care delivered in outside hospitals and health systems.
8			Concept	The proportion of EDs that have a system in place to provide feedback within referring providers for specific cases that may be useful for quality improvement.
9	Patient, Family, and Caregiver Information Exchange	Key Information Elements and Properties of its Transmission	Existing Measure	Transition Record with Specified Elements Received by Discharged Patients (Emergency Department Discharges to Ambulatory Care [Home/Self Care] or Home Health Care): Patients or their caregiver(s) who received a transition record at the time of emergency department (ED) discharge including, at a minimum, all of the following elements (NQF Measure #0649): 1) Summary of major procedures and tests performed during ED visit, AND 2) Principal clinical diagnosis at discharge which may include the presenting chief complaint, AND 3) Patient instructions, AND 4) Plan for follow-up care (OR statement that none required), including primary physician, other health care professional, or site designated for follow-up

#	Domain	Subdomain	Existing Measure or Concept	Title/Description
				care, AND 5) List of new medications and changes to continued medications that patient should take after ED discharge, with quantity prescribed and/or dispensed (OR intended duration) and instructions for each
10	Patient, Family, and Caregiver Information Exchange	Key Information Elements and Properties of its Transmission	Existing Measure	Patient Specific Education Resources from Certified Electronic Health Record Technology (CEHRT) provided to Patient
11			Existing Measure	Patient Electronic Access to their health information (view, download, and transmit)
12			Concept	Documentation of the percentage of all patients/family/caregivers who are provided an ED based telephone number (staffed 24/7) they may use to clarify discharge instructions, medication questions, or follow up post discharge from the ED.
13		Effective Communication and Shared Decision Making	Concept	ED documentation of provider (physician, nurse, pharmacist, care manager) and patient/family/caregiver discussion, that takes into account patient preferences, that includes condition, medications, other treatments, post-discharge plans, and follow up.
14			Concept	Percentage of patients of any age who do not have a designated Primary Care provider, who have received a Primary Care Appointment or Community Based Clinic Appointment for follow up post ED discharge.
15			Concept	Percentage of patient/family/caregiver who received appropriate discharge instructions that are in patients' preferred language, at their literacy level and take into account patients' social economic status.

#	Domain	Subdomain	Existing Measure or Concept	Title/Description
16			Concept	Percentage of patients of any age who are non-verbal and have been seen in the Emergency Room, who have documentation by a provider or other care team member of a designated health care point of contact for treatment planning that has been shared with available family or caregivers.
17			Concept	*Shared decision making process: The proportion of patients managed by a primary care physicians (or responsible specialist) who are frequent users of EDs (>=4 visits in a 12-month period) who have, (jointly when possible) created a care plan in collaboration with their primary care physician and ED (physician, nurse, PA, navigator, etc.).
18	Engagement of the Broader Community	Connection and Alignment	Concept	Availability of care managers/coordinators/navigators in the ED.
19			Concept	Assessing high-risk patients who are at risk for a transition failure due to unmet social needs.
20			Concept	System that allows for bidirectional communication between clinical and non-clinical facilities.
21		Accessibility of Services	Concept	Collect and maintain information on available resources (to include social, community and any other available resource that may support a transition of care).
22	Achievement of Outcomes	Healthcare Utilization & Costs	Concept	Reduction in duplicate testing based on payer-level data or facility level data, depending on where testing is provided.
23			Concept	Improved transitions for patients who are frequent users of the ED.
24		Provider Experience	Concept	Provider experience with select aspects of transitions (e.g., information received)
25		Patient/Family/Caregiver	Existing	3-Item Care Transition Measure

#	Domain	Subdomain	Existing Measure or Concept	Title/Description
		Experience	Measure	(Coleman)
26			Concept	Patient reported experience with care specific to culturally competent care delivery that takes into consideration patients' preferences, needs and values. Concept is based on CAHPS 3.0 and CAHPS American Indian Survey composite assessment: Getting Care Quickly; Getting Needed Care; Provider Communication; Clerks and Receptionists at Clinic; Health Education; Perceived Discrimination; Global Ratings.
27		Follow-up and Safety Outcomes	Existing Measure	Patients with a transient ischemic event ER visit that had a follow-up office visit. (NQF Measure #0644)
28			Concept	Follow-up occurred after patient leaves the ED, e.g., visit or phone call
29			Concept	The percentage of high-risk ED discharges (as designated by the ED provider) where there is contact (in-person follow-up or other) within a specified period of time by the primary care provider or responsible specialist
30			Concept	Reduction in adverse drug events through a combination of medication review, medication reconciliation, and the patients understanding of medications.
31			Concept	Return visits to the ED within 9 days or 30 days.

*Denotes same measure concept but crosscutting to other domains. For instance, the measure concept could be categorized in both provider information exchange and patient, family, and caregiver information exchange.

Appendix D: Measure Prioritization

The measure prioritization is a list of measures and measure concepts that were submitted to the Panel to be ranked based on importance and feasibility. Importance was rated on a scale of one through five (1 as low, 3 as moderate, and 5 as high). Feasibility was rated on a scale of one through five (1 as not feasible, 3 as aspirational/potentially feasible in the future, and 5 as very feasible today).

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
1	Provider Information Exchange	Key Information elements and Properties of its Transmission	[concept] Medication reconciliation collaboratively performed in the ED and with the primary care physician (or relevant specialist) for high-risk prescribing in the ED.	4.36	3.27	Mid-Term
2			[concept] The % of high-risk discharges from the ED where specific information elements are transferred to the primary care provider (or responsible specialist) by the next clinic day.	4.36	3.55	Mid-Term
3			[concept] The % of high risk transitions to the ED where specific information elements are transferred to the ED from the referring facility or provider.	4.36	3.55	Mid-Term
4			[concept] The proportion of EMS runs where a transition of care document or verbal report is provided to the ED at ED arrival.	4.64	4.36	Today
5		Care Coordination and Feedback	*[concept] The proportion of patients managed by a primary care physicians (or responsible specialist) who are frequent users of EDs	3.55	2.36	Future/ Aspirational

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
			(>=4 visits in a 12-month period) who have, (jointly when possible) created a care plan in collaboration with their primary care physician and the ED.			
6			[concept] A structural measure as to whether hospitals provide data to and facilitate a portal for providers to be able to view ED visits and other care delivered in outside hospitals and health systems**.**	4.18	3.45	Mid-Term
7	Provider Information Exchange		[concept] The proportion of EDs that have a system in place to provide feedback within referring providers for specific cases that may be useful for quality improvement.	3.45	3.36	Mid-Term
8			[measure] Emergency Transfer Communication: (% of patients transferred to another healthcare facility where several information elements and transmitted within 60 minutes of transfer (NQF Measure #0291): 1) Required information is communicated to the receiving facility prior to departure 2) Entire vital signs record is communicated	4.50	3.57	Mid-Term

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
			3) Medication information is communicated 4) Patient information is communicated 5) Physicians information is communicated 6) Nursing information is communicated Procedures and test information is communicated			
9	Patient, Family, and Caregiver Information Exchange	Key Information and Properties of its Transmission	[measure] Transition Record with Specified Elements Received by Discharged Patients (Emergency Department Discharges to Ambulatory Care [Home/Self Care] or Home Health Care): Patients or their caregiver(s) who received a transition record at the time of emergency department (ED) discharge including, at a minimum, all of the following elements (NQF Measure #0649): 1) Summary of major procedures and tests performed during ED visit, AND 2) Principal clinical diagnosis at discharge which	4.50	4.14	Today

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
			may include the presenting chief complaint, AND 3) Patient instructions, AND 4) Plan for follow-up care (OR statement that none required), including primary physician, other health care professional, or site designated for follow-up care, AND 5) List of new medications and changes to continued medications that patient should take after ED discharge, with quantity prescribed and/or dispensed (OR intended duration) and instructions for each			
10	Patient, Family, and Caregiver Information Exchange	Key Information and Properties of its Transmission	[measure] Patient Specific Education Resources from Certified Electronic Health Record Technology (CEHRT) provided to Patient	3.64	4.07	Today
11			[measure] Patient Electronic Access to their health information (view, download and transmit)	4.14	3.79	Mid-Term
12			[concept] Documentation of the percentage of all	4.36	3.91	Today

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
			patients/family/caregivers who are provided an ED based telephone number (staffed 24/7) they may use to clarify discharge instructions, medication questions, or follow up post discharge from the ED.			
13		Effective Communication and Shared Decision Making	[concept] ED documentation of provider (physician, nurse, pharmacist, care manager) and patient/family/caregiver discussion, that takes into account patient preferences, that includes condition, medications, other treatments, post-discharge plans, and follow up.	4.18	3.45	Mid-Term
14	Patient, Family, and Caregiver Information Exchange	Effective Communication and Shared Decision Making	[concept] % of patients of any age who do not have a designated Primary Care provider, who have received a Primary Care Appointment or Community Based Clinic Appointment for follow up post ED discharge.	4.36	3.36	Mid-Term
15			[concept] % of patient/family/caregiver who received appropriate discharge instructions that are in patients' preferred language, at their literacy level and take into account patients' social economic	4.55	3.73	Mid-Term

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
			status.			
16			[concept] Percentage of patients of any age who are non-verbal and have been seen in the Emergency Room, who have documentation by a provider or other care team member of a designated health care point of contact for treatment planning that has been shared with available family or caregivers.	3.91	3.91	Mid-Term
17			*[concept] Shared decision making process: The proportion of patients managed by a primary care physicians (or responsible specialist) who are frequent users of EDs (>=4 visits in a 12-month period) who have, (jointly when possible) created a care plan in collaboration with their primary care physician and ED (physician, nurse, PA, navigator, etc.).	3.55	2.36	Future/ Aspirational
18	Engagement of the Broader Community	Connection and Alignment	[concept] Availability of care managers/coordinators/navigators in the ED.	4.55	3.64	Mid-Term
19			[concept] Assessing high-risk patients who are at risk for a transition failure due to unmet social needs.	4.27	3.18	Mid-Term

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
20			[concept] System that allows for bidirectional communication between clinical and non-clinical facilities.	4.00	2.00	Future/ Aspirational
21		Accessibility of Services	[concept] Collect and maintain information on available resources (to include social, community and any other available resource that may support a transition of care).	4.45	4.09	Today
22	Achievement of Outcomes	Healthcare Utilization & Costs	[concept] Reduction in duplicate testing on payer-level data or facility level data, depending on where testing is provided.	4.27	3.00	Future/ Aspirational
23			[concept] Improved transitions for patients who are frequent users of the ED.	4.18	2.91	Future/ Aspirational
24		Provider Experience	[concept] Provider experience with select aspects of transitions, e.g., information received.	3.82	3.45	Mid-Term
25		Patient/Family/ Caregiver Experience	[measure] 3-Item Care Transition Measure	3.86	3.43	Mid-Term
26			[concept] Patient reported experience with care specific to culturally competent care delivery that takes into consideration patients' preferences, needs and values. Concept is based on CAHPS 3.0 and CAHPS American Indian Survey composite assessment:	4.27	3.82	Mid-Term

#	Domain	Subdomain	Proposed Measures & Concepts	Importance Score	Feasibility Score	Implementation
			Getting Care Quickly; Getting Needed Care; Provider Communication; Clerks and Receptionists at Clinic; Health Education; Perceived Discrimination; Global Ratings.			
27	Achievement of Outcomes	Follow-up and Safety Outcomes	[measure] Patients with a transient ischemic event ER visit that had a follow-up office visit. (NQF Measure #0644)	3.64	3.29	Future/ Aspirational
28			[concept] Follow-up occurred after patient leaves the ED, e.g., or phone call	4.36	3.64	Mid-Term
29			[concept] The percentage of high-risk ED discharges (as designated by the ED provider) where there is contact (in-person follow-up or other) within a specified period of time by the primary care provider or responsible specialist.	4.09	3.27	Mid-Term
30			[concept] Reduction in adverse drug events through a combination of medication review, medication reconciliation, and the patients understanding of medications.	4.18	3.18	Mid-Term
31			[concept] Return visits to the ED within 9 days or 30 days	4.55	4.55	Today

Emergency Department Operational Metrics, Measures and Definitions: Results of the Second Performance Measures and Benchmarking Summit

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There is a growing mandate from the public, payers, hospitals, and Centers for Medicare & Medicaid Services (CMS) to measure and improve emergency department (ED) performance. This creates a compelling need for a standard set of definitions about the measurement of ED operational performance. This Concepts article reports the consensus of a summit of emergency medicine experts tasked with the review, expansion, and update of key definitions and metrics for ED operations. Thirty-two emergency medicine leaders convened for the Second Performance Measures and Benchmarking Summit on February 24, 2010. Before arrival, attendees were provided with the original definitions published in 2006 and were surveyed about gaps and limitations in the original work. According to survey responses, a work plan to revise and update the definitions was developed. Published definitions from key stakeholders in emergency medicine and health care were reviewed and circulated. At the summit, attendees discussed and debated key terminology and metrics and work groups were created to draft the revised document. Workgroups communicated online and by teleconference to reach consensus. When possible, definitions were aligned with performance measures and definitions put forth by the CMS, the Emergency Nurses Association Consistent Metrics Document, and the National Quality Forum. The results of this work are presented as a reference document. [Ann Emerg Med. 2010;xx:xxx.]

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INTRODUCTION

Background

The Institute of Medicine has defined 6 domains of quality of care: safe, timely, effective, efficient, equitable, and patient centered.[1] Timeliness and efficiency are core attributes of emergency medicine, yet the details of which processes to measure and how to measure them are still a work in progress.[2,3] Time metrics (the time it takes for certain processes and subcycles of care) and proportion metrics (percentage of defects) have become de facto markers for quality in the literature. In February 2006, the first Performance Measures and Benchmarking Summit convened key stakeholders in emergency medicine to develop by consensus standards for emergency department (ED) operations and benchmarking terminology.[4] Much has changed since the publication of the original standards, including new models of ED intake, growing evidence that ED crowding and prolonged length of stay are associated with lower-quality care and worse outcomes, and an intense national focus on measurement of health care quality.[5-11] Length of stay, door-to-physician time, and left without being seen have been endorsed by the National Quality Forum as quality measures.[12] Additionally, the Centers for Medicare & Medicaid Services (CMS) are testing 2 ED timing measures (length of stay and boarding time) and plan to include them in the hospital pay for reporting program in 2014 and publish results on the Hospital Compare Web site.[13] Because interest in these metrics and how to improve them will be a growing concern for EDs, the Emergency Department Benchmarking Alliance organized a second summit to review and update critical terminology. The results are presented here.

Importance

As EDs, hospitals, and health systems work to improve the timeliness and efficiency of emergency care, it is critical that they use standard terminology and metrics to measure and benchmark performance. There are 3 compelling reasons to pursue standardization in this area: regulatory burdens, ED operations management, and research. Regulatory bodies, such

*Participants listed in Appendix.

as CMS and The Joint Commission (TJC), are beginning to include ED patient flow standards in their performance measurement and accreditation programs.[14-16] It is imperative that further regulatory requirements use parameters developed by experts from within the specialty who understand its practice and the nuances of ED operations. Many EDs are implementing and testing techniques to improve ED patient flow and processes.[17-22] To advance the growing research on ED operations and quality improvement, standardized terminology and methodology are necessary.[23-25]

Goals

The Second Performance Measures and Benchmarking Summit convened to develop a set of metrics and definitions. The summit addressed the following objectives: (1) to develop a core set of metrics for ED patient flow and operations; (2) to define those metrics clearly, using timestamps, time intervals, and proportions; (3) to standardize the vocabulary relevant to the practice of emergency medicine operations, including operating characteristics, processes, and utilization (service units). The summit participants were tasked with drafting definitions for ED operations while maintaining consistency with previous work in this area. The vision was to standardize the language for industry-wide application.

SUMMIT METHODOLOGY

The summit was organized by the Emergency Department Benchmarking Alliance, a nonprofit organization. It is a collaborative of 367 (EDs) with more than 14 million ED visits annually. The Emergency Department Benchmarking Alliance was founded in 1997 as an alliance of performance-driven EDs. It operates as a quality improvement collaborative and learning community, sharing performance data and operational strategies to identify best practices. The Emergency Department Benchmarking Alliance has developed a benchmarking database and educational programs focusing on ED operations and performance and disseminates new ideas and innovations through conferences and publications.[26-32]

Participants

Key stakeholders in ED operations practice, policy, and research were identified and invited to attend the summit. The summit attendees included 32 participants, representing leading EDs, hospitals, ED staffing groups, professional societies, and regulatory agencies (Appendix).

Summit Working Model

A survey was circulated before the Benchmarking Summit, asking respondents to comment on the original 2006 document. Criticisms, limitations, omissions, and successful features were all solicited and responses were collated. The agenda for the summit was developed according to the survey responses. During the in-person meeting, a work plan for the project was crafted and workgroups were formed for operating characteristics, time metrics (timestamps and time intervals), proportion metrics, process definitions, and utilization data. Workgroup leaders were chosen according to their expertise in the area.

Each workgroup leader was provided with instructional materials about running a successful workgroup, objectives, a work plan, and timetable. Workgroup members were provided with background materials. Information sharing took place through the Internet, e-mails, and conference calls. Project support was provided by the Emergency Department Benchmarking Alliance, including a conference call line, assistance with document processing, and project coordination. Each workgroup drafted a summary section. Two authors (S.J.W. and J.S.) collated and integrated the workgroup drafts into a final article, which was circulated numerous times to the workgroup leaders. Specific areas of disagreement were highlighted and addressed through conference calls and threaded e-mail discussions. The final article was then reviewed by the workgroup leaders and the Emergency Department Benchmarking Alliance board of directors.

FINDINGS

Operating Characteristics

To perform comparative analyses, EDs need to benchmark themselves against appropriate counterparts. EDs will use parameters to benchmark themselves, depending on the purpose of the comparison. Parameters currently in use to help EDs in this categorization are defined below:

ED Characteristics.

- ED census: Number of ED encounters tracked annually
- Acuity by Emergency Severity Index (ESI)/Canadian Triage Acuity Scale (CTAS): Patients receiving an ESI/CTAS scale 1 or 2 on arrival are considered high acuity; those with an ESI/CTAS scale 4 and 5, low acuity[33,34]
- Acuity by evaluation and management codes: Patients receiving codes of level 4 or 5 are high acuity; those receiving codes of 1 or 2, low acuity
- Admission rate: Percentage of ED visitors who are admitted as inpatients
- ICU admission rate: Percentage of ED visitors requiring an ICU bed on admission
- Pediatric rate: Percentage of ED visitors younger than 18 years
- Infant pediatric rate: Percentage of ED visitors younger than 2 years
- Geriatric rate: Percentage of ED visitors older than 65 years
- Transfer rate: Percentage of ED visitors transferred for care at another facility
- Teaching status: Does the ED serve as a training site for resident physicians

Timestamps and Interval Metrics

The workgroups identified and defined a set of key timestamps and time intervals for ED operations. Additionally, subcycle time intervals for critical ED processes such as

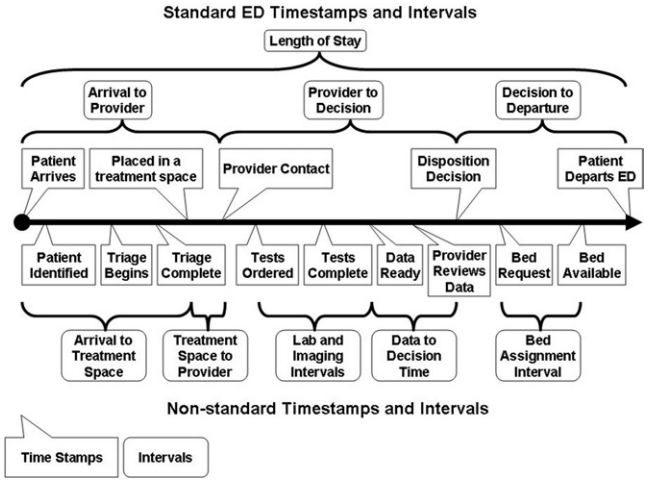

Figure. Timeline of ED timestamps and intervals.

emergency medical services (EMS) offload, laboratory, imaging, and bed management have also been defined. Where possible, they used language from the most recently published consensus document, *Definitions for Consistent Emergency Department Metrics*, developed by the Emergency Nurses Association (ENA) in 2009 and subsequently endorsed by many leading organizations in emergency medicine.[35] Timestamps and intervals that are identical to those of the ENA definitions are marked by an asterisk. In addition, the workgroups attempted to maintain consistency with performance measures endorsed by the National Quality Forum. The Figure is a schematic for the timestamps and intervals as they occur in a typical ED visit. It identifies a core set of standard timestamps that are necessary for ED operations and a more visionary set that an ideal future ED information system could collect.

Timestamps.

- Arrival time: The date and time that the patient first arrives at the institution for the purpose of requesting emergency care should be recorded as the arrival time. This is the first contact and not necessarily registration time or the triage time.*
- EMS offload time: The date and time that the patient is transferred from the EMS stretcher and placed in a treatment space and care is assumed by the ED staff.* This is typically recorded in the EMS run report.
- Treatment space time: The date and time of placement in a treatment space. "Treatment space" is any space the hospital/facility designates as a space to render emergency care and is facility specific.*
- Provider contact time: The date and time of first contact of the physician or the provider (defined as an institutionally credentialed provider) with the patient to initiate the medical screening examination, but specifically not the triage nurse.*
- Data ready time: The date and time when all relevant data (test results, image interpretations, and treatment responses) are available to the provider for decisionmaking about patient disposition. (This is more forward looking, when information system will enable its capture.)
- Disposition decision time: The date and time that the order about the disposition of the patient (transfer, observe, discharge) is documented.
- Admit decision time: The above applied to admitted patients. The date and time that the admit order is documented by the provider.
- Departure time: The date and time of physical departure of a patient from the ED treatment space. The time most closely represented by leaving the department for all categories of patients, including admitted, discharged, observed, and behavioral health patients.

Time intervals.

- Arrival to provider time (aka "door to doc"): Arrival time to provider contact time
- ED length of stay: Arrival time to departure time.* This is tracked for the following subsets of patients:
  - admitted patients
  - discharged patients
  - observation patients
  - behavioral health patients
- Arrival to treatment space time: Arrival time to treatment space time
- Treatment space to provider time: Treatment space time to provider contact time
- Provider to data-ready time: Provider contact time to data-ready time
- Data-ready to decision time: Data-ready to disposition decision time
- Decision to departure time: Disposition decision time to the actual departure time of the patient
- Admit decision to departure time: The above applied to admitted patients; the admit decision time to the actual departure time of the patient. This is undergoing testing as trial CMS hospital inpatient quality measures

Subcycle intervals. For clarity and consistency, the term *turnaround time* has been replaced with *interval* in the subcycles definitions. Turnaround time was used inconsistently in the literature and in practice and so was abandoned for the new term, keeping the terminology consistent.

- EMS offload interval: Arrival time to EMS offload time*
- Triage interval: The interval from when the rapid or comprehensive triage or intake is initiated by an institutionally credentialed provider to the time when triage is completed*
- Laboratory interval: The time from the placement of an order for laboratory testing until the time the results are available
- ED consultation interval: The time from the placement of an order for an ED consultation until the time the patient is evaluated by the consulting service and the final recommendation is communicated to the ED provider.

- Imaging interval: The time from the placement of an order for an imaging test until the time that the results are available. Institutions are recommended to track for each modality:
  - plain radiography
  - computed tomography (CT) scans
  - ultrasonography
  - magnetic resonance imaging (MRI)
- Bed assignment interval: The time from the placement of an order/request for an inpatient bed to the time a bed is assigned (empty, clean, and staffed) and the ED receives notification

Proportion Metrics

A number of measures reported as percentages or rates have been used to capture elements of performance in the ED. The proportion metrics are well established in the literature and in hospital operations. Patient complaints and the ultimate complaint, the walk away (referred to collectively in the 2006 document as "Patients Who Left Before They Were Supposed To") correlate with timeliness and can be thought of as indirect markers for timeliness and efficiency.

- Left without being seen: All patients who leave the ED before consulting a provider
- Left before treatment complete: All patients who leave the ED after being treated by a provider and before formal disposition is made
- Against medical advice: All patients who leave the ED against the advice of the provider and after the risks and benefits of further care have been explained and documented. Against medical advice patients are a subset of left before treatment complete patients.
- Complaint ratio: All spontaneous expressions of concern that are written, called in, or spoken and brought to the attention of the ED management or hospital staff. There must be a mechanism for recording these expressions, and the mechanism will be institution specific. Complaint ratios are tracked as complaints per 1,000 ED visits by convention.

Process Definitions

As the specialty identifies best practices, it is beginning to collect data on important ED processes, and these are defined below. Operations research in emergency medicine cannot advance without definitions of key processes.

- Identification: The process of collecting sufficient information critical to establishing and recording a unique patient encounter, with at minimum 2 unique identifiers. This is distinct from registration.
- Triage: The process of assessing patients who present for care to prioritize access according to the urgency of their need and complexity of the services required. Traditionally performed by a registered nurse, it involves a number of steps and information gathering. One of the most important features is the assignment of triage scale, now most frequently a 5-level ESI/CTAS scale.
- Intake: The process of receiving and sorting persons seeking access to acute episodic medical care in the ED. Triage is one intake model. Rapid medical screening, team triage, and physician in triage are other intake models.[36]
- Registration: The process of identifying and recording information to generate a patient-specific record. It includes collecting information pertaining to financial responsibility and sociodemographic statistics, and its main function is related to billing. Registration is distinct from patient identification
- Medical screening examination: The assessment by a provider to determine whether an emergency medical condition exists.
- Discharge: The process of releasing patients from the ED at the end of the encounter, including the distribution of discharge papers.
- ED diversion: ED diversion is a notification to the medical community of a temporary limitation of complete or partial institutional capability to handle medical or surgical conditions, communicated to EMS.
- Boarding: The practice of holding patients who have been admitted to the hospital in the ED for prolonged periods. Defined as an interval, it encompasses the admit decision time to the departure time.
- Overcapacity: Defined as having more patients than treatment spaces in the ED. It may be measured as time in a 24-hour period spent at overcapacity.

Utilization

Defined as emergency service units and tracked to understand utilization, the following are recommended as service units for tracking. Higher utilization has been correlated with longer length of stay and higher acuity. CMS and payers have become intensely interested in utilization and are developing utilization metrics to be used in public quality programs.[37] The emergency service units defined at the summit are listed below.

Emergency Service Units

- ECGs: The number of ECGs performed per 100 ED visits
- Plain radiography studies: The number of radiographic studies (not images) per 100 ED visits
- CT studies: The number of contrasted and noncontrasted CT studies (not images) per 100 ED visits. Includes CT-guided procedures.
- MRI studies: The number of MRI studies (not images) per 100 ED visits
- Ultrasonographic studies: The number of formal ultrasonographic studies (not images) performed by the radiology department and reported to the ED per 100 ED patients. Bedside ultrasonography is not reported in this measure.
- Laboratory studies: The number of patients per 100 ED visits who have any specimen ordered and sent to the

laboratory. (This is a yes/no data point). Point-of-care testing is not reported in this measure.
- Medication dosages: The number of medication doses administered by any route (intravenous, oral, intranasal or intramuscular) per 100 ED visits. These are typically counted as doses from an electronic dispensing system.
- Behavioral health consultations: The number of behavioral health consultations per 100 ED visits as a marker for mental health burden on the ED
- Specialty consultations: The number of medical or surgical specialty consultations arranged through the ED per 100 ED visits

LIMITATIONS

This work has several limitations. First, our methods did not adhere strictly to standardized qualitative research consensus processes such as the Delphi method, which has been used before in this type of work.[38] However, the model used here follows many of the same principles, such as an iterative process, with in-person meetings and follow-up calls or e-mail discussions, and it was used successfully by the Emergency Department Benchmarking Alliance in the original Performance Measures Summit and in another Agency for Healthcare Research and Quality (AHRQ)–sponsored summit to develop consensus around particular issues in emergency medicine.[39] Second, the group was a purposeful sample whose creation was open to selection bias, yet we solicited representation from leading organizations in emergency medicine and it incorporates existing work by prominent stakeholders. Third, the definitions focus on 2 domains of quality: timeliness and efficiency. Although it is important for future work to define standards for other quality domains in emergency medicine, there is a pressing need for consensus around these domains, as illustrated by the imprecision of the current CMS measures. Finally, this document has not yet been formally endorsed by leading professional organizations, and there has been no pilot testing.

DISCUSSION

In response to the growing demand for measures of ED performance, we convened a summit of key stakeholders. With an iterative team process, time metrics for ED operations were reviewed, revised, and developed by consensus. We present definitions for critical and future ED timestamps, time intervals, and proportion metrics. Additionally, we define key processes and utilization metrics. These standardized definitions should help ED administrators, researchers, and regulators by providing a common language.

As EDs increasingly incorporate information technology into work processes, electronic tracking systems will enable the routine capture of timestamps as part of patient care. The best systems will have timestamping and cueing built into the same computer interaction, minimizing repetition and rework. The most reliable timestamps will be those that also serve a patient flow function. To be operationally useful, timestamps must be clearly defined and easy to accurately capture, and their capture must be built into clinical workflow and future electronic health records.[40] Efforts have been made to develop timestamps that may be applied in EDs without electronic tracking systems or information technology support. Though EDs without information technology support will not be able to gather the robust data sets of those with information technology support, critical timestamps and intervals can be measured through logs or hand audits.

The Controversies

Among summit discussions, the timestamp causing the most debate was the admit decision time. The members of the workgroup defining the timestamps and intervals attempted to maintain alignment with work done by ENA and with CMS's definitions.[35,41] However these definitions were problematic. In particular, the definitions offered by ENA and CMS, titled "decision to admit time," have flawed language embedded in them. "Decision to admit time" is an unfortunate choice of words; the inclusion of "to" connotes an interval, rather than a point in time. Additionally, both organizations differentiated between an admit *decision* time and an admit *order* time because they were concerned that some EDs may face significant delays from the time they decide to admit a patient to the time they are permitted to place an admission order. Recently, the ENA went so far as to say that because the "decision to admit" time is difficult to capture, it should not be used in comparative measures. Because the interval indicated by "admit decision to departure" is currently undergoing feasibility testing and is proposed to become a CMS quality measure of inpatient care in 2014, clarification of the admit decision timestamp is critical.

Summit attendees were concerned that the "decision to admit" is an artificial timestamp that will not be recorded in the normal course of work, leading to inaccurate data entry or gaming the system to improve performance measures. CMS's goal for this measure is to quantify ED boarding and ultimately to ease the burden it places on the ED. To that end, the summit participants believed that the placing of the admit order is the most accurate and reliable proxy for the admit decision time. Using the admit order time to mark this timestamp and using language to clarify that it is a timestamp and not an interval maintains alignment with the goal of CMS definitions while lending more clarity to it.

It can be expected that the tracking of timestamps, intervals, and processes will continue to involve data that are increasingly granular. More subcycle times will be captured in future studies of ED patient flow and will identify delays. Other time measures for ancillary services, such as laboratory interval time, have been included in the subcycle intervals section. The timestamps for each subcycle will be defined at each institution because they depend on varying processes. Where possible, these mirror the measures suggested by National Quality Forum as ED quality measures.[13] For the sake of consistency and clarity, the authors have abandoned the old jargon of turnaround times for intervals.

Summit participants defined several proportion metrics that are widely reported in the literature as measures of ED operational performance. Measures of patients who left before visit completion are used in ED operations research and have been included on national data sets such as the AHRQ's annual National Healthcare Quality Report.[39] Referred to in the 2006 performance measures document as "People Who Left Before They Were Supposed To," this includes left without being seen, left before treatment complete, and against medical advice, which is a subset of left before treatment complete. Leaving against medical advice is perhaps the most widely misapplied. Leaving against medical advice has to do with the patient's decision to leave before all recommendations are given and after a legal warning is rendered. The decision to label a patient's action as against medical advice is largely physician and institution dependent and does not correlate with timestamps. Correctly assigned against medical advice patients are just a fraction of left before treatment complete patients, with left without being seen making up the majority of the walk-away patients. The National Quality Forum has endorsed the tracking of left without being seen as an ED quality measure.

Although discussed at the summit, proportion metrics for revisits (eg, readmissions or other adverse events) have not been included because participants could not come to consensus. Unscheduled return visits have been used in quality improvement work and reported as an outcome of interest in emergency medicine research to identify patients whose diagnosis or management at the initial ED visit was in error or suboptimal. Different time intervals have been used including unscheduled returns at 24, 48, and 72 hours and 1-week intervals. For example, 48 hours is recommended in the American College of Emergency Physicians' book *Continuous Quality Improvement for Emergency Departments*,[42] whereas an important article by Sklar et al[43] examined deaths within 7 days of ED discharge. There are several other complexities to this metric besides setting a standard time interval. The unscheduled return visit rate will be directly influenced by the factors outside of the ED's control, such as availability of follow-up care. Finally, distinguishing between unscheduled returns and appropriate follow-up visits is difficult, and there are no standard validated techniques to do this yet.

Building on the First Summit

This article differs from the original 2006 article in a number of areas. Since the publication of the original article, ED operations have matured and performance measures refined as more organizations are advancing this work. The concepts of meaningful use and pay for quality now are being incorporated into measurement work. Several significant changes deserve discussion. First, the original article proposed a comparison scheme for EDs that did not prove effective. The original comparison scheme was removed and this article simply offers definitions of operating characteristics that will help EDs to find other EDs with similar census and acuity to benchmark against. Second, we have removed terms that did not gain acceptance or were criticized as ambiguous, including "conversion time" and "ED boarding load." The definitions have been thoroughly revised and vetted, and now each clearly belongs to one of the following categories: operating characteristics, time metrics, proportion metrics, process definitions, and utilization data. Third, since the first summit, utilization has become an area of intense interest and focus by payers. Because little is known about utilization rates in emergency medicine, the specialty needs to begin research in this area and needs the terminology to do so. Finally, the first article was drafted in isolation. This document actively attempts to reconcile the definitions being put forth by the ENA, CMS, and National Quality Forum.

CONCLUSIONS

According to growing evidence that the timeliness of emergency care is associated with quality of care, there is internal and external motivation to improve ED operations. Common definitions of key terms, timestamps, and metrics will improve the comparability of ED operations research and publications. Without consistent definitions, it will be difficult to track, measure, and communicate in a meaningful way. This work provides all of the stakeholders in emergency medicine with the language to begin the important work that lies ahead.

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APPENDIX.

Participants in the Second Performance Measures and Benchmarking Summit, Salt Lake City, February 24, 2020

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Professional Associations of Summit Attendees*

ACEP
ENA
Emergency Department Benchmarking Alliance
Emergency Department Practice Management Association (EDPMA)
Institute for Healthcare Improvement (IHI)
AHRQ
Society for Academic Emergency Medicine (SAEM)
TJC
Emergency Care Coordination Center (ECCC) of HHS
American College of Health Care Executives (ACHE)
American Academy of Emergency Medicine (AAEM)
The Intermountain Institute for Health Care Delivery Research
The National Quality Forum

*Listing of these organizations does not imply endorsement of this document, but rather shows the diversity of representation at the summit.

Short abstract for Welch et al, YMEM There is a growing mandate from the public, payers, hospitals, and the Centers for Medicare & Medicaid Services to measure and improve emergency department (ED) performance. This creates a compelling need for a standard set of definitions about the measurement of ED operational performance. We report the consensus of a summit of emergency medicine experts tasked with the review, expansion, and update of key definitions and metrics for ED operations.

Emergency Department Operations Dictionary: Results of the Second Performance Measures and Benchmarking Summit

Shari J. Welch, MD, Suzanne Stone-Griffith, RN, Brent Asplin, MD, MPH, Steven Davidson, MD, MBA, James Augustine, MD, and Jeremiah D. Schuur, MD,MHS, on behalf of The Second Performance Measures and Benchmarking Summit and the Emergency Department Benchmarking Alliance

Abstract

The public, payers, hospitals, and Centers for Medicare and Medicaid Services (CMS) are demanding that emergency departments (EDs) measure and improve performance, but this cannot be done unless we define the terms used in ED operations. On February 24, 2010, 32 stakeholders from 13 professional organizations met in Salt Lake City, Utah, to standardize ED operations metrics and definitions, which are presented in this consensus paper. Emergency medicine (EM) experts attending the Second Performance Measures and Benchmarking Summit reviewed, expanded, and updated key definitions for ED operations. Prior to the meeting, participants were provided with the definitions created at the first summit in 2006 and relevant documents from other organizations and asked to identify gaps and limitations in the original work. Those responses were used to devise a plan to revise and update the definitions. At the summit, attendees discussed and debated key terminology, and workgroups were created to draft a more comprehensive document. These results have been crafted into two reference documents, one for metrics and the operations dictionary presented here. The ED Operations Dictionary defines ED spaces, processes, patient populations, and new ED roles. Common definitions of key terms will improve the ability to compare ED operations research and practice and provide a common language for frontline practitioners, managers, and researchers.

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Regulatory burdens, emergency department (ED) operations management, and research require emergency medicine (EM) experts to improve the timeliness and efficiency of emergency care. Patient flow standards and performance measurements are increasingly required by regulatory bodies like the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission,[1–4] compelling us to use a precise and standardized vocabulary in defining, measuring, communicating, and reporting ED operations. If EM does not craft the language necessary to communicate the work we do, no doubt regulators will.

Emergency departments of varying sizes, characteristics, and locations around the country are testing techniques to improve ED efficiency, quality, safety, and cost.[5–9] Mary Washington Hospital in Fredericksburg, Virginia, for example, has implemented an intake model that involves a ''pivot nurse'' and ''patient segmenta-

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Received October 28, 2010; revision received November 9, 2010; accepted November 22, 2010.

A list of The Second Performance Measures and Benchmarking Summit attendees is available in Table 1. (Listing does not imply endorsement of this document, but shows the diversity of representation at the summit.)

Information on the Emergency Department Benchmarking Alliance can be found at EDBenchmarking.org.

The summit was sponsored by the Emergency Department Benchmarking Alliance.

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tion'' that have demonstrated improved efficiency and patient and staff satisfaction.[10] Dissemination of these new ideas will be limited without the language to communicate them, with other EDs less likely to benefit from their innovation without a common definition of ''pivot nurse'' or ''patient segmentation.''

Standardized terminology and methodology are necessary if research in ED operations and quality improvement is to advance,[11–13] and it is fundamental that these terms be developed by stakeholders who understand the nuances of ED operations.

Participants in the Second Performance Measures and Benchmarking Summit were asked: 1) to discuss, debate, and revise a set of definitions pertaining to basic ED operations; 2) to maintain consistency with the recognized work already done in this area; 3) to define terms clearly so they may be applied uniformly in various ED settings; and 4) to build and standardize the terminology of EM operations. Participants also developed metrics and measurements that will be published separately,[14] but this work defines space, processes, patient populations, and new staff roles.

EMERGENCY DEPARTMENT BENCHMARKING SUMMIT

The ED Benchmarking Alliance (EDBA) is a nonprofit collaborative of 367 performance-driven EDs. Founded in 1997, it is composed of EDs representing 14 million annual ED visits. The EDBA operates as a think tank, quality improvement collaborative, and learning community and shares its performance data and operational strategies so member hospitals may identify best practices. The alliance has developed a benchmarking database and educational programs focusing on ED operations and performance. It disseminates new ideas and innovations through conferences and publications.[15–22] Its first set of ED operations and performance definitions, published in 2006, is widely referenced.[23] The work done in 2010 builds on this earlier document. The entire project was deemed exempt from review by the Intermountain Healthcare Institutional Research Board (RMS Number 1021398).

After the EDBA board of directors (BOD) identified organizations with expertise in performance measurement, benchmarking, and ED operations, invitations were e-mailed to 32 of them requesting participation by an experienced representative (Table 1). Possible attendees were vetted by the BOD for expertise or experience on technical expert panels, national committees, and task forces and in research. Requests to substitute less-experienced persons or to bring interns were denied. Participants from the first summit also were invited, not only because of their experience in the field, but because of expertise in consensus building, developing summary documents, and publishing and disseminating the first document. The final roster of attendees had associations with the organizations shown in Table 2.

Table 1
Participants in the Second Performance Measures and Benchmarking Summit, Salt Lake City, February 24, 2010

- Sherri Almeida, RN, Emergency Nurses Association
- Brent Asplin, MD, MPH, Chair, Emergency Medicine, Mayo Clinic
- James Augustine, MD, Director, Clinical Operations, Emergency Medicine Physicians (EMP)
- Kevin Baumlin, MD, Informatics, Mt. Sinai Medical Center
- Jody Crane, MD, MBA, Institute for Healthcare Improvement (IHI)
- Steven Davidson, MD, MBA, Chair, Emergency Medicine, Maimonides Medical Center
- Angela Franklin, Esq., Director, Quality and Health IT, American College of Emergency Physicians (ACEP)
- David Garvey, MD, Physician Executive, The T-System
- Azita Hamedani, MD, University of Wisconsin, Madison
- Michael Handrigan, MD, Center for Emergency Preparedness, Health & Human Services (HHS)
- Bruce Janiak, MD, Vice Chair, Emergency Medicine, Medical College of Georgia
- Ian Jones, MD, Director, Medical ED, Vanderbilt University
- Nick Jouriles, MD, Past President, ACEP
- John Lyman, MD, CMO, Premier Health Care Services, Inc.
- Mark McClelland, MN, RN, GWU-The Center for Health Care Quality
- Jeanne McGrayne, RN, Premier Consulting Services
- Michael Phelan, MD, Emergency Medicine Quality Review Officer, Cleveland Clinic
- Randy Pilgrim, MD, President, EDPMA; Vice President, Operations, The Schumacher Group
- Charles Reese, MD, Chair, EDBA
- Deb Richey, RN, Board Member, EDBA
- Jedd Roe, MD, MBA, Chair, Emergency Medicine, William Beaumont Medical Center
- Andrew Roszak, Center for Emergency Preparedness, HHS
- Lucy Savitz, PhD, MBA, Intermountain Institute for Health Care Delivery Research
- Jeremiah Schuur, MD, Director, ED Quality and Safety, Brigham and Women's Hospital
- Tim Seay, MD, Greater Houston Emergency Physicians
- Suzanne Stone-Griffith, RN, Vice President, HCA Healthcare
- Todd Taylor, MD, Physician Executive, Microsoft Corp.
- Pamela Turner, RN, MBA, Rudder Associates Consulting
- Ellen Weber, MD, Emergency Medicine, University of California-San Francisco
- Shari Welch, MD, Fellow, Intermountain Institute for Health Care Delivery Research
- Jennifer Wiler, MD, MBA, University of Colorado

EDBA = Emergency Department Benchmarking Alliance.

SUMMIT WORKING MODEL

Prior to the summit, the EDBA circulated a survey asking participants to comment on the limitations and omissions of the 2006 document and used those comments to form the summit agenda. Summit organizers selected workgroup leaders based on their knowledge and leadership experience, crafted a project plan, and formed workgroups. Each workgroup also was assigned a member of the BOD who had been through the process before to provide oversight and keep the workgroup on task.

Each workgroup leader received instructional materials about running a successful workgroup and copies of the project's objectives, work plan, and timetable. Workgroup members also received the 2006 document and other relevant papers and documents. Information sharing took place via the Internet, e-mails, and conference calls, and EDBA provided project support in the form of a conference call line, assistance with document processing, and project coordination. Two authors (SW

Table 2
Professional Associations of Summit Attendees

- Agency for Healthcare Research and Quality
- American Academy of Emergency Medicine
- American College of Emergency Physicians
- American College of Health Care Executives
- Emergency Care Coordination Center, US Department of Health & Human Services
- EDBA
- Emergency Department Practice Management Association
- Emergency Nurses Association
- Institute for Healthcare Improvement
- Intermountain Institute for Health Care Delivery Research
- Joint Commission
- National Quality Forum
- Society for Academic Emergency Medicine

*Listing does not imply endorsement of this document, but shows the diversity of representation at the summit.
EDBA = Emergency Department Benchmarking Alliance.

and JS) integrated each workgroup's summary section into a final manuscript. The composite document was circulated numerous times to the workgroup leaders and EDBA leadership for editing. Areas of disagreement were addressed through conference calls and threaded e-mail discussions until consensus was reached. The EDBA used this methodology successfully during the first summit and in a conference on ED intake. This dictionary is organized as follows: 1) space definitions, 2) process definitions, 3) patient populations, and 4) staff roles.

SPACE DEFINITIONS

Many EDs have created new areas for specific patients and tasks:

- **Emergency Department (ED):** A 24-hour location serving an unscheduled patient population with anticipated needs for emergency medical care, receiving emergency medical services (EMS) transports.
- **Psychiatric ED:** An ED developed and promoted to the community as serving the unscheduled needs of patients with mental health conditions.
- **Pediatric ED:** An ED designed and dedicated to serve the needs of pediatric patients, defined as patients younger than 18 years of age.
- **Triage Area:** The space where traditional triage assessment (e.g., history, cursory physical exam, and vital signs) takes place.
- **Intake Area:** The space where initial clinical assessment occurs, by whatever model, that allows for sorting and appropriate placement into a treatment space, treatment room, or waiting area. In many newer intake models, labs are drawn and intravenous lines may be started in the intake area.
- **ED Treatment Room:** An area in which complete health services can be delivered to the patient (does not include hallways, parking spaces, and holding areas).
- **ED Treatment Space:** An area where limited health services can be delivered. It may not be suitable for complete health service, and may include hallways or group treatment areas.
- **Fast Track:** Dedicated space within the ED or adjacent to it dedicated to treatment for minor illnesses, wounds, and injuries. Patients treated here should ideally have throughputs of 90 minutes or less.
- **Clinical Decision Unit:** Space within or adjacent to the ED with multiple treatment spaces designed for ED patients undergoing lengthy and more detailed workups with expected occupancies of 6 to 8 hours.
- **Observation Unit:** Space designed for patients needing a period of observation not intended to exceed 24 hours. These may be adjacent to or remote from the ED, or they can be virtual units.
- **Results Waiting Area:** Space where vertical patients (patients arriving ambulatory and whose conditions do not warrant a supine position and bed placement) await test results after the initial medical evaluation is complete. It may be a part of the traditional waiting room or space within the ED where patients are seated, not on stretchers.
- **Discharge Waiting Area:** Space allocated for ED patients awaiting discharge (the process and paperwork) who no longer need diagnostic or therapeutic interventions.
- **Discharge Kiosk:** Specified area, usually adjacent to ED, where patients go through the discharge process including receiving instructions and prescriptions. Copayments may be made here.
- **Express Admission Unit:** Designated space, often within or adjacent to the ED, for ED patients awaiting inpatient bed placement. Often admission processing takes place here. The diagnostic and therapeutic needs of the patients at this stage no longer require an ED treatment room, opening up ED beds and facilitating flow.

PROCESS DEFINITIONS

New processes for core ED operations are constantly evolving to improve ED patient flow and current practices, and these were refined during the second summit.

- **EMS Offloading:** The process of transferring a patient from an EMS stretcher and placing him or her in a treatment space. Care is assumed by the ED staff.
- **Identification:** The process of collecting sufficient information critical to establishing and recording a unique patient encounter with at least two unique identifiers. This is distinct from registration.
- **Triage:** The process of assessing patients who present for care by prioritizing access to providers and space according to the urgency of the patient's need and the complexity of the services required. Traditionally performed by a registered nurse, it involves a number of steps and information-gathering. One of the most important features is the assignment of triage scale, now most frequently a five-level scale, either the Emergency Severity Index (ESI)[24] or the Canadian Triage Acuity Scale (CTAS).[25]
- **Intake:** The process of receiving and sorting persons seeking access to acute episodic medical care in the

ED. Models include triage, rapid medical screening, team triage, and physician in triage.[26]
- **Registration:** The process of identifying and recording information to generate a patient-specific record. It includes collecting information on financial responsibility and sociodemographic statistics for billing. Registration is distinct from patient identification.
- **Medical Screening Exam:** The assessment by a provider to determine if an emergent medical condition exists.
- **Discharge:** The process of releasing patients from the ED at the end of the encounter, including the distribution of discharge papers.
- **ED Diversion:** A notification to the medical community of a temporary limit of complete or partial institutional capability to handle medical or surgical conditions, communicated to EMS.
- **Boarding:** The practice of holding patients who have been admitted to the hospital in the ED for prolonged periods. Defined as a time interval, it encompasses the admit decision time to the departure time.
- **Overcapacity:** The condition of having more patients than treatment spaces in the ED. It may be measured as the time within a 24-hour period spent at overcapacity.
- **Patient Segmentation:** The practice of grouping patients who require similar services and have similar anticipated lengths of stay together in a geographic space in the ED, such as placing patients in a fast track or a clinical decision unit (also called patient streaming).

PATIENT POPULATIONS

To understand demand, EDs must track patient populations, and this process is aided by standardized definitions. All volumes are tracked as the number of cases per 100 ED visits.

- **Acuity by ESI/CTAS:** Patients given an ESI code of 1 or 2 on arrival are high-acuity and an ESI scale of 4 and 5 are low-acuity.
- **Acuity by Evaluation and Management (E/M Codes):** Patients given E/M codes of level 4 or 5 are high-acuity and of E/M level 1 or 2 are low-acuity.
- **Admission Rate:** Percentage of ED visits admitted to an inpatient unit.
- **Transfer Rate:** Percentage of ED visits transferred for care to another facility.
- **ICU Admission Rate:** Percentage of ED visits requiring an intensive care unit bed on admission.
- **Pediatric Volume:** ED visits under age 18 years.
- **Infant Pediatric Volume:** ED visits under age 2 years.
- **Geriatric Volume:** ED visits age 65 years or older.
- **Follow-up Volume:** ED visits instructed to return to the ED for further diagnostic or therapeutic interventions after a specific time interval.
- **Acute Myocardial Infarction (AMI) Volume:** ED visits with discharge diagnosis of AMI.
- **Stroke Patient Volume:** ED visits with discharge diagnosis of acute stroke.
- **Community-Acquired Pneumonia (CAP) Volume:** ED visits with a discharge diagnosis of CAP.
- **Congestive Heart Failure (CHF) Volume:** ED visits with a discharge diagnosis of CHF.
- **Emergency Surgery Volume:** ED visits going directly to the operating room from the ED.
- **Behavioral Health Volume:** ED visits seeking care for mental illness or substance abuse.
- **Sexual Assault Volume:** ED visits seeking care for sexual assault.

NEW ED ROLES

As part of ED operational improvements, new members have been added to the ED team.

- **Bed Czar:** Person assigned and empowered to find and allocate inpatient beds for admitted patients from the ED. Some places refer to this person as a Hospital Patient Flow Coordinator (this should not be confused with the ED Patient Flow Coordinator).
- **Call-back Physician or Nurse:** A health care worker assigned to contact patients after an ED visit to inquire about the quality of the ED experience and the patient's condition and to communicate any results unavailable during the visit.
- **Case Manager:** A health care worker, typically a nurse or social worker, with training in case management. Duties may include reviewing cases for inpatient admission; facilitating bed placement; ensuring appropriate ED use; and arranging home care, follow-up care, transport, and nursing home care.
- **Crisis Worker:** A licensed social worker with psychiatric experience who may be stationed within or on call to the ED to assist in evaluating and making the disposition for patients presenting with behavioral health issues.
- **Discharge Team:** A team of health care workers, typically a nurse and a technician, dedicated to the discharge process. The goals of the discharge team are to expedite patient discharge and improve efficiency in ED treatment room throughput.
- **ED Coordinator, also Called Patient Flow Coordinator (PFC):** The PFC oversees discharges, admissions, and overall patient flow. Typically a nurse, the coordinator also monitors the ED for process defects, bottlenecks, waits, and delays.
- **ED Lab Tech:** A technician stationed in the ED with responsibility for collecting, labeling, and transporting specimens to the lab. Also collects results and presents them to the clinical staff. This person may be hired jointly by the ED and the laboratory.
- **Greeter:** A nonlicensed individual stationed in the ED waiting area who provides information, comfort services, and escort services for patients and their families. This is usually a volunteer position.
- **Health Unit Clerk (HUC):** Formerly called the ED secretary, the clerk is responsible for answering telephones, entering physician orders into the computer, calling consulting physicians, maintaining charts, and other clerical tasks as assigned.
- **Physician's Assistant and Liaison (PAL):** This individual functions at the interface between the provider

and information technology (IT). He or she documents and tracks patient test results and provides these data to the provider. The PAL is a scribe and personal patient flow coordinator for the provider.

- **Pharmacist:** Licensed professional responsible for providing comprehensive clinical pharmacy services including therapeutic consultation and formulation.
- **Physician Assistant (PA):** A licensed provider practicing medicine under the supervision of physicians and surgeons. PAs are formally trained to provide diagnostic, therapeutic, and preventive health care services, as delegated by a physician.
- **Pivot Nurse/Podium Nurse:** A nurse, typically with extra training and experience, who rapidly assesses patients and assigns them to a patient stream for care. This typically takes less than 2 minutes.
- **Scribe:** The scribe assists the ED provider by documenting the patient assessment and treatment plan in the medical record. Scribes often facilitate patient flow by following up on diagnostic study results, implementing the treatment plan, and assisting with consults and other care processes. Scribes are generally assigned to one physician per shift and often are students in health care programs.
- **Transport Technician:** This worker transports patients around the ED and to other departments for testing and treatment.
- **Valet:** The valet is stationed at the entrance of the ED, and physically assists fragile incoming and discharged patients to and from private vehicles. The valet will direct family members on parking, entry, and intake procedures. This is not to be confused with valet services outside of health care, whose function is to park cars.

Much has changed since the 2006 ED operational performance document was published.

CHANGING PARADIGMS

New ED intake models, growing evidence that ED crowding and prolonged length of stay are associated with lower quality care and worse outcomes, and an intense national focus on the measurement of health care quality has brought changes to the emergency care landscape.[26–33] As the field of ED operations management grows and accumulates a body of knowledge, the need for precise and standardized terminology will become even more critical. To that end, the EDBA organized this summit to review and update critical terminology.

This article differs from the 2006 article in a number of areas that deserve mention. The first paper suggested a comparison scheme for benchmarking that did not prove useful or survive validity testing. It has been removed, and this paper refines patient population definitions against which EDs can benchmark themselves. This dictionary also provides a more exhaustive list to help EDs characterize and track demand. By understanding the patient populations an ED serves, leaders and managers can predict the services that will be needed. The first consensus paper predominantly focused on measures and metrics with some relevant terms defined. This more comprehensive document functions as an operations dictionary encompassing the main elements of ED operations: space, processes, patients, and staff.

Summit attendees also removed terms that did not gain acceptance or that were criticized as ambiguous, including ''conversion time'' and ''ED boarding load.'' The definitions have been edited, revised, and vetted by the stakeholders, aligned with definitions from the Emergency Nurses Association, CMS, and the National Quality Forum.

LIMITATIONS

This work has two inherent limitations. First, recognized qualitative research consensus methodologies like the Delphi method, which have been used before in this type of work, were not employed.[34] The methodology employed, however, has been used successfully by EDBA in the past to develop consensus around particular issues in EM, and it has its own rigor.[35] Summit organizers incorporated strategies used in similar EDBA work including surveys, meetings, conference calls, e-mail, and iterative processes. Second, the creation of the group was open to selection bias, although representation from leading organizations in EM was solicited, and the document was reconciled with work done by other prominent stakeholders. This dictionary is the result of a complex process to achieve consensus and represents the collected views of informed individuals.

CONCLUSIONS

The need to define, standardize, and quantify the metrics, definitions, and data used in our industry has never been more compelling. In response to the growing demand for measures of ED performance, we convened a summit of key stakeholders. Using an iterative team process, a dictionary for ED operations was developed by consensus. We present definitions for ED spaces, processes, patient populations, and new staff roles. These standardized definitions should help ED administrators, researchers, and regulators by providing a common language with which to communicate.

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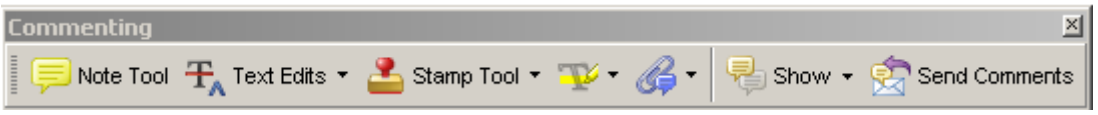
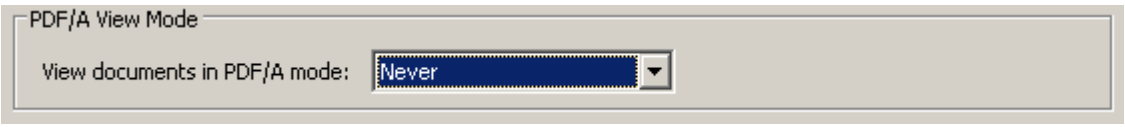
Adobe Acrobat Professional or Acrobat Reader (version 7.0 or above) is required to e-annotate PDFs. Acrobat 8 Reader is a free download: http://www.adobe.com/products/acrobat/readstep2.html

Once you have Acrobat Reader 8 on your PC and open the proof, you will see the Commenting Toolbar (if it does not appear automatically go to Tools>Commenting>Commenting Toolbar). The Commenting Toolbar looks like this:



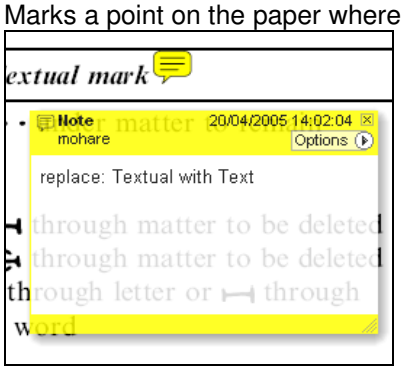
If you experience problems annotating files in Adobe Acrobat Reader 9 then you may need to change a preference setting in order to edit.

In the "Documents" category under "Edit – Preferences", please select the category 'Documents' and change the setting "PDF/A mode:" to "Never".



Note Tool — For making notes at specific points in the text

Marks a point on the paper where a note or question needs to be addressed.

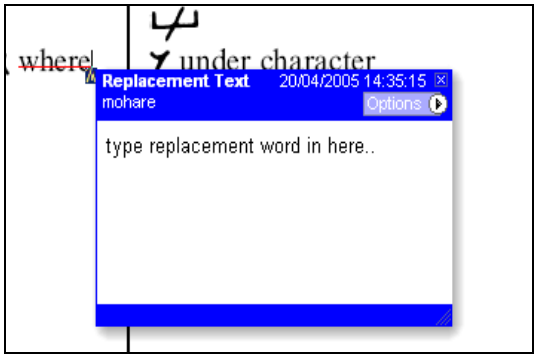


How to use it:

1. Right click into area of either inserted text or relevance to note
2. Select Add Note and a yellow speech bubble symbol and text box will appear
3. Type comment into the text box
4. Click the X in the top right hand corner of the note box to close.

Replacement text tool — For deleting one word/section of text and replacing it

Strikes red line through text and opens up a replacement text box.

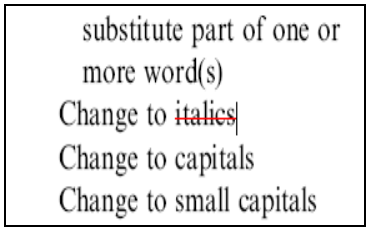


How to use it:

1. Select cursor from toolbar
2. Highlight word or sentence
3. Right click
4. Select Replace Text (Comment) option
5. Type replacement text in blue box
6. Click outside of the blue box to close

Cross out text tool — For deleting text when there is nothing to replace selection

Strikes through text in a red line.



How to use it:

1. Select cursor from toolbar
2. Highlight word or sentence
3. Right click
4. Select Cross Out Text

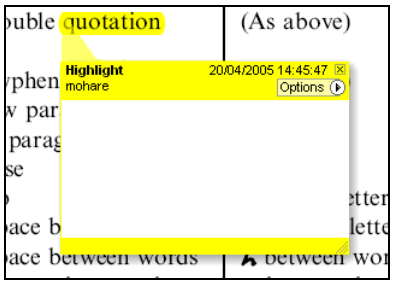
Approved tool — For approving a proof and that no corrections at all are required.

How to use it:

1. Click on the Stamp Tool in the toolbar
2. Select the Approved rubber stamp from the 'standard business' selection
3. Click on the text where you want to rubber stamp to appear (usually first page)

Highlight tool — For highlighting selection that should be changed to bold or italic.

Highlights text in yellow and opens up a text box.

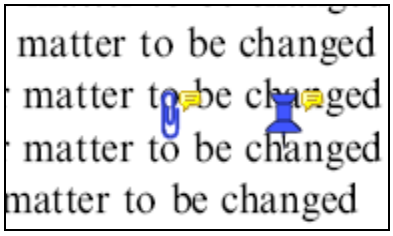


How to use it:

1. Select Highlighter Tool from the commenting toolbar
2. Highlight the desired text
3. Add a note detailing the required change

Attach File Tool — For inserting large amounts of text or replacement figures as a files.

Inserts symbol and speech bubble where a file has been inserted.

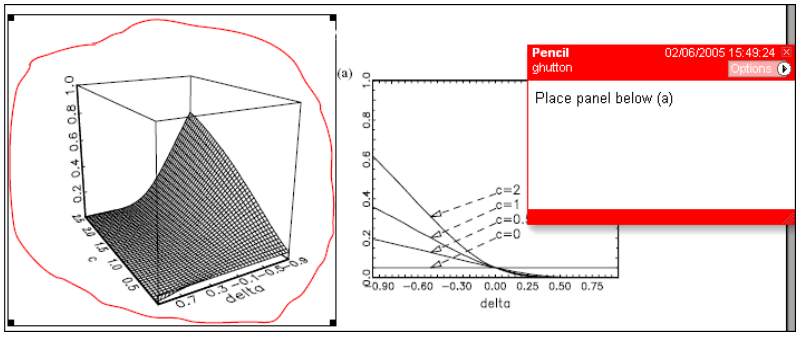


How to use it:

1. Click on paperclip icon in the commenting toolbar
2. Click where you want to insert the attachment
3. Select the saved file from your PC/network
4. Select appearance of icon (paperclip, graph, attachment or tag) and close

Pencil tool — For circling parts of figures or making freeform marks

Creates freeform shapes with a pencil tool. Particularly with graphics within the proof it may be useful to use the Drawing Markups toolbar. These tools allow you to draw circles, lines and comment on these marks.

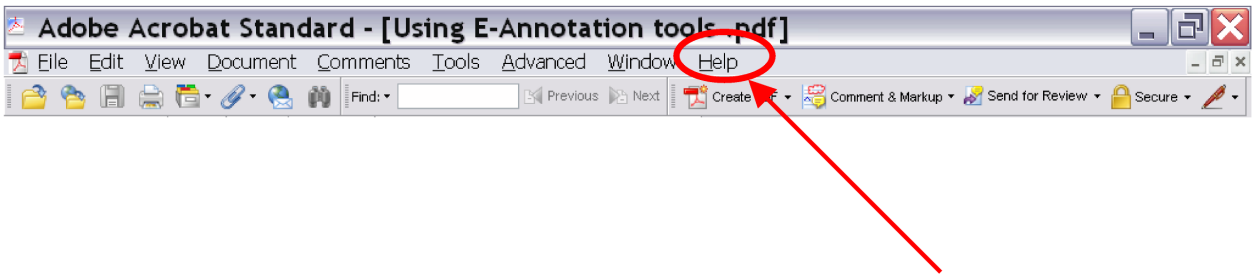


How to use it:

1. Select Tools > Drawing Markups > Pencil Tool
2. Draw with the cursor
3. Multiple pieces of pencil annotation can be grouped together
4. Once finished, move the cursor over the shape until an arrowhead appears and right click
5. Select Open Pop-Up Note and type in a details of required change
6. Click the X in the top right hand corner of the note box to close.

Help

For further information on how to annotate proofs click on the Help button to activate a list of instructions:



CA Unintentional Injury Prevention Strategic Plan Project

DRAFT Overview

for EMS Trauma Group & CHA

By
Steve Barrow, Program Director CCCSH
Co-Chair
CA Unintentional Injury Prevention Strategic Plan Project
(ID Purposes Only) Commissioner, CA EMS Commission
scbarrow88@gmail.com

Presentation Overview –

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- Project Vision and Goals
- Why Unintentional Injury focused on children and youth
- How project is organized
- Who are the project stakeholders
- Eight leading Unintentional Injury Issue areas of focus
- Project objectives:
  - Traffic, Non-Traffic, Drowning, Suffocation, Poisoning, Falls, Burns and Sports Related unintentional injury
- Outcome measurable metrics and data sources
- Accomplishments
- Where help is needed
- Contact information

Project's Long Term Vision

3

- California is a leader in reducing hospitalizations and death due to unintentional injury involving our children and youth
- [For CHA EMS/Trauma group would add – Reduction of Emergency Room visits due to unintentional injury involving our children and youth]

Goals of the Project

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- **Save kids lives** and protect them from harm
- **End unintentional injuries long reign** as leading cause of death and hospitalization for CA's children and youth
- **Elevate unintentional injury back onto the table of important issues** for our policymakers, foundations, media, community leaders and parents
- Create **sustainable collaboration** between not only unintentional injury prevention groups and leaders, but also with organizations working on other important health and well-being of children and youth issues – especially children and youth from underserved communities.

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Why Unintentional Injury is Focused on Children and Youth
Incident numbers

- According to Center for Disease Control Injury Prevention and California's Dept of Public Health EPICenter
  - Unintentional injuries are the leading cause of death and hospitalizations for children and youth ages 1-19 and leading cause of injury-related death for infants under the age of 1.
  - Between 2003-2013 unintentional injuries caused the death of nearly 10,000 CA children and youth – at a pace of around 1,000 child deaths per year
  - The annual death rate is equivalent to the death of every child in three averaged sized elementary schools each year
  - Every ten years in CA more than 240,000 children and youth are hospitalized, and another 4+ million are sent to the emergency room
  - The annual hospitalization rate is equivalent to sending every child from 65 elementary schools to the hospital every year.

All of this is Preventable

6

Why Unintentional Injury is Focused on Children and Youth
Incident numbers [Add for EMS/Trauma group]

- According to Center for Disease Control Injury Prevention and California's Dept of Public Health EPICenter
  - Every year there are more than 400,000 emergency room visits due to preventable Unintentional injury
  - Equivalent to sending every child from 1,000 elementary schools to the ER every year
  - Every ten years in CA more than 240,000 children and youth are hospitalized, and another 4+ million are sent to the emergency room
  - The annual hospitalization rate is equivalent to sending every child from 65 elementary schools to the hospital every year.

All of this is Preventable

7

Why Unintentional Injury Project is Focused on Children and Youth
Cost

- Unintentional injuries are a preventable expense to our state's health care system
  - According to California's Dept of Public Health EPICenter data child and youth unintentional injuries costs our state's healthcare system more than $1.6 billion in initial hospital costs 2003-2013
- Brain injuries is the leading severe type of injury
  - A child with a brain injury costs around $5 million in initial hospital costs
- On-going major costs
  - Example: The CA Dept of Developmental Services has more than 700 near-drowning clients, representing one of the leading sources for being a client of DDS
  - Example: One month's institutional care for a child with brain damage due to near drowning is in the $30,000 per month range.
- Unintentional injury annual medical and wage loss cost is $3.4 billion dollars
  - With wage loss associated with parents taking time off work caring for an injured child or to plan a funeral

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Why We Do This
Unintentional Injury Prevention Strategic Plan Project

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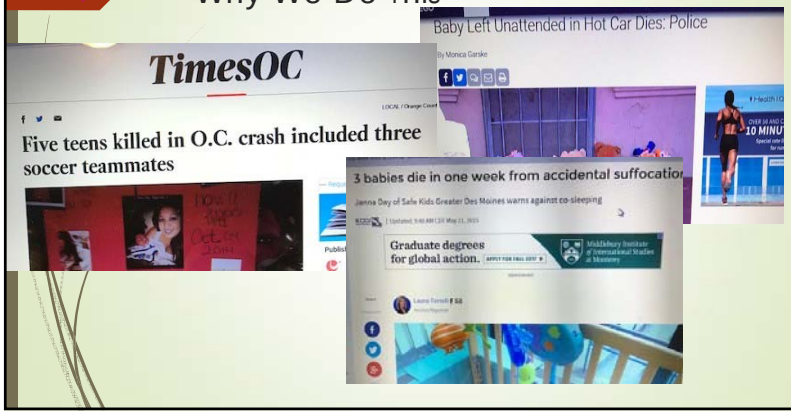
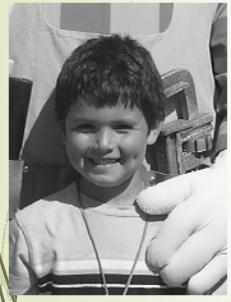
Why We Do This



10

Why We Do This

nicky.



On Father's Day, June 20, 2010, 5 year old Nicky, his sister, and their friends were playing outside. The older kids got bored and eventually wondered inside to play games and watch a movie. Unknown to Nicky's father, Nicky a neighbor friend went to her house where her mother was asleep. Somehow they ventured past a locked sliding door and a door alarm that was not connected and into the unprotected swimming pool without supervision. After a brief search, Nicky's father knocked on the neighbor's door and the little girl answered the door saying "Nicky went swimming and I think he drowned." He was pulled from the swimming pool by his father after an unknown time in the water. CPR was performed by another neighbor who heard all the screaming for help. Nicky was taken to the hospital but never regained consciousness. His parents' lives have never been the same.

Nicholas Joseph Norman/ Age 5 /
San Diego CA

- **Backyard pool**

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Why We Do This

samira and JJ.

Samira was two years old and JJ just 14 months old the day they slipped through a sliding door and out of sight of their babysitter. A few minutes later the babysitter found both of the children floating face down in the backyard pool. A neighbor helped provide CPR until the fire department arrived. Samira had no life signs and was not able to be resuscitated. JJ had a slight heart beat! He was resuscitated, but too late. JJ's mom recently held a 40th birthday party at the institution where he is cared for. He is the oldest living near-drowning victim cared for by CA's Department of Developmental Services. He has not walked or spoken since that fateful day. Multiple barriers would of kept Samira and JJ from gaining access to the pool and/or warned the sitter they were accessing the pool area.

Drowning Prevention Foundation

Samira and JJ Riggsbee/ Ages 2 and 14 months/ Bay Area CA
(www.DPF.Org – need DPF

- Backyard pool

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Why we Do This

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WHY WE DO THIS

JJ's story as a near drowning victim

JJ drowned in a backyard pool alongside his sister Samira when she was 2 and he was 14 months old. JJ survived. Samira did not.

The photo was taken at JJ's 40th birthday party this last May 11, 2017. In the picture with JJ are his Mom, Nadina, and his caregivers. JJ is California's oldest living near-drowning victim under the care of the CA Department of Developmental Services.

According to CA's EPICenter injury data from 2010 to 2014 more than 160 California children ages 1 to 4 died due to drowning. Most of these drowning incidents occurred in backyard pools. For every one drowning fatality there are another 4 to 5 children who drown, but survive, and many of these children have permanent brain damage.

During a five year period, from 2010 to 2015 more than 740 California children aged 1 to 4 years old were hospitalized due to a near-drowning incident. As of December 2016, CA's Department of Developmental Services is currently providing care to 755 near-drowning victims with brain damage.

For the parents and families of children who have suffered a near-drowning caused brain injury, the drowning incident is just the start of a long difficult and expensive journey through hospitalizations, rehabilitation, around the clock care, special education, and other issues that impact the whole family.

For the last 14 years JJ has been institutionalized in a round the clock care facility at a monthly cost of $30,000.

Because of JJ's brain injury due to drowning, JJ's two younger brothers never got to run and play with their older brother.

This is the other side of the drowning story for far too many California children.

Drowning is preventable.

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Why We Do This

A survey of more than 4,000 first responders found that 6.6 percent had attempted suicide, which is more than 10 times the rate in the general population, according to a 2015 article published in the Journal of Emergency Medical Services.

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Why We Do This

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How the Project is Organized

- Working subcommittees are organized around eight leading causes of Unintentional Injury
- Subcommittee rosters made up of 44 experienced national, state and local safety experts
- Project housed under 501c3 CA Coalition for Children's Safety and Health (CCCSH)
- Admin and staffing through CCCSH and Advocates for Health Economics and Development, a Program under CCCSH

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How the Project is Organized – Stakeholder Capabilities

- Linked to national and state data sources
- Linked to national and state policy experts – private and public sectors
- Linked to local and regional front line programs – working directly at the community level
- Linked to state level legislative and policy expertise and experience
- Linked to experts in coalition building, collaboration, and partnership development

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Who is Involved, Who are the Project Stakeholders

Project was designed by more than 70 initial stakeholders - Example & partial list of stakeholders:

- Injury prevention and safety groups including by not limited to: Safe Kids International & CA, CA Coalition for Children's Safety and Health, Drowning Prevention Foundation, Children's Safety Network, Safety Belt Safe USA, KidAndCars.org, Impact Teen Drivers, National Safety Council, Advocates for Highway and Auto Safety, etc.
- Children's Hospitals: Los Angeles, Oakland, L. Packard, Central CA, LA, Shriners
- Insurance associations: Assoc CA Life Health Ins Co (ACLHIC), CA Assoc Health Plans, Personal Insurance Federation of CA, CA Health Plan Association
- State agencies: Emergency Med Services Authority, CA Department Public Health Safe and Active Communities, Office of Traffic Safety
- Federal agency: Consumer Product Safety Commission
- Healthcare: American Academy of Pediatricians – CA
- Public Health: Health Officers Association of CA

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Project is Focused on Eight leading Unintentional Injury Issues Involving Children and Youth Up Through Age 19

- Traffic related – teen driver safety, safety seats, pedestrian and bicycle
- Non-Traffic vehicle related – kids left in cars, backovers & frontovers
- Poisoning – primarily inappropriate use of prescription meds
- Suffocation – primarily sleep suffocation infants and babies & ingestion small objects
- Drowning – residential pools and open bodies of water
- Burns – primarily home and kitchen fires
- Falls – primarily window fall prevention
- Sports related – concussion, cardiac arrest, spinal injury

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Current Project Objectives What the Project is focused on and Is not focused on

The CA Unintentional Injury Prevention Strategic Plan Project is focused on supporting:

- Creation and growth of collaboration and cooperation between organizations, proactive in civic engagement, and advocating for the development of best practice policies, laws, programs and funding that support unintentional injury prevention statewide
- Institutionalize best practices that are proven, effective and can be replicated
- Passage of new and updating existing unintentional injury focused laws based on best practices
- Increase resources to help sustain and grow to capacity local and regional "hands on" safety programs, organizations and projects

The CA Unintentional Injury Prevention Strategic Plan Project was not created to provide hands on local safety and prevention services, unless working with Project stakeholders to support pilot program(s) to test a hypothesis toward advancing unintentional injury prevention

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Current Project Objectives
Traffic related issue current Priorities

- Teen driver safety – Implement national recommendation GDL age change from 18 y/o to 21 y/o – cover 18, 19, and 20 year old new drivers with GDL – AB 63 (Frazier)
- Safety Seat Technicians – Create statewide safety seat technician goals and strategic plan, increase number of sustainable certification training courses and number of local safety seat technicians
- Revamp CA's bicycle helmet law citation back to original $25 ticket (currently $300), and allow local law enforcement or other local jurisdiction waive ticket if parent or guardian shows the child has and will wear helmet or pass bicycle safety program
- Increase sustainable support for local and regional school and community-based hands-on bicycle and pedestrian safety programs
- Increase collaboration, cooperation and communications between local and state agencies responsible for road and intersection design, maintenance and revamp, with focus on "hotspots" where multiple vehicle, bicycle and pedestrian crashes occur

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Current Project Objectives
Non-Traffic – Kids left in cars, backovers and frontovers

- Increase support in underserved communities around non-traffic issues and prevention actions that need to be taken by parents, caregivers, children and community leaders, regarding kids left in cars, backovers and frontovers
- Support development of technologies to help prevent infants and children being left in vehicles (Ex: Congressional bill "Hot Car NHTSA Regulations")
- Increase public awareness regarding backovers and access to affordable rearview vehicle cameras
- Reform incident reporting of kids left in cars, backovers and frontovers, to increase accurate picture of these issues in CA

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Current Project Objectives
Drowning prevention

- Legislation updating CA's 1996 Pool Safety Act law – SB 442 (Newman)
- Ensure drowning prevention concepts are included in school, hospital discharge, parent training, swimming lessons and Pediatrician safety lessons and curriculums
  - Core concepts are: all water comes with risk and understanding water risks; maintain safety barriers on residential pools and spas; ***active adult supervision*** of children around water; and having a strategic safety plan in place before accessing water

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Current Project Objectives
Suffocation Prevention

- Suffocation prevention is primarily focused on sleep suffocation, which is by far and away the leading cause of suffocation-injury and death to infants and babies in CA
  - Support the development of, refining and defining of the attributes associated with best practice local sleep suffocation prevention programs
  - Increase sustainable support to underpin ongoing access to local best practice sleep suffocation prevention programs
  - Institutionalize sleep suffocation prevention policies and protocols at all California hospitals regarding parent and caregiver sleep suffocation prevention knowledge and support upon the discharge of a baby or infant from the hospital
- Institutionalize suffocation education for parents, caregivers and families about preventing babies, infants and young children from ingesting small objects – working with hospital leadership, child care councils, EMSA primary health and safety training course curriculum review for licensed child care providers

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Current Project Objectives
Poisoning Prevention

- Support the retention of Poison Control Centers in the CA state and federal budgets
- Institutionalize best practices prescription med drop off policies and protocols for all pharmacies, to prevent children and youth access to unused prescription medication

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Current Project Objectives
Falls Prevention

- The main **child fall focus** is currently on institutionalizing best practice window fall prevention, with a primary focus on multistory residential buildings. The best practice window fall prevention strategy is to institutionalize the New York best practice window fall ordinance onto the California landscape. New York was able to nearly eradicate its child window fall public health problem, reducing fall incidents there by more than 90%.
- Comment on **senior falls**: Falls create one of the largest numbers of unintentional injuries for children and seniors. For children common falls on the same surface are less of a major unintentional injury issue. For seniors common falls can be deadly or a contributor to decline in health. The Project will - where appropriate - support information exchange about senior falls. So many of California's children in underserved communities depend on grandparents/grand uncles, aunts for care, losing these guardians and caregivers impact stability of children's lives.

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Current Project Objectives
Burns Prevention

A lot has been accomplished over the years in California through building code requirements, technology, state of the art fire departments, and better building materials. There are still too many home and kitchen fires resulting in death and severe injury.

- Re-instate fire department personnel positions in all areas of the state, with an expertise in community engagement, safety, prevention and unintentional injury prevention education
- Ensure all local hands on burn prevention and safety programs have access to free long term (10 year battery) smoke alarms, to install as a priority in homes where children live or are cared for
- Institutionalize safety inspection support and remediation programs for all local housing where children live, deemed to be at risk of fire dangers, including kitchen fire dangers, due to the age, design, kitchen or safety equipment, and status of building maintenance.

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Current Project Objectives
Sports Related

- Expanding concussion safety to cover not just school-based athletics, but all community-based sports leagues and programs. Supported contents and passage of AB 2007 (McCarty) of 2016.
- Follow up on the implementation of AB 2007 requiring all community-based sports programs' parent organizations are to institutionalizing concussion safety requirements per this 2016 legislation
- Institutionalize community-based sports program coaches training and parent and player education about sports related heat stroke, cardiac arrest and spinal injury prevention, and action steps when these unintentional injuries occur.

Outcomes - Measurable Metrics

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Examples of outcomes data that can be tracked

There are dozens of types of data that can be tracked with existing data systems. Here are a few examples:

- Number of UI caused ER, Hospitalizations and Deaths
- Number of and types of injuries due to teenage driver involved crashes, and cause of the crash – especially distracted driving underlying causes
- Number of vehicle crashes resulting in death or injury involving children required to be in safety seats
- Number and outcome residential pool and open body of water drownings
- Number of death and injuries due to sleep suffocation
- Number of head injuries associated with bicycle crashes
- Number of burn deaths and injuries due to home and kitchen fires
- Number of poisonings due to misuse of Rx medications
- Number and severity of sports related concussions
- Number of children harmed – fatal and non-fatal - due to being left in vehicles unattended, backover or frontover incidents

National Examples of Data Sources

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Nationally unintentional injury data sources

- CDC WISQUR http://www.cdc.gov/injury/wisqars/index.html (Web-based Injury Statistics Query and Reporting System)
- Children's Safety Network https://www.childrenssafetynetwork.org/
- KidsSafe
- KidsAndCars.org
- Children's Hosp of Philadelphia Center for Injury Research and Prevention
- Consumer Product Safety Commission
- National Highway Traffic Safety Administration
- Insurance Institute

State Examples of Data Sources

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State level settings that track detailed unintentional injury data collected from hospitals, first responders and public health community

- CA Dept of Public Health "EPICenter" http://epicenter.cdph.ca.gov/
- CA Highway Patrol
- County Health and Public Health Agencies
- CA Child Death Review Council aggregate report of local child death review data
- CA Emergency Medical Services Authority Trauma Data and CEMSIS

Accomplishments To Date (1)

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- Launching the project
- Created collaboration of wide array of private and public stakeholders supporting project and specific objectives under the project
- Development and support for eight working subcommittees to guide project Top Ten Issues action plan
- Support for CA DPH Kids Plate grant program on unintentional injury issues
- Has created one type of national model for moving unintentional injury issues forward at state level
- Project stakeholders are sponsoring Top Ten Issues legislation: teen driver safety, pool drowning prevention, bicycle helmet law update, window fall prevention, updating Kids Plate Child Health and Safety Fund formula and focus

Accomplishments to Date (continued)

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- Development of the Top Ten Issues action plan
- Kids Plates funding back to DPH
- Supported CA DPH Kids Plate grant program, which in 2016 put more than $1 million of safety equipment (safety seats, bicycle helmets, smoke alarms and life vests) out to local hands-on safety programs and fire departments across California
- Set up collaborative statewide initiatives on:
  - Supporting CA Department of Education reinstating age appropriate child safety education
  - Developing state strategic plan for optimal level of safety seat technicians
  - Expanding funding for EMSA child care primary health and safety training curriculum review and development
  - Developing project addressing brain injury impact on domestic violence, substance abuse and behavioral health issues

Where Help is Needed EMS Trauma Group Partnership

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- Participate in or follow CHA EMS Trauma Group SP Action Plan
- Partnering with UI Prevent SP Project
  - Project needs additional core operational funding
  - Project stakeholders provide a lot of in-kind support, such as issue expertise, research information, partnership development help, leadership on their key issues
  - CCCSH provides overall project leadership, administration, fund development, policy work, outreach to further develop and expand the stakeholder roster, and general staffing for the project
  - There needs to be recognition of the importance of sustaining and growing our state's broad based coalition setting hosting this collaboration work, which is CCCSH
- Need support for professional quality publishing of projects the stakeholders are producing, such as the Top Ten Issues action plan

Questions?

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Contact Information

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CA Unintentional Injury Prevention Strategic Plan Project

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Sacramento, CA 95814
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Recommendations on Selection and Use of Personal Protective Equipment and Decontamination Products for First Responders Against Exposure Hazards to Synthetic Opioids, Including Fentanyl and Fentanyl Analogues

I. BACKGROUND

Increased illicit use of opioids, including synthetic opioids such as fentanyl and its analogue carfentanil, is a source of increased risk to responders. Most routine encounters between patients or detainees and EMS or law enforcement do not present a significant threat of toxic exposure. While there are anecdotal reports of public safety personnel being exposed to opioids during operations, they are largely unconfirmed. To proactively address the potential risks, this document establishes guidance for personal protective equipment selection and use, decontamination, detection, and medical countermeasures for first responders who may be exposed to opioids in the course of their occupational activities. Throughout the remainder of this document, the term synthetic opioids will be used to include fentanyl, fentanyl analogues, morphine analogues, the U-series opioids, and others.

The InterAgency Board for Equipment Standardization and Interoperability (IAB) is a voluntary collaborative panel of emergency preparedness and response practitioners from a wide array of professional disciplines that represents all levels of government and the public safety sector. Based on direct field experience, IAB members advocate for and assist in the development and implementation of performance criteria, standards, and test protocols, and technical, operating, and training requirements for all-hazards incident response equipment with a special emphasis on Chemical, Biological, Radiological, Nuclear, and Explosive (CBRNE) issues.

Synthetic opioids (sufentanil, lofentanil, carfentanil, U-47700, and others) are highly toxic organic solids (UN 2811) Synthetic opioids may be found as powders, liquids, nasal sprays, and pills. The particulate size of synthetic opioid powders typically ranges from 0.2 to 2.0 mm, and the powders are easily aerosolized. The powders are both water and lipid soluble and present primarily a respiratory hazard. A secondary dermal hazard exists if there is direct skin contact with large bulk amounts of concentrated threat materials.

Powder-like substances can become airborne and present a respiratory hazard, particularly during activities such as “burping” containers of potential narcotics or “brushing” powdered residues from surfaces. Therefore, during encounters involving these types of materials, actions must be taken to avoid such aerosolization. Covering, wetting or leaving containers unopened are essential safety precautions. Use of proper personal protective equipment and standard safe work practices to prevent inhalation of powders and to minimize direct skin contact with residues should be instituted as soon as the potential presence of such materials is suspected.

Fentanyl and analogues are water soluble, so expedient decontamination (rinsing) of any contacted areas with water is advisable. Fentanyl in its hydrochloride form (the most common street form) is more soluble than the citrate form (medical grade). Both are more soluble than the free base. Consider adding soap to the wash water to account for the slightly soluble free base. Splashing should be kept to a minimum to avoid aerosolization of the materials. Do not use bleach, alcohol-based solutions, or high pH soaps, as they all may enhance dermal absorption of synthetic opioids.

Upon arrival on scene, if there are indicators that you may be entering a clandestine lab of any type, K-9 assets should not be employed. Should you encounter suspected synthetic opioids, remove the K-9 from the area.

The common production methods for synthetic opioids are available for responder awareness within the Laboratory Identifier Tool of the Emergency Response Decision Support System (available free to emergency response personnel in the U.S. and partner countries at www.chemicalcompanion.org).

Numerous agencies have produced recommended guidelines for risk assessment and personal safety when dealing with these materials. At times, these recommendations appear to focus on a specific area of public safety response and thus may appear to conflict. To simplify recommendations, the IAB is providing guidance for specific public safety response functions in this document.

On 28 November 2016, the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC)'s National Institute for Occupational Safety and Health released "Fentanyl: Preventing Occupational Exposure to Emergency Responders." The most current guidance is available at: https://www.cdc.gov/niosh/topics/fentanyl/risk.html. This guidance is based on potential hazards to law enforcement, public health workers, and first responders who may accidentally come into contact with this threat. The guidance includes information related to the performance of a risk assessment and recommended personal protective equipment (PPE).

II. PERSONAL PROTECTIVE EQUIPMENT RECOMMENDATIONS

The IAB recommends applying standard specifications, design attributes, test methods, and performance criteria when selecting PPE for first responders who may be occupationally exposed to synthetic opioids. These recommendations are intended to complement and supplement information provided by the CDC/NIOSH and the DEA, enabling responder organizations to make effective procurement and deployment choices addressing a wide range of missions, response environments, and varied work conditions.

WARNING

Personal protective equipment alone is not sufficient to ensure protection from synthetic opioids. *Each organization is responsible for conducting its own risk assessment to determine the appropriate PPE for its individual members. In addition, each organization must develop* ***specific standard operating procedures*** *related to the* ***selection***, ***use*** *(including proper donning and doffing), and* ***care*** *(decontamination, possible reuse, or disposal) of PPE, and* ***repeatedly train*** *its members in these procedures.*

Recommendations for PPE protection levels for emergency response personnel are based on a risk level determined by two major factors: (1) the PPE wearer's possible exposure to synthetic opioids, and (2) the wearer's operational response function. Please note that the potential exposure risk levels, defined in **Table 1**, are dynamic and may evolve throughout the response, requiring constant monitoring to ensure PPE remains commensurate with the risk.

Table 1. Definitions of Exposure Risk Levels and Operational Response Functions

Potential Synthetic Opioid Exposure Risk	Definition
Minimal (no visible product)	Law enforcement, fire, or EMS response to a suspected opioid overdose with no visible product evident.
Moderate (small volume)	Law enforcement, fire, or EMS response to a suspected opioid overdose with a small volume of known or suspected product evident. Law enforcement operation where small volumes of suspected materials are confiscated.
Moderate (large volume)	Response to a suspected opioid storage or distribution facility, with or without patients.
High (milling lab) [particulates]	Response to a suspected opioid milling operation where synthetic opioids are mixed with binders or other illicit materials to produce a street-level product. There is a high likelihood that threat materials will be suspended in the ambient air.
High (production lab) [chemicals]	Response to a suspected opioid production laboratory, which potentially also includes a milling operation, where the laboratory produces the illicit materials using any combination of chemical precursors. There is a high likelihood that threat materials will be suspended in the ambient air.
Operational Response Function	**Definition**
Emergency Medical Service (EMS) Patient Care	Emergency medical services commonly respond to incidents involving potential opioid overdoses. Patient care is the primary operational responsibility.
Law Enforcement (Patrol)	The variety of positions in law enforcement make exposure unique to the separate areas and job responsibilities. Officers should assume that direct contact with a synthetic opioid product is possible. Law enforcement functions such as detention, investigation, and/or arrest of suspects are the primary operational responsibilities. Please note that law enforcement officers often have EMS/first response functions that may affect their choice of PPE (see EMS Patient Care for appropriate PPE).
Structural Fire	The structural fire section is focused on a fire-based response which results in the identification of a suspected synthetic opioid, incidental to a fire, with fire suppression being the primary operational responsibility.
Decon Operations	The primary function of decon operations personnel is decontaminating people, equipment, and property. For small-scale incidents with minimal to moderate risk of exposure, decontamination operations may not be required, and therefore it is listed as not applicable in **Table 2**.

Operational Response Function	Definition
Special Operations	Special operations in the context of this paper includes teams formed for specific responses to hazardous materials, bombs, and clandestine laboratories, technical rescues, and potential hostage situations. The deployment of special operations teams to an event potentially involving synthetic opioids may also include other hazards specific to the nature of the operation, and thus require other appropriate PPE.
Investigations/Evidence Collection	The investigation and evidence collection phase of an incident may take place prior to the hazard being completely mitigated; therefore, recommended protection levels depend on the ambient threat at the time of entry. The primary responsibilities for investigations and evidence collection personnel include intelligence gathering, product identification, and packaging/securing evidence.

These two major factors combine to produce one of six possible risk-based PPE levels:

- **Low Risk PPE** is dictated by the nature of service provided, (e.g., EMS, and the routine exposure precautions for all patient contact dictated by CDC guidance and the state/local jurisdiction).
- **Moderate Risk, Small Volume PPE** is an increased protection level corresponding to increased likelihood of responder exposure to a small volume of threat materials.
- **Moderate Risk, Large Volume PPE** is an increased protection level corresponding to increased likelihood of responder exposure to a large volume of threat materials.
- **High Risk (Particulates) PPE** is a high level of recommended protection, corresponding to high likelihood of responder exposure to particulates.
- **High Risk (Chemical) PPE** is the highest recommended protection level, corresponding to high likelihood of responder exposure to chemicals and particulates.
- **Firefighting PPE** corresponds to the fire threat as the predominant hazard to the responder.

Each organization should determine the risk level based on an assessment of the specific mission responsibilities and work environment that may include the presence of specific hazards and the likelihood of exposure during operations. This risk assessment should consider:

- The amount and reliability of available information regarding the potential presence of synthetic opioids
- The first responder's expected proximity to bulk materials
- The duration of the first responder's proximity to materials

A. PPE Selection

The PPE recommendations in **Table 2** and **Table 3** are given in terms of a garment type (body protection), gloves, and eye/face/respiratory protection devices.

Table 2. Recommended Personal Protective Equipment by Operational Response Function

Potential Synthetic Opioid Exposure Risk	Operational Response Function					
	EMS Patient Care	Law Enforcement (patrol)	Structural Fire	Special Operations (Hazmat, Technical Rescue, SWAT, EOD, etc.)	Investigations/ Evidence Collection	Decon Operations
Minimal (no visible product)	I	I	III	I	I	N/A
Moderate (small volume; known or suspected product visible; patients)	II	II	III	II	II	N/A
Moderate (large volume storage/ distribution)	IV	IV	III	IV	IV	IV
High (milling lab) [particulates]	Do Not Enter		III	V	V	V
High (production lab) [chemicals]			III	VI	VI	V

Note: PPE requirements will be determined by the situation. Standard operating procedures may also be appropriate if the risk is acceptable.

As the principal hazard for exposure to synthetic opioids and their analogues is respiratory, some form of respiratory protection is recommended whenever there is moderate risk or higher. In all cases, first responders should wear some form of gloves to prevent potential transfer of opioid powders and residues to their bodies, where later re-aerosolization could cause subsequent exposure by inhalation or through mucous membranes. As the risk increases, full skin coverage is recommended for the same reason. Personal protective equipment recommendations for high-risk situations include full skin coverage provided by a certified ensemble that integrates suitable respiratory protection. Production laboratories may include various liquid chemicals; thus, in such cases, the ensemble must provide dermal and respiratory protection from vapors and liquids.

Where fire risks exist, the primary hazard present is assumed to be exposure to thermal and physical hazards. The recommended PPE is a protective ensemble consisting of structural fire fighting protective garments, helmets, hoods, gloves, and footwear worn with self-contained breathing apparatus (SCBA), which will afford an appropriate level of dermal and respiratory protection for all risk levels against synthetic opioids and their analogues. Specific recommendations are provided for each PPE category: garments, gloves, eye/face/respiratory protection devices, and footwear).

Table 3 describes the recommended PPE items in terms of their physical features and general performance characteristics. Several alternative configurations are suggested, along with approaches for their integration as an overall ensemble.

Table 3. Recommended Personal Protective Equipment Descriptions

PPE Recommendations	Skin Protection	Eye/Face/Respiratory Protection
Low Risk PPE (I)	• Nitrile gloves, certified to NFPA 1999 (Single Use Examination Gloves) • Uniform	• None
Moderate Risk / Small Volume Hazard (II)	• Nitrile gloves, certified to NFPA 1999 (Single Use Examination Gloves) • Uniform	• P100 Filtering face piece respirator with safety glasses
Fire Risk (III)	• Structural fire fighting protective ensemble (garments, helmet, hood, gloves, and footwear), certified to NFPA 1971	• Self-contained breathing apparatus, certified to NFPA 1981
Moderate Risk / High Volume Hazard (IV)	• Nitrile gloves, certified to NFPA 1999 (Single Use Examination Gloves) • Uniform • Long sleeve and/or sleeve covers	• P100 Filtering face piece respirator with non-vented or indirect vented goggles; Half mask air-purifying respirator (APR) with P100 filters and non-vented or indirect vented goggles; or full-facepiece APR with P100 filters
High Risk / Particulate Hazard (V)	• Multiple-use emergency medical protective ensemble (garments, gloves, and footwear), certified to NFPA 1999; or Class 4 or 4R protective ensemble (garment, gloves, footwear) certified to NFPA 1994	• Full-facepiece APR with P100 filters; powered air-purifying respirator (PAPR) with high-efficiency particulate air (HEPA) filter; or self-contained breathing apparatus, certified to NFPA 1981
High Risk / Chemical Hazard (VI)	• Class 3, 3R or higher protective ensemble (garments, gloves, footwear) certified to NFPA 1994 or NFPA 1991	• Full facepiece chemical , biological, radiological, nuclear (CBRN) APR or CBRN PAPR; or self-contained breathing apparatus, certified to NFPA 1981

The **Appendix** provides specific certifications, standards, and performance levels for recommended PPE. These should be reviewed before procuring any equipment. It also provides links to sites which provide assistance in locating certified products where applicable.

Tables 2 and 3 must be used together to determine the specifications for the respective PPE items.

B. PPE Use – Donning

The selected PPE must be donned in the correct order to provide effective protection against contact with synthetic opioids. The specific donning order depends on the PPE items comprising the ensemble, as the donning process is affected by how interfaces are formed. All PPE should be donned in accordance with an established SOP, under supervision, and with assistance as needed.

WARNING

While taping may be recommended for some interfaces, it is important to use tape that does not degrade protection. For example, when tape is removed during doffing (particularly a tape with strong adhesive, such as duct tape) it can tear the garment. ***Respirators should never be taped to the hood of a protective coverall or other PPE—this can disrupt the fit of the respirator, which affects its protective performance.***

C. PPE Use – Doffing

Extreme care must be exercised when doffing PPE following use where contamination has occurred or is suspected. A specific sequence for doffing the PPE must be followed, in an order that prevents any contamination transfer from the PPE to the wearer or others. The following considerations should be included in operating procedures for doffing ensembles with known or suspected contamination:

- The wearer must assume that any surface could be contaminated.
- All doffing must be performed under supervision and with assistance as needed.
- The *last items removed* should be the face/eye protection or respirator, and inner gloves.
- Any time the wearer or an individual assisting the wearer in the doffing process touches a potentially contaminated surface or PPE item, the wearer or assisting individual must rinse his/her gloved hands with an appropriate decontamination solution that does not cause the gloves to degrade.
- For some types of ensembles, it is possible to cut off the garment to permit easier doffing without contacting contaminated surfaces. If cutting of the garment is performed, then the procedures used for the cutting process should be accounted for in the garment's design (e.g., the placement of seams and closures).

D. Additional Considerations in PPE Selection and Use

Each organization should ensure that it develops specific SOPs covering all elements of use including donning, doffing, and disposing of PPE following use. If PPE is contaminated, it must be isolated, contained, and disposed in accordance with federal, state, and local regulations, as applicable to the specific jurisdiction. Finally, all organizations that engage in response operations where responders may need to use PPE against synthetic opioid exposure must annually train their members in these procedures.

E. Basis of IAB PPE Recommendations

Wherever possible, these PPE recommendations are based on recognized consensus standards that have been applied to PPE, including protective clothing and respiratory equipment. *Referenced standards and attributes should be part of any purchase specifications for selecting PPE*.

III. DECONTAMINATION RECOMMENDATIONS

A. Personal Decontamination

Areas of direct skin contact with any residue suspected of containing synthetic opioids should be immediately washed with copious amounts of water. As soon as feasible, skin surfaces should be additionally washed with soap and water. Use of alcohol-based hand disinfectants or hypochlorite bleach solutions must be avoided as they may enhance skin absorption of fentanyl analogues.

B. PPE Decontamination

Contaminated PPE should be removed using techniques that prevent aerosolizing powdered contaminants while avoiding unprotected contact with the outer layers of the PPE. All items should be isolated for further decontamination or disposal. Consider decontaminating the surface of the PPE prior to doffing using a highly absorbent wipe, like Fibertect™, and a peracetic acid (5%) or hydrogen peroxide-based (10%) decontamination solution. Minimize the use of free chlorine-based decontamination solutions, such as dichloroisocyanuric acid, on PPE surfaces as they may deteriorate the PPE materials.

Should potential exposure to synthetic opioids occur during firefighting operations, the PPE should be lightly wetted, removed, and stored in a bag until proper washing can be performed.

WARNING

Care must be taken in decontaminating PPE. Many recommended decontaminants are not designed for use on PPE. Improper decontamination processes or solutions can damage single-use PPE during the doffing process and cause exposure. Further, the impact of decontamination on multiple-use PPE items (e.g., respirator facepieces or the seams of multi-use garments) is not fully known. Multi-use PPE should be carefully inspected after decontamination and any deterioration monitored.

A common (and improper) approach to decontamination is to increase the strength of a decontamination solution to improve effectiveness. This should NEVER be attempted when decontaminating PPE.

C. Contaminated Surface and Equipment Decontamination

Contaminated surface areas should be decontaminated using one of the following:

- Dahlgren Decon solution
- a 5% solution of peracetic acid
- a 10% hydrogen peroxide
- a 12% dichlor/trichlor solution (dichloro- or trichloroisocyanuric acids)

WARNING

Never mix dichloro- or trichloroisocyanuric acids with hypochlorite (bleach) compounds, as severe chemical reactions can occur. Never use these decontamination solutions on human skin.

For jurisdictions that routinely employ environmental health resources to ensure community protection following an event, PPE recommendations in line with the Decon Operations sector should be employed.

D. Basis of IAB Decontamination Recommendations

Decontamination recommendations are based upon scientific studies available at the time of this document's development.

IV. DETECTION RECOMMENDATIONS

Do not interact with samples without appropriate PPE. In the case of synthetic opioids, the first determination should be whether detection and identification of the material will change the response. If the answer is no, then strong consideration should be given to not interacting with the threat material for detection purposes. Instead, while wearing appropriate PPE, it should be packaged and provided to law enforcement for laboratory testing.

Always develop incident-specific detection strategies to inform the selection of risk control measures and the overall status of the emergency.

The detection strategy should include the following detector performance characteristics:

- Linear range
- Limit of detection
- Cross sensitivities
- Response times
- Interferences
- Recommended operating environment
- Detector specificity
- Quantitative/qualitative capabilities
- Operating requirements

In responses to incidents involving potential synthetic opioids, the hazard is assumed to be present, usually because a synthetic opioid is visible or a patient is exhibiting symptoms of opioid exposure. If there is no visible material, a trace technique is required. Trace techniques can measure amounts less than 1 microgram, which are difficult to see without amplification. For this reason, samples are generally taken by "swiping" a surface and thermally desorbing the threat off the swab into the instrument of interest. When bulk samples are available (great than 1 microgram), a variety of options for detection are available, each with its own pros and cons. **Table 4** lists technologies for which there is data demonstrating their performance for the detection of synthetic opioids.

Table 4. Technology Recommendations for Synthetic Opioid Detection by Exposure Risk

Potential Synthetic Opioid Exposure Risk	Technology Recommendations
Minimal (no visible product)	Trace – Thermal Desorption Mass Spectrometry Trace – Ion Mobility Spectroscopy
Moderate (small volume; known or suspected product visible; patients)	Trace – Thermal Desorption Mass Spectrometry Trace – Ion Mobility Spectroscopy Bulk – Raman Spectroscopy Bulk – Infrared Spectroscopy
Moderate (large volume storage/distribution)	Trace – Thermal Desorption Mass Spectrometry Trace – Ion Mobility Spectroscopy Bulk – Raman Spectroscopy Bulk – Infrared Spectroscopy Bulk – Colorimetric
High (milling lab) [particulates]	Trace – Thermal Desorption Mass Spectrometry Trace – Ion Mobility Spectroscopy Bulk – Raman Spectroscopy Bulk – Infrared Spectroscopy Bulk – Colorimetric General – Dust Meter General – Oxygen/Lower Explosives Limit
High (production lab) [chemicals]	Trace – Thermal Desorption Mass Spectrometry Trace – Ion Mobility Spectroscopy Bulk – Raman Spectroscopy Bulk – Infrared Spectroscopy Bulk – Colorimetric General – Dust Meter General – Oxygen/Lower Explosives Limit/Carbon Monoxide General – Photoionization Detector

A. Drug Enforcement Administration

The DEA released a guidance document entitled "Fentanyl – A Briefing Guide for First Responders" (https://www.dea.gov/druginfo/fentanyl.shtml) earlier this year. The document provides the following guidance regarding sampling and detection of suspected fentanyl materials:

> *If the presence of fentanyl or any synthetic opioid is suspected, personnel should immediately contact the appropriate officials within their agency who have been trained to handle hazardous materials, or contact the nearest DEA field office for assistance. Having specially trained law enforcement (or hazardous materials "HAZMAT" incident response team) professionals equipped with the necessary equipment, to include Level "A" PPE, on-site to assess the situation prior to exposure or contamination is recommended. This includes situations involving unknown powdered substances and/or pill milling or encapsulating operations.*

B. Laboratory Response Network

The CDC established a network of laboratories known as the Laboratory Response Network (LRN) to respond to biological (LRN-B) and chemical (LRN-C) threats. These laboratories are located at state public health laboratories throughout the country and can be a vital resource to first responders with respect to suspected opioid exposures. Some LRN-C laboratories have the capability to rapidly identify opioids, including fentanyl and related analogues when an exposure is suspected.

Contact the LRN-C laboratory in your jurisdiction for guidance, prior to bringing samples to the laboratory. If you do not know who your LRN contact is, contact your local FBI WMD Coordinator for assistance.

V. MEDICAL COUNTERMEASURES

All first responders, particularly law enforcement, should be aware of several significant side effects that could complicate their contacts with overdose patients. Communities, states, and drug treatment professionals across the US have begun to support the use of naloxone to reduce the number of opioid overdose-related deaths. Naloxone (brand name Narcan) is a safe, rapid, and easily administered antidote previously used only by medical personnel to reverse the effects of opioid overdoses. In cases of accidental overdose where patients have difficulty breathing or stop breathing, first responders can use naloxone to save the patients' lives. For this reason, the IAB supports the position of state and local jurisdictions in favor of making naloxone available to law enforcement to facilitate its timely use in reversing opioid overdoses.

A. Naloxone

Naloxone is available over-the-counter in many jurisdictions. Naloxone is a liquid, administered intramuscularly by auto-injection, as a nasal spray, or intravenously by a medical professional to counteract an overdose. Opioid overdose symptoms include excessive sleepiness, not responding to loud voices, inadequate or absent breathing, and cyanosis (patient appears blue). If a patient possesses paraphernalia consistent with opioid use, has a history of overdose and/or a medical history consistent with opioid use, and shows symptoms of an overdose, responders may administer naloxone.

Shortly after the naloxone is administered, overdose symptoms should diminish and normal breathing and cognition should return. It is important to have an Emergency Medical Technician (EMT) or other medical personnel respond to the scene and handle further contact with the patient. The patient must be transported to

the appropriate medical facility for monitoring and treatment. It is appropriate and may be necessary to provide the patient with more than one dose of naloxone.

Patients receiving naloxone may show signs of opioid withdrawal, such as restlessness, agitation, nausea, vomiting, increased sweating, trembling, and headache. Rarely, patients may experience seizures, heart rhythm changes, or pulmonary edema. Patients experiencing these symptoms can be disruptive and will be very uncomfortable, angry, and possibly violent. As the naloxone wears off, the patient can exhibit the underlying effects of the opioid. For more information on the opioid overdose triad of symptoms, see the World Health Organization information sheet on opioid overdose at: http://www.who.int/substance_abuse/information-sheet/en.

B. Recommendations for Implementation

The IAB recommends that jurisdictions implementing or considering implementing responder-administered naloxone for opiate overdoses consider the following:

1. Confirm there are no state or jurisdictional statutes or regulations precluding law enforcement officers from functioning in this capacity.
2. Seek medical advice from a local EMS Medical Director.
3. Establish an opioid overdose treatment protocol within jurisdictional guidance and requirements.
4. Implement training for responders on opioid overdose treatment.
5. Implement response protocol with interdisciplinary representation.

APPENDIX – DETAILED SPECIFICATIONS/STANDARDS FOR RECOMMENDED PPE WITH ASSOCIATED STANDARDIZED EQUIPMENT LIST[1] (SEL) LINKS

Item	Description and Specifications	SEL Item No.
Uniform Uniform Uniform	Standard shirt and pants or coverall used by organization in course of normal duties; generally pants with short or long sleeve shirt *For moderate risk/high volume hazard, long sleeve shirt should be worn or sleeve covers provided if short sleeve shirt is worn*	01ZA-05-UNDR 01ZA-05-UNFR
Nitrile gloves Nitrile gloves Nitrile gloves	Disposable nitrile gloves certified as single-use emergency medical examination gloves in accordance with NFPA 1999 or meeting ASTM D6319; nitrile rubber is recommended over latex rubber due to large incidence of latex allergies among US population	01EM-03-GLME
P100 filtering facepiece respirator P100 filtering facepiece respirator	Disposable filtering facepiece respirator with P100 filter classification certified by NIOSH in accordance with 42 CFR Part 84. For a list of certified products, see: https://www2a.cdc.gov/drds/cel/cel_form_code.asp	01AR-06-DISP
Safety glasses	Safety glasses that meet ANSI/ISEA Z87.1	01ZA-03-EYEP
Structural fire fighting protective ensemble	Structural firefighting protective ensemble consisting of garment (coat and pants or coverall), helmet, hood, gloves, and footwear, with all items certified to NFPA 1971; ensemble elements should be selected for compatibility and interoperability	01SF-01-GARM 01SF-01-HMLT 01SF-01-HOOD 01SF-01-GLOV 01SF-01-FTWR
Self-contained breathing apparatus Self-contained breathing apparatus Self-contained breathing apparatus	Open circuit, self-contained breathing apparatus with CBRN protection, certified to NFPA 1981, with or without Personal Alert Safety System (PASS) device *Consider additional respirator protection when worn for high risk/particulate or high risk/chemical hazard applications*	01AR-01-SCBA
Sleeve covers	Disposable or washable sleeve protectives with elasticized ends; covers may be constructed of any textile or coated material and should worn over end of gloves and extend to upper arm leaving no exposed skin	No specific SEL item
Goggles	Cover style goggles that are either non-vented or indirect vented that meet ANSI/ISEA Z87.1	01ZA-03-EYEP

[1] The Standardized Equipment List (SEL) is a list of generic equipment items recommended by the IAB to local, tribal, state, and federal government organizations in preparing for and responding to all-hazards mass casualty events, with an emphasis on CBRNE. An interactive version of the SEL is available at https://iab.gov/SELint.aspx

Item	Description and Specifications	SEL Item No.
Half mask APR with P100 filters	Reusable, elastomeric, tightfitting half mask air-purifying respirator with filters meeting P100 particulate classification certified by NIOSH in accordance with 42 CFR Part 84. For a list of certified products, see: https://www2a.cdc.gov/drds/cel/cel_form_code.asp *Respirator must be worn with goggles to provide cover all mucous membrane areas of wearer's face*	01AR-06-REUS
Full facepiece APR with P100 filters Full facepiece APR with P100 filters	Reusable, elastomeric, tight fitting, full facpiece air-purifying respirator with filters meeting P100 particulate classification certified by NIOSH in accordance with 42 CFR Part 84. For a list of certified products, see: https://www2a.cdc.gov/drds/cel/cel_form_code.asp	01AR-06-REUS
Multiple-use emergency medical protective ensemble	Full protective ensemble consisting of multiple-use emergency medical garment, single-use examination gloves worn underneath either cleaning or utility gloves or multiple-use work gloves, with appropriate footwear *Overall ensemble and selected respiratory protection must be certified to NFPA 1999*	01EM-02-GARM 01EM-03-GLME 01EM-03-GLCL 01EM-03-GLMW 01EM-04-FTWC 01EM-04-FTWF
Class 4 or 4R protective ensemble	Full protective ensemble designed for particulate and biological aerosol protection, consisting of garment, gloves, with appropriate footwear *Overall ensemble and selected respiratory protection must be certified to NFPA 1994, Class 4 or 4R; Type 4R ensembles affords greater strength, durability, and ruggedness*	01CB-04-ENSM
PAPR with HEPA filter	Reusable, elastomeric, tightfitting full facepiece powered air purifying respirator with high-efficiency particulate air (HEPA) filter or loose-fitted (hooded) powered air purifying respirator with HEPA filter certified by NIOSH in accordance with 42 CFR Part 84. For a list of certified products, see: https://www2a.cdc.gov/drds/cel/cel_form_code.asp	01AR-03-PAPM
Class 3, 3R or higher protective ensemble	Full protective ensemble designed for low levels of chemical liquid and vapor protection, consisting of garment, gloves, with appropriate footwear *Overall ensemble and selected respiratory protection must be certified to NFPA 1994, Class 3 or 3R; alternatively, higher level ensembles can be employed that include Class 2 or 2R, Class 1, or NFPA 1991 compliant ensembles; Type R ensembles afford greater strength, durability, and ruggedness for the same class of ensemble; The specific level of protection should be based on a hazard and risk assessment that accounts for the specific anticipated chemical exposure hazards*	01CB-03-ENSM

Item	Description and Specifications	SEL Item No.
CBRN/APR	Reusable, elastomeric, tight fitting, full facepiece air-purifying respirator provided with CBRN cartridges or canisters certified by NIOSH in accordance with 42 CFR Part 84 and the NIOSH Statement of Standard for CBRN APR. For a list of certified products, see: https://www2a.cdc.gov/drds/cel/cel_form_code.asp	01AR-02-APR
CBRN/PAPR	Reusable, elastomeric, tight fitting full facepiece powered air purifying respirator or loose-fitted (hooded) powered air purifying respirator provided with CBRN cartridges or canisters certified by NIOSH in accordance with 42 CFR Part 84 and the NIOSH Statement of Standard for CBRN PAPR. For a list of certified products, see: https://www2a.cdc.gov/drds/cel/cel_form_code.asp	01AR-03-PAPA

Modern Healthcare

California ER use jumps despite Medicaid expansion

By Virgil Dickson

California is the latest state to report that emergency room usage is up despite expanding Medicaid eligibility.

Emergency room visits by people on Medi-Cal, the state's Medicaid program, rose 75% over five years from 800,000 in the first quarter of 2012 to 1.4 million in the last quarter of 2016, according to California's Office of Statewide Health Planning and Development.

Similar findings have also been noted in studies on Illinois, Massachusetts and Oregon. The trend contradicts what policy experts thought would happen if people gained more insurance coverage. They could also give Republican lawmakers the ammunition they need to dramatically overhaul Medicaid, as they propose in the American Health Care Act that passed the U.S. House of Representatives.

From 2013 to 2016, enrollment in Medi-Cal grew by 57%; 5 million new members were added, bringing current enrollment to 13.5 million. Medi-Cal now covers more than one-third of all Californians, leading some to claim that it's the closest to universal coverage of any state.

California health officials couldn't explain the rise, but providers think they have an answer.

"There has not been an increase in physicians willing to see Medi-Cal patients, mostly because the payment rates are so low," said Jan Emerson-Shea a spokeswoman for the California Hospital Association. Therefore, newly enrolled Medi-Cal patients continue to seek care in hospital ERs because they cannot access primary care in physician offices and clinics.

California ranks 47th in the nation for payment rates for providers, according to the CMS.

Republicans have already used reports of increased ER usage in expansion states and rising spending in the program as reasons to convert Medicaid into a per capita cap system.

Medicaid spending jumped 4.3% to $575.9 billion in 2016 with the federal share growing 4.5% to $363.4 billion, according to the CMS.

"Despite these significant investments, one-third of doctors in America do not accept new Medicaid patients," HHS Secretary Tom Price told the Senate Appropriations Committee on Thursday. "We need structural reforms that equip states with the resources and flexibility they need to serve their unique Medicaid populations in a way that is as compassionate

and as cost-effective as possible."

Price supports President Donald Trump's budget proposal that includes a $600 billion cut to Medicaid over the next decade.

The trend in rising ER visits could also support Republican's rationale for imposing co-pays on those services, according to Josh Archambault, senior fellow at the Foundation for Government Accountability, a conservative think tank. Wisconsin **recently submitted a waiver** for such a requirement.

"Hopefully these kinds of reports grant urgency to change Medicaid and the health system it operates in," Archambault said.

High ER use in expansion states also gives Republicans some political cover as they seek to roll back Medicaid expansion.

"The argument that expanding coverage would reduce ER use was always a bit of a canard used to sell the ACA," said Charles Blahous a senior research fellow for the Mercatus Center, a conservative research organization, adding that while the information would have been useful when crafting the ACA, the findings could still be useful to discount the notion that any decrease in Medicaid coverage would lead to more ER visits.

Dr. Larry Stock, president of the California chapter of the American College of Emergency Physicians, worries how Medicaid cuts and ER visit co-pays could affect patients.

"We don't want to scare people from coming into the emergency department if they need to," he said.

In California, provider groups have lobbied for new taxes that could increase reimbursement for providers and boost the number of residency slots in the state.

Insurers say in order to affect the number of ER visits, patients need to be better informed about their options in healthcare especially since many who enrolled under expansion had never before had coverage.

Mary Ellen Grant, a spokeswoman for the California Association of Health Plans, said plans will continue to work with providers to lower ER overuse.

Article links

Homeless people overuse ERs. Sacramento has a $64 million plan to fix the problem

BY ANITA CHABRIA
achabria@sacbee.com

JUNE 13, 2017 5:00 AM

Sacramento is set to receive about $32 million in federal funds over nearly four years to keep homeless people out of emergency rooms, making it the only city in California to participate in a pilot program meant to reach the state's poorest and sickest people before they need critical care.

Mayor Darrell Steinberg, who has long focused on mental health issues, said Monday that if approved by the City Council, the funds would help the city take an "aggressive approach" to getting people off the streets by targeting those with the most severe problems and often the greatest resistance to accepting help. The state-run program uses federal health care dollars to target people who overuse expensive services such as emergency rooms and ambulances.

"We're living with the consequences of untreated mental illness and the lack of a comprehensive way to alleviate homelessness in a significant way," Steinberg said.

Previously, only counties, tribal agencies or certain other groups could apply for the money, which is officially known as the Whole Person Care pilot program. But after the county of Sacramento decided not to pursue the funding last year, the city asked and received permission from the California Department of Health Care Services to apply alone, Steinberg said.

The city expects the money will let it reach 3,250 people during the 3 1/2 years the program will run, doubling or tripling its current capacity for outreach and potentially putting half of those people into housing. The city also hopes to lower the caseload of outreach workers during the same period by up to 75 percent so that those navigators can give more attention to each client.

The pilot program is run by the state but uses federal money from Medicare and Medicaid. The money can't be used for housing, but is meant to fund medical and

social services that can get people on the path toward housing and help them obtain medical and psychological treatment.

Participating hospitals will create a database of people who frequently come into emergency rooms, said Emily Halcon, the city's homeless services coordinator. If they qualify for Medi-Cal and are homeless or at risk of homelessness, the city will pay for outreach workers to find them on the streets and intervene before they use expensive critical care services.

"We don't want it to be you happen to run across a navigator in the system so you get service," said Halcon. "We're going to have the resources to go there and find them."

Along with finding out who is using emergency rooms, Steinberg envisions putting mental health professionals on ambulances and with police to funnel more people into housing programs where they can also receive "wrap-around" services such as counseling and addiction treatment. He also wants to hire more skilled outreach workers so they can serve severely mentally ill people or those resistant to help.

"The amount of time and money that our Police Department, our Fire Department and Public Works spends on the mess that is homelessness, we can put those resources to other community priorities," Steinberg said.

The city is partnering with local health care providers including Sutter Health, Dignity Health, UC Davis and Kaiser Permanente as well as nonprofit agency Sacramento Covered to gather an initial investment of about $8 million a year for almost four years. For every dollar the city invests, it will get a matching dollar from the state, bringing in up to $64 million by 2020 for health-related services to homeless people and those at risk of losing their housing.

The first year, the city expects to invest $2.3 million of its own money and $5.7 million from health care partners in the program. Sacramento Covered has pledged about $2.2 million annually over four years while Sutter is giving just over $2 million a year. Dignity is contributing $1.5 million annually, Kaiser will give $500,000 a year for three years and UC Davis will contribute $250,000 annually for three years.

The Sacramento program is expected to start by early next year if the City Council votes Tuesday to join the program.

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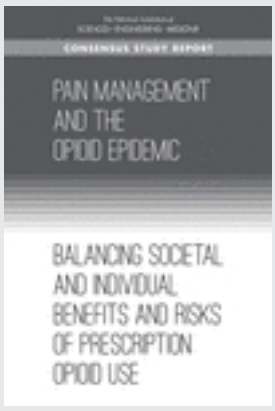

Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use

DETAILS

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PAIN MANAGEMENT AND THE OPIOID EPIDEMIC

BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE

Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse

Richard J. Bonnie, Morgan A. Ford, and Jonathan K. Phillips, *Editors*

Board on Health Sciences Policy

Health and Medicine Division

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This Consensus Study Report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We thank the following individuals for their review of this report:

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Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this report nor did they see the final draft before its release. The review of this report was overseen by **KRISTINE M. GEBBIE,** Flinders University, and **SARA ROSENBAUM,** George Washington University. They were responsible for making certain that an independent examination of this report was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

Preface

Nature and human ingenuity have spawned a class of opioid drugs that alleviate pain and, not coincidentally, induce feelings of well-being. Unfortunately, overprescribing and misuse of these drugs pose serious risks to individuals who consume them and the population at large. Industrial and post-industrial societies have been grappling with the challenge of balancing these benefits and risks for more than 150 years. Alarmingly, rates of opioid use disorder (OUD) and opioid overdose deaths have reached unprecedented levels over the past two decades, and have risen much faster in the United States than in most other countries.

U.S. Department of Health and Human Services data suggest that at least 2 million Americans have an OUD involving prescribed opioids and nearly 600,000 have an OUD involving heroin, with about 90 Americans dying every day from overdoses that involve an opioid. Recognizing the magnitude of the problem, the U.S. Food and Drug Administration (FDA) asked the National Academies of Sciences, Engineering, and Medicine to characterize the epidemic and to recommend actions that the FDA and other public and private organizations should take to address it, balancing society's interest in reducing opioid-related harms with the needs of individuals suffering from pain. It was my privilege to chair a committee of talented experts chosen by the National Academies to carry out this important charge.

Few communities have been left untouched by the recent surge of opioid-related deaths. Perhaps at no time in modern history has there been broader public understanding of the nature and consequences of substance use disorder, including OUD. Indeed, the broad reach of the epidemic has blurred the formerly distinct social boundary between use of prescribed opioids and use of heroin and other illegally manufactured ones. These unfortunate developments may have finally reframed the "cops vs. docs" debate that has characterized U.S. drug policy since World War II.

It has become clear (and is well-documented in this Consensus Study Report) that the opioid epidemic will not be controlled without deploying multiple policy tools. Increasing access to treatment for individuals with OUD is imperative, together with a substantial program of research to develop new non-addictive treatments for pain. The committee urges the FDA to reshape and monitor the legal market for opioids and to facilitate use of safe and effective agents for treating persons with OUD and reducing overdose deaths. In addition, the professional societies, insurers, health care organizations, pharmaceutical manufacturers, and state and federal agencies collectively responsible for shaping prescribing practices should attend to the multiple weaknesses in the nation's health system that led to this epidemic. Meanwhile, law enforcement agencies will continue to be responsible for curtailing trafficking in illegally manufactured opioids, most recently the low-priced, high-potency fentanyl manufactured in clandestine labs domestically and also streaming into the country from abroad. Although criminal drug law

enforcement was beyond the scope of this report, the need for improved tools for tracking the dynamic interaction between the legal and illegal markets is one of its core themes.

The Controlled Substances Act, which provides one of the two prongs of federal statutory regulation of opioids (the other being the Food, Drug and Cosmetic Act), was enacted by Congress in 1970, as part of an omnibus drug policy bill that also established the National Commission on Marijuana and Drug Abuse, for which I had the honor of serving as Associate Director. The Commission's second report, issued in 1973, championed strong roles for federal public health agencies, and for federally funded scientific research, in a coordinated national policy for substance use disorder prevention and treatment. Perhaps the tragic effects of the opioid epidemic will reinvigorate federal leadership and provide the impetus for comprehensive and sustained national action.

Richard J. Bonnie, *Chair*
Committee on Pain Management and Regulatory Strategies
to Address Prescription Opioid Abuse

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BOXES

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Abbreviations and Acronyms

ACA	Patient Protection and Affordable Care Act
ADF	abuse-deterrent formulation
ADAM	Arrestee Drug Abuse Monitoring
APAP	N-Acetyl-p-Aminophenol (acetaminophen)
ARRIVE	Animals in Research: Reporting In Vivo Experiments
ASAM	American Society of Addiction Medicine
BMT	buprenorphine maintenance therapy
CASP6	caspase-6
CB	cannabinoid receptor
CBT	cognitive behavioral therapy
CDC	U.S. Centers for Disease Control and Prevention
CHARM	Children and Recovering Mothers
CNS	central nervous system
CoEPE	Center of Excellence in Pain Education
COX	cyclooxygenase
CRPS	complex regional pain syndrome
CSA	Controlled Substances Act
CSF1	colony-stimulating factor 1
DA	dopamine
DATA	Drug Addiction Treatment Act of 2000
DAMP	damage-associated molecular patterns
DDD	defined daily dose
DEA	Drug Enforcement Administration
DIRE	Diagnosis, Intractability, Risk, Efficacy tool
DOD	U.S. Department of Defense
DOPR	delta opioid receptor
DSM	Diagnostic and Statistical Manual of Mental Disorders
DTC	direct-to-consumer
DUR	drug utilization review
EEG	electroencephalogram
EMR	electronic medical record
EpFAs	epoxy fatty acids

ER/LA	extended-release/long-acting
ERK	extracellular signal-regulated kinases
ETASU	elements to assure safe use
FAERS	FDA's Adverse Event Reporting System
FDA	U.S. Food and Drug Administration
FDASIA	FDA Safety and Innovation Act of 2012
FDCA	Food, Drug, and Cosmetic Act
fMRI	functional magnetic resonance imaging
FQHC	Federally Qualified Health Center
GI	gastrointestinal
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
HCV	hepatitis C virus
HHS	U.S. Department of Health and Human Services
HIV	human immunodeficiency virus
HMGB1	high mobility group box 1 protein
ICD	International Classification of Diseases
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
IND	Investigational New Drug
IOM	Institute of Medicine
IPRCC	Interagency Pain Research Coordinating Committee
IR	immediate-release
KOPR	kappa opioid receptor
MAT	medication-assisted treatment
MCH	maternity care home
MDE	morphine daily equivalent
MED	morphine equivalent dose
MME	morphine milligram equivalents
MMT	methadone maintenance treatment
MOMS	Maternal Opioid Medical Supports
MOPR	Mu (μ) opioid receptor
NAc	nucleus accumbens
NAS	neonatal abstinence syndrome
NAVIPPRO	National Addictions Vigilance Intervention and Prevention Program
NDA	New Drug Application
NeuPSIG	Neuropathic Pain Special Interest Group
NFLIS	National Forensic Laboratory Information System
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NMDA	N-methyl-D-aspartate receptor

NMPR	nonmedical pain relief
NNT	number needed to treat
NorBNI	Norbinaltorphimine
NSAID	non-steroidal anti-inflammatory drug
NSDUH	National Survey on Drug Use and Health
OIH	Opioid-induced hyperalgesia
ONDCP	Office of National Drug Control Policy
OPRM1	micro opioid receptor gene 1
OR	opioid receptor
ORT	Opioid Risk Tool
OTC	over-the-counter
OTP	opioid treatment program
OUD	opioid use disorder
PAMP	pathogen-associated molecular patterns
PDMP	prescription drug monitoring program
PDUFA	Prescription Drug User Fee Act
PG	prostaglandin
PHN	postherpetic neuralgia
POATS	Prescription Opioid Addiction Treatment Study
POMAQ	Prescription Opioid Misuse and Abuse Questionnaire
PPA	patient-provider agreement
PPRECISE	Preclinical Pain Research Consortium for Investigating Safety and Efficacy
PRBC	packed red blood cells
PRR	pattern recognition receptors
PSUR	Periodic Safety Update Report
PVB	paravertebral blocks
PWID	people who inject drugs
QALY	quality-adjusted life years
QL	quantity limit
RA	rheumatoid arthritis
RADARS	Researched Abuse, Diversion, and Addiction-Related Surveillance
RAGE	receptor for advanced glycation end products
RCRA	Resource Conservation and Recovery Act
RCT	randomized controlled trial
REMS	Risk Evaluation and Mitigation Strategies
RF	radiofrequency
RICO	Racketeer Influenced and Corrupt Organizations Act
SAFE	Safety, Appropriateness, Fiscal Neutrality, and Effectiveness
SAMHSA	Substance Abuse and Mental Health Services Administration
SCS	spinal cord stimulation
sEH	soluble epoxide hydrolase

SIF	safe injection facility
SIH	supervised injectable heroin
SIS	Spinal Intervention Society
SMB	state medical board
SNP	single nucleotide polymorphism
SNRI	serotonin–norepinephrine reuptake inhibitors
SOAPP	Screener and Opioid Assessment for Patients with Pain
SSRI	selective serotonin re-uptake inhibitors
SUD	substance use disorder
TCS	tricyclic antidepressants
TEDS	Treatment Episodes Data Set
TEDS-D	Treatment Episodes Data Set - Discharges
THC	tetrahydrocannabinol
TIRF	transmuscosal immediate-release fentanyl
TNF	tumor necrosis factor
TLR	toll-like receptor
TRPA1	transient receptor potential cation channel, member A1
TRPV	transient receptor potential cation channel, subfamily V
TTX	tetrodotoxin
UK	United Kingdom
US	United States
VA	Department of Veterans Affairs
VGSC	voltage-gated sodium channel
VHA	Veterans Health Administration
VTA	ventral tegmental area
WHO	World Health Organization

Summary[1]

The ongoing opioid crisis lies at the intersection of two substantial public health challenges—reducing the burden of suffering from pain and containing the rising toll of the harms that can result from the use of opioid medications. In March 2016, the U.S. Food and Drug Administration (FDA) asked the National Academies of Sciences, Engineering, and Medicine (the National Academies) to convene an ad hoc committee to

- update the state of the science on pain research, care, and education since publication of the 2011 Institute of Medicine (IOM) report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,* including the evolving role of opioids in pain management;
- characterize the epidemiology of the opioid epidemic and the evidence on strategies for addressing it;
- identify actions the FDA and other organizations can take to respond to the epidemic, with a particular focus on the FDA's development of a formal method for incorporating individual and societal considerations into its risk-benefit framework for opioid approval and monitoring; and
- identify research questions that need to be addressed to assist the FDA in implementing this framework.[2]

In the context of the growing opioid problem, the FDA launched an Opioids Action Plan in early 2016. One component of the FDA plan is to reassess the agency's risk-benefit framework for opioid approval and monitoring. The FDA commissioned this study specifically to inform this reassessment.

The committee interpreted its charge as focusing primarily on prescribed opioids, although its analysis of the epidemiology of the opioid epidemic and strategies for addressing it took into account the diversion of prescription opioids into illicit markets and the impact of use of prescription opioids on use of illicit opioids, such as heroin. This analytical approach was necessary because markets for these drugs have been found to be interrelated. Furthermore, as the FDA cannot address the opioid problem on its own, the committee directs a number of its recommendations at other stakeholders, such as federal agencies other than the FDA, state agencies, and payers, among others.

[1]This summary does not include references. Citations for the findings presented in the summary appear in subsequent chapters of the report.
[2]The full statement of task is presented in Chapter 1 of the report.

BACKGROUND

Over the past 25 years, the United States has experienced a dramatic increase in deaths from opioid overdose, opioid use disorder (OUD), and other harms in parallel with increases in the prescribing of opioid medications for pain management. During the period from 1999 to 2011, the annual number of overdose deaths from prescription opioids tripled (see Figure S-1). While the annual number of deaths from prescription opioids remained relatively stable between 2011 and 2015, overdose deaths from illicit opioids (including heroin and synthetic opioids such as fentanyl) nearly tripled during this time period, driven in part by a growing number of people whose use began with prescription opioids. Drug overdose, driven primarily by opioids, is now the leading cause of unintentional injury deaths in the United States. As of 2015, 2 million Americans aged 12 or older had an OUD involving prescription opioids, and nearly 600,000 had an OUD involving heroin.

Pain is a complex syndrome, often difficult to measure or treat, and is associated with comorbidities (e.g., depression); disability; and social costs, such as work absenteeism and increased utilization of medical resources. Accordingly, meeting the needs of the tens of millions of U.S. residents suffering from pain (including acute pain, chronic pain, or pain at the end of life) requires access to a broad armamentarium of therapies for pain management.

The vast majority of people who are prescribed opioids do not misuse them. However, opioids can produce feelings of pleasure, relaxation, and contentment, leading to an overreliance on these drugs in many patients and to misuse and OUD in others. Moreover, many lawfully dispensed opioids make their way into the hands of people for whom they were not intended, including participants in illicit markets. As a result, harms associated with use of prescription opioids affect not only patients with pain themselves but also their families, their communities, and society at large.

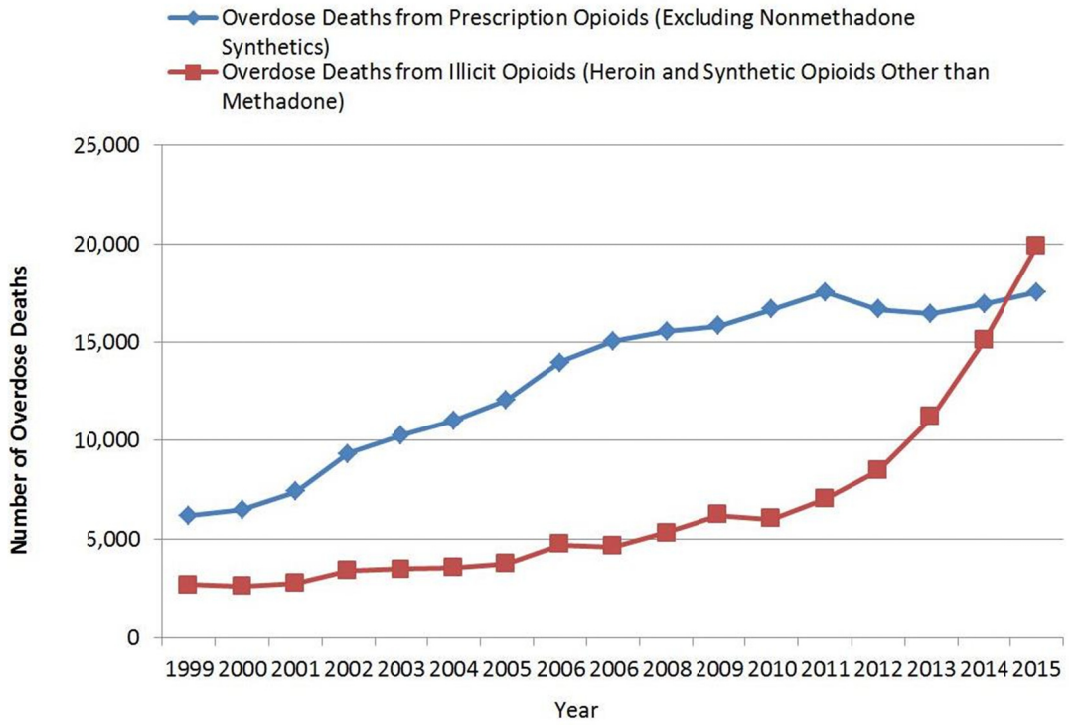

FIGURE S-1 Number of overdose deaths from prescription and illicit opioids, United States, 1999–2015.

The complexity of pain is matched by the complexity of achieving appropriate use of opioids in the context of the often suboptimal clinical management of pain within the fragmented U.S. health care delivery system. A further complication is the stigma associated with OUD and the persistent poor access to evidence-based OUD treatment services. The committee believes it is possible to stem the still-escalating prevalence of OUD and other opioid-related harms without foreclosing access to opioids for patients suffering from pain whose physicians have prescribed these drugs responsibly.

PAIN MANAGEMENT AND PROGRESS AND FUTURE DIRECTIONS IN RESEARCH ON PAIN AND OPIOID USE DISORDER

Opioids are prescribed in a variety of settings for treatment of both acute and chronic pain. However, data demonstrating benefits of long-term use of opioids to manage chronic noncancer pain are lacking, while the evidence clearly demonstrates that long-term use of opioids is associated with an increased risk of OUD and overdose as well as a number of other adverse outcomes (e.g., cardiovascular events, fractures). In studies in which OUD has been carefully defined, rates of OUD among individuals who were prescribed opioids to help them manage their pain have averaged about 8 percent, and estimates of combined rates of misuse, OUD, and aberrant behaviors thought to be indicative of OUD among people taking opioids for pain have ranged from 15 to 26 percent. Because of these risks, no widely accepted guideline for opioid prescribing recommends the use of opioids as a first-line therapy for management of chronic noncancer pain.

A number of nonopioid pharmacologic treatments can be used successfully to manage pain. While each such alternative has its own indications and risks, there are some circumstances in which nonopioid analgesics (e.g., nonsteroidal anti-inflammatory drugs) are likely to be as effective as opioids, or more so, for reducing pain associated with the conditions for which they are indicated, and when used appropriately, these analgesics carry a lower risk of adverse outcomes relative to opioids.

Nonpharmacologic interventions for pain treatment, including acupuncture, physical therapy and exercise, cognitive-behavioral therapy, and mindfulness meditation, also are powerful tools in the management of chronic pain. Many are components of successful self-management. While further research is needed for some nonpharmacologic interventions to better understand their mechanism of action and optimal frequency and intensity, they may provide effective pain relief for many patients in place of or in combination with pharmacologic approaches. Interventional therapies[3] also have been found to be beneficial for the management of some forms of pain (e.g., low back and neck pain) in the context of a multidisciplinary approach. Research on interventional therapies is still developing.

Several advances in understanding pain and its treatment have occurred since the release of the 2011 IOM report *Relieving Pain in America*. The basic mechanisms related to MOPR (μ opioid receptor)-biased analgesia, inflammation, pain transmission, innate immunity, and treatment of neuropathic pain are now better understood. Likewise, progress in preclinical and translational research includes several developments related to the creation of nonaddictive alternatives to the opioid analgesics currently on the market. The movement toward pragmatic,

[3]Interventional pain management involves the use of invasive techniques, such as joint injections, nerve blocks, spinal cord stimulation, and other procedures, to reduce pain.

practice-based trials is a critical step forward in clinical pain research. The ideal balance of opioid reduction in the context of more comprehensive pain management (e.g., stepped care models) continues to be investigated. Precision medicine (broadly defined) has the potential to improve clinical pain research and management, but is another area in which continued research is needed.

Little is known about why individuals who use prescribed opioids to alleviate pain develop opioid dependence or OUD, yet these outcomes have become a driving force in the opioid epidemic. Better identification of individuals at risk of OUD requires better characterization of the neurobiological interaction between chronic pain and opioid use. In particular, research on the interactions among pain, emotional distress, and reward, including pain-induced alterations in the reward pathway, would help in understanding and reducing the misuse potential of opioids.

Chronic pain and OUD are complex human conditions affecting millions of Americans and causing untold disability and loss of function. Yet despite the prevalence of pain and OUD and related costs to society and repeated calls to action (including the 2011 IOM report), research on pain remains poorly resourced.

Recommendation 3-1. Invest in research to better understand pain and opioid use disorder. Given the significant public health burden of pain and opioid use disorder (OUD) in the United States, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, the U.S. Department of Veterans Affairs, industry, and other relevant research sponsors should consider greater investment in research on pain and OUD, including but not limited to research aimed at

- improving understanding of the neurobiology of pain;
- developing the evidence on promising pain treatment modalities and supporting the discovery of innovative treatments, including nonaddictive analgesics and nonpharmacologic approaches at the level of the individual patient; and
- improving understanding of the intersection between pain and OUD, including the relationships among use and misuse of opioids, pain, emotional distress, and the brain reward pathway; vulnerability to and assessment of risk for OUD; and how to properly manage pain in individuals with and at risk for OUD.

TRENDS IN OPIOID USE AND HARMS

The level and type of risk to a patient from a given opioid are influenced by specific features of the medication itself, including the compound; the formulation (whether the medication is an extended- or immediate-release formulation and/or a combination product [coformulated with naloxone, acetaminophen, or aspirin]); and the route of administration. How opioids are prescribed (e.g., on an "as-needed" basis) also may influence the risk of overdose. Studies consistently demonstrate that the risk of overdose increases in a dose-response fashion, that is, with increasing morphine-equivalent milligram doses.

It is also important to recognize that people who inject drugs are vulnerable to harms related to drug use that can be reduced by safe access to injection materials. New medications

with "abuse liability" will be used by people with established patterns of injecting drugs. Tracking the toll of expected nonmedical use of specific products on the health of people who inject drugs is of public health importance.

Another critical feature of the opioid crisis is that the prescription and illicit opioid epidemics are intertwined; indeed, a majority of heroin users report that their opioid misuse or OUD began with prescription opioids. In addition, the declining price of heroin, together with regulatory efforts designed to reduce harms associated with the use of prescription opioids (including the development of abuse-deterrent formulations [ADFs][4]), may be contributing to increased heroin use.

> **Recommendation 4-1. Consider potential effects on illicit markets of policies and programs for prescription opioids.** In designing and implementing policies and programs pertaining to prescribing of, access to, and use of prescription opioids, the U.S. Food and Drug Administration, other agencies within the U.S. Department of Health and Human Services, state agencies, and other stakeholders should consider the potential effects of these interventions on illicit markets—including both the diversion of prescription opioids from lawful sources and the effect of increased demand for illegal opioids such as heroin among users of prescription opioids—and take appropriate steps to mitigate those effects.

Gaps exist in the reporting of data with which to accurately describe the epidemiology of pain, OUD, and other opioid-related harms in the United States, including how pain and OUD relate to one another and how often they co-occur. Closing these data gaps would improve understanding of pain, OUD, and overlapping prescription and illicit opioid use and enable more effective and measurable policy interventions.

> **Recommendation 4-2. Improve reporting of data on pain and opioid use disorder.** The Substance Abuse and Mental Health Services Administration, the U.S. Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention should collaborate to identify best practices and reporting formats that portray the epidemiology of both pain and opioid use disorder accurately, objectively, and in relation to one another.

> **Recommendation 4-3. Invest in data and research to better characterize the opioid epidemic.** The National Institute on Drug Abuse and the Centers for Disease Control and Prevention should invest in data collection and research relating to population-level opioid use patterns and consequences, especially nonmedical use of prescription opioids and use of illicit opioids, such as heroin and illicitly manufactured fentanyl.

[4]Abuse-deterrent formulations are opioid medications designed to reduce the likelihood that they will be "abused." For example, some opioid pills have properties that make them difficult to manipulate (e.g., crush) or that render them ineffective or unpleasant once manipulated.

OPIOID APPROVAL AND MONITORING BY THE U.S. FOOD AND DRUG ADMINISTRATION

The FDA traditionally has taken a product-specific approach to drug approval decisions by focusing on the data generated and submitted by a drug's manufacturer and balancing the benefits revealed by those data against the risks known (and unknown) at the time of the agency's review. While this approach works well in most cases, the committee believes it is necessary to view regulatory oversight of opioid medications differently from that of other drugs because these medications can have a number of consequences not only at the individual level but also at the household and societal levels.

Recommendation 6-1. Incorporate public health considerations into opioid-related regulatory decisions. The U.S. Food and Drug Administration (FDA) should utilize a comprehensive, systems approach for incorporating public health considerations into its current framework for making regulatory decisions regarding opioids. The agency should use this approach, in conjunction with advisory committee input, to evaluate every aspect of its oversight of prescription opioid products in order to ensure that opioids are safely prescribed to patients with legitimate pain needs and that, as actually used, the drugs provide benefits that clearly outweigh their harms. When recommending plans for opioids under investigation; making approval decisions on applications for new opioids, new opioid formulations, or new indications for approved opioids; and monitoring opioids on the U.S. market, the FDA should explicitly consider

- benefits and risks to individual patients, including pain relief, functional improvement, the impact of off-label use, incident opioid use disorder (OUD), respiratory depression, and death;
- benefits and risks to members of a patient's household, as well as community health and welfare, such as effects on family well-being, crime, and unemployment;
- effects on the overall market for legal opioids and, to the extent possible, impacts on illicit opioid markets;
- risks associated with existing and potential levels of diversion of all prescription opioids;
- risks associated with the transition to illicit opioids (e.g., heroin), including unsafe routes of administration, injection-related harms (e.g., HIV and hepatitis C virus), and OUD; and
- specific subpopulations or geographic areas that may present distinct benefit-risk profiles.

To implement the systems approach proposed by the committee, it will be necessary to broaden the evidence used to demonstrate safety and efficacy during approval and for post-market monitoring. Specific means for meeting this need may extend beyond the protocolized setting of traditional clinical trials to encompass use of data from less traditional sources, such as online forums. The agency should consider reports of family members or other third parties affected by the drug, as well as data on outcomes in subpopulations that are at high risk of OUD or that exhibit mental health comorbidities common in patients with pain. Outcomes of interest

include impact on function and long-term efficacy for pain reduction. Other data that could inform the agency's decisions include the estimated impact of an opioid medication on the demand for and availability of all other prescription and illicit opioids, as well as interactions with other drugs (both prescription and illicit) commonly used with opioids or by people who use opioids illicitly. The FDA also should take steps to ensure that clinical development programs examine the full range of public health considerations.

> **Recommendation 6-2. Require additional studies and the collection and analysis of data needed for a thorough assessment of broad public health considerations.** To utilize a systems approach that adequately assesses the public health benefits and risks described in Recommendation 6-1, the U.S. Food and Drug Administration (FDA) should continue to require safety and efficacy evidence from well-designed clinical trials while also seeking data from less traditional data sources, including nonhealth data, that pertain to real-world impacts of the availability and use of the approved drug on all relevant outcomes. The FDA should develop guidelines for the collection of these less traditional data sources and their integration in a systems approach.

> **Recommendation 6-3. Ensure that public health considerations are adequately incorporated into clinical development.** The U.S. Food and Drug Administration (FDA) should create an internal system to scrutinize all Investigational New Drug (IND) applications for opioids. This review should examine whether public health considerations are adequately incorporated into clinical development (e.g., satisfactory trial design; see Recommendation 6-2). In implementing this recommendation, the FDA should rarely, if ever, use expedited development or review pathways or designations for opioid drugs and should review each application in its entirety.

The committee believes a commitment to transparency is critical to maintain balance between preserving access to opioids when needed and mitigating opioid-related harms and to maintain public trust.

> **Recommendation 6-4. Increase the transparency of regulatory decisions for opioids in light of the committee's proposed systems approach (Recommendation 6-1).** The U.S. Food and Drug Administration should commit to increasing the transparency of its regulatory decisions for opioids to better inform manufacturers and the public about optimal incorporation of public health considerations into the clinical development and use of opioid products.

The committee also believes aggressive use of the FDA's currently available authorities, such as Risk Evaluation and Mitigation Strategies (REMS), safety labeling changes, and risk communications, is critical to supporting the safe and effective use of opioids.

Recommendation 6-5. Strengthen the post-approval oversight of opioids. The U.S. Food and Drug Administration should take steps to improve post-approval monitoring of opioids and ensure the drugs' favorable benefit-risk ratio on an ongoing basis. Steps to this end should include use of Risk Evaluation and Mitigation Strategies that have been demonstrated to improve prescribing practices, close active surveillance of the use and misuse of approved opioids, periodic formal reevaluation of opioid approval decisions, and aggressive regulation of advertising and promotion to curtail their harmful public health effects.

Evidence on the effectiveness of the current REMS for opioids is limited. To improve the evidence on this REMS, the FDA could continue to evaluate the data on its performance, collecting additional data if needed, and then modify features of the REMS accordingly so that it more optimally ensures the evidence-based use of opioids.

Consistent regulatory oversight of opioid products under the committee's proposed approach will necessarily raise concerns about the safety and efficacy of products currently approved for market. The committee believes the FDA has the authority and responsibility to reexamine the opioid class of drugs to ensure that these drugs remain safe and effective. The committee believes this could be accomplished in a relatively short time frame because the review would be limited to a single drug class for which substantial evidence already exists.

Recommendation 6-6. Conduct a full review of currently marketed/approved opioids. To consistently carry out its public health mission with respect to opioid approval and monitoring, the U.S. Food and Drug Administration should develop a process for reviewing, and complete a review of, the safety and effectiveness of all approved opioids, utilizing the systems approach described in Recommendation 6-1.

The process for Drug Enforcement Administration (DEA) scheduling of drugs also could benefit from the explicit incorporation of the public health considerations discussed in this report. The FDA and DEA are already required to take "risk to public health" into account in making scheduling decisions, but the considerations included under this heading have not been enumerated in detail. Moreover, the ultimate impact on health outcomes related to these decisions remains largely unknown.

Recommendation 6-7. Apply public health considerations to opioid scheduling decisions. To ensure appropriate management of approved opioids, the U.S. Food and Drug Administration and the Drug Enforcement Administration should apply the same public health considerations outlined in Recommendation 6-1 for approval decisions to scheduling and rescheduling decisions, and study empirically the outcomes of scheduling determinations at the patient and population health levels.

STRATEGIES FOR ADDRESSING THE OPIOID EPIDEMIC

A constellation of policies, interventions, and tools related to lawful access to opioids and clinical decision making are available for use in reducing or containing opioid-related harms while meeting the needs of patients with pain. These strategies include those that (1) restrict the lawful supply of opioids, (2) influence prescribing practices, (3) reduce demand, and (4) reduce harm. The committee offers several recommendations based on its review of the evidence regarding the effectiveness of these strategies.

Each of these strategies entails costs and trade-offs. The committee believes the restrictions, policies, and practices recommended leave adequate space for responsible prescribing and reasonable access for patients and physicians who believe an opioid is medically necessary.

It also is important to keep in mind that restrictions on lawful access to prescription opioids can have other untoward effects: any policy designed to shrink the incidence of future OUD (and other harms) due to use of prescribed opioids by curtailing legal access to these medications will inevitably drive some people who already have OUD into the illegal market. In the committee's view, it is therefore ethically imperative to couple a strategy for reducing lawful access to opioids with an investment in treatment for the millions of individuals who already have OUD.

Strategies for Restricting Supply

One recent controversy concerns whether any opioid should be permitted on the market unless it is an ADF. The committee applauds the FDA's current cautious approach toward ADFs because the evidence is insufficient to warrant a recommendation on this question at this time. The potential for benefit remains counterbalanced by recent examples of unexpected harm. Ongoing studies will help clarify the optimal role for ADFs as a strategy for reducing misuse of prescription opioids.

States and localities also have regulatory authority over the practice of medicine in their jurisdictions unless their actions are preempted by federal action, and they have exercised that authority to stem the opioid epidemic. Overall, although further research is warranted, limited evidence suggests that state and local interventions aimed at reducing the supply of prescription opioids in the community (e.g., regulations limiting days' supply of opioid medications) may help curtail access. It should be emphasized, however, that none of these studies investigates the impact of reduced access on the well-being of individuals suffering from pain whose access to opioids was curtailed.

The available evidence suggests that drug take-back programs in the United States can increase awareness of the need for the safe disposal or return of many unused drugs, but effects of these programs on such downstream outcomes as diversion and overdose are unknown. Many drug take-back programs in the United States are once-a-year events. International examples and the recent success of a year-round disposal program at one pharmacy chain support policies expanding such programs to reduce the amount of unused opioids in the community.

Recommendation 5-1. Improve access to drug take-back programs. States should convene a public–private partnership to implement drug take-back programs allowing individuals to return drugs to any pharmacy on any day of the year, rather than relying on occasional take-back events.

Strategies for Influencing Prescribing Practices

Current efforts to improve pain education and knowledge about prescription opioid misuse and OUD among prescribers are inadequate. Any meaningful effort to improve pain management will require a fundamental shift in the nation's approach to mandating pain-related education for all health professionals who provide care to individuals with pain. Prescribing guidelines may be able to improve provider prescribing behavior, but may be most effective when accompanied by education and other measures to facilitate implementation.

Recommendation 5-2. Establish comprehensive pain education materials and curricula for health care providers. State medical schools and other health professional schools should coordinate with their state licensing boards for health professionals (e.g., physicians, nurses, dentists, pharmacists), the National Institutes of Health's Pain Consortium, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the Drug Enforcement Administration to develop an evidence-based national approach to pain education encompassing pharmacologic and nonpharmacologic treatments and educational materials on opioid prescribing.

Insurance-based policies have substantial potential to reduce the use of specific prescription drugs, although their impact on health outcomes remains uncertain. The judicious deployment of insurer policies related to opioid prescribing would benefit from a commensurate increase in coverage of and access to comprehensive pain management, encompassing both pharmacologic and nonpharmacologic modalities.

Recommendation 5-3. Facilitate reimbursement for comprehensive pain management. Public and private payers should develop reimbursement models that support evidence-based and cost-effective comprehensive pain management encompassing both pharmacologic and nonpharmacologic treatment modalities.

Evidence suggests that prescription drug monitoring programs (PDMPs) can help address the opioid epidemic by enabling prescribers and other stakeholders to track prescribing and dispensing information. State laws differ widely with respect to access to PDMP data, with some states denying access to certain stakeholders that could use the data to monitor opioid use and related harms. Some states do not require prescribers and/or dispensers to check PDMP information. As a result, PDMP data currently are not being used to their full potential.

Recommendation 5-4. Improve the use of prescription drug monitoring program data for surveillance and intervention. The U.S. Department of Health and Human Services, in concert with state organizations that administer prescription drug monitoring programs, should conduct or sponsor research on how data from these programs can best be leveraged for patient safety (e.g., data on drug–drug interactions), for surveillance of policy and other interventions focused on controlled substances (e.g., data on trends in opioid prescribing, effects of prescriber guidelines), for health service planning (e.g., data on discrepancies in dispensing of medications for treatment of opioid use disorder), and for use in clinical care (i.e., in clinical decision making and patient–provider communication).

Strategies for Reducing Demand

The committee's recommended changes to provider education and payer policy should be accompanied by a change in patient expectations with respect to the treatment and management of chronic pain. The committee was struck in particular by the relative lack of attention to the impact of educating the general public (i.e., all potential patients) about the risks and benefits of opioid therapy and the comparative effectiveness of opioid and nonopioid analgesics and nonpharmacologic interventions.

Recommendation 5-5. Evaluate the impact of patient and public education about opioids on promoting safe and effective pain management. The nation's public health leadership, including the surgeon general, the Centers for Disease Control and Prevention, and heads of major foundations and professional organizations, should convene a body of experts in communication and in pain and opioid use disorder to evaluate the likely impact (and cost) of an education program designed to raise awareness among patients with pain and the general public about the risks and benefits of prescription opioids and to promote safe and effective pain management.

Medication-assisted treatment is the standard of care for OUD, even for special populations such as pregnant and postpartum women. Although several efficacious medications for treatment of OUD are available, they are underutilized because of an array of factors, including insufficient numbers of providers eligible to provide OUD treatment, coverage barriers, and other limitations on access.

Recommendation 5-6. Expand treatment for opioid use disorder. States, with assistance from relevant federal agencies, particularly the Substance Abuse and Mental Health Services Administration, should provide universal access to evidence-based treatment for opioid use disorder (OUD), including use of medication, in a variety of settings, including hospitals, criminal justice settings, and substance use treatment programs. Efforts to this end should be carried out with particular intensity in communities with a high burden of OUD. State licensing bodies should require training in treatment for OUD for all licensed substance use disorder treatment facilities and providers.

Recommendation 5-7. Improve education in treatment of opioid use disorder for health care providers. Schools for health professional education, professional societies, and state licensing boards should require and provide basic training in the treatment of opioid use disorder for health care providers, including but not limited to physicians, nurses, pharmacists, dentists, physician assistants, psychologists, and social workers.

Recommendation 5-8. Remove barriers to coverage of approved medications for treatment of opioid use disorder. The U.S. Department of Health and Human Services and state health financing agencies should remove impediments to full coverage of medications approved by the U.S. Food and Drug Administration for treatment of opioid use disorder.

Strategies for Reducing Harm

Life-saving medication for treating opioid overdose is available. The provision of naloxone to overdose victims by laypersons or health professionals in the prehospital setting is the standard of care, and community-based programs and other first responder agencies have adopted this protocol for treating opioid overdose. Mechanisms for increasing naloxone prescribing and dispensing, equipping first responders, and possibly enabling direct patient access (e.g., over-the-counter status) are warranted, but are impeded by high and unpredictable medication costs.

Recommendation 5-9. Leverage prescribers and pharmacists to help address opioid use disorder. State medical and pharmacy boards should educate and train their members in recognizing and counseling patients who are at risk for opioid use disorder and/or overdose, and encourage providers and pharmacists to offer naloxone when an opioid is prescribed to these patients or when a patient seeks treatment for overdose or other opioid-related issues.

Recommendation 5-10. Improve access to naloxone and safe injection equipment. To reduce the harms of opioid use, including death by overdose and transmission of infectious diseases, states should implement laws and policies that remove barriers to access to naloxone and safe injection equipment by

- permitting providers and pharmacists to prescribe, dispense, or distribute naloxone to laypersons, third parties, and first responders and by standing order or other mechanism;
- ensuring immunity from civil liability or criminal prosecution for prescribers for prescribing, dispensing, or distributing naloxone, and for laypersons for possessing or administering naloxone; and
- permitting the sale or distribution of syringes, exempting syringes from laws that prohibit the sale or distribution of drug paraphernalia, and explicitly authorizing syringe exchange.

FINAL THOUGHTS

Years of sustained and coordinated effort will be required to contain the current opioid epidemic and ameliorate its harmful effects on society. Trends indicate that premature deaths associated with the use of opioids are likely to climb and that opioid overdose and other opioid-related harms will dramatically reduce quality of life for many people for years to come. Access to evidence-based treatment for OUD and efforts to prevent overdose deaths and other harms should therefore be increased substantially and immediately as a public health priority. Action by the nation's political and public health leadership also is warranted to reduce the occurrence of new cases of prescription opioid-induced OUD through the implementation of scientifically grounded policies and clinical practices to promote responsible opioid prescribing and through advocacy for research aimed at identifying and developing nonaddictive alternatives to opioids for treatment of pain. The FDA has a crucial role to play in these efforts.

1

Introduction

Over the past 25 years, the United States has experienced an unprecedented increase in opioid use disorder (OUD), opioid overdose, and other opioid-related harms. As of 2015, 2 million Americans aged 12 years or older had an OUD involving prescription opioids, and about 600,000 had an OUD involving heroin, an illicit opioid (HHS, 2016a). Drug overdose, driven primarily by opioids, is now the leading cause of unintentional injury death in the United States (more than 60 percent of overdose deaths in 2015 involved a prescription or illicit opioid) (Rudd et al., 2016). This increase in opioid-related deaths has occurred in tandem with an equally unprecedented increase in prescribing of opioid medications for purposes of pain management.

Millions of Americans experience acute and/or chronic painful conditions each year, and many of them are prescribed opioids. The vast majority of these patients do not misuse these drugs. Yet the pain-relieving and other effects of opioids (e.g., the feelings of pleasure, relaxation, and contentment opioids can produce) may lead to an overreliance on these drugs in many patients and to misuse and OUD in others. Moreover, many lawfully dispensed opioids make their way into the hands of people for whom they were not intended, including participants in illicit markets. As a result, the harms associated with use of prescription opioids (including OUD, overdose, and death) affect not only the patients with pain themselves but also their families, their communities, and society at large. The purpose of this report is to assess the nation's response to what is, by any measure, a grievous public health problem.

STUDY CHARGE

When the U.S. Food and Drug Administration (FDA) approved OxyContin in 1995, the drug had not been shown to be more efficacious or safe than short-acting oxycodone, which was already on the market. The idea promoted by OxyContin's manufacturer was that it was less likely to lead to addiction and misuse because of its time-release formulation. Yet, as discussed below, OxyContin was widely diverted, and many people became addicted to it. In 2013, the FDA approved Zohydro ER (extended-release) (hydrocodone bitartrate), an opioid without abuse-deterrent properties, although several abuse-deterrent formulations (ADFs) were by then available. The approval of this drug exacerbated frustration among some stakeholders that the societal impacts of opioids were not being sufficiently accounted for. In 2014, the FDA approved an ADF version of Zohydro to replace the original version.

In the wake of these decisions and in light of concerns about the growing opioid problem, the FDA launched an Opioids Action Plan in early 2016. In this plan, the agency described actions it would take in its role as the federal agency responsible for protecting the public's

health by ensuring the efficacy and safety of drugs in the United States (Califf et al., 2016; FDA, 2016a,b). The actions outlined in the FDA plan include the following:

- Expand the use of advisory committees, including by
  - convening an expert advisory committee before approving any new drug application for opioids without abuse-deterrent properties;
  - consulting an advisory committee on ADFs when they raise novel issues; and
  - assembling and consulting with a pediatric advisory committee regarding a framework for pediatric opioid labeling before any new labeling is approved.
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information incorporating elements similar to the ER/long-acting (LA) opioid labeling, to give providers better information about the risks of opioids and how to prescribe safely.
- Strengthen the requirements for drug companies to generate post-market data on the long-term impact of ER/LA opioids.
- Update the Risk Evaluation and Mitigation Strategy (REMS) program[1] requirements for opioids based on advisory committee recommendations and review of existing requirements to decrease inappropriate prescribing.[2]
- Expand access to and encourage the development of ADFs of opioid products.
- Support better treatment by making naloxone more accessible and supporting the Centers for Disease Control and Prevention (CDC) guideline for prescribing opioids for chronic pain (discussed later in this chapter) (Dowell et al., 2016).
- Reassess the risk-benefit approval framework for opioids to incorporate risks of opioids to patients as well as to others who obtain them (FDA, 2016a,b).

As part of efforts to implement its Opioids Action Plan, the FDA asked the National Academies of Sciences, Engineering, and Medicine (the National Academies) to establish an ad hoc committee to advise the agency on the development of "a regulatory framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of abuse and misuse" (Califf et al., 2016). This specific task was embedded in a broad charge (see Box 1-1). Specifically, the committee was asked to provide an update on the state of the science of pain research, care, and education since publication of the 2011 Institute of Medicine (IOM) report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (IOM, 2011), including the evolving role of opioids in pain management and practices for reducing their misuse; to characterize the epidemiology of the opioid epidemic; and to review the evidence on approaches for addressing the problem. Based on its review of the evidence, the committee was to identify regulatory actions the FDA can take to address the opioid epidemic, with a focus on the agency's development of a formal method (a regulatory framework) for incorporating the

[1]A REMS is a safety strategy used by the FDA "to manage a known or potential serious risk associated with a medicine to enable patients to have continued access to such medicines by managing their safe use" (FDA, 2017a).
[2]ER/LA opioids are currently subject to a REMS program that requires sponsors to fund continuing medical education for providers on the appropriate use of these products at low or no cost. The FDA has stated that it is expanding the REMS requirements to include IR opioids as well (FDA, 2017b).

broader public health impacts of opioids into its future opioid approval decisions. The committee also was asked to outline steps that can be taken by other stakeholders (e.g., prescribers; professional societies; federal, state, and local government agencies). In addition, the committee was charged to identify important research questions that need to be addressed to assist the FDA with the development of its regulatory framework.

BOX 1-1
Statement of Task

The Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine will convene an ad hoc committee to develop a report that will inform the U.S. Food and Drug Administration (FDA) as to the state of the science regarding prescription opioid abuse and misuse, including prevention, management, and intervention, and to provide an update from the 2011 Institute of Medicine (IOM) report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, which includes a further characterization of the evolving role that opioid analgesics play in pain management. The report additionally will make recommendations on the options available to FDA to address the prescription opioid overdose epidemic, from both the individual and public health perspectives, and to otherwise further advance the field.

Specifically, the report will address the following items:

- Provide an update on the state of the science of pain research, care, and education since the 2011 IOM report and characterize the evolving role of opioid analgesics in pain management.
- Review the available evidence on best practices with regard to safe and effective pain management, including practices to reduce opioid abuse and misuse, including an assessment of possible barriers to implementation of those best practices by prescribers and patients.
- Characterize the epidemiology of prescription opioid abuse and misuse, to include an assessment with regard to patient characteristics (such as indication, acute versus chronic pain; formulation, immediate-release versus extended-release; duration of use; and dose) and approaches to address the problem (such as approval of abuse-deterrent opioids, FDA communication strategies, prescription drug monitoring programs, and state or local policies) and review the available evidence on differences in pain experiences and treatment effectiveness across subpopulations.
- Given the state of the available data, identify important research questions to be addressed to assist FDA in meeting the goal of further developing a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid abuse and misuse.
- Given the state of the available data, identify additional actions FDA and others should consider now, with a particular focus on those actions FDA can undertake, to balance the needs of pain patients and the need to address opioid misuse and abuse. Areas of particular focus include:
  - FDA actions to be taken as a part of development, review and approval, and safe use of pain medicines, such as:
    - Development of a formal method to incorporate the broader public health impact of opioid abuse in future FDA approval decisions regarding opioids

- The development of non-opioid pain medicines to treat severe pain
- The development of abuse-deterrent opioids
- The incorporation of prevention strategies into safe opioid prescribing, including modification of the standard opioid indication statements
- The development of medicines for medication assisted treatment for patients with opioid use disorder
- The development of medicines to treat opioid overdose
- The education of prescribers and patients about safe use of pain medications
- The education of prescribers and patients about appropriate medication storage and disposal

– Actions by prescribers, professional societies, and government agencies (local, state, and federal).

In spring 2016, the National Academies convened an 18-member committee to carry out this task. Members included individuals with expertise in pain management, basic pain research, epidemiology, medical anthropology, substance use disorder (SUD), nursing, law, drug development, public health, health policy and policy modeling, and decision science. Two consultants with expertise in health care and food and drug law were appointed to contribute to the regulatory components of this report.

STUDY APPROACH

The committee conducted an extensive review of the scientific literature relevant to its statement of task. This literature review entailed English-language searches of a number of databases, including the Cochrane Database of Systematic Reviews, Embase, Google Scholar, Medline, PubMed, Scopus, and Web of Science. In addition to research published in peer-reviewed journals and books, the committee reviewed reports issued by government agencies and other organizations.

FDA representatives provided the committee with a number of background materials describing the agency's current processes and activities related to regulation of prescription drugs, including opioids. Among these materials were FDA guidance documents, presentations from FDA science board and advisory committee meetings, and research articles.

In addition, the committee held two public workshops to hear from researchers and agency representatives on topics germane to its task. The first workshop featured presentations on and discussion of topics relevant to the first four bullet points in the committee's statement of task (see Box 1-1); these presentations are summarized in a Proceedings of a Workshop—in Brief titled *Pain Management and Prescription Opioid-Related Harms: Exploring the State of the Evidence* (NASEM, 2016). The second workshop focused on the regulatory aspects of the committee's charge, including how the FDA might incorporate public health considerations into its regulatory framework for evaluation of prescription drugs.

Additional detail on the committee's literature search and workshops can be found in Appendix A.

DEFINITIONS AND TERMINOLOGY

In recent years, several factors have increased attention to the language of SUD. Patient advocacy groups have long advocated for language describing SUD that avoids stigma and negative stereotypes. In 2013, the fifth edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) replaced the categories of "abuse" and "dependence" with the single term "substance use disorder." This change led major addiction journals to publish guidelines for clinical, nonstigmatizing language that is viewed as acceptable terminology for manuscripts. On October 4, 2016, the Office of National Drug Control Policy (ONDCP) released a guidance document titled *Changing the Language of Addiction* (ONDCP, 2017). And in a related effort, the American Society of Addiction Medicine (ASAM) proposed a series of definitions aimed at the development of a vocabulary that is humanizing, nonstigmatizing, medically defined, and precise. This proposed terminology is a partial basis for the definitions presented in Box 1-2, which reviews both acceptable language and language that has been identified as no longer acceptable.

BOX 1-2
Key Definitions

Addiction refers to "…a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response" (ASAM, 2011). The criteria for substance use disorder in the fifth edition of the *Diagnostic and Statistical Manual for Mental Disorders* (DSM-5) are contained in the category of Addictions and Related Disorders; the preferred term for the disease, and the one used in this report, is **substance use disorder** (or **opioid use disorder**).

The severity of a substance use disorder can differ across individuals and across time for the same individual. Different from opioid use disorder and addiction, **dependence** in this report refers to a state associated with withdrawal symptoms upon cessation of repeated exposure to a drug. It is important to note that a person who is physically dependent on a drug may not meet the definition of addiction. **Tolerance** refers to the diminishing effect of a drug resulting from the repeated administration of a given dose.

Abuse (as in substance abuse or substance abuser) is no longer acceptable terminology, as research has found the term to be associated with negative and stigmatizing perceptions. Accordingly, the committee avoids use of this term except when quoting other sources; when referring to abuse-deterrent formulations of opioids (those with properties designed to prevent misuse [e.g., properties to prevent crushing so the drug can be snorted or dissolving so it can be injected]); and when referring to statutes, such as the Controlled Substances Act, that use this term. The term **misuse** is commonly used to describe any use of a prescription medication beyond what is directed in a prescription. It encompasses such specific behaviors and motivations as (1) medically motivated use more frequently or in a higher dose than prescribed, (2) nonmedically motivated use by the person to whom the drug has been prescribed, (3) medical use by a person other than the person to whom the drug has been prescribed, and (4) nonmedical use by a person other than the person to

whom the drug has been prescribed. Some have argued that use of the term "misuse" to encompass both medical and nonmedical motivations (such as "to get high") is misleading and imprecise. While the American Society of Addiction Medicine (ASAM) acknowledges this problem, it prefers "misuse" as the umbrella term encompassing a continuum of use patterns based on degree of risk, ranging from "low-risk" and "at-risk" use to "harmful use" and addiction. Under the ASAM approach, once a patient misusing prescription medication meets the criteria for an opioid use disorder, the term "misuse" is no longer appropriate. **Diversion** refers to the transfer of regulated prescription drugs from legal to illegal markets. The term is not used in this report to refer to the sharing of drugs with friends, family members, or other contacts for medical or nonmedical purposes.

Traditionally, the term **opiates** refers to substances derived from opium, such as morphine and heroin, while **opioids** refers to synthetic and semisynthetic opiates. However, the term **opioids** is now often used for the entire family of opiates, including natural, semisynthetic, and synthetic.

Finally, the acronym **MAT** refers to the use of medication in the treatment of opioid use disorder, regardless of whether the modification is used conjunction with counseling and behavior therapies. This acronym may refer either to **medication for addiction treatment**, where medications are used without counseling and behavior therapies, or to **medication-assisted treatment**, where medication is used in conjunction with these therapies. Current medications approved for treatment of opioid use disorder are methadone, buprenorphine, and naltrexone. The terms **substitution therapy** and **replacement therapy** are not accurate and therefore are not used in this report.

STUDY CONTEXT

Historical Context

Opioids have been used for medicinal and recreational purposes for millennia. While the use of opioids for treatment of acute severe pain has generally been accepted, their use for managing chronic noncancer pain has been controversial since the 19th century, with the popular view shifting over the decades between broad acceptance and a more restrictive perspective (Rosenblum et al., 2009). The tension between the desire to make opioids available to those who may benefit from them and the recognition that opioids are addictive drugs with societal consequences began with medical developments that occurred during the 1800s (Booth, 1986; Musto, 1999; Rosenblum et al., 2009). These developments included the extraction of morphine from opium in 1803 and the development of the hypodermic needle (which can be used to inject morphine to relieve neuralgic pain) in the 1850s (Rosenblum et al., 2009). Morphine was used widely for pain management during the American Civil War, and many soldiers developed OUD. With few effective alternatives, moreover, many medical professionals used morphine to treat chronic pain conditions. This and the nonmedical use of opioids were major drivers of an opioid addiction epidemic that took place in the latter 19th century (Courtwright, 2015).

By the late 1800s, scientists were starting to recognize the problem of OUD, and a policy response began to emerge. What is thought to be the first accurate and comprehensive description of addiction to morphine was produced in 1877. In hopes of developing a less addictive alternative to morphine, heroin (diacetylmorphine) was synthesized in 1874 (although it was later found to be more potent than morphine) (Rosenblum et al., 2009). Medical professionals became increasingly critical of the use of opioids to treat pain and lobbied

successfully for state and local laws to control the sale of opioids and other narcotics. Consumption of medicinal opioids declined as a result (Courtwright, 2015).

Reform efforts continued in the early 20th century. The Harrison Narcotics Act, enacted by Congress in 1914, required persons who imported, produced, sold, or dispensed opium-based drugs (as well as coca-based drugs) to register, pay a tax, and keep detailed records that officials could use in enforcing laws to restrict opioid transactions to legitimate medical channels. This act had the effect of criminalizing the use of opium for nonmedical purposes (Courtwright, 2015; Hoffman, 2016).[3] The use of heroin for medicinal and other purposes was specifically banned by the Heroin Act, enacted by Congress in 1924.

The consensus among medical professionals for most of the 20th century was that opioids should not be used for the management of chronic pain because of the lack of evidence regarding their effectiveness for this type of pain and the risk of OUD (Rosenblum et al., 2009). Research aimed at developing new and potentially less addictive opioids continued, however, and Percocet and Vicodin—which combined semisynthetic opioids with acetaminophen—became available in the 1970s for relief of moderate to moderately severe pain. These and most other prescription opioids are now regulated under the Controlled Substances Act (CSA) of 1970 as Schedule II drugs—those with a "high potential for abuse which may lead to severe psychological or physical dependence" (DEA, 2017b).[4]

Liberalization of Prescribing in 1990s

Medical practice in the United States began to shift markedly toward more liberal use of opioids for chronic noncancer pain following the development and marketing of new formulations of opioid drugs in the 1990s (Compton and Volkow, 2006; Rosenblum et al., 2009). As noted earlier, in 1995 the FDA approved OxyContin (oxycodone controlled-release), which allowed dosing every 12 instead of every 4 to 6 hours (FDA, 2017c). The drug's manufacturer (Purdue Pharma) marketed it aggressively to providers and patients in the years following its release to the market in 1996. Purdue claimed in some of its promotional materials that the risk of addiction to the drug was small (Van Zee, 2009).

Around the same time, there was growing recognition in the medical community that many individuals with chronic pain were being treated inadequately (Pokrovnichka, 2008). In 1996, the American Academy of Pain Medicine and American Pain Society issued a joint consensus statement titled *The Use of Opioids for the Treatment of Chronic Pain*, describing potential benefits of using opioids for management of chronic (including noncancer) pain (Haddox et al., 1997; Hoffman, 2016). Advocates representing the interests of pain patients suggested that pain be considered a "fifth vital sign" in an effort to improve pain assessment and treatment (Campbell, 1996), and some health care organizations incorporated this concept into guidelines and clinical practice (Mularski et al., 2006). There were also concerted efforts by pain specialists to persuade state medical boards and state legislatures to remove legal impediments to

[3]The Harrison Narcotics Act has since been replaced by the Controlled Substances Act, enacted in 1970.

[4]Some opioids are not classified in Schedule II. These include opioids containing less than 90 milligrams of codeine per dosage unit (e.g., Tylenol with Codeine®) and buprenorphine (used in the treatment of OUD), which are Schedule III drugs—those that have "a potential for abuse less than substances in Schedules I or II" and whose "abuse may lead to moderate or low physical dependence or high psychological dependence" (DEA, 2017b).

medically accepted pain treatment (Hoffman, 2016).[5] This shift in professional understanding was accompanied by a public campaign to call public and professional attention to the prevalence of pain and its seriousness as a public health problem.

Congress declared 2001–2011 the "Decade of Pain Control and Research" (Brennan, 2015). The 2010 Patient Protection and Affordable Care Act (ACA) directed the U.S. Department of Health and Human Services (HHS) to work with the IOM to increase recognition of pain as a public health problem (IOM, 2011). In response, HHS, through the National Institutes of Health (NIH), commissioned an IOM committee to review the science on pain and recommend actions to advance the field. The resulting report, *Relieving Pain in America*, provided a blueprint for "transforming the way pain is understood, assessed, treated, and prevented" (IOM, 2011, p. 2).

In the context of Purdue's substantial promotional expenditures and these changing professional attitudes, sales of OxyContin rose from $48 million in 1996 to more than $1 billion by 2000 (Van Zee, 2009). Sales of prescription opioids are estimated to have quadrupled between 1999 and 2010 (CDC, 2011), driven in part by OxyContin during the early portion of this period (GAO, 2003). However, problems began to emerge around 2000, with reports of widespread diversion, tampering, and misuse of OxyContin (Cicero et al., 2005; GAO, 2003; Hoffman, 2016). In response, the FDA changed the OxyContin label in 2001 "to add and strengthen warnings about the drug's potential for abuse and misuse" and in 2003 issued a warning letter to the manufacturer regarding promotional materials that omitted and minimized the drug's safety risks (FDA, 2017c).[6] The Drug Enforcement Administration (DEA) prosecuted many physicians for illegal distribution of OxyContin (Hoffman, 2016).[7]

Nonetheless, sales of prescription opioids continued to increase (Pan, 2016). Data from the National Prescription Audit show that the number of opioid prescriptions dispensed from U.S. outpatient retail pharmacies for all approved and marketed ER/LA and some of the most common IR opioid analgesics grew from 148 million in 2005 to 208 million by 2011. Opioid dispensing during this period was driven primarily by IR opioids (which work quickly and often are prescribed for short-term, intermittent, or "breakthrough" pain) rather than ER/LA opioids such as OxyContin (see Figure 1-1).[8] Sales of OxyContin increased from just over $1 billion in 2000 to $1.84 billion in 2003 and then declined in the wake of the FDA actions described above until 2006, after which there was another increase in sales until 2010.

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[5]Liberalization of prescribing was resisted in some quarters, and worries about possible discipline by state medical boards or even prosecution by the Drug Enforcement Administration (DEA) continued to affect professional practice during this period.

[6]Purdue Pharma was eventually prosecuted and, in 2007, paid a $600 million settlement after pleading guilty for its misrepresentation of OxyContin's addiction and abuse potential.

[7]DEA reported investigating 247 OxyContin diversion cases between October 1999 and March 2002, which led to 328 arrests. Between May 2001 and January 2004, DEA arrested approximately 600 people for violation of laws related to distribution, dispensing, or possession of OxyContin. Of these, 60 percent were doctors, pharmacists, or other professionals (Hoffman, 2016).

[8]The preponderance of IR opioid prescribing may be the result of many factors, including but not limited to the effect of hydrocodone IR combination products being Schedule III drugs/refillable until 2014 (when they were reclassified as Schedule II drugs), the number of prescriptions for acute pain after injuries/surgeries/procedures, the comfort of many providers with short-acting drugs, an overall practice of using relatively low doses of drugs, and the preferences of patients to have control over when they take their drugs.

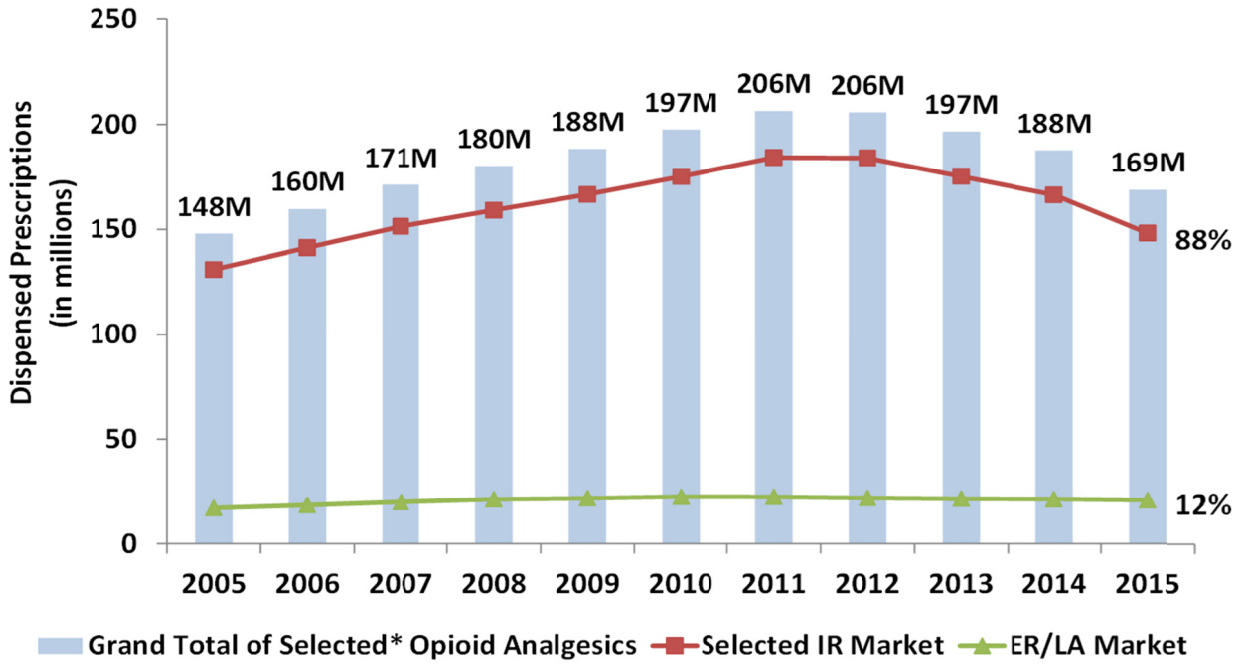

FIGURE 1-1 Nationally estimated number of prescriptions dispensed for extended-release/long-acting (ER/LA) and selected immediate-release (IR) opioid analgesics (oral solids and transdermal products) from U.S. outpatient retail pharmacies, 2005–2015.
NOTES: *ER/LA opioid molecules* include buprenorphine transdermal patch, fentanyl transdermal patch, hydrocodone ER, hydromorphone ER, morphine ER, oxycodone ER, oxymorphone ER, tapentadol ER, and methadone (all approved and marketed ER/LAs at the time). *IR opioid molecules* include hydrocodone IR combination analgesics (hydrocodone in combination with acetaminophen, ibuprofen, or aspirin), oxycodone IR combination analgesics (oxycodone in combination with acetaminophen, ibuprofen, or aspirin), oxycodone IR, hydromorphone IR, morphine IR, tapentadol IR, and oxymorphone IR. Buprenorphine indicated for medication-assisted treatment is not included.
SOURCE: Staffa, 2017.

Public Health Consequences

During the years coinciding with the growth in opioid prescribing, the United States experienced an increase in deaths from opioid overdose and in admissions to treatment associated with opioid use. According to CDC data, there was a 1.9-fold increase in the total number of deaths from prescription opioids (excluding nonmethadone synthetics) between 1999 and 2011 (see Figure 1-2). While the number of overdose deaths from prescription opioids remained relatively stable between 2011 and 2015, overdose deaths from illicit opioids (e.g., heroin and synthetic opioids such as fentanyl) continued to increase, related in part to a growing number of people with OUD in connection with prescription opioids. Overdose deaths from illicit opioids increased rather steadily during 1999 to 2015, growing 6.4-fold over that period (see Figure 1-2). Poisoning, driven largely by opioids, became the leading cause of death due to injury in the United States in 2008, surpassing motor vehicle crashes (Warner et al., 2011). The annual incidence of hospitalization for prescription opioid poisoning among children and adolescents aged 1–19 increased 165 percent (from 1.4 to 3.7 per 100,000) between 1997 and 2012 (Gaither et al., 2016). Between 2003 and 2013, the proportion of admissions to treatment associated primarily with nonheroin opioid use and heroin use increased from 3 to 9 percent and 15 to 19 percent, respectively (SAMHSA, 2015).

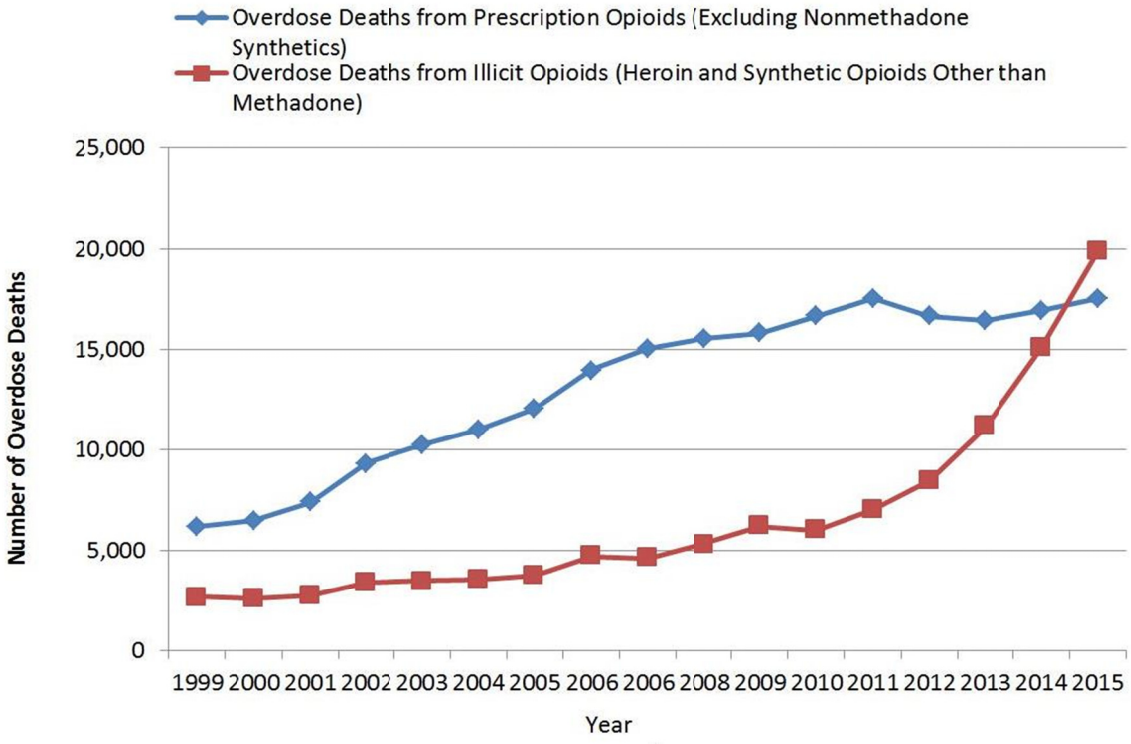

FIGURE 1-2 Number of overdose deaths from prescription and illicit opioids, United States, 1999–2015. SOURCE: NCHS, 2016.

Policy Responses

By the end of the first decade of the 21st century, alarm about the opioid epidemic was growing in public health circles. An increasing number of medical organizations were urging greater caution in prescribing opioids in light of the growing opioid problem and the lack of evidence that the drugs are effective for long-term pain management (VonKorff et al., 2011). At the federal level, in 2009, the FDA held public and stakeholder meetings to discuss opioid-related harms; partnered with the Substance Abuse and Mental Health Services Administration (SAMHSA), the DEA, and others on efforts to improve the safe use and disposal of opioids; and launched a Safe Use Initiative to reduce preventable harms from opioids and other drugs. In 2010 the agency approved an ADF of OxyContin (FDA, 2017c). During approximately 2013–2015, ONDCP and HHS ramped up efforts to reduce OUD and opioid overdose, including the creation of an HHS opioid initiative in 2015 (HHS, 2015). CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain explicitly declares that nonpharmacologic and nonopioid therapies are preferred for treating chronic pain (Dowell et al., 2016). And in December 2016, the U.S. Congress passed the 21st Century Cures Act, which included $1 billion in funding over 2 years for grants to states targeting opioid prevention and treatment activities.

State and local governments also have scaled up efforts to identify problematic prescribing (e.g., via prescription drug monitoring programs [PDMPs], discussed in Chapter 5), prevent diversion of prescription opioids, and increase access to naloxone and to treatment for OUD. Some jurisdictions have declared public health emergencies (e.g., Massachusetts Department of Public Health, 2014; Virginia Department of Health, 2016).

In the context of these federal and state policy initiatives, the total number of prescriptions for opioid analgesics dispensed from outpatient retail pharmacies decreased between 2012 and 2015.[9] Large health care providers and professional associations also have recently suggested that pain no longer be considered a vital sign (Frieden, 2016; Lowes, 2016). Some have suggested that routine pain assessment is not in the best interest of providers and may contribute to overprescribing (Lowes, 2016).

International Context

Historically, the United States has consumed a large majority of the world's supply of opioid drugs. An older figure that continues to be cited is that approximately 80 percent of the world's supply of opioid drugs is consumed in the United States (Manchikanti and Singh, 2008). According to another estimate, 90 percent of the world's supply of morphine, fentanyl, and oxycodone was used in the United States, Canada, Australia, and New Zealand in 2009, and in that same year, the United States consumed 83 and 99 percent of the world's oxycodone and hydrocodone, respectively (Hauser et al., 2016). Based on available data (UNODC, 2017), other countries, including Mexico and countries in Central and South America, Africa, and Asia, appear to have a considerably lower prevalence of past-year use of both prescription and illicit opioids, although this does not necessarily mean that these countries are free of problems related to opioids.

Consumption of opioid drugs has increased globally since the 1980s. Data indicate that in more recent decades, increases in consumption have been highest in the United States and to a lesser extent in other industrialized nations. For example, during 2000–2010, opioid consumption increased 400 percent in the United States, compared with 65 percent in Great Britain and 37 percent in Germany (Hauser et al., 2014). In Australia, where the prevalence of opioid use also is high, opioid dispensing increased nearly four-fold between 1990 and 2014 (from 4.6 to 17.4 defined daily doses/1,000 population/day) (Karanges et al., 2016). Spain saw a 14-fold increase in opioid daily doses between 1992 and 2006 (Garcia del Pozo et al., 2008).

The responses in countries experiencing high rates of opioid misuse, OUD, and opioid overdose have varied. Some are noteworthy for their public health orientation. In the Canadian province of British Columbia (Canada has the second highest rate of opioid consumption after the United States), harm reduction strategies implemented to reduce opioid overdose included making the opioid overdose reversal drug naloxone available outside of pharmacies without a prescription and opening supervised injection facilities (SIFs) (British Columbia was the first region in North America to open a SIF, in 2003) (Voon, 2016). The British Columbia Ministry of Health also issued guidelines for the clinical management of OUD to foster improved linkage to medically supervised treatment (Dunlap and Cifu, 2016). SIFs, which have been found to be associated with reductions in syringe sharing and overdose fatality (Kerr et al., 2005; Marshall et al., 2011), are operating as well in several other countries that have experienced significant opioid misuse problems, including Spain, Australia, and Germany, and are now being considered in the United States.

[9]It is important to note, however, that opioid prescribing practices, and therefore trends in dispensing, vary widely among states and other localities.

Some countries have reduced criminalization of drug use, with positive results. Portugal, while not having opioid-related problems at the levels seen in other countries, became the first country to decriminalize the possession and use of drugs in 2001, making these violations administrative as opposed to criminal offenses (Greenwald, 2009). Individuals who are addicted to heroin or other drugs are offered access to treatment, which is widely available through health centers, hospitals, and pharmacies, as well as to needle exchange and other services. Since these changes were implemented, the country has seen more people enter treatment, and HIV transmission rates have declined among injection drug users (EMCDDA, 2016).

The United States' response to the opioid epidemic also has taken on an increasingly public health focus. Examples include efforts to make OUD treatment, naloxone, syringe exchange, and other services more widely available, and the promulgation of guidelines for prescribers that emphasize greater caution in opioid prescribing and recommend referral to evidence-based treatment for patients with OUD. As discussed in this report, these strategies are at various stages of implementation and evaluation.

Statutory Context

Opioid regulation lies at the intersection of two federal statutes, each with its roots in the early 20th century. The first is the Food, Drug, and Cosmetic Act (FDCA), a successor to the groundbreaking Pure Food and Drug Act of 1906, which now requires manufacturers of medical drugs and devices to prove that they are safe and effective for their intended uses before they may be marketed to consumers. The second applicable statute is the CSA, enacted in 1970 as a successor to the Harrison Narcotics Act of 1914, mentioned above. The CSA was designed to provide an overarching framework for tight federal regulation, including both public health oversight and aggressive enforcement, for all drugs with "potential for abuse," whether or not intended for medical use. Previously, those functions had operated relatively autonomously, with drug development and prescription control under the FDA, and enforcement responsibility originally lodged in the U.S. Department of the Treasury and later transferred to the U.S. Department of Justice (Spillane, 2004). Enforcement duties under the CSA are now exercised by the DEA, but the CSA also retains a significant role for HHS, usually acting through the FDA, in the regulation of controlled substances with medical uses.

The CSA created tiered levels of control and reporting responsibilities based on the potential danger posed by a given drug, and established a structure for coordinating regulatory and enforcement action (Spillane, 2004). The act also was designed to create a "big tent" for all drugs that might be subject to misuse and to explicitly subject such drugs as barbiturates and amphetamines to the same control as narcotics. Each controlled substance is assigned to a specific schedule. Schedule I substances are strictly limited and may be used only in some highly controlled research contexts, if at all. Schedule II substances are subject to production quotas and registry requirements for importers and exporters. Drugs assigned to the lower schedules are subject to progressively diminished levels of control. A controlled substance may be prescribed only for a "legitimate medical purpose" by a practitioner licensed by DEA "acting in the usual course of his professional practice." The CSA gives the DEA the power to revoke licensure when a physician is determined to have violated that standard, and offending practitioners may be subject to criminal prosecution.

The primary focus of the CSA was ambiguous from the outset: the Nixon Administration saw it principally as a way to control street use of illicit drugs, while its congressional sponsors

saw it as a vehicle for limiting overproduction and overprescription of legally marketed drugs based on balancing the dangers of abuse against the health benefits of legitimate medical use (Spillane and McAllister, 2003, p. S8). To its congressional sponsors, the CSA represented a key step in the direction of a national public health approach to drug abuse and addiction. The second step, taken in the Drug Abuse Office and Treatment Act of 1972, established a Special Action Office for Drug Abuse Prevention in the White House and enacted sweeping federal protection of the confidentiality of SUD treatment records that continues to serve as a centerpiece of national policy.

The DEA was created in 1973 to carry out the U.S. Department of Justice's responsibility for enforcing the CSA (Senate Committee on Government Operations, 1973, pp. 5–6). It was believed that making one agency accountable would "maximize coordination between Federal investigation and prosecution efforts." The new agency was to draw on Federal Bureau of Investigation expertise with organized crime, and to provide a single focal point for enforcement with state, local, and international authorities (Senate Committee on Government Operations, 1973, pp. 5–6). The DEA enforces both the criminal and noncriminal regulatory requirements of the CSA, but it does so as a law enforcement agency; it is not designed to function as a public health agency, nor does it pretend to be one (DEA, 2017a).

Over the four and a half decades since its passage, the CSA has been amended many times, usually to increase law enforcement authority. The Comprehensive Crime Control Act of 1984 and the Anti-Drug Abuse Acts of 1986 and 1988 added provisions to deal with synthetic compounds and new enforcement mechanisms, such as forfeiture provisions, and introduced mandatory minimum sentences. The Illicit Drug Anti-Proliferation Act of 2003 amended the CSA to deal with MDMA (*3,4-methylenedioxy-methamphetamine*, or ecstasy) and other club drugs. The Ryan-Haight Act of 2008 amended the CSA to regulate online pharmacy distribution. The Secure and Responsible Drug Disposal Act of 2010 requires the DEA to establish programs for voluntary disposal of controlled substances that are no longer required by patients. And the Synthetic Drug Abuse Prevention Act of 2012 mandated restrictive scheduling for various synthetic drugs but also streamlined the scheduling process so that newly approved drugs could enter the market more quickly.

Among the many important issues that have surfaced during the opioid crisis are whether the public health goals of the CSA envisioned by its architects have been achieved, and whether regulatory activities carried out by the FDA and the DEA under the FDCA and the CSA have been suitably coordinated and harmonized. One issue of particular interest in the context of this report is surveillance. As a key component of its public health aims, the CSA mandated the collection of epidemiologic data on use and abuse of the drugs controlled by the act and on other substances that might warrant control. The first such effort, the Drug Abuse Warning Network (DAWN), created in 1972 and discontinued in 2011, revealed a problem that continues to this day: it is difficult to break the data down by specific drug products (Mansbach et al., 2010; Spillane, 2004), which is essential to determining the nature and level of misuse for specific substances. The discontinuation of DAWN in 2011 left a substantial gap in the nation's capacity to monitor, anticipate, and respond to the opioid epidemic as it unfolded.

Recent Federal Policy Initiatives

As noted above, the IOM's 2011 report *Relieving Pain in America* highlighted the public health significance of pain and the need for fundamental changes in pain policy and practice

(IOM, 2011). The report details the landscape of pain in the United States of that time, including such key factors as its overall prevalence; its personal, economic, and social consequences; and the significant shortcomings of prevailing treatment approaches. The report also describes the status of some of the available pain treatment approaches, including pharmacologic options, injection-based interventions, surgery, rehabilitative strategies, psychological therapies, and complementary modalities. The report presents highlights of then-current knowledge about pain mechanisms and the impact of interacting comorbid conditions such as depression, anxiety, and SUD, as well as areas in which knowledge was critically lacking. While the report ably describes the contemporary state of the art, however, important advances have since occurred on many fronts.

One element of this committee's charge was to "provide an update on the state of the science of pain research, care, and education since the 2011 report and characterize the evolving role of opioid analgesics in pain management," a task that the committee carries out in several chapters of this report. The subsections below summarizes three major federal policy activities related to pain management and opioids that have taken place since the 2011 report was published and that provide additional context for the present study: the ongoing formulation of a National Pain Strategy, promulgation of a guideline for opioid prescribing under the auspices of the CDC, and ONDCP's development of a comprehensive plan for managing the opioid crisis.

National Pain Strategy

One of the principal recommendations of the 2011 IOM report was that HHS develop "a comprehensive population health-level strategy for pain prevention, treatment, management, and research" (IOM, 2011). In response, the HHS assistant secretary requested that the Interagency Pain Research Coordinating Committee (IPRCC) develop a National Pain Strategy to provide a blueprint for transforming pain prevention, care, education, and research. After several years of work, the National Pain Strategy was published in 2016 (HHS, 2016b). The document's findings and recommendations fall into six primary areas: population research, prevention and care, disparities, service delivery and reimbursement, professional education and training, and public awareness and communication.

The National Pain Strategy highlights difficulties surrounding the use of opioids in pain management. Its recommendations include augmenting the use of population-level data to inform national policy on opioid use, including regulatory actions undertaken by the FDA and the DEA. Perhaps more significant, the Strategy lists as an objective, "Develop and implement a national educational campaign to promote safer use of all medications, especially opioid use, among patients with pain" (HHS, 2016b, p. 48). The document, however, makes no specific recommendations to the FDA.

The work of the IPRCC is far from complete. The committee, composed of 7 federal and 12 nonfederal members, is engaged in several ongoing tasks, including summarizing advances in pain research, identifying critical gaps in the research, and advising NIH and other federal agencies on how best to streamline research efforts and improve the collection and dissemination of information on pain research and treatment.

Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain

In parallel with the efforts of the IPRCC, the CDC issued its Guideline for Prescribing Opioids for Chronic Pain in 2016, offering a detailed set of recommendations for prescribing opioids to adults for chronic pain (Dowell et al., 2016). Specific issues addressed by the guideline include (1) when to consider opioids for chronic pain; (2) what types and doses of opioids to use, as well as when to consider tapering off the drugs; and (3) how to assess patient-specific risks. The CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and its recommendations are based on a systematic review of the scientific evidence, as well as consideration of benefits and harms, values and preferences, and resource allocation. The guideline was specifically developed for primary care clinicians, including physicians, nurse practitioners, and physician assistants, prescribing opioids to patients with chronic pain (>3 months' duration) in outpatient settings. It acknowledges the existence of other sets of opioid prescribing guidelines, such as those issued by the American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel and the U.S. Department of Veterans Affairs (Chou et al., 2009; VA and DOD, 2010). The CDC guideline, however, has the advantage of reflecting more recent data on the effectiveness and risks of prescription opioids. In addition to review of the direct clinical evidence and complementary contextual evidence, the CDC process engaged federal partners and other stakeholders, and entailed subjecting the guideline to peer review and publishing it for public comment prior to dissemination.

The guideline ultimately published provides 12 recommendations concerning the use of opioids for the management of chronic pain (see Box 5-3 in Chapter 5) (Dowell et al., 2016). The guideline generally can be regarded as more conservative than many previous sets of recommendations on this topic. Some of its specific provisions should be noted. First, the guideline stresses the general approach of using nonopioid and nonpharmacologic therapy for chronic pain. In fact, it stresses that opioids are not first-line medications for the treatment of chronic pain. This recommendation is based on the finding that nonpharmacologic therapies appear to have efficacy similar to that of pharmacologic therapies, at least for the first several months of treatment, as well as a superior long-term risk profile. Second, the guideline recommends that when opioid therapy is used, IR rather than ER/LA opioids be prescribed and at relatively low doses. The guideline generally recommends doses below 50 morphine milligram equivalents (MME)/day and suggests careful justification of doses above 90 MME/day. Finally, the guideline stresses the evaluation of risks prior to opioid initiation, careful ongoing evaluation of those risks, and regular assessment of response to the therapy. The guideline specifically mentions the potential for adverse interactions between opioids and such sedatives as benzodiazepines as it is now clear that such interactions contribute to many opioid-related deaths (Park et al., 2015).

Some have cautioned that the CDC guideline may have unintended consequences in terms of unduly limiting access to opioid medications (e.g., Guerriero and Reid, 2016; Pergolizzi et al., 2016). It should be noted, however, that additional publications providing separate analyses of the use of opioids for low back pain, a common indication, have become available since the CDC guideline was published (Abdel Shaheed et al., 2016; Qaseem et al., 2017). Consistent with the CDC findings and recommendations, these more recent analyses also find little evidence of meaningful pain relief provided by opioids for low back pain.

Office of National Drug Control Policy's Comprehensive Plan

ONDCP was created in 1989 by the Anti-Drug Abuse Act of 1988 to coordinate activities of DEA, the FDA, the CDC, the National Institute on Drug Abuse (NIDA), and SAMHSA. In 2011, ONDCP issued a four-pronged comprehensive plan for managing the opioid crisis aimed at balancing the need to curb opioid-related harms with the needs of individuals for adequate pain treatment (ONDCP, 2011, p. 2).

The first prong entailed educating the public and health care providers. Practitioners seeking DEA registration for prescribing controlled substances would have been required to receive training on responsible opioid prescribing practices. Opioid REMS would have been required to include effective educational materials, and efforts would have been made to enhance education in health professional schools as well as continuing education through state and federal agencies. Second, the plan called for improved monitoring through state-authorized PDMPs. The plan noted that standardized monitoring programs with enhanced interoperability (with each other and with national monitoring systems) and access were needed in all 50 states. The plan also encouraged legal changes to allow more sharing of clinical data and innovative use of electronic health records. Third, the plan recommended new actions to increase environmentally responsible disposal of prescription drugs to prevent misuse and diversion. Finally, the plan recommended methods for improving enforcement, including a Model Pain Clinic Regulation Law and improved coordination among federal, state, and local agencies for investigation of illicit trafficking and illegitimate prescribing and prosecution of offenders (ONDCP, 2011).

In 2014, the DEA issued a new rule that largely addressed the goals of the 2011 ONDCP plan's drug disposal requirements. The DEA also has created a DEA 360 program, developed "Tactical Diversion Squads," and formulated the HIDTA (High Intensity Drug Trafficking Areas) Heroin Response Strategy, all of which are designed to improve enforcement while taking a "balanced public health and public safety approach" (White House, 2016, p. 68). However, the ONDCP plan's education goals, which would have linked DEA registration and training requirements, have not been implemented, and the REMS education goals have been underutilized. ONDCP has pointed to the new CDC practice guideline as evidence of progress in education (White House, 2016, p. 66), but adherence to those recommendations is voluntary. Similarly, while progress has been made in expanding PDMPs—now in 49 states—and new federal monitoring plans have been developed, a lack of standardization and interoperability and poor access impede the effectiveness of these systems.

Ethical Context

The statement of task for this study (see Box 1-1) directed the committee to recommend policy actions by the FDA and other policy makers that would properly "balance the needs of pain patients and the [societal] need to address opioid misuse." This deceptively simple statement entails many technical challenges related to measurement quantification that are explored in Chapter 6. However, it also exposes a genuine ethical quandary that is fundamental to this entire report: How exactly does a regulator (or this committee) weigh and balance, for any particular regulatory action limiting access to opioids, the otherwise avoidable suffering that patients with pain would experience against the harms, not only to those individuals and their families but also to society, that would be prevented by the restriction? The "societal need to reduce opioid misuse" is particularly challenging in ethical terms because much of the harm to society arising from opioid misuse is attributable to diversion of the prescribed drugs from lawful

markets and to the operation of black markets. Are these two sets of needs morally commensurate? Are they convertible to a common metric?

The task is made somewhat easier if one recognizes that the point of contention regarding the use of opioids in serving the "needs of pain patients" focuses almost entirely on treatment of chronic noncancer pain. As long as the quantity prescribed, dispensed, and administered is suitably limited, there is little disagreement about the need for opioids for treatment of patients with acute pain within controlled settings such as hospitals (e.g., the perioperative use of opioids for many types of surgeries), or for treatment of patients with cancer or terminal conditions. The area of dispute concerns long-term use of take-home doses for chronic noncancer pain by people who are not terminally ill.

It is instructive to attempt to operationalize the balancing task at the policy level. On the one hand, the policy maker must quantify or otherwise characterize the aggregate reduction in pain experienced by patients if opioids are prescribed and used for these chronic indications. As discussed in Chapter 2, this is a difficult task because of a lack of data on the effectiveness of opioid therapy for long-term (>1 year) outcomes related to pain, function, and quality of life (Chou et al., 2015; Dowell et al., 2016)—notwithstanding the reported experience of many patients and their providers who believe the drugs are beneficial. On the other hand, policy makers must quantify or otherwise characterize the harms that would not have occurred had prescribing of opioids been more restricted. These harms include death from overdose and other harms to patients who become addicted to opioids in the course of treatment, and importantly, it also includes harms due to the misuse of drugs that have been diverted from lawful channels to people other than the patients to whom the drugs are prescribed.

This policy balance between benefits and harms inevitably involves many uncertain parameters requiring considerable speculation: the numbers of patients with pain who will be affected, the nature and intensity of the pain that will be experienced or mitigated under different sets of assumptions about access to the drugs, and the effect of more or less restrictive regulatory approaches on access to the drugs by persons other than the patients to whom they have been prescribed and the harms that might subsequently occur. Converting all these postulated impacts to a common metric, such as quality-adjusted life years (QALYs), would be one way to proceed, although this approach would require overcoming many technical challenges. Moreover, other outcomes at the societal level might be difficult to quantify, such as the impact of one or another policy on public trust in the medical profession and the health care system. Loss of confidence can arise from perceived overprescribing or perceived underprescribing.

This analytic approach of identifying, quantifying, and balancing relevant outcomes at the societal level is the only way policy makers can think clearly about such a complex issue and make their arguments transparent and open to critical review by others. However, one of confounding features of the policy discourse on the regulation of opioids and opioid prescribing is that many physicians and patient advocates ground their arguments not in an aggregated balance of benefits and harms at the population level but in the patient-centered ethics of clinical medicine (ethics "at the bedside," so to speak). When viewed from the perspective of an individual physician and an individual patient seeking treatment for chronic pain, regulations restricting access to opioids may be objectionable because they are perceived as unduly constraining the options available to physicians seeking to alleviate the suffering of each patient under their care. This ethical duty entails making an individualized judgment about each patient's needs, recognizing that the needs of a particular patient may differ from those of the "average" patient experiencing a particular type of pain; that the patient's response to treatment

may differ from the "typical" response in relation to both specific risks and potential benefits; and that these effects in any particular case are difficult to quantify, especially when there is so little evidence about long-term use of opioids for chronic noncancer pain. From this perspective, the duty to exercise individualized clinical judgment lies at the heart of the physician–patient relationship. Individualized decision making is all the more important in the context of pain, given its inherently subjective nature, and in the context of the ethical paradigm of shared decision making.

In thinking about the task of balancing the aggregated needs of patients in pain at the societal level and the need to prevent harms associated with misuse of opioid analgesics, the committee was sensitive to the ethical tension between the population perspective of public health and the patient-centered perspective of clinical ethics. The bottom line is that these two perspectives address two different questions. The committee's charge was to answer the societal question: What should the FDA and other government entities do when acting to further society's collective interest? The committee was not charged with asking what physicians and other prescribers should do or what options they should have available for particular clinical indications. This does not imply, however, that the ethics of clinical medicine are irrelevant: the framework used by policy makers in balancing the aggregated needs of patients with pain against society's collective interest in preventing opioid-related harms must be sensitive to the impact of alternative policies on public confidence in the health care system, including trust in the physician–patient relationship.

STUDY SCOPE AND EMPHASIS AND REPORT ORGANIZATION

Study Scope and Emphasis

The breadth of the committee's charge posed several challenges. First, the charge envisioned two fairly distinct tasks—an update of the science of pain research, care, and education since the IOM's 2011 report, including the evolving role of opioids in pain management, and a "new" report summarizing the "state of the science" on the use and misuse of prescription opioids and on approaches for addressing the problem. The committee interpreted its charge as focusing primarily on the misuse of prescribed opioids, the occurrence of OUD, and the associated public health harms, with updates to the 2011 report being limited to those bearing on indications for opioid prescribing, alternatives to opioids for pain management, physician education, and priorities for research.

A second challenge was the multiple audiences for this report. The charge requested that the committee provide advice not only to the FDA but also to other policy makers and stakeholders. The committee understood that the FDA's primary reason for requesting this report was its desire for an expanded framework for review, approval, and monitoring of opioids that would encompass the societal harms resulting from opioid prescribing, and accordingly attempted to develop such a framework. However, the FDA knows it cannot address the opioid problem on its own, and its charge to the committee clearly invited a broader view of the report's intended audience. The committee chose to take this broader view because it was convinced that successful efforts to prevent, ameliorate, and minimize the public health harms associated with use and misuse of prescription opioids will require coordinated action at all levels of government and by a diverse array of stakeholder organizations.

A third challenge was that the committee was charged with addressing a complex, multifaceted problem that can be viewed through many lenses. The approach the committee took to carrying out this charge was shaped by the expertise of the its members and its interpretation of the charge. Accordingly, the committee focused on improving the treatment of pain and on responding to the policy challenges presented by the opioid epidemic. Many other relevant topics could have been included, such as why this epidemic has occurred. However, the committee was not directed to investigate the causes of the prescription opioid problem or to judge how it could have been avoided or ameliorated. Indeed, in its initial conversations with FDA officials, the committee was specifically advised that the purpose of this report was not to place blame for the current state of affairs.

Not surprisingly, however, questions about who bears responsibility for the current situation surfaced repeatedly in the committee's public workshops. Some observers, for example, suggested that the 2011 IOM report underemphasized then-emerging opioid-related harms as it highlighted the prevalence and cost of inadequately treated pain. Other speakers argued that the FDA has not been aggressive enough in its regulatory decisions, while still others directed attention to the systemic failures of the nation's health care system.

Nonetheless, the committee did not aim to assign responsibility for past mistakes. Its task was to review and assess approaches and actions that the FDA and others have taken, and could take, to resolve the problem and prevent such problems from arising in the future. To this end, the committee naturally posits a predictive model concerning what interventions might work. In so doing, it relies on a traditional multifactorial causal model commonly used in public health, encompassing considerations ranging from structural factors to individual susceptibility. Using this approach, certain hypotheses about causes of the epidemic are inescapable. For example, the data presented earlier in this chapter make a prima facie case that heavy promotion of opioid prescribing by drug manufacturers (including misleading claims by some) and substantially increased prescribing by physicians were key contributors to the increase in misuse, OUD, and accompanying harms.

It is also clear, however, that overprescribing was not the sole cause of the problem. While increased opioid prescribing for chronic pain has been a vector of the opioid epidemic, researchers agree that such structural factors as lack of economic opportunity, poor working conditions, and eroded social capital in depressed communities, accompanied by hopelessness and despair, are root causes of the misuse of opioids and other substances and SUD (Carpenter et al., 2016; Compton et al., 2014; Nagelhout et al., 2017). It was beyond the scope of the committee's task to review and offer recommendations for mitigating the effects of these underlying structural determinants of opioid misuse and OUD. Nonetheless, the committee believes it is extremely important to keep these determinants in mind while reading this report, which focuses largely, although not entirely, on the supply side of the equation (increased prescribing of opioids) rather than on the more complex structural and environment factors that contribute to the demand side of the equation.

Report Organization

This report is divided into six chapters. Part I, comprising Chapters 2 and 3, updates the 2011 IOM report. Chapter 2 describes the scope of the problem of pain in the United States and the state of the science on pain management, with an emphasis on the evolving role of prescription opioids and other forms of treatment in pain management. Areas for future research on pain and its management and on OUD to assist the FDA with the development of a

framework for opioid approval and monitoring are discussed in Chapter 3. Part II, comprising Chapters 4, 5 and 6, characterizes the opioid epidemic and the nation's response to it. Chapter 4 describes the epidemiology of opioid use and misuse, OUD, overdose, and other harms from both prescription and illicit opioids (e.g., heroin). Chapter 5 reviews the evidence regarding the effectiveness of strategies being used to address the opioid epidemic and makes recommendations where indicated. Specific topics covered include regulating the types of products approved for use (e.g., ADFs); restricting legal access to approved drugs; modifying prescribing practices; providing patient education; increasing access to treatment for OUD; and reducing harms from opioid use, such as by providing naloxone to prevent opioid overdose and making clean needles available for injection drug users to reduce transmission of HIV and hepatitis C virus. Finally, based on content presented in earlier chapters, Chapter 6 outlines steps the FDA can take to improve its regulation of opioids, including a framework for improving incorporation of individual and public health risks and benefits into future FDA approval and monitoring of these drugs.

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PART I

PAIN MANAGEMENT AND RESEARCH

2

Pain Management and the Intersection of Pain and Opioid Use Disorder

This chapter addresses the scope of the problem of pain in the United States and its association with opioids, and the effectiveness of pharmacologic (both opioid and nonopioid) and nonpharmacologic treatments that may, alone or in combination, help individuals manage pain. The first section summarizes the scope of the problem of pain, focusing in particular on chronic, or persistent, pain, the form most associated with problematic use of opioids. The chapter then presents a detailed discussion of the various pain treatment modalities, reviewing in turn opioid analgesics, nonopioid pharmacologic treatments, interventional pain therapies, and nonpharmacologic treatments. This section is particularly important in helping to contextualize the evidence of effectiveness and limitations for various treatments for pain, given the burden of pain, the risks associated with undertreatment, and the pervasiveness of opioid use and related dose-dependent risks. The next section examines differences in pain experiences and treatment effectiveness among subpopulations, and the final section briefly addresses the intersection between pain and opioid use disorder (OUD) (discussed in greater detail in Chapter 3). A main objective of this chapter is to situate opioids within the broader armamentarium of treatments available for management of pain and to identify potential opportunities for reduced reliance on these medications.

THE SCOPE OF THE PROBLEM OF PAIN

Chronic pain generally is defined as pain lasting 3 or more months or beyond the time of normal tissue healing (Dowell et al., 2016). As described in the 2011 Institute of Medicine (IOM) report *Relieving Pain in America* (IOM, 2011), pain is a significant public health problem, although estimates of the number of people living with chronic pain in the United States vary widely in population-level surveys (see Croft et al., 2010; Johannes et al., 2010; Nahin, 2015; Portenoy et al., 2004). Using self-reported data from the 2011 National Health Interview Survey's Functioning and Disability Supplement, Nahin (2015) estimates that at the time of the survey, 11.2 percent of the adult U.S. population (25.3 million people) was experiencing daily chronic pain (pain every day for the last 3 months).

The 2011 IOM report appropriately calls attention to the substantial burden of pain in the United States and estimates that "chronic pain alone affects approximately 100 million U.S. adults," a figure that has routinely been quoted in recent years (IOM, 2011, p. 100). The present committee found that it is difficult to formulate a reliable estimate of the prevalence of chronic pain because of differences across surveys in the way pain is defined and measured. The 100 million figure cited in the IOM 2011 report was based on an analysis of data from surveys

conducted in 17 developed and developing countries, including the United States, to evaluate differences in the prevalence of common chronic pain conditions by age and sex, as well as the comorbidity of chronic pain conditions with depression and anxiety disorders (Tsang et al., 2008). The age-adjusted prevalence of chronic pain conditions in the previous 12 months for adults in the United States was found to be 43 percent (roughly 100.86 million people based on the total U.S. population aged 18 and over in 2010) (Howden and Meyer, 2011; Tsang et al., 2008). A limitation of that study, in this committee's view, is that the questions asked of survey participants did not distinguish occasional aches and pains from daily continuous or chronic intermittent pain that may interfere with quality of life.[1] As noted by Tsang and colleagues (2008) themselves, one of the limitations of the study is that "the assessment of pain condition did not include severity and duration of pain." Nonetheless, regardless of the exact number of people living with chronic pain in the United States, it clearly affects the lives of millions of Americans.

Chronic pain is associated with multiple comorbidities, including, among others, impaired memory, cognition, and attention; sleep disturbances; reduced physical functioning; and reduced overall quality of life (Dahan et al., 2014; Fine, 2011; IOM, 2011). Chronic noncancer pain also has been found to be associated with work absenteeism (Agaliotis et al., 2014). Severe chronic pain at the highest levels is associated with poor health and increased use of medical resources (IOM, 2011), and painful conditions are among the most frequently reported reasons for outpatient visits with physicians in the United States (CDC, 2017). An argument has been made that chronic pain may itself be considered a disease syndrome when it leads to changes in the nervous system over time (IOM, 2011). As discussed later in this chapter, adding to the public health burden of pain are disparities in access to and quality of pain treatment among subpopulations (Anderson et al., 2009; IOM, 2011; Mossey, 2011).

The very real problems of underdiagnosis and undertreatment of pain are valid concerns, but it would be a mistake to infer that greater utilization of opioids would ameliorate these problems. As discussed below, opioids have long been used for the effective management of acute pain (e.g., acute postsurgical and postprocedural pain), but available evidence does not support effectiveness for the long-term use of opioids for chronic pain management. On the other hand, evidence indicates that patients taking opioids long-term are at increased risk of OUD and opioid overdose, as well as a number of other adverse outcomes (e.g., cardiovascular events, fractures) (Baldini et al., 2012; Chou et al., 2015; Krashin et al., 2016). Nevertheless, opioids often are used in the management of chronic noncancer pain. As discussed in Chapter 1, for many years physicians prescribed opioids for chronic noncancer pain, sometimes in very high doses, because of the incorrect belief that the risk for the development of substance use disorders and addiction was low (Krashin et al., 2016). Emphasis was appropriately placed on inadequate recognition and treatment of pain. However, these concerns often were not balanced by a similar emphasis on precautions to avoid adverse effects, such as the development of addiction (Kolodny et al., 2015), and the increase in opioid prescribing that began during the 1990s was associated with a parallel increase in opioid-related substance use disorders and opioid-related deaths (Dowell et al., 2016; Kolodny et al., 2015; SAMHSA, 2015). It is estimated that opioid pain relievers (excluding nonmethadone synthetics) directly accounted for more than 17,500 deaths in

[1]Survey participants were asked whether they had ever had "arthritis or rheumatism" in their lifetime. Respondents who replied that they had were asked whether the arthritis or rheumatism had been present in the prior 12 months. Participants also were asked whether they had ever had "chronic back or neck problems" (referred to as back pain), "frequent or severe headaches" (referred to as headaches), and "other chronic pain" in the prior 12 months.

2015, up from approximately 6,160 in 1999 (NCHS, 2016). Moreover, these figures do not account for deaths from related conditions (e.g., bloodborne infections associated with OUD; see Chapters 4 and 5 for further detail). There are indications that opioid prescribing is decreasing, but as recently as 2015, tens of millions of opioids were dispensed by U.S. outpatient retail pharmacies (see Figure 1-1 in Chapter 1). The United States consumes the vast majority of opioids worldwide (Hauser et al., 2016).

Acute pain also is relevant to this report. Millions of Americans are diagnosed each year with acute pain conditions (e.g., those associated with surgery, trauma, or acute illness) that typically resolve over days to weeks. Opioids are frequently prescribed to treat these conditions. Opioids may be effective for managing acute pain when used appropriately, but as with chronic noncancer pain, harms to individuals and society may arise from these uses of opioids (Dowell et al., 2016). See Chapter 5 for discussion of the effectiveness of strategies for addressing these harms.

Little is known about the relationship between or the progression from acute to chronic pain, although preoperative chronic pain is thought to be a risk factor (Gerbershagen et al., 2014). It has been proposed that inadequate management of acute pain may increase an individual's risk for development of chronic pain (Sinatra, 2010). Indeed, some evidence suggests that appropriate treatment of acute pain, particularly persistent postsurgical pain, could decrease the likelihood of the future development of chronic pain (Clarke et al., 2012). Similarly, the use of gabapentin or pregabalin in the immediate preoperative setting has the potential to decrease the need for postsurgical opioids (Tan et al., 2015a). Research is ongoing to identify strategies that can decrease the risk of acute pain developing into persistent pain (McGreevy et al., 2011).

It is important to emphasize that the term "pain management" has not been clearly defined and sometimes is used erroneously to denote solely pharmacologic tools. Yet pain management may involve the use of a number of tools—both pharmacologic and nonpharmacologic—to relieve pain and improve function and quality of life. Before proceeding to a review of these various treatments, it should be noted that, while each may be used on its own, their integration in multimodal strategies that cut across medical disciplines and incorporate a full range of therapeutic options—including cognitive-behavioral, physical/rehabilitation, pharmacologic, and interventional therapies—has been shown to be most effective in the treatment of chronic pain (Koele et al., 2014; Scascighini et al., 2008). In contrast, use of a single pharmacologic modality such as an opioid analgesic, often used for the relief of acute nociceptive pain, is inherently limited in its ability to provide long-term relief and/or reverse ongoing plasticity changes driving chronic pain. Such pain encompasses a complex condition that has defied simple remedies. As noted, persistent pain is classified as chronic if someone has endured it for at least 3 months. Unfortunately, over this time period, the person experiencing the pain may have changed in complex ways. From the neuroscientist's perspective, pathologic plasticity changes in the central and peripheral nervous system have taken hold and have become self-perpetuating, signaling pain and frequently limiting meaningful function. Chapter 3 describes the complex neurobiology related to pain (and reward) processing, identifies promising research areas, and highlights knowledge gaps that could be addressed to help improve the management of chronic pain.

Thus, it must be stressed that a single therapeutic switch to turn off the perception of chronic pain has yet to be found and in fact may not exist. From the perspective of those suffering chronic pain, any remedy, even one that may simply remit the pain for a few hours or

days, may be a welcome relief despite risks or side effects. However, just as chronic pain represents a complex pathophysiologic condition that develops over time, its successful management often requires an equally complex and time-intensive approach. Therefore, combining multiple therapeutic modalities, nonpharmacologic and pharmacologic (nonopioid and opioid), holds promise not only to temper the ongoing pain but also to help return the nervous system and its owner back to a less painful and more functional state. It is significant, then, that many of the nonpharmacologic techniques are reimbursed poorly if at all by third-party payers, creating a disincentive to provide this effective care for patients. See Chapter 5 for further discussion of policies regarding reimbursement of comprehensive pain management.

OPIOID ANALGESICS

Effectiveness and Risks

Opioid analgesics encompass a wide range of medicinal products that typically share the ability to relieve acute severe pain through their action on the μ opioid receptor—the major analgesic opioid receptor expressed throughout the nervous system. Since the isolation of morphine from crude opium by Sertürner in 1803, there has been a progressive increase in the number of opioid analgesics that differ in their chemical composition, route of administration, uptake, distribution, type/rate of elimination, and ability to bind to opioid receptors. Certain of these drugs have ultra-short durations of action uniquely suited to providing analgesia as a component of a balanced surgical anesthetic. Others have very long durations of action resulting either from the intrinsic properties of the opioid molecule or the pharmaceutical formulation; in either case, these opioids are released at a predictable rate into a patient's body. An additional feature of these medications contributing to their clinical utility is the availability of oral, intravenous, transdermal, intranasal, epidural, and intrathecal preparations.

Opioids have long been used successfully to treat acute postsurgical and postprocedural pain, and they have been found to be more effective than placebo for nociceptive and neuropathic pain of less than 16 weeks' duration (Furlan et al., 2011). For other types of acute pain, however, such as low back pain, the efficacy of opioids is less clear (Deyo et al., 2015; Friedman et al., 2015). And as noted earlier, while evidence exists to support the use of opioids for the treatment of some acute and subacute pain, evidence to support their use to treat chronic pain is very limited (Chou et al., 2015; Dowell et al., 2016). The few randomized controlled trials (RCTs) demonstrating the efficacy of opioids have had small sample sizes and rarely have produced data that extend past 3 months, the length of time after which pain is considered to be chronic.

The average reduction in chronic noncancer pain ascribed to opioids has been found to be approximately 30 percent (Kalso et al., 2004), and data on functional improvement are limited. A Danish epidemiological study evaluating the effects of long-term (>6 months) use of opioids in more than 10,000 patients with chronic noncancer pain failed to show improvement on any of the items in the 36-Item Short Form Health Survey (SF-36) used to score health-related quality of life (Eriksen et al., 2006). A meta-analysis of 26 studies examining various opioid drugs (compared with placebo as well as other treatments, including nonsteroidal anti-inflammatory drugs [NSAIDS]) in chronic noncancer pain found that "all patients with CNCP [chronic noncancer pain] do not respond to opioid analgesics, only 30–50% of carefully screened subjects report decrease in pain with opioids; [and] the results of RCTs cannot be generalized to the

CNCP population because clinical trials do not include…multiple pain complaints…or other psychiatric comorbidities" (Sehgal et al., 2013, p. 1211). There is some evidence that return to work is more often delayed than expedited for patients using opioids chronically (VonKorff, 2013). And today, despite the existence of a number of opioid compounds and formulations, there is no evidence that one opioid analgesic is superior to another in its ability to manage either acute or chronic pain, and there is insufficient evidence on appropriate dosing. A study of 1,477 adults prescribed opioids for chronic pain, for example, showed that patients who used lower or intermittent doses of opioids had pain outcomes similar to those of patients who used regular or higher doses (Turner et al., 2016).

With regard to the risks associated with the use of prescription opioids, it has been shown that once patients have been taking opioids longer than 90 days, the risk that they will continue to take them chronically and develop a substance use disorder increases (Krashin et al., 2016). In addition to substance use disorder, morbidity related to opioid therapy for chronic pain includes reduced testosterone, cardiac abnormalities, fractures, and immunosuppression, among other adverse outcomes (Chou et al., 2015). A 2015 systematic review of studies of adults prescribed oral opioids for chronic pain estimates the prevalence of opioid misuse (defined in the study as "opioid use contrary to the directed or prescribed pattern of use, regardless of the presence or absence of harm or adverse effects") in the United States to be 21.7–29.3 percent and the prevalence of addiction (defined as continued use despite harm) to be 7.8–11.7 percent (Vowles et al., 2015). In the elderly and other patients with a higher risk of cognitive impairment, opioids may result in further impairment of cognition and executive function (Schiltenwolf et al., 2014). As noted earlier, moreover, there is a risk of death from these drugs due to opioid-induced respiratory depression (Chou et al., 2015).

Of the many long-term consequences of using opioids, tolerance and opioid-induced hyperalgesia (OIH) are commonly cited as reasons for their waning therapeutic effect over time. Strong laboratory evidence demonstrates that these phenomena occur after even short periods of exposure to opioids or after exposure to large doses of the drugs (Angst and Clark, 2006; Trang et al., 2015; Yi and Pryzbylkowski, 2015). Likewise, tolerance and OIH have been demonstrated in people with OUD, and abnormal pain sensitivity in this population is associated with drug craving (Ren et al., 2009). On the other hand, OIH has been observed after short-term exposure to potent, rapidly eliminated opioids such as remifentanil in human volunteers (Angst and Clark, 2006; Eisenach et al., 2015). Correspondingly, patients for whom remifentanil is incorporated into their surgical anesthetic appear to have higher postoperative pain levels or opioid requirements consistent with either tolerance or OIH (de Hoogd et al., 2016; Fletcher and Martinez, 2014). However, the rapidity, severity, and pervasiveness of tolerance and OIH are poorly defined in chronic pain populations, as are possible differences among opioids with respect to causing these adverse consequences. The situation is made more problematic by difficulties in assessing tolerance and OIH in clinical settings. Rapid dose escalation with worsening pain and the spread of painful symptoms have been suggested as indicators of tolerance and OIH, but well-validated clinical methods for quantifying tolerance and OIH in chronic pain patients are lacking (Mao, 2002).

One of the U.S. Food and Drug Administration's (FDA's) required post-marketing studies for extended-release/long-acting (ER/LA) opioid analgesics is an ongoing clinical trial to estimate risk for the development of hyperalgesia following long-term use (at least 1 year) of these drugs to treat chronic pain. This study, which includes an assessment of risk relative to efficacy, is anticipated to be completed in 2019 (see Chapter 6, Annex Table 6-1).

It is important to remember that nonopioid pharmacologic therapies carry their own distinct risks. For example, gastrointestinal bleeding and renal dysfunction are known risks associated with NSAIDs. Likewise, hepatotoxicity and unintended death are risks associated with acetaminophen, and acetaminophen toxicity is thought to contribute to at least some opioid-related mortality (Dunn et al., 2010; McLellan and Turner, 2010). Accordingly, some of the most difficult patients for whom to provide pain relief are those with end-stage liver or kidney disease or with bleeding disorders, many of whom end up taking opioids chronically because of the perceived paucity of effective alternatives.

While all prescription opioids interact with opioid receptors, some more recently developed agents possess additional pharmacologic activity, and even newer agents have been engineered to interact with opioid receptors in ways that may enhance analgesic benefits while minimizing side effects, such as respiratory depression (Dahan, 2016). Therefore, it is likely that additional opioid drugs with properties perhaps superior in important ways to those of existing drugs will be developed for a wide range of painful conditions. On the other hand, these new drugs are likely to rely at least in part on the activation of the μ opioid receptor, a structure closely linked to important side effects of opioids, including respiratory depression and euphoria. Thus the propensity of opioid medications to cause overdose or misuse is likely to continue to be cause for concern with these new formulations.

Opioid Prescribing Practices

Beyond differences in analgesic potency (e.g., hydrocodone versus morphine versus hydromorphone), one might ask what dictates prescribing of opioid analgesics for chronic pain. Addressing this question is challenging given the lack of a single integrated source of information on the use of prescription opioids in the United States. This is the case despite calls from both governmental and nongovernmental organizations for improved methods for tracking and accountability of opioid prescribing practices, indications, efficacy, or disposal and the more than decade-long development of the opioid epidemic. Government institutions rely in part on private consulting firms and/or literature generated from industry-sponsored research, or when available, post-marketing data (IOM, 2010). Other information comes from academically directed research focused on specific diagnostic areas, such as opioid use in musculoskeletal disorders (rheumatologic, back pain); treatment of specific disease states, such as sickle cell disease; and dental and emergency department practices. Although a full understanding is constrained by the limited information available, the committee compiled a brief summary of opioid prescribing practices in the United States from these accessible resources.

In 2015, 169 million prescriptions for some of the most common ER/LA and immediate-release (IR) opioid analgesics were dispensed by U.S. outpatient retail pharmacies, down from a high of 206 million in 2011 (see Chapter 1, Figure 1-1). The majority of opioid analgesic prescriptions dispensed during 2005-2015 were for IR opioids, whereas the number of ER/LA opioids dispensed remained nearly constant during this period (~12 percent in 2015).

During 2007–2012, self-reported use of opioid analgesics was higher among women (7.2 percent) than men (6.3 percent) and higher among non-Hispanic white adults (7.5 percent) than Hispanic adults (4.9 percent), while there was no significant difference in self-reported use between non-Hispanic white and non-Hispanic black adults (Frenk et al., 2015). From 1999–2002 to 2003–2006, the percentage of adults aged 20 and over who reported that they had used a prescription opioid analgesic in the past 30 days increased from 5.0 to 6.9 percent. From 2003–2006 to 2011–2012, the percentage who used an opioid analgesic remained stable at 6.9 percent.

From 1999–2002 to 2011–2012, however, the percentage of users of opioid analgesics who were prescribed an opioid analgesic stronger than morphine increased from 17 to 37 percent (Frenk et al., 2015). Such a shift to more potent formulations may represent an important signal if one is attempting to understand the current ecology of prescription opioid use in the United States. Specifically, a shift from opioid analgesics that are weaker than morphine (codeine, dihydrocodeine, meperidine, pentazocine, propoxyphene, and tramadol) and "morphine-equivalent" (hydrocodone, morphine, and tapentadol) to those stronger than morphine (fentanyl, hydromorphone, methadone, oxycodone, and oxymorphone) may represent an unwarranted change in opioid prescribing practices relative to evidence for the treatment of chronic painful conditions (Frenk et al., 2015). Although information is limited, such a shift to more potent opioids may correlate with reports of increased use of some opioid analgesics, such as oxycodone.

Clinical Contexts in Which Opioids Are Commonly Prescribed

An analysis of IMS Health's national prescription data showed that in 2012, nearly 49 percent of all dispensed opioid prescriptions were accounted for by primary care specialists. Opioid prescribing also varies by provider specialty. In 2012, the rate of opioid prescribing among specialists was highest for specialists in pain medicine (48.6 percent), followed by surgery (36.5 percent) and physical medicine and rehabilitation (35.5 percent). From 2007 to 2012, the greatest increase in the rate of opioid prescribing was among physical medicine and rehabilitation specialists, while the greatest declines were in emergency medicine (-8.9 percent) and dentistry (-5.7 percent) (Levy et al., 2015).

The clinical contexts in which pharmaceutical opioids are used also can be quite diverse. The evaluation of risks and benefits may therefore be different for specific opioids depending on their intended application. A few examples of common clinical contexts in which opioids are used demonstrate some of these differences.

Surgery and Acute Pain

Opioids are used commonly during and following surgery. During a surgical procedure, opioids contribute to the analgesic component of a balanced anesthetic. Often the opioids used are of high potency and short duration of action. In addition to intravenous administration, opioids are sometimes administered intrathecally or into the epidural space to provide relatively high local concentrations without exposing respiratory centers in the brainstem to the same levels of the drugs.

Postoperatively, opioids are used in the postanesthesia care unit and hospital wards and as predominantly oral medications for a period ranging from days to a month or more during the convalescent period. The rate of discontinuation of opioids after surgery has been studied and is believed to be impacted by ongoing pain, as well as psychological factors and patients' self-perception of their risk for developing OUD (Carroll et al., 2012; Hah et al., 2015). The rate of discontinuation of opioid therapy after surgery is strongly impacted by preoperative use, and is higher for some types of surgery (e.g., joint replacement) than others (Mudumbai et al., 2016; Sun et al., 2016). It remains unclear how intraoperative exposure to opioids contributes to the risk for OUD. Perisurgical exposure to opioids may be an inciting event for the eventual development of OUD in some patients (Sun et al., 2016). Patients with OUD (e.g., individuals on methadone maintenance) are not necessarily excluded from receiving a short course of opioids

for acute or acute postoperative pain. Providing excessive amounts of opioids postoperatively is now discouraged, however, and some health care organizations have attempted to limit the amount of postsurgical take-home opioid medication. The effectiveness of such policies is discussed in Chapter 5.

Another commonly encountered acute pain context leading to opioid exposure is the treatment of acute injuries, such as those due to household, sporting, or motor vehicle accidents. In these situations, limited supplies of opioids may be prescribed by emergency departments, urgent care clinics, specialty physicians, and primary care providers. The prescribing of opioids by emergency departments has been especially closely studied, and an increase was found to coincide with an increase in overall opioid prescribing (Maughan et al., 2015). Prescribing in this context can set the stage for a pattern of more chronic use; indeed, observational evidence suggests that long-term opioid use may begin in the emergency department (with 1 in 48 patients prescribed opioids becoming long-term users) (Barnett et al., 2017). Likewise, the use of prescription opioids by former professional athletes is very high, and participants in interscholastic sports may have an elevated risk of opioid use and misuse relative to their nonathlete counterparts (Veliz et al., 2015). Motor vehicle accidents, particularly severe ones, also appear to lead to chronic opioid use in some patients (Zwisler et al., 2015). Opioid prescribing guidelines targeting emergency departments and other acute care settings might contribute to reducing opioid prescribing and increase the use of such measures as urine drug screening prior to prescribing (Chen et al., 2016; del Portal et al., 2016).

Chronic Pain Syndromes

The use of opioids for the management of chronic pain has generated a great deal of attention, and represents the rationale for the prescribing of a large percentage of overall opioid medication consumed each year in the United States. Common types of pain for which these drugs are prescribed include back pain, arthritis, and neuropathic pain (e.g., pain involving tissue injury). Among the complications now associated with the chronic use of opioids for pain are dependence, tolerance, hyperalgesia, addiction, hypogonadism, falls, fractures, sleep-disordered breathing, increased pain after surgery, and poorer surgical outcomes (Baldini et al., 2012; Chou et al., 2015).

Several meta-analyses now available examine the efficacy of opioids for specific pain conditions, such as neuropathic (Gaskell et al., 2016; McNicol et al., 2013) and back (Abdel Shaheed et al., 2016; Chaparro et al., 2014) pain. Additional analyses have included reports on studies involving participants with mixed types of chronic pain (Chou et al., 2014; Pedersen et al., 2014). In general, these meta-analyses suggest that any positive effects of such opioid use have been demonstrated only for relatively short periods of time and that the size of those effects was small. Data are lacking on long-term (>1 year) outcomes such as pain, function, quality of life, and OUD (Chou et al., 2015). Dropout from studies of the use of opioids for chronic pain due to side effects is common, as is discontinuation of the therapy in clinical settings, making it difficult to estimate the benefits of these drugs. Nonetheless, although opioids are commonly prescribed for chronic pain, no widely accepted guidelines suggest their use as first-line analgesic therapy for a chronic pain condition.

Arthritis According to data from the National Health Interview Survey (NHIS), the prevalence of doctor-diagnosed arthritis among adults in the United States during 2013–2015 was 22.7 percent (54.4 million people), with even higher prevalence among individuals with chronic

conditions such as heart disease, diabetes, and obesity (Barbour et al., 2017). It is estimated that by 2040, 78 million adults in the United States (26 percent of those aged 18 and older) will have been diagnosed with arthritis (Hootman et al., 2016). Adults with arthritis made up more than half (53 percent) of adults taking prescribed opioids in 2013 (Hootman et al., 2016). Given the widespread use of opioids for noncancer pain and the fact that individuals with musculoskeletal disorders, including arthritis, represent the largest population using prescription opioids, understanding the factors driving opioid use among these individuals could shed light on the broader landscape of prescribing practices.

In a retrospective cohort study evaluating prescription data on patients with rheumatoid arthritis (RA) (n = 501), which after osteoarthritis is one of the more common forms of arthritis, and comparable non-RA subjects (n = 532) during 2005–2014, total and chronic opioid use[2] in 2014 was found to be substantially higher in RA than in non-RA participants (40 versus 24 percent and 12 versus 4 percent, respectively). Opioid use had increased by 19 percent per year in both the RA and non-RA cohorts over the study period (95 percent confidence interval [CI] 1.15, 1.25), with an odds ratio of 3.35 to start first chronic use of opioids within the 10-year study period (Zamora-Legoff et al., 2016). Curiously, factors measuring disease severity for RA were not associated with an increased risk of chronic opioid use, posing the unanswered question of what, if any, pathophysiologic and/or functional factor(s) influence the decision to escalate to more potent and/or long-term opioid therapy (Zamora-Legoff et al., 2016).

Fibromyalgia Ten to 20 percent of patients with RA have fibromyalgia, which often involves widespread musculoskeletal pain. A review of available treatments for the chronic pain of fibromyalgia revealed no evidence from clinical trials that opioids are effective for the treatment of this pain (Goldenberg, 2016). In fact, observational studies found that patients with fibromyalgia receiving opioids had poorer outcomes than those receiving nonopioid therapies, and current guidelines recommend against the use of opioids for treating this pain. Yet despite the lack of efficacy and evidence to the contrary, real-world studies revealed that among patients with fibromyalgia who had been newly prescribed amitriptyline, duloxetine, pregabalin, or gabapentin, opioid use was greater than 50 percent during their baseline period (Kim et al., 2013).

Back Pain Back pain is one of the main reasons people visit a primary care or family practice physician, and also predominates in other clinical contexts, such as in the care of veterans. In a study of veterans treated in a regional health care network for chronic noncancer pain, for example, factors associated with use of high-dose opioids (≥180 milligrams morphine-equivalent dose), after controlling for demographic factors and facility, included low back pain, neuropathy, and nicotine dependence. Within the high-dose group, approximately equal percentages of patients had received oxycodone IR (48 percent) and/or morphine ER (52 percent) (Morasco et al., 2010). Although the long-term efficacy of opioids in the management of back pain is unknown, the clinical benefits of shorter-term opioid therapy to treat this condition appear to be relatively moderate compared with the many well-documented adverse effects (Deyo et al., 2015). In their review, Deyo and colleagues (2015) note that for seven short-term trials (≤12-week follow-up) examining the use of strong opioids for chronic low back pain, there was

[2]Chronic opioid use was defined as opioid prescriptions for 60 days or more within a 6-month period and use of one or more of the following opioids: transdermal fentanyl, methadone, and oxycodone ER (Zamora-Legoff et al., 2016).

moderate evidence of pain reduction and functional improvement compared with placebo. Nevertheless, opioids continue to be used widely in an attempt to manage back pain for longer periods of time. For example, in a large study of a managed care plan (Kaiser Permanente Northwest health care system in Portland, Oregon) examining the pattern of opioid use 6 months before and after an index visit for back pain, 61 percent of the 26,014 eligible patients had received a course of opioid therapy, and 19 percent had become long-term (≥120 days or >90 days with 10 or more fills) opioid users. Among the long-term users, 59 percent had received short-acting (SA) opioids, and 39 percent had received both SA and LA opioids. Psychological and behavioral difficulties appeared to drive long-term opioid use in persons with back pain (Deyo et al., 2011).

Musculoskeletal Conditions and Fractures, Sprains, and Contusions

Tracking of opioid prescriptions currently is not linked to such details as medical indication, whether the patient's pain is acute or chronic, or other pertinent details of medical history. Rather, the primary tracking factors are the 9th and 10th revisions of the *International Classification of Diseases* (ICD) (Pan, 2016). On this basis, diseases of the musculoskeletal system and connective tissues (ICD-9 codes 710–739) are among the conditions most commonly associated with the use of opioids (FDA, 2016; Pan, 2016). According to office-based physician reports, in 2015 nearly 54 percent of diagnoses of chronic conditions associated with use of hydrocodone/acetaminophen were for diseases of the musculoskeletal system and connective tissues (which include arthritis and back pain). Among acute conditions, injuries (fractures, sprains, and contusions [ICD-9 codes 800–999]) were the conditions most commonly associated with the use of hydrocodone/acetaminophen (42 percent), followed by diseases of the musculoskeletal system and connective tissues (17 percent) (FDA, 2016). Cumulative ICD data for the period January 2007–November 2011 indicate that the shares of musculoskeletal system and connective tissue diagnoses associated with the use of different types of opioids were as follows: morphine ER (68 percent), morphine IR (56 percent), oxycodone IR (41 percent), hydrocodone combination (25 percent), and oxycodone combination (20 percent) (Pan, 2016). The shares of individuals with fractures, sprains, and contusions using various types of opioids were considerably different, with oxycodone combination (26 percent) and hydrocodone combination (19 percent) dominating, followed by oxycodone IR (8 percent), morphine ER (3 percent), and morphine IR (4 percent) (Pan, 2016). Based on these data, it appears that oxycodone IR and morphine IR and ER, as opposed to combination products, have been used more frequently to treat chronic pain associated with musculoskeletal and connective tissue disorders.

Cancer-Related Pain and End-of-Life Care

The aggressive use of opioids has long been accepted and strongly promoted for the treatment of pain in patients with cancer or those in end-of-life and palliative care. Foundational work in this area suggested that in most patients, control of pain due to active cancers could be achieved using oral analgesics, including opioids. Such data led to the development of the World Health Organization "Analgesic Ladder," which outlines the use of progressively stronger analgesics as necessary to control pain in these patients (WHO, 1986). The pain, oncology, and palliative care literatures are replete with studies of various IR and LA opioids used to control cancer pain, generally with positive results. It was within the contexts of cancer and palliative

care that the concept of "breakthrough" pain treatment gained popularity. The emergence of this concept has in turn supported the development of fast-acting high-potency opioid preparations such as transmucosal and intranasal products. Overall, the aggressive use of opioids for control of pain in cancer and palliative care patients is common and strongly supported by both the available literature and the medical community (Hadley et al., 2013; Schmidt-Hansen et al., 2015; Wiffen et al., 2016; Zeppetella and Davies, 2013).

However, the use of opioids in these patients is not without caveats. For example, nausea, constipation, sedation, and other side effects are common after the administration of opioids in patients with cancer pain, just as they are in those suffering from other pain conditions. Accidental overdose also can occur. Moreover, studies examining the results of urine drug screens from patients with cancer and in palliative care have provided significant evidence of opioid misuse and diversion (Barclay et al., 2014; Childers et al., 2015), while many cancer pain and palliative care clinics lack formal policies addressing drug misuse and diversion (Tan et al., 2015b). Thus, improperly stored or monitored medications prescribed to cancer or palliative care patients may make their way into the community.

An additional problem increasingly being recognized relates to chronic pain in cancer survivors. In addition to common non-cancer-related causes, chronic pain in cancer survivors can result from the sequelae of the disease itself or such treatments as surgery, radiation, and chemotherapy. Opioid use in cancer survivors is common (Carmona-Bayonas et al., 2016), although data with which to quantify its frequency are scarce. Guidelines have been issued suggesting that providers use approaches similar to those employed for noncancer paints when making decisions about ongoing opioid prescribing (Kurita and Sjogren, 2015; Paice et al., 2016).

Dentistry

It has been estimated that dentists prescribe 12 percent of all IR opioids (hydrocodone, oxycodone), second only to family physicians (Denisco et al., 2011), although their rates of prescribing may have declined in recent years (Levy et al., 2015). Dentists prescribe opioids mainly for the short term to treat acute postsurgical pain. Third molar extraction, for example, is probably the most common surgical procedure performed in healthy adults. It is estimated that 3.5 million third molar extractions are performed by oral and maxillofacial surgery specialists annually (and this number does not include the extractions performed by general dentists). One study found ibuprofen to be the peripherally acting postsurgical drug of choice among 73.5 percent of oral surgeons; however, 85 percent of them almost always prescribed a centrally acting opioid alone or in combination with another analgesic agent. Hydrocodone is among the opioids most commonly prescribed by oral surgeons; one study found that the combination usually was with acetaminophen, and 20 tablets on average were prescribed (Moore et al., 2006a,b). Based on these data, at least 3.5 million people with an average age of 20 (the average age for third molar extraction) may be exposed to opioids related to dental treatment (Denisco et al., 2011).

Opioids also may be prescribed for dental pain in emergency departments. One study found that 45 percent of emergency department visits for a nontraumatic dental condition ended with an opioid prescription (Okunseri et al., 2014). It is important to note that nontraumatic acute dental pain can be treated with a relatively simple dental procedure in a dental office; however, few emergency departments are equipped, staffed, or designed to provide dental care.

Leftover opioids prescribed by dentists may be a concern if they are shared with friends or family members to help with apparent symptoms of pain, or for other reasons (O'Neil and

Hannah, 2010). Therefore, it is recommended that opioids be prescribed only for several days following an oral surgical procedure. Although literature on the duration of pain following oral surgery is scarce, 2–3 days of treatment is often thought to be sufficient (Biron et al., 1996). Moreover, extended severe pain after oral surgery may indicate infection or some other complication, and thus a visit to the dentist is a better option than prolonged treatment with opioids or other pain medications.

Therapy with opioids following third molar extraction or other oral surgery procedures may be indicated as it does provide adequate pain relief (Weiland et al., 2015). However, treatment with peripherally acting analgesic agents, such as ibuprofen and naproxen, has been shown to provide good pain relief as well (Moore et al., 2015) and can be as effective as opioids for many patients who undergo impacted tooth extraction (Hersh et al., 1993). Nonopioid analgesic agents such as NSAIDs may be advisable as the first line of therapy for the routine management of acute postoperative dental-related pain for patients who have no contraindications for their use (Becker, 2010; Donaldson and Goodchild, 2010).

Mandatory checking of data from prescription drug monitoring programs (which are discussed in more detail in Chapter 5) was shown to be effective in changing the prescribing pattern for pain medications among dentists in a dental urgent care clinic in New York State (Rasubala et al., 2015). Before prescribing opioids, it may be beneficial for dentists (as well as other providers; see below) to screen patients for substance misuse as well as substance misuse risk factors. General dentists often have long-term relationships with their patients and therefore are well positioned to perform this screening. Oral surgeons or specialists, who often see patients only for a specific procedure, may consult the referring dentist or physician for this purpose (Denisco et al., 2011).

Decision Making About Opioid Prescribing

The list of factors contributing to the decision of whether to prescribe opioids includes not only the provider's desire to reduce a patient's suffering but also the expectations of the patient regarding pain control. Concern has been raised that increased attention to the issues of acute and chronic pain has led to the expectation that patients should experience little or no pain once a provider has been informed of the problem. The prescription of medication represents a rapid method of addressing a pain complaint, certainly accomplished more easily than providing a course of physical therapy, psychological counseling, spinal injection, or many other available approaches to the treatment of pain. For that reason, analgesics including powerful opioid pain relievers are an attractive option. On the other hand, emphasis is increasing on setting reasonable expectations and establishing mutually agreed-upon goals for the control of chronic pain, with an emphasis on communication and safety (Dowell et al., 2016).

Regrettably, providers may feel pressured to provide opioids for fear of poor evaluations of their performance. Measures instituted over the last decade or so that may contribute to this pressure include the designation of pain as the "fifth vital sign" (Lanser and Gessell, 2001) and the increasing attention to patient feedback on surveys regarding pain control as part of their care. Importantly, in 2016 the Centers for Medicare & Medicaid Services issued a proposed rule to remove posthospitalization patient survey questions about pain management from scores that are tied to Medicare payments in an effort to reduce unnecessary opioid prescribing.[3] However,

[3]81 FR 45603.

rankings of patient satisfaction remain important to hospitals and providers as the rankings can affect their business, and providers' pay may be impacted by patient evaluations as well. The precise impact of pain control on patient satisfaction is somewhat unclear, although some have suggested that communication and compassion may be more important than pain control itself in influencing a patient's survey response (Lee, 2016). Further discussion on the related topics of clinical practice guidelines and industry promotion is included in Chapters 5 and 6, respectively.

Discussions between providers and patients about the use of nonopioid alternatives may be difficult. In some instances, providers may find it easier to write an opioid prescription than to have a discussion with the patient about the balance of risks and benefits of using an opioid versus alternative therapies. This may be the case in particular with patients who have come to believe that opioids are the best treatment for their chronic pain and who feel that alternative forms of treatment will not work as well. As discussed in Chapter 5, educating providers and patients about alternative forms of treatment may be one means of reducing reliance on the use of prescription opioids to manage chronic pain.

Assessment and Mitigation of Risk When Prescribing Opioids

As discussed in Chapter 5, growing recognition of important areas of overlap between opioid therapy for pain and opioid misuse has led to multiple forms of response, including statements, policies, and guidelines issued by federal agencies, state governments, advocacy groups, professional societies, academic panels, and others. Yet while the need for a more cautious approach to opioid prescribing has generally been acknowledged, there has been no overarching effort to coordinate responses among concerned groups. In addition, a tension exists between efforts to curtail prescribing and the interests of at least some groups of patients in maintaining access to opioids.

Many of the recommendations commonly discussed in considering opioids for the management of chronic noncancer pain are encapsulated in the so-called "universal precautions" of pain medicine (Gourlay et al., 2005). These 10 steps (see Box 2-1) were not proposed for use exclusively when managing opioids, although opioid management is an important area for their application.

Beyond these overarching principles of responsible opioid management are efforts to construct risk assessment tools. Generally, the goal has been to assemble and validate reasonably brief questionnaires useful in clinical situations that would provide prescribers with information concerning the likelihood of development of opioid misuse should opioids be provided for the management of pain. Several such tools have been developed. Those used commonly include the Screener and Opioid Assessment for Patients with Pain (SOAPP and SOAPP-Revised) (Butler et al., 2004, 2009); the Diagnosis, Intractability, Risk, and Efficacy inventory (DIRE) (Webster and Webster, 2005); and the Opioid Risk Tool (ORT) (Belgrade et al., 2006). Each has been studied, and some information directly comparing their properties is available (Moore et al., 2009). Reviews of the utility of these screening tools suggest some predictive value, yet significant caveats exist (Chou et al., 2009b). For example, the predictive power of these tools is limited, they differ in their definitions of misuse or aberrant behavior, and the body of data validating them is fairly small. See further discussion on the evidence of effectiveness of these tools in Chapter 3.

BOX 2-1
Universal Precautions in the Use of Pain Medicine for Treatment of Chronic Pain

1. Make a Diagnosis with Appropriate Differential
2. Psychological Assessment Including Risk of Addictive Disorders
3. Informed Consent
4. Treatment Agreement
5. Pre- and Post-Intervention Assessment of Pain Level and Function
6. Appropriate Trial of Opioid Therapy +/– Adjunctive Medication
7. Reassessment of Pain Score and Level of Function
8. Regularly Assess the "Four As" of Pain Medicine: Analgesia, Activity, Adverse Effects, and Aberrant Behavior
9. Periodically Review Pain Diagnosis and Comorbid Conditions, Including Addictive Disorders
10. Documentation

SOURCE: Excerpted from Gourlay et al., 2005.

Opioid Tapering

In addition to initiation of opioids, providers face questions about how to manage patients who are already taking the drugs, some of whom have been maintained chronically on them for months to years. Over the past decades, millions of Americans have been exposed to and many are now maintained chronically on opioid pain medications. The short- and longer-term risks of opioid use are more serious than previously estimated, and as discussed above, the likely benefits of chronic opioid use for pain are lower for many patients than previously believed. As a result, a large group of "legacy" chronic pain patients are receiving opioids at doses or under circumstances that are inappropriate in light of current knowledge. Information useful in understanding how best to manage this group of patients is lacking in many clinical settings.

The Centers for Disease Control and Prevention's (CDC's) Guideline for Prescribing Opioids for Chronic Pain (see Chapter 5) recommends that patients who have been on high dosages of opioids "be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk" and that providers review the risks and benefits of continued opioid therapy with these patients. The guideline further recommends consideration of opioid tapering when there is no evidence of improvement in pain or function, particularly when the opioid dose has reached more than 50 morphine milligram equivalents (MME) with or without added benzodiazepines or signs of harm (Dowell et al., 2016). Implicit here is the importance of assessment and reassessment of patients on chronic opioids. If the patient's pain and function have not improved significantly with the initiation or increase in the dose of opioids, providers might reconsider continuing use given the risk of adverse effects. Evidence suggests that tapering of opioids prior to elective surgery may decrease the risk of developing chronic pain after surgery, thereby reducing postsurgery analgesic requirements (Chapman et al., 2011). A slow taper is likely better tolerated, particularly in patients taking opioids chronically. The CDC guideline calls for as slow as a 10 percent reduction per month in combination with support from the patient's clinician and psychological and other specialists as needed (Dowell et al., 2016). A study of a small sample of

patients in a primary care setting found that patients considered the risk of increased pain and of withdrawal symptoms from the tapering of opioids to be greater than the risk of overdose from continuing to use the drug. Discussions of tapering with patients may be more successful if these fears are addressed as part of the conversation (Frank et al., 2016).

Practice Tools to Reduce Potentially Harmful Opioid Use in the Course of Pain Treatment

Patient–Provider Agreements

The use of patient–provider agreements (PPAs), also referred to as opioid treatment agreements (OTAs) or pain contracts, has been reported as a possible tool in the clinical management of chronic pain (Fishman et al., 2002a,b). The precise components of PPAs may vary among practices, but in general they serve to document the understanding between patient and clinician about the treatment plan and its goals. PPAs provide an opportunity to discuss with patients the risks and benefits of opioid therapy. The agreement may describe the roles and responsibilities of the patient and the provider and the grounds for discontinuation or continuation of the opioid treatment based on the risk-benefit ratio (Gourlay et al., 2005; Quill, 1983). Addiction, misuse, significant nonadherence to the agreement, or risk to the public may be the major reasons for discontinuation of treatment.

Despite the potential of such agreements, it is clear that the ability of providers to recognize nonadherence to treatment plans is limited (Osterberg and Blaschke, 2005). The ability to apply the contract may also be limited because patients do not have the choice of whether to agree to it. Moreover, while data on effectiveness are limited, one study reports that the use of PPAs may be relatively low (aside from high-risk patients) and that patients may not always realize when they have signed one, which could limit their utility (Penko et al., 2012). One study showed that more than 60 percent of patients adhered to an OTA with a median follow-up of 22.5 months; 7 percent of OTAs were canceled because of substance misuse and noncompliance (Hariharan et al., 2007). Ongoing ethical debate surrounding PPAs is important to acknowledge. Despite their potential, universal utilization of PPAs is resisted on a variety of grounds, including limited health literacy and concerns about increasing disparities and further stigmatizing pain patients (Payne et al., 2010). Indeed, use of PPAs does not guarantee better care: "[unscrupulous physicians] practicing in 'pill mills' regularly require their patients to sign pain contracts" (Payne et al., 2010, p. 11). Overall, while there is no consensus regarding the use of PPAs, they are being used to varying degrees in chronic pain treatment and may facilitate monitoring of adherence to treatment plans. More research could clarify their effective use and outcomes to help improve adherence and monitoring, as well as reduce the potential for unintended negative consequences.

Consultation with and Referral to Pain Specialists

Primary care providers, including those in emergency medicine settings, often are the first point of medical contact for patients with pain. Given the limited number of pain specialists, primary care providers play an essential role in pain management and in overcoming the challenge of undertreatment of pain (IOM, 2011). Yet there are occasions when these providers can benefit from consultation with or referral of patients to pain specialists—providers who have

had specialty training in the diagnosis and treatment of painful conditions (often from the fields of anesthesiology, neurology, physical medicine and rehabilitation, psychology, or psychiatry).

Partnership with pain specialists may help primary care providers maximize pain relief and function for patients while minimizing the risk of use of opioids and other treatments. Working in tandem with a pain specialist may help all involved define shared goals in the patient's pain treatment plan. Establishing expectations at the outset is helpful for both patient and physician[4]; setting realistic expectations at the beginning of treatment can affect outcomes and patient satisfaction. Some pain specialists have had specialized training in psychiatry and/or addiction medicine, which can enable them to evaluate whether opioids are appropriate for the individual patient and to treat patients with substance use disorders. There are models for coordination with primary care to treat pain in high-risk patients in the context of a patient-centered medical home (Cheatle et al., 2012).

Pain specialists also may be consulted prior to surgery for recommendations regarding chronic use of opioids as patients' tolerance for the drugs may adversely affect their postoperative experience. Pain specialists may offer recommendations on maximizing nonopioid therapy prior to surgery and on employing regional anesthetic techniques that may assist in minimizing the use of opioids intra- and postoperatively (Huxtable et al., 2011; McGreevey et al., 2011). Pain specialists that work in the context of multidisciplinary pain centers are able to individualize patient care and treat patients holistically. (The section on clinical research in Chapter 3 includes discussion of improving pain management in the primary care setting despite a relative lack of access to pain specialists, while the discussion of Project ECHO in Chapter 4 describes a model for providing high-quality care through expert teleconsultation with community providers.)

Summary

Opioids are widely prescribed in a variety of settings for treatment of both acute and chronic pain, frequently including back pain, pain due to arthritis and other musculoskeletal conditions, and dental pain. However, data are lacking on the longer-term benefits of opioids in the management of chronic noncancer pain. Moreover, studies do show an increased risk for a number of adverse outcomes from long-term use of opioids, including OUD, overdose, and other adverse effects. Moreover, no widely accepted guidelines recommend the use of opioids as a first-line therapy for management of chronic noncancer pain. Despite the lack of evidence supporting the practice, however, providers continue to prescribe opioids for extended periods.

NONOPIOID PHARMACOLOGIC TREATMENTS

Nonsteroidal Anti-Inflammatory Drugs (NSAIDS)

NSAIDs are commonly used to treat acute pain following trauma or interventional procedures, as well as pain due to some chronic inflammatory musculoskeletal conditions, such

[4]A retrospective review of 248 patients for whom treatment expectations and anticipated level of pain relief were documented in the initial intake record found that the expectation in back pain patients was at least 58 percent pain relief. Fibromyalgia patients anticipated 54 percent pain relief from their office visit, along with reduction of other distressing symptoms, while those with migraine expected complete relief without associated side effects (O'Brien et al., 2010).

as arthritis. These drugs inhibit the cyclooxygenase (COX) enzymes that catalyze the transformation of arachidonic acid to prostaglandins (PGs)—evanescent, locally acting lipid mediators with diverse biological effects. PGs include PGE_2 and PGI_2, which have been shown to mediate pain and inflammation. COXs are of two types: COX-1, which tends to be ubiquitously expressed and accounts for the greater part of hemostatic and gut barrier integrity; and COX-2, which is readily upregulated by cytokines and mitogens and largely accounts for PG formation in pain, inflammation, and cancer. Older NSAIDs, such as ibuprofen and naproxen, inhibit both COX-1 and COX-2 at therapeutic doses. The development of NSAIDs specifically for inhibition of COX-2, such as rofecoxib and celecoxib, was prompted by serious adverse gastrointestinal (GI) effects of those older agents, attributed to inhibition of platelet COX-1-dependent thromboxane A_2 formation (predisposing to bleeding) and disruption of barrier function due to inhibition of COX-1-dependent formation of PGE_2 and PGI_2 by gastroduodenal epithelium. However, a reduction in the serious adverse GI effects of these earlier drugs was accompanied by an increase in cardiovascular adverse effects, such as myocardial infarction, stroke, and heart failure, resulting from suppression of the cardioprotective properties of COX-2-derived PGI_2 and PGE_2 in the cardiovascular system (Grosser et al., 2010).

Aspirin, also an NSAID, relieves pain at high (>325 mg) doses that inhibit COX-1 and COX-2. As with other nonspecific NSAIDs, however, such efficacy is accompanied by adverse GI effects. Aspirin is by far more commonly consumed at low (<100 mg/day) doses for cardioprotection, and although the incidence of serious adverse GI effects is roughly doubled with these lower doses, such events are much less common than at higher analgesic doses. Aspirin differs from other NSAIDs in that it covalently modifies COX (the other drugs are competitive active site inhibitors), requiring de novo synthesis of the enzyme for recovery of PG formation from aspirin exposure. In the case of the anucleate platelet, which contains only COX-1, this requires the production of new platelets. Chronic administration of low-dose aspirin suppresses platelet COX-1-derived production of thromboxane A_2, a vasoconstrictor and platelet agonist, and this mechanism is sufficient to explain the efficacy of low-dose aspirin in the secondary prevention of heart attack and stroke (Fitzgerald and FitzGerald, 2013). The place of low-dose aspirin in primary prevention is currently unclear; the number of heart attacks prevented and serious adverse GI effects caused are roughly in balance.

APAP (Paracetamol), or acetaminophen, is another NSAID, inhibiting both COX-1 and COX-2 by ~50 percent at the most commonly used daily dose of 1,000 mg (Catella-Lawson et al., 2001). At this dose, it is effective in relief of mild pain but is commonly used as an antipyretic. A recent Cochrane review found that ibuprofen in combination with acetaminophen provided better analgesia than either drug alone at the same dose, and with a smaller chance of an adverse event (Derry et al., 2013a). However, it is unclear whether this finding reflects a distinct mechanism of action of acetaminophen or merely more efficient COX inhibition by the combination.

Studies in mice suggest that the antipyretic property of APAP derives from suppression of PGE_2-dependent activation of the E prostanoid receptor 3 (EP3) (Ushikubi et al., 1998). This COX/PGE/EP3 pathway is activated by the receptor activator of nuclear factor kappa-B ligand (RANKL) acting on its tumor necrosis factor (TNF) receptor-related RANK receptor in astrocytes (Hanada et al., 2009). While GI complications of APAP are uncommon, indirect higher doses (>4,000 mg/day) may have an adverse GI effect profile similar to that of other nonspecific COX inhibitors. Many effects beyond COX inhibition have been attributed to APAP, but the importance of their contribution to either its efficacy or its adverse effect profile is

unclear. The biggest concern with APAP is liver toxicity; overdose may cause fatal acute liver failure (Fontana, 2008). This effect may also be mechanism-based as hepatotoxicity complicates treatment with diclofenac, an older NSAID that turns out to be a quite specific inhibitor of COX-2. The genetic basis for predisposition to hepatotoxicity from lumiracoxib, a diclofenac analog specifically designed to inhibit COX-2, has been established (Singer et al., 2010).

Combination therapy, including APAP and other NSAIDs, was found to be superior to the combination of the opioid hydrocodone and APAP, with fewer side effects, for pain from dental extractions (Moore and Hersh, 2013). And a systematic review comparing oral NSAIDS with opioids for treatment of pain due to knee osteoarthritis over at least 8 weeks' duration found similar pain relief for both analgesics (Smith et al., 2016b).

Antidepressants

Antidepressants—including tricyclic antidepressants (TCAs), combined serotonin-noradrenalin reuptake inhibitors (SNRIs), and selective serotonin reuptake inhibitors (SSRIs)—are one of the oldest pharmacological treatments for chronic pain. Studies have found specific antidepressants (or classes of antidepressants) to be effective for the treatment of various types of pain. For example, amitriptyline improves pain for postherpetic neuralgia (Graff-Radford et al., 2000) and for fibromyalgia (Moore et al., 2012), while duloxetine can improve pain for diabetic peripheral neuropathy (Lunn et al., 2014) and osteoarthritis knee pain (Wang et al., 2015). TCAs and SNRIs are recommended as a first choice (along with gabapentinoids) for postherpetic neuralgia, painful neuropathies, and central pain (Dworkin et al., 2010). SSRIs generally are better tolerated by patients relative to other antidepressants, but the evidence on their efficacy for treating chronic pain is inconclusive (Patetsos and Horjales-Araujo, 2016).

Although depression is common among patients with chronic pain (Fishbain et al., 1997; Iacovides and Siamouli, 2008), the analgesic effect of antidepressants is separate from their effect on depression. Pain relief occurs at lower doses than doses with an antidepression effect (Hameroff et al., 1984; Langohr et al., 1982; Magni, 1991), and has been noted in both depressed and nondepressed patients (Couch and Hassanein, 1976; Jenkins et al., 2012; Lance and Curran, 1964; Max et al., 1987).

The mechanism of action of antidepressants on pain is not fully understood. Antidepressants act mainly by reducing noradrenalin and serotonin reuptake and enhancing the descending inhibition (Gillman, 2007). While both norepinephrine and serotonin have an effect on mood and pain (Sindrup and Jensen, 1999), catecholamine blockade appears to be more important in pain reduction. Indirect mechanisms of action may include (1) enhancement of the effects of endogenous opioids by increasing either their production or expression of opioid receptors (Hamon et al., 1987; Sacerdote et al., 1987), (2) antagonism of N-methyl-D-aspartate (NMDA) receptors (Luccarini et al., 2004), (3) blockade of sodium and/or calcium channels (Gerner et al., 2003; Wang et al., 2015), (4) blockade of histamine or cholinergic receptors (Abdel-Salam et al., 2004; Butler et al., 1985), and (5) increased expression of γ-aminobutyric acid (GABA) type B receptors in the spinal cord (McCarson et al., 2006). It is important to note that attenuation of chronic pain by antidepressants is not immediate; the clinical effect usually is noted only after days or weeks of treatment.

Common side effects of antidepressants include dry mouth, blurred vision, constipation, difficulty in passing urine, weight gain, and drowsiness. The SSRIs are generally better tolerated than other antidepressants, but their side effects can include nausea, tremor, hyperarousal, and drowsiness (Goodman et al., 2001). Adverse effects may be less likely with gradual dose

escalation. Combination therapy with gabapentinoids, opioids, and topical agents is sometimes considered in refractory cases (Gilron et al., 2009, 2013).

Anticonvulsants

Anticonvulsant medications, principally gabapentin (and, more recently, pregabalin), have come to serve as first-line therapies in the treatment of chronic neuropathic painful conditions (with the exception of trigeminal neuralgia), as well as acute perioperative pain. Gabapentin, an anticonvulsant initially introduced for the treatment of partial complex seizures, is approved in the United States for postherpetic neuralgia (PHN). With the expiration of the exclusivity patent on gabapentin, pregabalin was introduced and obtained FDA approval for the treatment of PHN, as well as diabetic polyneuropathy and fibromyalgia. Independently, gabapentin also has been found effective in the treatment of fibromyalgia. Expert opinion in the form of guideline recommendations has emerged as well, in many cases being updated by societies dedicated to the evidence-based management of neuropathic pain, such as the Neuropathic Pain Special Interest Group (NeuPSIG) (Dworkin et al., 2007, 2010; Sardar et al., 2016). Regrettably, these drugs have an emerging potential for misuse, particularly in individuals with OUD (Havens, 2016).

Mechanistically, the goal of these agents is to suppress the sensation of peripheral neuropathic pain, described as arising from both unmyelinated C-type (slowly conducting) nerve fibers, associated with sensations of dull, aching, burning, and poorly localized pain, and thinly myelinated A-delta nerve fibers, which are more rapidly conducting and signal sensations of sharp, stabbing, and often well-localized pain. Central nervous system (CNS)/spinal-glial pathways underlie a combination of signs (hypoesthesia, hyper/hypoalgesia, heat/cold hyperalgesia, allodynia) and symptoms (paraesthesias, sensation of burning and/or shooting pain) that, together with the appropriate clinical context, increase the diagnosis of neuropathic pain (Haanpää et al., 2009).

Unlike opioids, gabapentinoids (gabapentin, pregabalin) act primarily to reduce hyperalgesic states under conditions of inflammation and nerve injury rather than changing pain thresholds under nonpathological conditions (Werner et al., 2001). Therefore, gabapentinoids modulate the pain pathway under pathophysiologic conditions. Under hyperalgesic conditions, gabapentin and pregabalin act supraspinally to enhance the descending inhibitory noradrenergic system onto the dorsal horn of the spinal cord (Hayashida et al., 2007; Tanabe et al., 2008). In addition, it has been proposed that gabapentin and pregabalin act at the level of the spinal cord through binding to alpha$_2$-δ_1 subunits of a voltage-gated calcium channel (VGCC) expressed in presynaptic terminals of primary afferent nociceptors (Li et al., 2006). As discussed earlier in the chapter, the use of gabapentin or pregabalin in the immediate preoperative setting has the potential to decrease the need for postsurgical opioids (Tan et al., 2015a).

Analgesic response rates for peripheral neuropathic painful conditions tend to average approximately 30 percent and rarely if ever exceed 50 percent. Therefore, despite their "effectiveness" in the treatment of PHN, diabetic polyneuropathy, and fibromyalgia, gabapentin and pregabalin have not been proven effective in the treatment of postamputation/phantom limb pain. Nevertheless, they may still offer a benefit to those patients who have failed other analgesic therapy. More recently, gabapentin and pregabalin have been emerging in a widening range of applications initially considered "off-label," including as single or part of multimodal therapies for perioperative pain management (Chaparro et al., 2013), opioid-sparing strategies and

reduction of the risk of opioid-induced hyperalgesia (Stoicea et al., 2015), and neuropathic pain originating from cancer or its treatment (Vadalouca et al., 2012).

Capsaicin Creams and Patches

Persons suffering from chronic neuropathic pain often encounter difficulty with their pharmacotherapy and are unable to tolerate the side effects of such agents as anticonvulsants, antidepressants, and other centrally acting therapies. Moreover, such therapies may be ineffective. Long before the advent of clinical trials, physicians successfully used native plant derivatives to provide pain relief. Among these, medicinal plant derivatives from hot chilies in South America were used as far back as 4000 BC. Capsaicin, the pungent principal ingredient in hot chili peppers, is now recognized as the primary therapeutic agent acting on the capsaicin receptor TRPV1 in many of these medicinal plants (Schumacher, 2010). Acting predominantly on C-type primary afferent nociceptors, capsaicin has long been appreciated as inducing pain following its initial application, but paradoxically, having a topical analgesic effect with repeated application. A series of overlapping capsaicin-induced effects that include desensitization, nociceptor dysfunction, neuropeptide depletion (Cao et al., 1998; Yaksh et al., 1979), and nociceptive terminal destruction (Robbins et al., 1998; Simone et al., 1998) are now understood as underlying the analgesic action of topically applied capsaicin.

Topical creams or patches containing capsaicin can sometimes be effective for certain dermatomally restricted neuropathic conditions. However, several aspects of topical capsaicin treatment appear to limit its overall effectiveness and application in clinical practice: the area of pain has a restricted pattern of distribution (dermatomal or nondermatomal); repeated capsaicin application (up to four to five times daily) is required to establish and maintain an adequate degree of analgesia; and topical application may cause initial or ongoing pain/irritation. In response to these limitations, the capsaicin content in these preparations tends to be “low-dose” (0.025 or 0.075 percent). When such low-dose capsaicin preparations have been studied or compared with so-called first-line neuropathic pain treatments using a grading system requiring multiple RCTs, they typically have not provided robust neuropathic pain relief and showed poor to moderate efficacy in the treatment of either musculoskeletal or neuropathic symptoms (Attal et al., 2006; Mason et al., 2004).

PHN is one of the most prevalent painful conditions associated with neuropathy that clinicians may encounter. It is driven in the United States by some 800,000 annual cases of primary herpes zoster infection (Schmader, 2002). A Cochrane review examined six studies of topical capsaicin involving 2,073 patients conducted through December 2012, which included RCTs and controlled trials of at least 6 weeks’ duration. Four studies of a combined 1,272 participants with PHN showed estimated numbers needed to treat (NNT) to attain “much improved or very much improved pain” of 8.8 and 7.0, respectively (Derry et al., 2013b).

In one study, high-dose (5 to 10 percent) capsaicin, initially under regional anesthesia and later following topical local anesthetic pretreatment, was used in an attempt to circumvent the limitations of repeated low-dose capsaicin application and resulted in a wide range of posttreatment pain relief (Robbins et al., 1998). The strongest evidence exists for the use of high-dose capsaicin for the management of painful PHN. As with other therapeutic options for the treatment of painful neuropathic conditions, however, there appear to be responders and nonresponders to capsaicin among patients experiencing PHN and a range of other neuropathic conditions. Overall, the quantified magnitude of the analgesic effect of capsaicin is typically modest (10 to 30 percent), although one study showed that among participants followed for

12 months, 10 percent experienced complete resolution of painful symptoms from PHN and other peripheral neuropathic conditions (Mou et al., 2013). Beyond PHN, other painful neuropathic conditions sensitive to the analgesic effects of topical capsaicin (with decreasing levels of evidence) include HIV-associated painful neuropathy (Derry et al., 2013b), painful diabetic neuropathy, and postsurgical neuropathic pain.

Local Anesthetics/Sodium Channel Blockers

The use of local anesthetics for the relief of acute and chronic pain has typically relied on the restricted deposition of the anesthetic within subcutaneous tissues, adjacent to target nerves and/or spinal epidural routes. The analgesic action is based on the ability to block voltage-gated sodium channel (VGSC)-mediated sodium influx into neuronal cells in response to local membrane depolarization. Ideally, the goal is to achieve analgesia through the blockade of sodium currents in small-diameter (nociceptive) neurons of C and Aδ fiber type that are carried by members of the tetrodotoxin (TTX)-resistant sodium channel family (predominantly Nav1.8 and Nav1.9) that are differentially expressed in small-diameter/pain-sensing neurons (Devor et al., 1992; Persaud and Strichartz, 2002). Since increased VGSC subtype expression on primary afferent neurons (nociceptors) is now linked to inflammatory and neuropathic pain, the blockade by local anesthetics represents a plausible mechanistic approach to treatment of chronic pain (Waxman et al., 1999). Accordingly, efforts are under way to develop a new generation of local anesthetics/sodium channel blockers that selectively block sodium channel subtypes in sensory neurons, with the goal of obtaining an analgesic effect while sparing normal touch or motor function (Kort et al., 2008).

However, widespread administration of local anesthetics is limited by toxicity to the CNS and the cardiac conduction system. Selective, continuous infusion of low-dose local anesthetics adjacent to the nerve trunks, such as the brachial plexus or peripheral nerves, as well as through the epidural route, offers advantages over other modes of postoperative analgesia (Guay, 2006). In many cases, these techniques have been extended to cancer and noncancer chronic pain treatments.

Alternatively, continuous systemic infusion of the local anesthetic lidocaine has shown promise in the treatment of a wide range of chronic painful conditions that have not responded to more established analgesic approaches in both adults and pediatric patients (Gibbons et al., 2016; Kandil et al., 2017). Although studies are still emerging, intravenous lidocaine infusion may help reduce intensity of pain and improve activity levels in a selected group of chronic pain patients. Lidocaine infusion also has been used safely and successfully in patients suffering from advanced cancer pain, both in the hospital setting without telemetric monitoring and in palliative care units, hospices, or even patients' homes, given suitable nursing supervision (Peixoto and Hawley, 2015). The outcomes of lidocaine infusion in perioperative settings are mixed, with focused clinical applications, such as following complex spine surgery, showing promise (Farag et al., 2013). On the other hand, broader application across the spectrum of perioperative pain care may yield less than expected outcomes as there is only low to moderate evidence that lidocaine infusion compared with placebo has a large impact on pain scores, especially in the early postoperative phase (Kranke et al., 2015). Questions that need to be addressed before lidocaine can be used as a mainstream treatment include precise dosing regimen, infusion duration, and patient selection criteria (Kandil et al., 2017).

Lidocaine (topical) patches (5 percent), represent yet another route of delivery of local anesthetics for the treatment of acute and chronic pain, having been shown to be efficacious for

PHN and diabetic neuropathy (Mick and Correa-Illanes, 2012). The efficacy of broader use of lidocaine patches in the treatment of other neuropathic pain ailments is undetermined (Finnerup et al., 2015), and there is as yet no evidence for the effectiveness of lidocaine patches in the relief of postoperative pain (Bai et al., 2015; Mooney et al., 2014).

Alpha 2 (α_2) Adrenoreceptor Agonists

Although practitioners may be familiar with the antihypertensive and sedative properties of α_2 adrenoreceptor agonists (clonidine, dexmedetomidine), substantial evidence indicates that they function as analgesic agents, having a synergistic effect with opioids and efficacy in opioid-tolerant patients. Anecdotal case reports suggest that α_2 adrenoreceptor agonists may offer an alternative analgesic strategy for patients that have failed classic opioid management for painful conditions (Pirbudak et al., 2014).

Two complementary mechanisms couple α_2 adrenoreceptor agonists to analgesic action: activation of descending spinal inhibition and direct activation of presynaptic α_2 receptors on sensory afferent terminals in the dorsal horn (Buerkle and Yaksh, 1998; Sanders and Maze, 2007). Agonists such as clonidine can directly produce spinal analgesia, and intrathecal administration augments spinal levels of norepinephrine and acetylcholine, both of which may play a role in the consequent spinal analgesia (Hassenbusch et al., 2002; Klimscha et al., 1997). Accordingly, epidural/spinal clonidine has been approved for infusion in the treatment of cancer/neuropathic pain that is refractory to opioid analgesics (Hassenbusch et al., 2002). As there is no apparent cross-tolerance between clonidine and opioid analgesics at a spinal site of action, their ability to synergize with morphine under nerve injury and neuropathic conditions has emerged as a critical translational finding (Ossipov et al., 1997).

Such α_2 adrenoreceptor agonists have also been found to be useful in perioperative analgesia for thoracic paravertebral blocks (PVBs) in patients undergoing modified radical mastectomy and for other perineural infusions (Mohamed et al., 2014). In addition, their systemic use in the perioperative period has been found to reduce opioid requirements and improve analgesia, although with common adverse effects such as bradycardia and arterial hypotension (Blaudszun et al., 2012).

The use of systemic clonidine and dexmedetomidine for the treatment of chronic pain has been described, but well-controlled studies are lacking. More commonly, these agents have found a role in opioid-dependent patients and are FDA-approved for the treatment of opioid withdrawal symptoms in the detoxification of opioid dependence. More recently, these agents have appeared in detoxification protocols in the setting of hyperalgesia (Monterubbianesi et al., 2012). Beyond the continuous intrathecal administration of clonidine for intractable pain conditions, the clinical utility of systemic α_2 adrenoreceptor agonists in chronic pain or hyperalgesia remains unresolved (Blaudszun et al., 2012).

NMDA Antagonists (Ketamine)

The analgesic action of ketamine is a consequence of its noncompetitive blockade of the NMDA receptor expressed both in the brain (supraspinally) and in the dorsal horn of the spinal cord. Ketamine's effects are dose dependent and may be broadly categorized as "anesthetic" (high dose), "analgesic" (medium dose), and "opioid-sparing"/antihyperalgesic (low dose). One key principle underlying the action of the low- to medium-dose effects involves blockade of

NMDA-mediated neurotransmission under conditions of tissue injury (inflammation/nerve injury).

Following nociceptor activation, excitatory amino acids (glutamate) are released from the central terminals of primary afferent nociceptors onto spinal neurons expressing NMDA receptors. Under persistent nociceptive pain and activation of C-type nociceptors and in turn, activation of ionotropic NMDA receptors, changes occur in neuronal plasticity at the nociceptive processing center of the spinal cord—the dorsal horn (Li et al., 1999). This increase in excitability of dorsal horn spinal cord neurons, which has been described as "central sensitization" (Li et al., 1999; Woolf and Mannion, 1999), encompasses several features, including the spreading of pain sensitivity beyond the original site of injury (secondary hyperalgesia), as well as mechanical allodynia. Blockade of NMDA receptor function in the dorsal horn has been shown selectively to attenuate the pain, hyperalgesia, and allodynia associated with ongoing tissue injury. Importantly, the action of an NMDA antagonist such as ketamine at the dorsal horn can block sensitization but spare the normal signaling of acute pain detection (Yaksh et al., 1999).

The notion that opioid-induced tolerance and hyperalgesia may share a common mechanism with central sensitization has been proposed. Although the exact mechanism of opioid tolerance is not known, it is believed to include the involvement of NMDA receptors, nitric oxide pathway, and μ opioid receptors. Escalating doses of opioids given in an attempt to manage the pain of progressive malignant and nonmalignant diseases in adults and children can drive further pain and hyperalgesia. Under these difficult clinical conditions, low-dose ketamine has been shown to offer improvement in both pain control and opioid dose reduction that are often greater than 50 percent (Eilers et al., 2001; Loftus et al., 2010). Use of low-dose ketamine is intended to reverse or prevent central sensitization, opioid tolerance, and hyperalgesia while improving pain control (Aggarwal et al., 2013). More recently, the role of low-dose ketamine was investigated in the treatment of complex chronic painful conditions in a study at an outpatient chronic pain clinic, with some promising outcomes (Kosharskyy et al., 2013). Such positive findings are tempered by the variable and dose-dependent profile of ketamine-related adverse effects (psychomimetic), which can limit its clinical application. The development of GRIN2B-directed or other more selective NMDA receptor agents may avoid some of ketamine's troublesome side effects (Niesters and Dahan, 2012; Preskorn et al., 2008).

Modest reductions in pain and short-term opioid requirements have been observed with the use of perioperative ketamine infusions (Barreveld et al., 2013; Cenzig et al., 2014; Elia and Tramer, 2005; Souzdalnitski et al., 2014; Zakine et al., 2008), but complete avoidance of opioids and other analgesics is generally not achieved. Limited additional evidence (Loftus et al., 2010) suggests that ketamine may reduce the persistence of postoperative pain.

Cannabinoids

Cannabis and its subcompounds, cannabinoids, have been used for medical and recreational purposes for hundreds of years. The use of cannabis as a recreational drug is illegal in most countries. Recently, however, some countries around the world and several U.S. states have legalized its use for chronically ill patients. Various studies have shown a positive effect of cannabinoids on chronic pain (Whiting et al., 2015), but potential cognitive effects and possible dose-dependent long-term risk for mental illness remain a concern, especially for patients with chronic pain that will require long-term therapy.

More than 100 cannabinoids have been identified in nature or chemically synthesized (ElSohly and Gul, 2014). The best-known cannabinoid is tetrahydrocannabinol (THC), known mainly for its psychosedative effects. Two cannabinoid receptors (CBs) have been cloned. CB1 is present in the brain, the spinal cord, and the peripheral nervous system, as well as in a number of neuronal tissues, including the liver, skeletal muscle, and the gastrointestinal tract; most of its analgesic effect is mediated by the CB1 receptor. CB2 is found mainly in immune cells in the peripheral nervous system or microglia in the CNS and to a lesser extent in the peripheral nervous system, primarily after injury and inflammatory response (Atwood and Mackie, 2010; Howlett, 2002). Several endocannabinoids have been identified, anandamide and 2-arachidonoylglycerol (2-AG) probably being the best studied. They are synthesized mainly by neurons but also by immune cells (Bisogno et al., 1997; De Petrocellis et al., 2000).

The endogenous action of cannabinoids is not limited to the cannabinoid receptors; it may be associated with calcitonin gene-related peptide (CGRP), transient receptor potential vanilloid (TRPV), and NMDA receptors as well (Mitrirattanakul et al., 2006). In animal studies, the combination of opioids with cannabinoids has shown notable synergistic effects (Cichewicz, 2004). Interestingly, some NSAIDs inhibit anandamide degradation (Duggan et al., 2011). For medical use, cannabinoids can be smoked; inhaled; mixed with food or drinks; or administered orally, sublingually, or even topically. They can be taken in herbal form, extracted naturally from the plant, or manufactured synthetically.

Recent systematic reviews and meta-analyses have found evidence to support the use of cannabinoids for the treatment of such chronic pain conditions as neuropathic pain, cancer-related pain, fibromyalgia, and HIV-associated neuropathy (Lynch and Ware, 2015; Whiting et al., 2015). A recent National Academies report on the health effects of cannabis and cannabinoids cites substantial evidence that cannabis is an effective treatment for chronic pain in adults and effects improvements for some pain patients with chemotherapy-induced nausea and vomiting. The report also notes a lack of evidence regarding the efficacy, dose, routes of administration, and side effects of cannabis products in the United States (NASEM, 2017). Low- to moderate-quality evidence has been found regarding the ability of cannabinoids to effect improvements in appetite reduction and weight loss in HIV/AIDS patients, sleep outcomes in individuals with certain illness-related sleep disorders, or symptoms of Tourette syndrome. While further research is needed, some studies also have shown that cannabinoids are associated with an increased risk of short-term adverse events such as cognitive and psychiatric effects, nervous systems disorders, dry mouth, and drowsiness (Lynch and Ware, 2015; Whiting et al., 2015).

The precise magnitude and consequences of the risk associated with therapeutic cannabinoid use are presently unknown. However, psychoactivity, memory deficiencies, impaired coordination and performance, and long-term risk for mental illness are the major issues in the development of cannabinoid-based analgesics (Karila et al., 2014; Semple et al., 2005). Alternative approaches to overcome the undesired effects of cannabinoids can include the development of endocannabinoid degradation inhibitors (Lomazzo et al., 2015) and cannabinoids that affect only peripheral receptors (Richardson et al., 1998). More research is necessary to determine the efficacy and safety of cannabinoid-related therapy for chronic pain patients and whether adjunctive therapies with existing analgesics may enhance its therapeutic effect while reducing unwanted side effects.

Naltrexone

Naltrexone is an oral opioid antagonist that is FDA-approved for the treatment of OUD. Some evidence, currently limited to a few case reports, indicates that greatly reduced doses of naltrexone (one-tenth normal) may have analgesic properties for limited chronic pain conditions, such as fibromyalgia and complex regional pain syndrome (CRPS). Although the mechanism of action for analgesia associated with low-dose naltrexone is unclear, it is thought to involve an anti-inflammatory effect through the blocking of toll-like receptor 4 (TLR4) on microglial cells, inhibiting microglial activation. Activated microglia are thought to play a major role in the development of neuropathic pain (Chopra and Cooper, 2013; Tsuda, 2016; Younger et al., 2014). Experimental animal models also demonstrate reversal of neuropathic pain by naltrexone via TLR4 antagonism (Hutchinson et al., 2008). In a small randomized, double-blind, placebo-controlled, crossover design study, 31 women with fibromyalgia were given low-dose naltrexone or placebo. Those taking 4.5 mg of naltrexone daily reported modest pain reduction and improved satisfaction and mood (Younger et al., 2013). Chopra and Cooper (2013) report two cases of long-standing CRPS whose signs and symptoms were significantly improved with 4.5 mg daily low-dose naltrexone. More research, particularly replication of these limited reports, could help ascertain the potential role of low-dose naltrexone in the treatment of chronic pain.

Summary

A number of pharmacologic treatments can be used to manage pain. While each nonopioid alternative has its own indications and risks, some are likely to be as effective as opioids or more so for reducing pain associated with the conditions for which they are indicated and when used appropriately, carry lower risk of adverse outcomes. Nonopioids such as cannabinoids and ketamine, which have shown promise for relief of some forms of pain in some pain management settings, also have potential adverse side effects. In cases of opioid tolerance, α_2 androreceptor agonists can provide improved analgesia and help reduce signs and symptoms of opioid withdrawal. Subanesthetic doses of NMDA receptor antagonists can be highly effective in blocking/reversing the pain amplification and hyperalgesic states, although dose-dependent side effects, such as altered perceptions and vivid dreams, limit their widespread application.

INTERVENTIONAL PAIN THERAPIES

Interventional pain management involves the use of invasive techniques, such as joint injections, nerve blocks, spinal cord stimulation, and other procedures, to reduce pain. Such techniques are best performed in the context of a multimodal treatment regimen, including physical therapy to maximize functional restoration. There has been a significant increase in the volume of certain interventional procedures over the past 10 years, much of it focused on low back and neck pain with or without radiation to the hip and other lower extremities (Chou et al., 2009a; Friedly et al., 2007). Low back pain is the most common cause of chronic pain in adults in the United States, followed by severe headache or migraine and then neck pain (Freburger et al., 2009; HHS, 2016; Rubin, 2007).

Types of Interventional Pain Therapies

Epidural steroid injections are the most commonly performed interventional pain therapies (Manchikanti et al., 2012), increasing in number each year. This increase, however, has not been matched by similar reductions in disability or improvements in health status among those with low back and leg pain, and may have contributed to the rise in health care costs (Chou et al., 2009a). The injections are commonly given to relieve radicular pain or sciatica associated with disc protrusions. An analysis of all types (cervical, thoracic, and lumbar) and routes (caudal, interlaminar, and transforaminal) of epidural injections using Medicare data from 2000–2011 showed an overall procedural increase of 130 percent/100,000 Medicare beneficiaries (representing an increase of 7.5 percent per year), with only an 18 percent increase in new Medicare beneficiaries for the same time period (an increase of 1.5 percent per year). The highest increases were seen for lumbosacral transforaminal injections, at 665 percent/100,000 Medicare beneficiaries, an increase of 20.3 percent per year over the study period (Manchikanti et al., 2013). Epidural steroid injections came under increased scrutiny after reports of serious neurologic events related to contaminated compounded glucocorticoids, in addition to other catastrophic injuries related to the injection itself. Injuries related to the performance of cervical epidurals have garnered significant attention. Guidelines for preventing associated neurologic complications were published in 2015 (Rathmell et al., 2015).

Other interventional pain therapies for axial low back pain include such techniques as trigger-point injections for myofascial pain of the low back, injections involving either the lumbar facet or sacroiliac joints, and denervation of the nerves that supply those joints. Lumbar facet (or zygapophyseal) joints are richly innervated and a source of axial low back pain. The medial branch of the dorsal rami of the spinal nerves innervates both the facet joints and the overlying multifidus muscle, the interspinous ligament, and surrounding muscle, as well as the periosteum (Cohen and Raja, 2007). Evidence to support the use of intra-articular facet joint injections for long-term pain relief is limited (Chou et al., 2009a). The medial branches are first anesthetized using local anesthetic as a diagnostic tool to confirm the location of the pain. If pain is relieved, the medial branches may be lesioned using radiofrequency (RF) denervation to provide pain relief for an average of 10.5 months (after which the nerves regenerate). The RF may then be repeated for prolonged relief (Schofferman and Kine, 2004). Another type of lesioning, cooled RF, has been used in treating sacroiliac joint pain.

Spinal cord stimulation (SCS) has expanded in scope in recent years, from being utilized mainly for neuropathic pain related to painful postlaminectomy pain syndrome or failed back surgery syndrome to being applied for other neuropathic, sympathetic, vascular, and even visceral pain syndromes (Deer et al., 2014). The therapy involves placing an electrical lead in the epidural space that is connected to a programmable generator to relieve pain. A trial stimulator is first placed percutaneously under image guidance and left in place for up to 1 week, followed by implantation if the trial provides significant pain relief. Traditional SCS has been successful in treating extremity pain, but other areas and types of pain have been difficult to treat. Newer models of SCS utilize higher-frequency stimulation of 10,000 Hz (compared with 40 to 60 Hz) to improve relief of intractable axial low back pain. A comparison study found that the higher-frequency SCS provided superior pain relief (Kapural et al., 2016), and also was not associated with the stimulation-induced paresthesias that can lead to trial failures with traditional SCS (Kapural et al., 2016). Other new forms of SCS include burst stimulation, which uses bursts of five spikes at 40 Hz (De Ridder et al., 2010, 2013), and targeting of SCS at the dorsal root

ganglion rather than the central spine (Deer et al., 2014). SCS has the advantage of being reversible and adjustable, and of being capable of providing years of pain relief (Deer et al., 2014). There is evidence for its cost-effectiveness in the relief of pain due to failed back surgery syndrome, CRPS, painful peripheral artery disease, and refractory angina (Kumar and Rizvi, 2013).

Interventional therapies also are offered for pain relief from migraine and other forms of severe headache. Botulinum toxin, a protease exotoxin derived from Clostridium botulinum, may be used for chronic migraine when other therapies have failed (Persaud et al., 2013). Other forms of headache, particularly occipital headache, cervicogenic headache, and headache originating from the upper cervical spine, may be amenable to targeted spinal intervention, such as occipital nerve blocks and cervical medial branch RF denervation.

Careful patient selection is critical to the success of interventional therapies. It is recommended that before such interventions are considered, a targeted history and assessment be performed to rule out the presence of potentially harmful conditions (e.g., malignancy, vascular abnormalities, spinal cord compression, fracture, or infection) and to assess for potential side effects (e.g., adrenal suppression from cumulative steroid use) (Leary and Swislocki, 2013). Complications of interventional pain management are multifactorial and are related to issues including performance of the procedure, patient anatomy, and comorbidities. The use of S.A.F.E. (Safety, Appropriateness, Fiscal neutrality, and Effectiveness) principles has been proposed as a foundation for interventional pain treatment algorithms (Krames et al., 2009). This approach has been used in advocating for early intervention for some pain syndromes (e.g., complex regional pain syndrome) for which the timing of interventional therapies may affect outcomes, and their early application may be cost-effective in the long run despite initial costs (Poree et al., 2013).

Summary

Further research is needed to better understand the effectiveness of a variety of interventional techniques for painful conditions, as well as optimal patient selection to improve health outcomes. However, these treatments may provide effective pain relief for many patients with some forms of pain (e.g., low back and neck pain) in the context of a multidisciplinary approach.

NONPHARMACOLOGIC TREATMENTS

Acupuncture

The use of acupuncture for the treatment of pain has become widespread in recent decades. Acupuncture is a key component of traditional Chinese medicine that involves insertion of needles through the skin to acupuncture points. Pressure, heat, electrical current, laser light, and other means also may be used to stimulate these points. Investigations have demonstrated that the nervous system, neurotransmitters, and other endogenous substances respond to the needling stimulation to induce analgesia (Foster and Sweeney, 1987). It has been shown that acupuncture analgesia is mediated by opioids produced in the periaqueductal gray and can be reversed by naloxone, an opioid antagonist (Cheng and Pomeranz, 1980). Recent studies also suggest activation of cannabinoid receptors as a possible mechanism of action (Gondim et al., 2012).

Systematic reviews evaluating the effect of acupuncture in treating pain have revealed mixed results. Some reviews have found minimal or no effect (Lee et al., 2008; Madsen et al., 2009), while others have found acupuncture to be superior to sham acupuncture and placebo (Berman et al., 1999; White et al., 2007), and still others have concluded that data are insufficient to support a recommendation (Furlan et al., 2005; Paley et al., 2015; Smith et al., 2016a; van Tulder et al., 1999). Recent reviews and meta-analyses examining the effect of acupuncture on musculoskeletal pain (neck and back pain, osteoarthritis, chronic headache and shoulder pain, fibromyalgia) have found that overall, acupuncture is superior to sham and no acupuncture, but with relatively modest differences between true and sham acupuncture (Vickers et al., 2012; Yuan et al., 2016). Although it has been suggested that acupuncture is an effective treatment for pain, additional factors, such as potent placebo and context effects, may play a role in its observed effect as well (Linde et al., 2010a,b; Vickers et al., 2012). It also has been suggested that acupuncture may have value in the treatment of chronic and tension headaches (Linde et al., 2009b; Vickers et al., 2012), as well as in prophylactic treatment for migraine (Linde et al., 2009a). Additional RCTs are needed to determine the effect of acupuncture on neuropathic and postsurgical pain.

Manual Therapies

Manual therapies, including massage and chiropractic and osteopathic manipulation (such as spinal manipulative therapy), are commonly recommended for the treatment of musculoskeletal pain. However, high-quality evidence about these therapies is sparse, and there is little evidence that these therapies are as effective or more so than standard treatments. Cochrane reviews have been conducted on the evidence for these therapies in low back pain. For massage, the quality of the evidence was found to be "low" or "very low," and the authors "have very little confidence that massage is an effective treatment for low-back pain" (Furlan et al., 2015). Evidence on combined chiropractic interventions shows a slight improvement in pain in the short and medium terms, but there is no evidence showing that chiropractic interventions have a clinically meaningful advantage over other treatments (Walker et al., 2011). Spinal manipulative therapy has not been shown to be different from other common interventions (Rubinstein et al., 2011).

A 2014 systematic review of massage therapy for fibromyalgia pain found that massage therapy of at least 5 weeks' duration resulted in significant improvement in pain, anxiety, and depression. However, the authors note that larger-scale and longer-term RCTs are needed to confirm these findings (Li et al., 2014).

Physical Therapy and Exercise

Physical therapy and exercise often are included in the treatment plan offered to patients suffering from musculoskeletal pain conditions such as fibromyalgia, arthritis, and back and neck pain. In addition to its direct effect on pain, exercise may improve overall physical and mental health (Iacovides and Siamouli, 2008). The exact mechanisms by which physical therapy and exercise affect pain are unknown. It is believed, however, that activation of the CNS pain modulation pathways (Lannersten and Kosek, 2010) and the release of beta-endorphins play a major role in the palliative effect (Bement and Sluka, 2005; Stagg et al., 2011). Other suggested mechanisms include activation of such neurotransmitters as norepinephrine and serotonin (Dietrich and McDaniel, 2004), interactions with the cardiovascular system (Lovick, 1993), and

involvement of the adenosinergic system (Martins et al., 2013). Despite the lack of strict guidelines or protocols for physical activity that may help patients with chronic pain, it appears that various types of physical activity can alleviate pain, including aerobic exercise, strength and flexibility training, walking, and manual therapy. Exercises such as yoga, tai chi, and qi gong have received particular attention for the treatment of pain because of the potential effect of the "mind–body" component of these practices. Systematic reviews have shown that these practices may be effective (Bai et al., 2015; Cramer et al., 2013; Kong et al., 2016), but further high-quality research is needed. Exercise has been shown to be effective for treatment of many types and locations of pain, including fibromyalgia (Busch et al., 2013; Carson et al., 2010; Hauser et al., 2010), back pain (Chang et al., 2016; Hayden et al., 2005; van Middelkoop et al., 2010), osteoarthritis (Fransen et al., 2014; Jansen et al., 2011), whiplash-associated pain (Stewart et al., 2007), and potentially even neuropathic pain (Dobson et al., 2014).

However, there are a number of barriers to the successful use of exercise therapy for pain management. These barriers include patient factors, such as lack of knowledge about exercise, fears of worsening existing pain, depression, excessive deconditioning, and a lack of self-efficacy. Patients also may lack access to a safe place to exercise, time to exercise, and support from family or the workplace. Finally, there are health care delivery barriers, including the system's overly rigid focus on the biomedical model for pain, a lack of attention to or education about the value of exercise, a lack of supervision to ensure patient safety and comfort (Kroll, 2015), and a lack of insurance coverage of the costs of exercise and physical therapy.

Although it appears that recommending physical activity and exercise is warranted for patients suffering from chronic pain, further research is needed to evaluate the optimal treatment and intensity to recommend, and to explore the benefit of combining physical activity with other nonpharmacologic therapies and pharmacologic treatment for pain reduction. In particular, there is some evidence that multidisciplinary rehabilitation, which includes physical treatments such as exercise as well as psychosocial interventions, may improve pain and function (Kamper et al., 2015; Lee et al., 2014), but further research is needed.

Cognitive-Behavioral Therapy (CBT)

CBT has been shown to be effective in managing chronic pain, either on its own or together with other pain management tools, such as medication. Over the last half century, evidence has accrued that the experience of pain is not based solely on sensory or neurologic states but is influenced by cognitive and affective processes (Ehde et al., 2014). A person's thoughts and beliefs about pain can affect a number of pain-related issues, including the intensity of pain, anxiety and depression, physical disability, activity limitations, and catastrophizing (Ehde et al., 2014). Altering these thoughts and beliefs through CBT can change a person's experience of and adaptation to pain, decreasing its intensity and improving day-to-day functioning and the ability to cope with the pain (Knoerl et al., 2016). CBT usually is delivered through multiple sessions of individual or group therapy in which a variety of strategies are conveyed to participants, including practicing relaxation techniques, reframing negative thoughts, scheduling activity to maximize functionality, and improving sleep patterns (Knoerl et al., 2016).

Numerous studies have demonstrated the efficacy of CBT (e.g., Ehde et al., 2014; Morley et al., 1999; Williams et al., 2012). A 2012 Cochrane review (Williams et al., 2012), for example, found that CBT, compared with treatment as usual at posttreatment, had a small but significant effect on pain intensity and disability and a moderate effect on catastrophizing and

anxiety and depression (Knoerl et al., 2016). CBT is currently "the prevailing psychological treatment for individuals with chronic pain conditions such as low back pain, headaches, arthritis, orofacial pain, and fibromyalgia" (Ehde et al., 2014). However, the studies of CBT that have been performed have varied in the method of its delivery, the specific strategies used, and which outcome variables were studied, making it difficult to evaluate whether and to what extent CBT is efficacious for achieving specific pain-related outcomes (Knoerl et al., 2016). Knoerl and colleagues (2016) sought to remedy this evidence gap with an integrative review of 35 studies on CBT and chronic pain. They found that CBT was effective at reducing pain intensity in 43 percent of these trials (only 8 of 35 studies used pain intensity as a primary outcome, although it was measured in all studies); for a wider group of pain-related variables, including physical functioning, anxiety, depression, and quality of life, CBT was effective in 86 percent of trials. The authors note that CBT has been understudied in military veterans and patients with chronic pain related to cancer treatment.

Barriers to the provision of CBT include limited access to providers, inadequate insurance coverage, lack of knowledge about CBT among health care providers, and patients' perception of stigma associated with CBT (Ehde et al., 2014). A 2016 study (Bee et al., 2016) of the acceptability of CBT among chronic pain patients found that preintervention patients viewed CBT as less relevant to their condition than other interventions (e.g., exercise). Some patients believed that the suggestion of using a psychological approach for a predominantly physical problem implied that the pain was not valid or was the result of "an underlying character weakness" (Bee et al., 2016). However, patients who received the CBT intervention reported high satisfaction, finding that it helped them shift toward proactive pain management (Bee et al., 2016).

In addition to CBT, there are other psychosocial interventions for chronic pain, such as acceptance and commitment therapy (ACT), in which patients are encouraged to change their responses to pain rather than seek a reduction in the pain itself. Studies on ACT have shown promise, but further research is needed (Vowels et al., 2014; Wetherell et al., 2011).

Mindfulness Meditation

Mindfulness is defined as purposefully paying attention in the present moment, nonjudgmentally (Kabat-Zinn, 2003). Operationalized, it means "(a) regulated, sustained attention to the moment-to-moment quality and character of sensory, emotional and cognitive events, (b) the recognition of such events as momentary, fleeting and changeable (past and future representations of those events being considered cognitive abstractions), and (c) a consequent lack of emotional or cognitive appraisal and/or reactions to these events" (Zeidan et al., 2012). One such intervention, mindfulness-based stress reduction (Kabat-Zinn, 2003), the most studied mindfulness intervention, trains individuals in acquiring and practicing these skills, including for the management of various forms of chronic pain. Although of mixed quality, a large number of studies have found mindfulness interventions to have beneficial effects for patients with pain.

A meta-analysis of 38 RCTs of various forms of mindfulness meditation intervention for chronic pain management found that mindfulness improved pain, reduced symptoms of depression, and improved quality of life compared with treatment as usual, support groups, education, stress management, and waitlist controls (Hilton et al., 2017). Evidence is strongest for the efficacy of mindfulness in reducing symptoms of depression and improving mental health–related quality of life, for which the quality of evidence is rated high and moderate, respectively. While small, statistically significant effects on pain are promising, these findings

are tempered by the low quality of the evidence (e.g., lack of intent-to-treat analysis, low follow-up rate, small samples, inadequately powered studies). Effects on reducing analgesic use were mixed, with some studies showing reductions and others not. The authors conclude that more well-designed RCTs are needed to develop an evidence base on the effectiveness of mindfulness interventions.

Beyond demonstrating efficacy, it is important to understand the hypothesized mechanisms underlying the use of mindfulness interventions as therapy for pain management. An understanding of the neuronal and molecular basis of changes in the brain that accompany mindfulness meditation is also nascent (Tang et al., 2015). Nonetheless, emerging evidence is providing useful information on how mindfulness meditation may cause neuroplastic changes in the structure and function of the brain regions involved in regulation of attention, emotion, and self-awareness, which are also factors involved in the cognitive modulation of pain (Zeidan et al., 2012). Accumulating evidence indicates that it can attenuate the subjective experience of pain, and that it shares as well as has distinct neural substrates engaged by cognitive factors known to modulate pain (Hilton et al., 2017).

One question has been whether the analgesic effects of mindfulness meditation are different from those of placebo. Zeidan and colleagues (2015) directly explored this question in healthy volunteers. They conducted an RCT involving four conditions (mindfulness meditation, sham mindfulness meditation, placebo conditioning, and book-listening control). Intervention efficacy was assessed using psychophysical evaluation of experimental pain and functional neuroimaging. The authors found that mindfulness meditation produced significantly greater reductions in pain intensity and unpleasantness relative to the other conditions. Importantly, their findings indicate that mindfulness meditation employs distinct neural mechanisms—specifically, higher-order brain regions, including orbitofrontal and cingulate cortices. They suggest that these findings may foster greater acceptance of meditation as an adjunct pain therapy.

Taken together, this emerging body of work suggests that the practice of mindfulness meditation for pain management may be promising. There is a need for further research with rigorous designs and larger samples that include patients with chronic pain to provide high-quality tests of the efficacy of this therapy. In addition, studies are needed to connect findings from studies of the neuronal and molecular bases of changes in the brain that accompany mindfulness meditation with behavioral measures.

Placebo Analgesia

Placebo is a dummy treatment, such as a pharmacologically inert preparation ("sugar pill") or sham procedure. The difference in treatment effect between a group that has received no treatment and one that has received placebo is considered the "placebo effect." Pain is one of the areas in which placebo has been most studied.

It has been shown in research and clinical settings that the expectation of pain relief can induce a strong analgesic effect. Placebo analgesic response is the result of this phenomenon. Consistent placebo analgesic effect has been demonstrated in dental pain, postthoracotomy pain, low back pain, irritable bowel syndrome, neuropathic pain, and experimental pain (Enck et al., 2008; Finniss et al., 2010; Kaptchuk and Miller, 2015; Price et al., 2008). The response to placebo is heterogeneous, being affected by individual differences in conditioning (Colloca and Benedetti, 2006; Kantor et al., 1966), expectations (Morton et al., 2010), optimism (Morton et al., 2009), and suggestibility (De Pascalis et al., 2002), as well as the nature of the placebo provided (Kong et al., 2013) and other factors. The placebo effect was found to be as strong as

that of 7.5 mg of morphine following third molar extraction (Levine et al., 1981), and open administration of medication has been shown to be more effective than hidden administration (Colloca et al., 2004). Moreover, patients who are told that they are receiving a very potent pain killer have been found to require less of the same opioid than patients who are not (Pollo et al., 2001). And patients provided with a treatment that they believe is good for them benefit more from that treatment (Kalauokalani, 2001).

The "nocebo effect" is the term used to describe an undesirable outcome, such as an increase in pain, due to negative expectations (or conditioning). The nocebo effect is longer-lasting and probably greater than the placebo effect (Colloca et al., 2008). Patients in placebo groups often report side effects similar to those of the active drug if they were exposed to the possible side effects described in the consent form (Barsky et al., 2002).

Placebo cannot be considered sham or no treatment. Its effect on pain is probably a combination of its effect and the placebo effect (Beecher, 1955; Howick et al., 2013).

The placebo effect is associated with activity in the prefrontal cortex, insular cortex, thalamus, forebrain structures, and spinal cord. An opioid antagonist (naloxone) can reverse placebo analgesia (Levine et al., 1978), suggesting involvement of the endogenous opioid system and probably the descending pain modulatory system. It also has been suggested that the endocannabinoid system is involved in placebo's analgesic effect (Benedetti and Amanzio, 2011). Better understanding of the placebo effect could lead to the development of independent treatment protocols or methods that would augment the effect of existing treatments.

Focus on Self-Management

An important recommendation of the 2011 IOM report *Relieving Pain in America* was that health care provider organizations promote and enable self-management of pain as the starting point of pain management (IOM, 2011). Self-management can be defined as "the ability to manage the symptoms, treatment, physical and psychosocial consequences and life-style changes inherent in living with a chronic condition" (Barlow et al., 2002). In the context of chronic pain, self-management involves acceptance of the painful condition, exercise, pacing, relaxation, and other positive steps toward higher levels of functioning if not immediate reduction in pain intensity. Such approaches tend to deemphasize the role of medications such as opioids. Although significant barriers to pain self-management exist, such as lack of family support, limited resources, and depression (Bair et al., 2009), research on chronic pain self-management and the implementation of self-management programs is expanding. Examples of self-management programs for chronic pain include those designed for low back pain (Slater et al., 2012), knee pain (Button et al., 2015), arthritis (Vermaak et al., 2015), and other forms of chronic pain. It may be hoped that the reliance on opioids as a first-line management strategy by both patients and medical providers will diminish as self-management programs become more common.

Summary

Nonpharmacologic interventions for pain treatment, including acupuncture, physical therapy and exercise, CBT, and mindfulness meditation, represent powerful tools in the management of chronic pain. Many are components of successful self-management. While further research is needed to better understand the mechanism of action and the appropriate

dosage and delivery for some nonpharmacologic approaches, they may provide effective pain relief for many patients in place of or in combination with pharmacologic approaches.

DIFFERENCES IN PAIN EXPERIENCES AND TREATMENT EFFECTIVENESS AMONG SUBPOPULATIONS

Part of the committee's charge was to review the available evidence on differences in the experience of pain and the effectiveness of treatments across subpopulations. This section briefly reviews research findings on this issue among selected subpopulations in the United States, including findings pertinent to prescription opioids. A review of the effectiveness of all of the available treatments for pain for subpopulations is beyond the scope of this study. For additional discussion of disparities in pain among subpopulations, the reader is encouraged to see the report *Relieving Pain in America* (IOM, 2011). The discussion here does not address individual (e.g., genetic) differences in susceptibility to pain, which are touched upon in Chapter 3.

Sex

Research indicates that women are more likely than men to experience chronic pain and report higher sensitivity to pain (Bartley and Fillingim, 2013). Findings have been mixed regarding severity of pain, with women reporting greater severity than men in some studies but no sex differences in severity being found in other studies (Bartley and Fillingim, 2013). Certain chronic pain conditions, such as fibromyalgia, migraine and headache, irritable bowel syndrome, temporomandibular disorders, and interstitial cystitis, are diagnosed more commonly in women than in men (Bartley and Fillingim, 2013). The reasons for differences in the experience of pain by sex are not entirely understood, may be multifactorial, and may depend on the type of pain and/or condition. Possible explanations include differences in genotype and endogenous opioid functioning, sex hormones, psychosocial processes, and stereotypical gender roles that may make men less expressive about pain (Bartley and Fillingim, 2013; Fillingim et al., 2009). Provider beliefs also may play a role in differential rates of diagnosis of painful conditions between men and women.

With respect to prescription opioids, the sex of a patient can impact both the efficacy of an opioid and the likelihood that an opioid-related adverse event will be experienced. In acute administration settings, opioids have been observed to cause more respiratory depression, nausea, and pruritus in female compared with male patients (Angst et al., 2012; Riley et al., 2010). The chronic use of opioids also can alter sex hormones in men and women, leading to impotence in men and menstrual irregularities in women (Rhodin et al., 2010). A review of 18 studies showed lower opioid consumption postoperatively among women than men, but this finding has not been consistent, may depend on the type of procedure performed, and may reflect increased prevalence or reduced tolerance of side effects from opioids in women rather than less need for pain relief (Miaskowski et al., 2000). A meta-analysis found no sex-specific effects for μ opioid analgesia across 25 clinical studies of μ opioids and greater analgesic effects for women when analyses were restricted to patient-controlled analgesia (Niesters et al., 2010).

Race and Ethnicity

Research consistently shows differences in pain experiences among racial and ethnic groups (Hoffman et al., 2016; IOM, 2011). African American patients have been found to be less likely than whites to be prescribed pain medications for both cancer and noncancer pain (Anderson et al., 2009; Goyal et al., 2015; Todd et al., 2000). African Americans also report greater pain than whites for several painful conditions (IOM, 2011). Some experimental data show that African Americans have a lower pain threshold than whites, but these differences are small and may be clinically insignificant. A recent review of research on the pain experiences of Hispanic Americans found that this population reports fewer pain conditions and significantly lower rates of chronic pain compared with non-Hispanic whites in national surveys. However, Hispanic Americans report experiencing more severe pain and higher sensitivity to pain (Hollingshead et al., 2016).

The impact of race and ethnicity on opioid prescribing in particular has been evaluated in several studies. Some research indicates that blacks are less likely than non-Hispanic whites to receive an opioid for chronic noncancer pain (Cintron and Morrison, 2006; Dickason et al., 2016; Ringwalt et al., 2014, 2015), and this disparity appears to be more common in some specialty settings than in others (Ringwalt et al., 2014). These observations are consistent with reports showing that pain in minority versus white patients tends to be underestimated by health care providers (Cintron and Morrison, 2006). Evidence does not strongly suggest that patients of different races/ethnicities are more or less likely to display aberrant behaviors in prescription opioid use (Ives et al., 2006; Vijayaraghavan et al., 2012), although providers may be more likely to believe that a black or Hispanic versus a white patient is misusing prescription opioids (Becker et al., 2011; Vijayaraghavan et al., 2011).

Lower socioeconomic status also is a risk factor for pain and its undertreatment. This association may be due to poorer overall health, employment-related factors (e.g., a higher proportion of individuals employed in occupations with a higher risk of injury), lower access to quality pain care, and other factors. Some of the observed disparity in treatment for pain by race and ethnicity likely is explained by socioeconomic status, as racial and ethnic minority populations are disproportionately low-income or poor (IOM, 2011).

Age

Age is positively associated with increased risk for the development of conditions, such as osteoarthritis and other musculoskeletal conditions, and chronic diseases, such as diabetes, that can be painful. Yet while some studies show a continual increase in pain prevalence with age, others show a decrease with age, an increase up to ages 75–85 followed by a decrease, or no differences by age (Abdulla et al., 2013). Experimental and clinical studies have found that the elderly are more vulnerable than younger individuals to severe and persistent pain and have reduced ability to tolerate severe pain. In addition, older people are more likely to have comorbidities that complicate diagnosis and treatment of painful conditions (IOM, 2011). Other factors that may influence the severity of pain in the elderly are complex manifestations of pain, underreporting of or reduced ability to report pain, and higher rates of treatment side effects (IOM, 2011).

The aging process can affect the safety of opioid prescribing as a result of alterations in drug metabolism, elimination, and sensitivity. In addition, the presence of comorbid conditions and the use of potentially interacting medications to treat those conditions may increase with age.

Concern exists, for example, about the use of opioids for noncancer pain in older adults because of the risks of sedation, overdose, and falls. These risks have prompted recommendations for lower starting doses, slower titration, and avoidance of use of other sedating drugs such as benzodiazepines (Kahan et al., 2011). The use of methadone in the elderly raises particular concern as this is a potent opioid with variable pharmacokinetics and a propensity for drug–drug interactions, and may also cause cardiac dysrhythmias (van Ojik et al., 2012).

Geography

Many rural communities in the United States have limited access to providers with training in pain management (Eaton et al., 2014; IOM, 2011). At the same time, residents of rural areas tend to be older and more likely to have painful chronic health conditions relative to those in urban areas (Eaton et al., 2014; Jukkala et al., 2008). As discussed in Chapter 4, states with large rural populations have experienced disproportionate morbidity and mortality from nonmedical use of prescription opioids (Keyes et al., 2014). Telemedicine/Internet-based technologies are one approach that has been used to bridge geographic distance to improve the quality of pain care in communities with limited access to providers with expertise in pain management (Currie et al., 2015; Eaton et al., 2014).

History of Substance Use Disorder

It is common for patients with histories of substance use disorders to also have chronic pain. Among patients receiving methadone maintenance treatment, for example, more than 40 percent have chronic pain (Dunn et al., 2015; Voon et al., 2015). In addition, patients maintained on methadone and buprenorphine have measurably lower pain thresholds and tolerances than non-opioid-receiving controls (Compton et al., 2001, 2012). Likewise, it is common when looking cross-sectionally at populations of patients managed with opioids to identify a significant percentage with substance use disorders. The percentage of such patients in a treatment population is dependent upon such risk factors as younger age and higher overall opioid dosage (Palmer et al., 2015). This complexity is addressed further in Chapter 3, where research on the intersection of pain and OUD is discussed, and knowledge gaps are identified.

A history of substance use disorder is a risk factor for aberrant opioid use among those being treated for pain (Chou et al., 2009b). Opioid risk assessment tools often take this characteristic into account, and such risk assessment is advocated in the CDC Guideline for Prescribing Opioids for Chronic Pain (Dowell et al., 2016).

Summary

In summary, differences have been observed among subpopulations in the types and severity of pain experienced and in access to and receipt of quality pain care depending upon such factors as sex, age, race and ethnicity, location of residence, and history of substance use disorder. Moreover, while further research is needed, different subpopulations of patients may have different levels of analgesic response to opioids, experience side effects of differing severity, and display drug misuse at different rates.

THE INTERSECTION BETWEEN PAIN AND OPIOID USE DISORDER

Pain and reward are considered opponent processes but are processed within overlapping brain structures. Rewarding stimuli can decrease pain sensitivity (Leknes and Tracey, 2008), whereas pain can impair reward processing, leading to an anhedonic state (Elman et al., 2013). Few studies have examined the disruption of this circuitry caused by pain and whether the dopaminergic system contributes to the aversive component of ongoing persistent pain (Navratilova et al., 2012, 2015). Furthermore, how the presence of pain modifies the reinforcing properties of natural rewards or opioids is not known. The mesolimbic pathway is a critical brain circuit altered in opioid addiction, making it an ideal system in which to investigate the mechanistic basis for opioid misuse in the presence of pain (Cui et al., 2014; Fields and Margolis, 2015). Opioid-induced release of dopamine in the nucleus accumbens contributes to opioids' misuse potential, whereas an allostatic shift in reward signaling leads to the pathological state of addiction (Koob, 2008). μ opioid receptor agonists are positively reinforcing and are used extensively as a first-line treatment for clinical pain. Furthermore, recent research (Blanco et al., 2016) shows that persistent pain may lead individuals to use prescription opioids in patterns different from what their prescribing physician initially intended, resulting in opioid misuse or OUD. The neurobiology of the reward pathway and of the intersection of pain and OUD is described in more in detail in Chapter 3.

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Progress and Future Directions in Research on Pain and Opioid Use Disorder

The past several years have seen a number of advances in research on pain and opioid use disorder (OUD). This chapter provides a brief overview of some of these key developments, with a focus on those that have taken place since the publication of the 2011 Institute of Medicine (IOM) report *Relieving Pain in America* (IOM, 2011). It also identifies areas for future research to inform efforts by the U.S. Food and Drug Administration (FDA) and other organizations to address the opioid epidemic. The chapter reviews developments and research needs in basic pain research; the neurobiology of the reward pathway and the intersection of pain and OUD; preclinical and translational research, including the development of new analgesics; clinical pain research, including optimizing opioid analgesia in the context of comprehensive pain management and opioid risks, the role of interventional pain therapies, and the potential of precision health care; and research at the intersection of pain and OUD. The chapter concludes with a summary that includes the committee's recommendations for this portion of its charge. The evidence presented in this chapter strongly argues for research to elucidate the biology of pain, to discover novel nonaddictive analgesics, and to refine substantially the ability to deliver analgesia at the level of the individual patient—i.e., precision analgesia.

BASIC PAIN RESEARCH

Opioid Analgesics

The search for an effective means of relieving pain and suffering has been ongoing since the dawn of civilization. What overarching lessons have been learned and successes achieved that may help propel identification of the next generation of analgesic agents with reduced risk of addiction or organ toxicity? Clearly opioid analgesics, originally derived from the opium poppy and acting principally at the μ opioid receptors (MOPRs), represent one of the most effective analgesic classes to date. Much of modern synthetic opioid analgesic development revolves around the original action of morphine at the MOPRs. The success of exogenous opioids in treating painful conditions reflects the fact that MOPRs are expressed at multiple sites along the pain detecting and modulating pathway, which includes specialized peripheral sensory neurons, signaling through the dorsal horn of the spinal cord, and ultimately transmission to and from multiple centers of the brain. Therefore, MOPR activation functions in a highly coordinated manner to provide a reduction in pain perception.

Unfortunately, MOPR activation also is linked to a range of unwanted side effects, including its action on reward centers (dependence, addiction); reduced intestinal motility

(constipation); and suppression of respiratory drive, which can result in overdose and death (Fields, 2007). Until recently, it had been fanciful to consider that the analgesic properties of MOPR agonists could be separated from these unwanted side effects. However, as a result of leveraging advances in MOPR signaling, it is now appreciated that Gi/o coupling drives predominantly analgesic responses, whereas MOPR coupling to β-arrestin may drive opioid reward and respiratory depression. The concept of identifying a G protein "biased" ligand that can preferentially activate the Gi/o analgesic linkage of MOPR signaling away from β-arrestin is being pursued through classical screening of compounds (Chen et al., 2013b; DeWire et al., 2013) and computational screening of MOPR-biased ligand candidates (Manglik et al., 2016). Although it remains to be seen whether these MOPR-biased candidates will translate into useful analgesics in humans, encouraging steps are being taken, including an active clinical trial of one of the candidate compounds (DeWire et al., 2013).

Inflammation

A tissue's response to injury, whether caused by infection, trauma, metabolic catastrophe, progression of disease/cancer, or ischemia, involves a complex cellular cascade of responses designed to alert and protect the organism and begin the process of healing. This response typically entails inflammation of the affected tissue and pain and/or heightened pain sensitivity (hyperalgesia and allodynia, respectively) that when it persists can degrade a person's quality of life. Inflammation that continues well past the period of expected healing or despite appropriate treatment remains one of the great medical challenges. Regardless of its source, the management of inflammatory pain often is limited to the use of nonsteroidal anti-inflammatory drugs (NSAIDs) for short periods because of the reduced risk of gastrointestinal bleeding, kidney injury, and adverse cardiovascular effects. Given the multiple overlapping pathways recruited during inflammation, effective analgesic management would appear to require action at multiple points of the inflammatory cascade, analogous to the sites of action of opioids throughout the pain pathway. What research advances in this area show promise for the development of novel analgesic strategies that would both spare protective and restorative pathways and act effectively against inflammatory pain?

Part of the answer may lie at the intersection between the primary afferent nociceptor (peripheral nervous system) and the innate immune system (Guan et al., 2016). Nociceptors are specialized C-type and thinly myelinated Aδ sensory neurons dedicated to the detection of painful stimuli, especially products of inflammation. Two important receptor channels, TRPV1 and TRPA1, expressed in nociceptors, have been identified and found to respond to multiple endogenous inflammatory products and noxious physical stimuli (Julius, 2013; Schumacher, 2010; Zygmunt and Högestätt, 2014). Importantly, because of the relatively high level of TRPV1/TRPA1 expression in nociceptors (rather than in sensory neurons responsible for simple touch or proprioception), the development of a high-affinity antagonist has been pursued in the hope of identifying compounds capable of blocking nociceptor activation (pain) despite the ongoing tissue production of inflammatory mediators. Considerable challenges have arisen in the clinical translation of TRPV1 antagonists with the concurrent development of hyperthermia (fever) due to core temperature dysregulation (Gavva et al., 2008). Research is ongoing to devise a TRPV1 antagonist that provides analgesia while maintaining the detection of acute pain and central homeostatic mechanisms (Gomtsyan and Szallasi, 2015). Investigation into the development of TRPA1 receptor antagonists for the treatment of pain also is ongoing (Schenkel et al., 2016).

While efforts to develop clinically useful TRP channel antagonists are ongoing, numerous complementary efforts are focused on identifying and blocking the action of inflammatory mediators at prostanoid and purinergic receptors. These receptor systems play multiple roles, including augmenting the responsiveness of TRPV1 under inflammatory conditions. In this regard, one of the principal proinflammatory products of arachidonic acid metabolism, the prostanoid PGE_2, is understood to drive inflammatory hyperalgesia through various receptor subtypes (Chen et al., 2013a). For example, the inflammation and pain that arise from endometriosis have been linked to EP2 and EP4 receptor activation, and specific antagonists acting at these receptor sites show therapeutic promise in preclinical models (Arosh et al., 2015; Greaves et al., 2017). Moreover, the development of antagonists to certain purinergic (ATP-gated channel) receptor subtypes (P2X3) and the metabotropic P2Y receptor show promise in the treatment of inflammatory pain (Burnstock, 2016; Park and Kim, 2017; Viatchenko-Karpinski et al., 2016).

Another perspective is the observation that pain-transducing components are upregulated under persistent tissue inflammation/injury. Therefore, the relative overexpression (or underexpression) of critical gene products within the pain pathway (peripheral and central) represents both a point of dysregulation and, in turn, an opportunity to better study what is driving changes in nociceptive gene expression, one type of plasticity change proposed to drive chronic pain. Research into whether there is a plausible way to reverse such pathophysiologic changes in a network of genes, perhaps through the control of nuclear transcription factors or micro-RNAs, is emerging (Chu et al., 2011; Neumann et al., 2015; Zavala et al., 2014).

Pain Transmission

The ability of nociceptor activation to signal the central nervous system of real or impending tissue damage relies on the transmission of that signal by specialized voltage-gated sodium channels (VGSCs) that propagate depolarizing action potentials along axons. As presented in Chapter 2, the analgesic properties of local anesthetic action rely on the ability to block VGSCs expressed in nociceptors. Although the pharmacology of local anesthetics has been exploited for anesthesia and analgesia based on their discrete application adjacent to nerves and the spinal cord, their general properties to block all sodium channels, including those expressed in heart and motor neurons, have significantly limited their widespread application as analgesic agents. With advances in molecular pharmacology and genetics over the past decade, one subtype of VGSCs has risen to prominence as a plausible analgesic target. Nav1.7 is a VGSC that has been linked to human pain conditions, based on defects in its gene *SCN9A* leading to either loss-of-function (congenital insensitivity to pain) or gain-of-function mutations that drive a rare spontaneous pain syndrome (erythromelalgia), as well as other painful neuropathies. The development of Nav1.7-selective blocking agents has been highly challenging; however, several lead candidates have emerged and are under advanced preclinical testing or clinical trial (Cao et al., 2016; Shcherbatko et al., 2016). Research on selective antagonists of other members of this family of VGSCs (Nav1.8, 1.9) is under way, but also faces tremendous challenges.

Beyond the proposed Nav1.7 selectivity of candidate blocking agents, properties that allow blockade of only activated (open) forms of the channel may provide an additional measure of clinical safety and reduction of potential offsite effects. Research in this area may also reveal the effectiveness of previously established pharmaceuticals for subsets of neuropathic pain conditions, such as carbamazepine, an agent typically reserved for the treatment of trigeminal neuralgia (Alexandrou et al., 2016; Geha et al., 2016). Whether this class of channel blockers

will be applicable to a broad range of neuropathic pain conditions or only for rare conditions is unknown. Given the limited scope of existing disease-based preclinical models of neuropathic pain and the complexity of the human genetic and epigenetic factors that influence susceptibility, much more work is required to synthesize these concepts for broader therapeutic utility.

Despite their prominent role in the detection of noxious stimuli (pain transduction), primary afferent nociceptors do not necessarily encode the final perception of pain. Rather, perception of pain is the result of a complex set of neural, glial, and cellular connections with both ascending and descending modulatory components (for a review, see Peirs and Seal, 2016). The basic structure of this pain pathway begins with the majority of nociceptive input entering the central nervous system through the spinal dorsal horn, roughly dividing into the superficial layers of the dorsal spinal cord as well as input into deeper layers associated with non-nociceptive sensory input, such as simple touch. Whether at superficial or deeper spinal levels, nociceptive input is dynamically regulated by both local spinal circuits and synaptic connections with descending pathways onto the secondary-order dorsal horn neurons. Following crossover, nociceptive signaling is transmitted to higher centers via the spinothalamic tracts that split, divide, and project into and through multiple brain nuclei within the pons, midbrain, and thalamic regions. Although the somatosensory cortex is considered a potential resting place for the perception of pain, the experience of pain is inherently complex and dependent on multiple brain regions.

Building on advances in the peripheral nociceptors mentioned above, a better understanding of spinal neural circuits, especially those that modulate mechanical allodynia, could reveal modality-specific excitatory microcircuits and distinct pain pathway "gates" that could be modified to better treat inflammatory and neuropathic pain (Peirs and Seal, 2016). Although interventions capable of selectively influencing the perception of pain at higher brain centers remain elusive, advances in understanding of the cognitive processing of pain perception offer hope. Something as apparently simple as distraction that reduces pain illustrates that the perception of pain relies on cognitive processes and learning (Wiech, 2016). Therefore, a detailed understanding of placebo analgesia and how individual expectations of an effective resolution of pain impact the success of any particular analgesic strategy is a critical area for further research (see the discussion of placebo analgesia in Chapter 2).

Innate Immunity

Intersecting with the transduction/transmission of nociceptive pain is activation of the innate immune system designed to initiate the acute inflammatory response to both infectious and sterile injury (Guan et al., 2016). In the case of bacterial infection, innate immune responses are triggered through pattern recognition receptors (PRRs) by components of microorganisms known as pathogen-associated molecular patterns (PAMPs) and/or by factors released by stressed or injured host cells that are collectively known as damage-associated molecular patterns (DAMPs) (Takeuchi and Akira, 2010). The binding of PAMPs or DAMPs to their cognate PRRs triggers a cascade that ultimately leads to the expression and/or activation of numerous inflammatory mediators including cytokines and chemokines with enhanced leukocyte trafficking and activation within tissues. PRRs are expressed not only in leukocytes but also in glial and neuronal cells and are postulated to contribute to neuropathic pain and other pain syndromes, such as sickle cell disease (Guan et al., 2016; Qi et al., 2011). DAMPs also can induce acute inflammation via PRRs and have been implicated in chronic neuropathic pain.

Although early leukocyte responses are designed to contain the extent of infection or injury, dysregulation of the inflammatory response with overexpression of proinflammatory mediators can be deleterious. In this regard, monocytes and macrophages are major contributors to later-phase inflammatory infiltrates and are well known to drive peripheral hyperalgesia (Ji et al., 2016). CCL2, a monocytic chemokine linked to neuropathic pain, also has been implicated in inflammatory pain, in part through its action on CCR2-expressing macrophages and the release of reactive oxygen species (ROS) (Hackel et al., 2013). With recent advances in understanding of the structure of CCR2 and its binding to antagonists (Zheng et al., 2016), it maybe be hoped that a new generation of CCR2 antagonists with properties to treat both inflammatory and neuropathic pain will emerge.

Members of the toll-like receptor (TLR) family and the receptor for advanced glycation end products (RAGE) are emerging as significant contributors to the pathogenesis of inflammation and pain (Brederson et al., 2016), as both are bound and activated by multiple endogenous agonists, including high-mobility group box 1 protein (HMGB1). TLRs also are expressed on monocytes and macrophages. Targeting cross-talk molecules such as HMGB1 and its receptors represents a novel direction in inflammation and chronic pain research. Since the immune system and nervous system are linked bidirectionally, there is evidence that activation of TLR- and RAGE-dependent pathways contributes to the development of chronic pain. Importantly, TLR agonists can directly activate nociceptors and increase levels of TRPV1 expression in dorsal root ganglion neurons (Wadachi and Hargreaves, 2006). Since the TLR4 and RAGE agonist HMGB1, a molecule previously associated with sepsis, has emerged as an important participant in neuroinflammatory pain states, strategies based on the blockade of HMGB1 and/or downregulation of the overexpression of TLR4 or RAGE also represent novel directions in inflammatory pain research.

Although this section has thus far focused on either blocking or downregulating proinflammatory receptors/factors, an alternative paradigm is the enhancement of molecules that combat excessive inflammation and pain. Within this category is another class of molecules with therapeutic potential in the treatment of inflammatory pain—resolvins —which not only regulate the resolution of acute inflammation but also can directly inhibit nociceptor activation (Park et al., 2011; Xu et al., 2013). However, evidence for their importance as an endogenous system regulating inflammation is lacking (Skarke et al., 2015).

Emerging from basic science on the metabolism of the insect juvenile hormone mimic R-20458 (Gill et al., 1972, 1974), a new group of chemical mediators—the epoxy fatty acids (EpFAs)—has come to light and been found to play important roles in cellular signaling and pain (Zhang et al., 2014). Following purification of the enzyme (soluble epoxide hydrolase [sEH]) responsible for the degradation (hydrolysis) of this class of fatty acids, inhibitors of the sEH enzyme were developed. It was found that inhibition of sEH prevented experimental models of acute inflammation and concomitant pain behaviors (Schmelzer et al., 2005). Curiously, other models of pain not considered "inflammatory," such as mechanical nerve injury or diabetic neuropathy, also were prevented by sEH inhibition (Inceoglu et al., 2012). More recently, research has focused on the mechanism underlying the prevention of experimental neuropathic pain, with a focus on the prevention of subcellular organelle stress in the peripheral nervous system.

EpFA-mediated analgesia, if translated successfully to treat human pain, may represent a promising analgesic approach. EpFA is inactive in the absence of pain, is nonsedating, is active over a large range of pain models, synergizes with NSAIDS, and has no addictive properties in

rodents. Its preclinical profile has been shown to be as good as or better than that of other medications currently used to treat neuropathic pain, and it may have other applications in the field of pain that have yet to be explored.

Neuropathic Pain

Following peripheral nerve injury, spinal cord microglia, the tissue-resident immune-like macrophages of the central nervous system, become activated, signaling the central nervous system in a pattern of neuroinflammation (Guan et al., 2016). The pain associated with partial nerve injury is of a type that appears to engender fundamentally different mechanisms driving the sensation of pain. This is exemplified not only by certain unique characteristics of the associated painful sensations but also by the relative resistance of this pain to analgesics typically effective in the treatment of inflammatory pain, such as NSAIDs. The pain is incited by a range of insults, from postherpetic neuralgia, to diabetic neuropathy, to traumatic disruption (surgical interventions), to chemotherapy. From the perspective of the nervous system, the chronic pain resulting from such injuries may represent the consequence of unexpected survival.

Despite the extensive use of anticonvulsants, tricyclic antidepressants, opioids, and topical preparations, the majority of patients suffering from chronic neuropathic pain obtain only partial relief in the face of significant medication side effects (see also Chapter 2). Efforts to develop new and more effective therapies rely on understanding of the underlying mechanism(s) of neuropathic pain, an area of ongoing research. Understanding how spinal microglia drive neuropathic pain may hold promise for the development of a new class of analgesic agents. Based on findings derived from experimental models of nerve injury, research continues to focus on the role of microglial activation in the development of chronic neuropathic pain and possible therapeutic targets (Ji et al., 2014). Importantly, the link between peripheral nerve injury and microglial activation has been poorly understood. A recent study identified colony-stimulating factor 1 (CSF1) as a critical signaling factor, upregulated in injured sensory neurons and transported to the spinal cord, where it targeted the microglial CSF1 receptor (CSF1R). Moreover, the downstream microglial membrane adaptor protein DAP12 was required for nerve injury upregulation of pain-related microglial genes and the ensuing experimental neuropathic pain behaviors. These findings suggest that both CSF1 and DAP12 are potential targets for further investigation and pharmacotherapy of neuropathic pain (Guan et al., 2016).

However, spinal microglial activation is not triggered solely by nerve injury, as there is evidence that certain peripheral inflammatory stimuli (e.g., formalin) can activate spinal microglia that can be reduced by the downregulation of microglial p38 (Tan et al., 2012). Surprisingly such formalin-induced spinal microglial activation cannot be blocked by local anesthetic treatment of the peripheral nerve, suggesting multiple routes of microglial activation. Under these inflammatory conditions, it has been proposed that caspase-6 (CASP6) is upregulated in the central terminals of primary afferent neurons and is released in the spinal cord. The resultant cascade activates spinal cord microglia and stimulates microglial TNF (tumor necrosis factor)-α synthesis and release through p38 and extracellular signal-regulated kinase (ERK)-mediated pathways. The blockade of spinal CASP6 under painful pathophysiologic conditions such as bone cancer, sickle cell disease, and inflammatory bowel disease may represent an important research opportunity in analgesic development.

The Need for Improved Research Methods

If the perception of pain is not "caused" by a single factor, looking for a single, highly restricted receptor target may be an inherently limited approach from the outset. The notion of a "blockbuster" analgesic drug that can be utilized on a widespread population basis with little physician oversight, propelled forward by a simple pain model in genetically identical male rodents, is fraught with difficulties. Absent a change in approach, the current problem with the use of opioids in the treatment of severe chronic pain may be repeated. One size clearly does not fit or help all. Therefore, research aimed at determining the impact of genetics, sex, and other variables in experimental models of pain is essential. Another critical stumbling block is the inability to translate reliably what appeared to be extremely promising preclinical analgesic targets developed in rodents (mice or rats), but when tested in humans had little to no analgesic efficacy and/or were associated with intractable adverse effects/toxicity. As described elsewhere, the development of humanized preclinical models of pain (in vitro and in vivo) will be required to establish more reliably clinically relevant basic and translational pain science. Progress in this regard cannot come too soon, as investigators are experiencing increased pressure to demonstrate earlier and earlier proof of concept. Providing additional review and revision of current pain research methods and models may hold promise for a more successful translation of the basic science of pain.

The need for improved research methods is evidenced by the fact that, despite robust research in pain-related areas of neuroscience, inflammation, and other fields, few novel analgesics have been introduced in the past 20 years. New drugs have been designed primarily to interact with established targets such as opioid receptors, cyclooxygenase, neurotransmitter reuptake proteins, and previously targeted ion channel constituents. Thus, while drugs offering improved pharmacokinetics and side effect profiles are available, the efficacy of pharmacological tools has not improved appreciably. This failure is not due to a lack of targets identified using animal models. In fact, analgesic programs targeting NK1 receptors, NMDA receptors, cytokine/chemokine signaling, and other targets strongly supported in animal studies have been successful in bringing molecules to advanced stages of human testing, only to have poor efficacy and side effects halt their development. The costs of these failures have been high. This failure of translation has been widely recognized, and many have commented on the challenges facing this type of research (Chaplan et al., 2010; Clark, 2016; Mao, 2012; Woolf, 2010).

One of the principal problems believed to limit analgesic development efforts relates to the pain models selected for laboratory use. Many investigators and pharmaceutical companies have used models bearing little similarity to the clinical syndromes they were intended to represent. For example, such irritants as carrageenan and formalin often are used to represent inflammatory pain such as that resulting from trauma-induced tissue injury or inflammatory arthritis even though there is little evidence for shared mechanisms. Another example is the common use of models of nerve injury, typically within days of the occurrence of injuries. The typical forms of clinical neuropathic pain, however, often do not entail discrete injury to isolated branches of peripheral nerves (e.g., diabetic neuropathy) and may entail symptoms present for years. Degenerative diseases of the joints and axial spine, as well as trauma, are among the most common etiologies for pain complaints bringing patients to pain clinics (Crombie et al., 1998), but animal models designed specifically to mimic these conditions are employed relatively infrequently in pain research. For many types of pain, there are models possessing higher face validity, and they might be used preferentially. It is also possible, although more expensive and

perhaps less convenient, to use large-animal models for some types of pain studies, such as large-breed dogs for studies of osteoarthritis, which may occur naturally or after surgically induced injuries (Brimmo et al., 2016; Harman et al., 2016; Knazovicky et al., 2016). Likewise, analgesic research in dogs and other species that develop cancers has been employed successfully (Brown et al., 2015).

Another approach to selection of a laboratory pain model is to choose one for which there is strong evidence of a mechanism present in the test animal that likely exists in the human pain patient as well (Woolf, 2010). Such a model would in theory provide a system in which observations might be most relevant to improving analgesia in clinical populations. Yet while laboratories are starting to adopt this approach, understanding of the mechanisms supporting pain conditions, including back pain, fibromyalgia, and others, is relatively limited, which in turn limits the confidence one can have in the selection of laboratory models.

A set of factors closely related to pain models themselves comprises factors known to affect the prevalence of painful diseases, pain intensity, rates of response to treatments, and side effects of medications. Many such factors have been identified, including sex, weight, age, nutritional status, genetic background, depression, and anxiety (see also the discussion of differences in pain experiences and treatment effectiveness among subpopulations in Chapter 2). Clearly, some of these factors are more easily represented in laboratory research than others. Relevant laboratory observations demonstrating the importance of some of these factors are the mouse strain dependence in displaying nociceptive sensitization after nerve injury (Mogil et al., 1999), the strain dependence of responsiveness to analgesics such as opioids (Liang et al., 2006), and the sex dependence of analgesic responses to modulators of glial activity (Brings and Zylka, 2015). Likewise, genetic differences have a strong impact on the degrees of tolerance (Liang et al., 2006), physical dependence (Liang et al., 2006), and use reinforcement behaviors (Berrettini et al., 1994) displayed by laboratory animals, suggesting that care is necessary in selecting a particular strain or breed of animal for pain and analgesic research.

A second major area of concern surrounding the use of animals in preclinical pain research involves the types of measures used in assessing pain-like responses. Because pain is defined as a sensory and emotional experience, one cannot directly infer that pain in animals is identical to that experienced by humans. Researchers therefore tend to rely on behavioral responses. Some of the more popular methods for assessing "pain" in animals actually assess withdrawal behaviors in response to noxious stimuli, such as heat and mechanical pressure applied to an animal's hind paw. These evoked responses are rapidly available, readily quantifiable, and easy for laboratory staff to employ, but they do not well represent major drivers of clinical pain complaints, which are more likely to involve spontaneous pain (Maier et al., 2010). In some types of pain syndromes, allodynia can be reduced by the use of medication; however, the resulting differences in spontaneous or overall pain are small (Rauck et al., 2015). To address this problem, laboratories have recently turned to more sophisticated methods of testing involving operant pain models or models in which place preference is used to detect an ongoing aversive pain state (King et al., 2009b). Quantifying flinching, guarding, vocalization and other nonevoked pain measures may also provide means of assessing spontaneous aspects of pain. Another approach to assessment of the effects of a candidate analgesic molecule on model animals involves quantifying an activity or function, such as running on an exercise wheel or the normalization of abnormal gait (Amagai et al., 2013; Cobos et al., 2012; Ishikawa et al., 2015). Conducting such measurements in the preclinical setting is consistent with the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) guidelines for

analgesic research, which emphasize incorporating measures of function into clinical studies (Turk et al., 2003).

Beyond the models and measures used for preclinical research, however, is the issue of improving the transparency of reporting and reproducibility of the research. Problems related to faulty study design, inappropriate data processing, and other procedural issues are believed to contribute to the poor reproducibility of laboratory results, an issue that results in approximately $28 billion in wasted research and development efforts each year in the United States (Freedman et al., 2015). To address these problems two sets of guidelines have been developed. First is the Animals in Research: Reporting In Vivo Experiments (ARRIVE) guidelines (Drummond et al., 2010), aimed at enhancing the transparency of laboratory research by requiring the reporting of details of the experimental design, animal care, disposition of animal subjects, blinding of investigators, and other factors potentially affecting the experimental results. A second, related effort is the construction and dissemination of the guidelines of the Preclinical Pain Research Consortium for Investigating Safety and Efficacy (PPRECISE) Working Group (Andrews et al., 2016), which stress the identification of a primary hypothesis and outcome measure, as well as the use of power calculations to justify cohort sizes.

Summary

Basic pain research is progressing across multiple interconnected fronts. These include mechanisms related to MOPR-biased analgesia, inflammation, pain transmission, innate immunity, and treatment of neuropathic pain. MOPR-biased analgesia may one day allow the separation of opioid-induced analgesia from opioid-induced respiratory depression or addiction by uncoupling MOPRs from the β-arrestin pathway. The diverse approaches discussed in this section demonstrate that one-size-fits-all pain management is neither achievable nor preferable, however, and that difficulties in translating discoveries into clinical pain medicine persist. Further studies to determine the impact of clinical characteristics (e.g., genetics and sex) are necessary to improve experimental models of pain.

The translation of the basic science of pain into effective therapies is limited by the failure of preclinical models to reflect the human condition and the inability to target pain networks. The development of humanized preclinical models of pain (in vitro and in vivo) could be instrumental to more reliably establishing clinically relevant basic and translational pain science. Such models could incorporate the functional as well as the organic response to pain, and assess pain's affective and cognitive components. Such research would benefit from quantitative biomarkers of pain and its relief that translate from model systems to humans, as well as studies of the impact of sex and aging on pain. These efforts, in turn, would require precise molecular phenotyping of both animal models of pain and patients to identify those models with the highest predictive validity for specific human pain phenotypes. The reproducibility of basic pain research and its subsequent impact on clinical pain medicine could be improved through more rigorous reporting guidelines and greater transparency.

THE NEUROBIOLOGY OF THE REWARD PATHWAY AND THE INTERSECTION OF PAIN AND OPIOID USE DISORDER

Neurobiology of the Reward Pathway

Although multiple brain regions constitute a reward network, the mesolimbic system is a key network node that regulates reward. Dopamine (DA) transmission in the mesolimbic system via the ventral tegmental area (VTA) to the nucleus accumbens (NAc) has long been recognized for its role in motivation (Wise et al., 1995). Natural rewards, as well as rewarding drugs (such as opioids), activate mesolimbic neurons to elicit DA release in the NAc (Devine et al., 1993; Giuliano et al., 2013; Le et al., 2009; Xiao and Ye, 2008). DA neurons in the VTA respond by burst firing following salient stimuli, and phasic bursting of DA neurons is sufficient to produce reward-seeking behavior (Kim et al., 2013; Tsai et al., 2009). The GABAergic input onto DA neurons includes the NAc, the ventral pallidum, the rostromedial tegmental nucleus (RMTg), and the bed nucleus of stria terminalis, among others, and has been estimated to make up at least 70 percent of synaptic input onto DA neurons (Matsui et al., 2014; Omelchenko and Sesack, 2005; Tepper and Lee, 2007; Watabe-Uchida et al., 2012).

The opioid system is involved in modulating pain and reward. Opioid receptors are a group of G protein-coupled receptors divided into three families: the MOPRs, the delta opioid receptors (DOPRs), and the kappa opioid receptors (KOPRs). These receptors are activated by three classes of endogenous opioid peptides—beta-endorphin, dynorphin, and enkephalin—that are derived from three precursor peptides. The selectivity and distribution of the opioid peptide and receptor systems suggest that encephalin and beta-endorphin act through the MOPRs and DOPRs, and dynorphin through the KOPRs. The opioid receptors and their peptides are distributed throughout the central and peripheral nervous system in a distinct but overlapping manner (Mansour et al., 1988). The MOPRs are widely distributed throughout the brainstem, midbrain, and forebrain structures, and mediate most of the analgesia and reinforcing effects of opioid agonists such as morphine (Kieffer and Gavériaux-Ruff, 2002). DOPRs, on the other hand, are highly expressed in forebrain regions (Mansour et al., 1988). Activation of DOPRs produces minimal analgesia in acute pain models but develops an analgesic effect in rodent models of chronic pain (Cahill et al., 2007; Pradhan et al., 2011). KOPR and MOPR expression overlaps throughout the brain. MOPRs located in the mesolimbic pathway are thought to mediate the reinforcing properties of opioids and natural reinforcers via regulation of extracellular DA within the NAc (Devine et al., 1993; Giuliano et al., 2013; Le et al., 2009; Xiao and Ye, 2008). This effect is mediated by inhibition of GABA release in the VTA through activation of local presynaptic MOPRs on GABA interneurons or on GABA projections from the RMTg (Matsui et al., 2014; Siuda et al., 2015). MOPR activation on these GABA neurons then leads to an increase in DA release in the NAc through a disinhibition mechanism (Johnson and North, 1992) and/or through local activation of MOPRs in the NAc core and shell (Hipólito et al., 2008).

In contrast to MOPRs, KOPR agonists block the rewarding effects of MOPR agonists by acting to decrease DA release in the NAc (Niikura et al., 2010). As mentioned above, KOPR and MOPR expression overlaps widely throughout the brain, and in these regions the two have a "push-and-pull" relationship. Expression of KOPRs has been detected in the VTA, NAc, prefrontal cortex, amygdala, and other areas implicated in the modulation of reward (Peckys and Landwehrmeyer, 1999; Shippenberg, 2009). KOPR activation in the NAc leads to dysphoria and other aversive effects (Land et al., 2008; Shirayama et al., 2004; Van't Veer and Carlezon, 2013). Expression and release of dynorphin, the endogenous KOPR agonist, is dynamically

regulated by reward, stress, and the opioid or other drug taken (Carlezon et al., 1998; Land et al., 2008). Thus, these dynorphin/KOPR-mediated alterations in reward states are likely to be directly linked with changes in DA transmission.

Neurobiology of the Pain Processing Pathway

As described by Garland and colleagues (2013), the brain actively regulates nociception via interactions between descending pain modulatory system (Heinricher et al., 2009; Reynolds, 1969) and corticocortical networks (Rainville, 2002) rather than passively receiving nociceptive information from the body. The descending pain modulatory system influences nociceptive input from the spinal cord through a network of cortical, subcortical, and brainstem structures (including the prefrontal cortex, anterior cingulate cortex, insula, amygdala, hypothalamus, periaqueductal grey region, rostral ventromedial medulla, and dorso-lateral pons) (Tracey and Mantyh, 2007). This system is believed to be the means by which the central nervous system inhibits nociceptive signals at the spinal outputs (Heinricher et al., 2009). Endogenous and exogenous opioids have been found to relieve pain by targeting the descending pain modulatory system, particularly in the periaqueductal grey region of the brain, which is involved in processing the placebo analgesia (Besson, 1999; Tracey, 2010). In addition, acute single-dose administration of opioids has been found to lead to analgesia in healthy individuals by reducing sensory evaluation processes, as is demonstrated by reductions in activation of brain regions that correspond with lower-level afferent processes (Wagner et al., 2007; Wise et al., 2002) and by modulation of neurotransmission in the substantia gelatinosa of the dorsal horn of the spine (Le Bars et al., 1980; Yaksh, 1987).

In addition, a recent review alluded to earlier highlights the influence of cognitive processes on pain perception (Wiech, 2016). It is thought that pain perception is determined by expectations and their modification through learning. The powerful influence of cognitive processes and learning mechanisms on the way pain is perceived is highlighted by placebo analgesia and pain relief through distraction (see also Chapter 2).

Opioid analgesia operates through both neuropharmacologic and psychological mechanisms. In addition to lessening the sensory aspects of pain, opioids may alleviate the affective dimensions of pain (e.g., suffering) (Garland et al., 2013). Analgesia induced through acute opioid administration in healthy individuals has been found to operate in part through the modulation of neural circuits that play a role in the regulation of attention, emotion, and neurovisceral integration (Becerra et al., 2006; Oertel et al., 2007; Thayer and Lane, 2009; Wagner et al., 2007). As with other drugs that are misused, opioids also stimulate mesolimbic DA reward systems (Johnson and North, 1992), and opioid-induced DA release in the NAc associated with positive mood and reward may promote pain management. While most of the available evidence regarding the psychobiological mechanisms of opioid-induced analgesia comes from research involving healthy individuals exposed to pain induction in the laboratory setting, the development of co-occurring chronic pain and OUD over time may modify the neurobiological response to opioids in ways that are of clinical importance (Garland et al., 2013), as discussed in the next section.

Neurobiology of the Intersection Between Pain and Opioid Use Disorder

It is well documented that positive reinforcement is decreased in the presence of chronic pain (Cahill et al., 2013; Hipólito et al., 2015; Leitl et al., 2014a,b; Martin et al., 2004;

Shippenberg et al., 1988). This chronic pain-induced alteration has been linked to a decrease in reinforcer-induced dopaminergic transmission (Hipólito et al., 2015; Loggia et al., 2014; Niikura et al., 2010). Despite this evidence, only a few preclinical studies have assessed the impact of pain on opioid intake. Most studies have used a conditioned place paradigm to test the reinforcing properties of opioids in rodents undergoing neuropathic or chronic pain (Cahill et al., 2013; Narita et al., 2005; Ozaki et al., 2002; Taylor et al., 2015). Of interest, Wu and colleagues (2014) revealed that the known reinforcing doses of morphine were unable to induce a place preference under painful conditions. However, animals exposed to chronic pain developed a clear preference for the morphine-paired side when the dose of morphine was increased (Wu et al., 2014). In line with these findings, rodents self-administering opioids while experiencing pain showed a decrease in their consumption of low drug doses compared with controls (Hipólito et al., 2015; Lyness et al., 1989; Martin and Ewan, 2008; Taylor et al., 2015; Wade et al., 2013), but this opioid consumption increased when high doses were accessible (Hipólito et al., 2015). Together these important results suggest a rightward shift in the dose response for opioid consumption in conditions of chronic pain that correlates with modifications in dopaminergic transmission from the VTA to the NAc (Hipólito et al., 2015). The dopaminergic release in the NAc is highly controlled by the opioid system, and Hipolito and colleagues (2015) demonstrated that inflammatory pain induces a desensitization of MOPRs in the VTA. These changes in opioid receptor function lead to decreased heroin- and DAMGO-induced DA release in the NAc. As mentioned above, the KOPR system may also be involved in these changes in DA release. Evidence points to a role for the KOPR system in many of the changes induced by chronic pain (Cahill et al., 2014).

In conjunction with the data showing that inflammatory pain decreases morphine- and heroin-induced NAc DA release and impairs the rewarding effects of morphine (Hipólito et al., 2015; Narita et al., 2005), Narita and colleagues (2005) showed that pain-induced attenuation in place preference can be reversed by systemic or local NAc blockade of KOPRs using norbinaltorphimine (NorBNI), a highly selective antagonist for KOPRs. The aversive component of exogenous KOPR stimulation, measured by place preference conditioning, also is suppressed when animals are experiencing inflammatory pain conditions (Shippenberg et al., 1988), suggesting the presence of a kappa opioid tone during painful conditions that induces a sustained dysphoric state.

There is, however, some controversy regarding the role of the dynorphin/kappa opioid system in the regulation of reinforcing properties of reward during pain. Some studies showed that KOPR antagonism did not reverse the pain-induced decrease in intracranial self-stimulation of the mesolimbic pathway in rats (Leitl et al., 2014a,b). These discrepancies could be explained by the presence of hot and cold spots (areas that appear particularly attuned to either accentuate or suppress reward response), two distinct areas in the NAc shell in which activation of KOPRs can drive either aversive or reinforcing behaviors (Al-Hasani et al., 2015; Castro and Berridge, 2014). Systemic application of KOPR antagonists likely targets both of these discrete areas, while microinjections of KOPR agonists/antagonists to specifically target these discrete areas in the NAc could yield opposing behaviors and interpretations.

Finally, it is important to acknowledge the role of other brain regions (besides the VTA and the NAc) critical in the regulation of pain, stress, and reward responses. The amygdala is very much involved in the processing of both positive and negative valence (see the review by Janak and Tye, 2015). Specifically, the basolateral amygdala (BLA) and the central nucleus of the amygdala play important roles in affective pain, in addition to better-studied roles in the

processing of mood and fear disorders, as well as reinforcement (Pare and Duvarci, 2012; Veinante et al., 2013). More recently, it has been shown that the habenula and NAc dopaminergic neurons drive inhibitory antireward tone during stress and pain conditions (Lee and Goto, 2011). The lateral hypothalamus, a region critical to positive reinforcement, also plays a role in the pain response through sensory mechanisms (Ezzatpanah et al., 2015). These structures contribute as well to increases in norepinephrine, corticotropin-releasing hormone (CRH), vasopressin, hypocretin, and substance P, driving a stress-like emotional state.

Summary

Pain and reward are processed by overlapping brain structures. This finding is supported by clinical and preclinical evidence showing that positive or negative reinforcement (i.e., rewarding properties of opioids or the rewarding effect of pain relief, respectively) is decreased by the presence of pain. In this regard, preclinical studies have shown that pain promotes opioid dose escalation in animals with a prior history of opioid intake. However, additional studies are needed at both the preclinical and clinical levels. Much of the available evidence regarding the mechanisms underlying opioid analgesia and reward comes from studies of healthy individuals, and such studies would benefit from including individuals with chronic pain. Indeed, preclinical studies have shown that pain promotes opioid dose escalation in animals with a prior history of opioid intake.

PRECLINICAL AND TRANSLATIONAL RESEARCH

Development of New Analgesics

Despite the complexity entailed in researching pain described thus far, modern approaches examining pain at the genetic and mechanistic levels are relatively recent. Much more remains to be discovered by researchers seeking to translate their findings into clinical applications. This section describes some of these opportunities toward the development of nonaddictive alternatives to the opioid analgesics currently on the market.

Biased Opioid Receptor Ligands

The concept of ligands interacting with receptors differentially to modulate their interaction with downstream signaling pathways and effector systems has been extant for decades but has gained considerable traction in the past 5 years (Kenakin, 2015; Reiter et al., 2012). The recognition that receptor conformation may be dynamically and variably altered by interaction with distinct ligands has coincided with the emergence of diverse tools relevant to dissection of spatiotemporal patterns of opioid receptor (OR) signaling, consequences of downstream pathway activation, and the in vivo consequences of such biased approaches. Developments of direct relevance to the opioid field include structural elucidation of μ, κ, and δ ORs in the basal and bound state; intracellular OR domains complexed with the rat rhodopsin receptor (optogenetic activation); and tissue-specific deletions of ORs and their endogenous ligands in mice (Bruchas and Roth, 2016). Although the clinical importance of these discoveries remains to be established, several examples illustrate the speed at which this field is evolving.

Engagement of MOPRs by a ligand such as morphine recruits both inhibitory guanosine-5'-triphosophate (GTP) binding proteins such as Gi/o and β-arrestin, which serves ultimately to terminate G protein-dependent signaling. The βγ subunit of the G protein dissociates, permitting the α subunit to inhibit adenylate cyclase and indirectly activate kinases such as JNK (c-Jun N-terminal kinases) and ERK (extracellular signal-regulated kinases). In the meantime, the βγ subunit activates inwardly rectifying potassium channels to increase membrane hyperpolarization and inhibit voltage-gated calcium ion channels and hence neuronal hyperpolarization. These actions combine to explain the analgesia consequent to MOPR activation (Dogra and Yadav, 2015). However, ligand engagement also activates G protein receptor kinases that phosphorylate the intracellular tails of ORs, attracting β-arrestins that result directly and indirectly in activation of the ERK and p38 signaling pathways. Experiments in β-arrestin-depleted mice revealed this to be the pathway that may drive such effects as tolerance, respiratory depression, and constipation with certain opioids, such as morphine (Raehal and Bohn, 2014). Yet while the ability to segregate analgesic efficacy from a range of troubling adverse effects has clear translational implications, screening for such biased ligands is complicated by contextual influences that complicate translation of ligand bias from in vitro systems to rodent systems, let alone to humans (Kenakin, 2015). Nonetheless, several promising examples have emerged (Gupta et al., 2016; White et al., 2014), and one compound already has advanced from encouraging results of conserved analgesia with reduced respiratory and gastrointestinal adverse effects in 200 abdominoplasty patients in phase II to a larger randomized trial (Kingwell, 2015).

An exciting element of this work is the increasing recognition of OR heterodimerization as an in vivo phenomenon and the possibility that what are regarded as specific OR ligands may also engage, perhaps preferentially, heterodimers, perhaps to augment their analgesic efficacy. Screening approaches have yielded bivalent ligands, antibodies, and membrane permeable peptides that target heterodimers, for example, of the MOPRs/DOPRs. These approaches, combined with approaches mentioned above, should clarify the underlying biology and the promise of such heterodimers as drug targets (Fujita et al., 2015). Heterodimerization may extend beyond the OR family; for example, heterodimerization of the KOPRs with the neurotensin receptor induces a switch of the former from G protein activation to β-arrestin-based signaling (Liu et al., 2016).

Abuse-Deterrent Formulations of Opioids

Although not representing an innovation in changing the intrinsic activity of opioid action, abuse-deterrent formulations (ADFs) are opioid medications that have been reformulated to reduce the likelihood that the medication will be "abused." For example, some opioids have been reformulated to discourage manipulation by either making the pill difficult to manipulate or rendering it ineffective or unpleasant once manipulated. In addition to ADFs currently on the market, such as agonist/antagonist combinations (e.g., oxycodone plus naloxone) and crush-resistant extended-release (ER) formulations (e.g., oxymorphone), a number of new technologies are in development. These include formulations designed to limit the rate or extent of release of opioids when multiple pills are ingested; cause the pill to turn to gel if dissolved; irritate the nasal passages if snorted; and slow the release of the drug into the brain, thereby reducing euphoria (Bulloch, 2015). Many opioid analgesics, such as morphine, activate primarily the MOPRs, which relieves pain but is also associated with such side effects as respiratory

depression. KOPR agonists currently in development are intended instead to activate the KOPRs, potentially providing pain relief without the MOPR-associated side effects (Beck et al., 2016).

Eicosanoids, Cannabinoids, and Transient Receptor Potential Channels

As mentioned in Chapter 2, prostaglandins E_2 and I_2, particularly but not exclusively formed by cyclooxygenase (COX)-2, mediate pain and inflammation; suppression of their formation accounts for the analgesic and anti-inflammatory actions of NSAIDs. Unfortunately, COX-2-dependent formation of these same eicosanoids serves a protective function in the cardiovascular system, where their suppression has resulted in myocardial infarction and stroke; hypertension and heart failure; and in mice, evidence of accelerated atherogenesis (Grosser et al., 2010). For these reasons, attention has focused on the microsomal prostaglandin E (PGE) synthase (S)-1, the enzyme downstream of COX that largely accounts for PGE_2 formation (Chandrasekhar et al., 2016). When this enzyme is blocked or deleted, its prostaglandin H2 (PGH2) substrate, formed by COX, is available for rediversion to other PG synthases. Global deletion of microsomal prostaglandin E synthase (MPGES)-1 in mice largely retains the analgesic efficacy of NSAIDs as assessed in mice, but augments rather than depresses prostacycline (PCI2). This coincides with attenuation or abrogation of the enhanced thrombogesis, hypertension, and atherogenesis seen in COX-2 knockout mice (Yang and Chen, 2016). Indeed, deletion of MPGES-1 in myeloid cells conserves this profile (Chen et al., 2014), and the impact of targeting macrophage MPGES-1 is under investigation. A phase II study of an MPGES-1 inhibitor found rediversion to augment PGI2 formation in volunteers (Jin et al., 2016). An open question is how faithfully MPGES-1 inhibitors will conserve the analgesic efficacy of NSAIDs in human pain syndromes, given that in some settings in rodent models, PGI2 has been shown to mediate pain and inflammation (Sugita et al., 2016). PGE2 activates 4 E prostanoid (P) receptors. As mentioned previously, EP3 mediates the hyperthermic effects of PGE2 and the EP1 (Johansson et al., 2011), EP2 (Ganesh, 2014), and EP4 (St-Jacques and Ma, 2014) receptors, just as the I prostanoid receptor (Honda et al., 2006) may mediate pain. While antagonists for all four of these receptors have been developed, it is unclear how safely such drugs could be used as analgesics given the importance of these PGs in cardioprotection.

These PGs mediate pain, at least in part, by sensitizing transient receptor potential (TRP) channels in nociceptors to activation by thermal, mechanical, or chemical stimuli. TRPs have particular relevance to the neuropathic pain that complicates diabetes, traumatic nerve injury, and chemotherapeutic drug administration. Besides PGs, other inflammatory mediators, such as bradykinin, nitric oxide (NO), and nerve growth factor (NGF), can subserve a similar function (Basso and Altier, 2017). Aside from the PG metabolites of arachidonic acid, p450 catalyzed metabolites (epoxyeicosatrienoic acids [EETs]) can sensitize nociceptors, especially TRPA1 and TRPV4, and deletion and inhibition of the soluble epoxide hydrolase that catalyzes their formation has shown promise in preclinical models (Wagner et al., 2016). Yet while TRPs themselves (TRPV1/A1, TRPV4/M8) have emerged as diverse and attractive targets for analgesic drug development given their role in inflammatory and neuropathic pain, concurrent impairment of their endogenous signaling functions (e.g., thermal regulation for TRPV1) may limit their clinical application (Dai, 2016; Mickle et al., 2016). Indeed, the fact that TRPs sustain some physiological functions, such as thermoregulation and hyperthermia, has complicated the early human pharmacology of TRPV1 antagonists. Also in model systems, their role may be highly context dependent: they serve as protective cellular sensors of warning signals under

physiological conditions, but may contribute to pain and inflammation under pathological conditions (Dai, 2016).

Cannabinoids are lipids closely related to the eicosanoid family. The principal endogenous cannabinoids, anandamide and 2-arachidonoylglycerol (2-AG), are formed in postsynaptic neurons and act centrally on cannabinoid receptor type 1 (CB1) G protein-coupled receptors (GPRs) that are expressed on presynaptic neurons, thereby regulating neurotransmitter release. Although there is some evidence that they are also expressed centrally, CB2 receptors generally are expressed peripherally on both neurons and immune cells. The principal psychoactive constituent of cannabis, Δ9-tetrahydro cannabinol (THC) is active on both CB1 and CB2 receptors. Anandamide levels are regulated by its breakdown through the action of fatty acid amide hydrolase (FAAH), while 2-AG levels are regulated by monoacylglycerol lipase (MAGL), which accounts for ~85 percent of the hydrolysis, and by α/β hydrolase domain-containing 6 (ABHD6) and ABHD12, which also hydrolyze 2-AG to arachidonic acid and glycerol. Cannabinoids act as well on other receptors, such as GPR18 and GPR55, and may act in concert with TRP channels and MOPRs (Maguire and France, 2016) in a bidirectional manner (Zádor and Wollemann, 2015) to modulate the expression of pain.

Cannabinoid action in the amygdala is of particular interest given the coincidence of pain with depression and the modulating effects of cannabinoids on both the physical perception of and emotive response to pain (Huang et al., 2016). Cannabinoids have been shown to be effective in several settings as analgesics in humans, albeit limited by central side effects such as drowsiness. There is some evidence for sex-dependent differences in mice in the analgesic response to cannabinoids (Cooper and Haney, 2016). Legalization of cannabis use for cancer pain has been advancing at the state level. Beyond the development of biased agonist ligands for cannabinoid receptors as novel analgesics with an improved adverse effect profile (Diez-Alarcia et al., 2016; Mallipeddi et al., 2016), interest in enhancing the formation of anadamide by inhibition of FAAH (Guindon, 2017; Pawsey et al., 2016) has been tempered by a severe reaction (a cerebellar syndrome including generalized ataxia, dysarthria, and nystagmus) to at least one such compound in healthy volunteers (Kerbrat et al., 2016).

Sodium Channel Blockade

VGSCs are crucial to the transmission of electrical signals in sensory neurons, and specific patterns of sodium current activity, such as persistent and resurgent currents, also are likely to be relevant to nociception (Barbosa and Cummins, 2016). The importance of sodium channels in pain is illustrated nicely by human genetics; gain-of-function mutations of Nav1.7, Nav1.8, and Nav1.9, which are expressed preferentially in peripheral neurons, cause pain in such syndromes as erythromelalgia (Brown, 2016; Rolyan et al., 2016), while loss-of-function mutations of Nav1.7 result in loss of pain in otherwise healthy people (Emery et al., 2016). A painful neuropathy caused by the chemotherapeutic oxaliplatin has been linked to mutations in Nav1.6, a VGSC linked also to the conversion of acute to chronic pain (Barbosa and Cummins, 2016). Optogenetic silencing of Nav1.8 positive afferents alleviates inflammatory and neuropathic pain (Daou et al., 2016).

While mutational analysis has tied pain perception particularly to the α subunit of VGSCs, auxiliary subunits, such as β, and multiple auxiliary proteins, such as fibroblast growth factor homologous factors, may bind to and regulate α subunits and modulate aspects of nociception. Acid-sensing ion channels (ASICs) are activated with acidification of the synaptic

cleft and exhibit specificity for sodium, although some also allow passage of calcium. Gene depletion in mice has implicated ASICs in mechanosensation, and several drugs targeting ASICs are in clinical trials (Boscardin et al., 2016).

VGSCs are complex drug targets given their multiple subunits, numerous configurations, and auxiliary binding proteins and the necessity of restricting targeting to the periphery. For example, to achieve selectivity with respect to tissue expression requires avoiding disruption of cardiac conductivity. Selectivity also may be enhanced by targeting microproteins to less conserved elements of VGSCs, such as voltage sensing, rather than pore residues (Barbosa and Cummins, 2016; Shcherbatko et al., 2016).

Nerve Growth Factor

NGF sensitizes and proliferates nociceptors augmenting the response to painful stimuli and has an established place in both neuropathic and inflammatory models of pain. Proliferation of nociceptor axons and terminals in target tissues is a particular feature of NGF action in cancer pain (Miyagi et al., 2016), driving a dramatic increase of small nerve fiber proliferation in bone (Kelleher et al., 2017). Perhaps unsurprisingly, NGF is believed to play an important role in the transition of acute to chronic pain. NGF (and its pro-NGF form) activates (1) a high-affinity tropomyosin receptor kinase (trk)A receptor, selectively expressed on peripheral terminals of Aδ and peptidergic unmyelinated C fibers, and (2) a lower-affinity, more ubiquitously expressed and promiscuous p75 neurotropin receptor, a member of the TNF receptor superfamily. While activation of the former promotes neuronal proliferation, activation of the latter promotes apoptosis. Despite these contrasting effects, the two receptors also can interact to modulate downstream effects, adding a layer of complexity that is incompletely understood. Although several anti-NGF monoclonal antibodies completed phase III trials and were effective analgesics, they also accelerated disease progression in patients with osteoarthritis and were put on clinical hold in 2010 by the FDA (Chang et al., 2016). This hold was released in March 2015, and translational and clinical trials (Miller et al., 2017) of diverse therapeutic modalities, including sequestration of free NGF, prevention of NGF binding, and inhibition of trk function, are being pursued (Chang et al., 2016).

Interleukin (IL)-6

This T cell-derived cytokine plays a central role in host defense against infection but also has been implicated in neuropathic pain. Unlike NGF, which is restricted to the periphery but transported retrogradely along axons complexed with its trkA receptor, IL-6 is upregulated in the central nervous system, where it promotes neuronal proliferation and restrains apoptosis. Both IL-6 and its soluble receptor can sensitize nocireceptors. This has prompted interest in the possibility that targeting the sIL-6R, leaving the canonical IL-6R untouched, might achieve analgesia while leaving the immunologic functions of the cytokine intact (Kelleher et al., 2017).

Emerging Drug Targets

Human genetic studies have revealed a relationship between variants in guanosine triphosphate (GTP) cyclohydrolase 1, which reduces tetrahydrobiopterin (BH4), and decreased pain. In mice, production of BH4 is increased by damaged nerves and attendant infiltrating

macrophages, while reduction of BH4, by interfering with its degradation, reduces injury-induced hypersensitivity without interfering with the protective properties of nociception (Latremoliere et al., 2015). BH4 is an essential cofactor for enzymes relevant to generation of catecholamines, NO, and serotonin, all of which are mediators of hypersensitivity. For example, nitric oxide synthase (NOS)1 in neurons and NOS2 in macrophages have cumulative effects on NO generation and hypersensitivity (Choi et al., 2016; Kuboyama et al., 2011).

Purinoreceptors are activated by adenosine (P1) or adenosine triphosphate (ATP)/adenosine diphosphate (ADP) (P2; P2X ion channels and P2Y G protein-coupled receptors). Such nucleotides are released by most cells in response to mechanical stimulation and are rapidly inactivated by ecto-ADPases. P2Y-dependent ATP-induced hyperalgesia is transduced via TRPV1 channels. P2X7 receptors mediate pain caused by the chemotherapeutic oxaliplatin, while activation of glial P2Y12 receptors appears to be important in neuropathic pain. P2X3, P2X2/3, P2X4, P2X7, and P2Y12 have attracted attention as drug targets for both neuropathic and inflammatory pain (Burnstock, 2016; Matsumura et al., 2016; Teixeira et al., 2016).

Other areas of emerging interest include the potential of potassium channel openers as analgesics (Busserolles et al., 2016) and elucidation of the role of store-operated calcium channels in the biology of nociception (Munoz and Hu, 2016).

Summary

A number of opportunities have emerged in recent years toward the development of nonaddictive alternatives to the opioids available on the market. Those of direct relevance to opioids include biased ligands directed at opioid receptors and continued development of new abuse-deterrent technologies. Other developments include inhibitors of the microsomal PGE synthase, drugs targeting VGSCs, anti-NGF biologics, transient receptor potential cation channel antagonists, cannabinoid receptor agonists, excitatory amino acid receptor blockers, anticytokine signaling drugs, neuromodulation, and agents directed at other targets. Specialized channels expressed in primary afferent nociceptors, such as TRP channels, serve as cellular sensors of actual or impending tissue injury and are targets for a new class of analgesic development. The selective blockade of pain transmission from the sensory terminals to the spinal cord may be possible through targeting of subtypes of VGSCs.

CLINICAL RESEARCH

Clinical pain research has continued since the IOM (2011) report *Relieving Pain in America* was issued. As discussed in Chapter 2 of the present report, opioids, while effective in the short and intermediate terms, lack data to support their chronic long-term use. Moreover, significant adverse effects are associated with chronic use of high-dose opioids (Chou et al., 2015). Research aimed at separating the beneficial pain-relieving effects of opioids from those that cause harm is under way (Manglik et al., 2016; Schneider et al., 2016). This section summarizes promising clinical research into the management of pain and opioid risk, including nonpharmacologic and interventional approaches, and the potential role of precision health care in improving clinical practice and health outcomes with respect to pain management.

Optimizing Opioid Analgesia in the Context of Comprehensive Pain Management and Opioid Risk

Opioid Prescribing for Chronic Pain

Many professional organizations have published standards of care for judicious prescribing of opioids for chronic pain (Dowell et al., 2016; Mai et al., 2015; Nuckols et al., 2014). Full disclosure of the risks versus benefits of initiating opioid therapy is encouraged, along with individual assessment of the risk of opioid misuse. Several instruments have been developed to assess this risk based on patient self-report, including the Screener and Opioid Assessment for Patients in Pain, Revised (SOAPP-R) (Butler et al., 2009), the Opioid Risk Tool (Webster and Webster, 2005), and the Current Opioid Misuse Measure (COMM) (Butler et al., 2010), among others. Such instruments can be used along with other information to guide decision making regarding an appropriate pain management plan. A review that involved an analysis of studies on the accuracy of the SOAPP-R, the ORT, and other instruments for predicting opioid misuse showed mixed results, with several studies having methodological shortcomings (Chou et al., 2015). Another review of studies on instruments (including the COMM and other self-report measures) used to assess the safety, efficacy, or misuse of current opioid therapy found that most studies demonstrated statistical significance, but had bias and generalizability limitations. Data on feasibility of use in clinical settings were limited by a lack of testing in those settings (Becker et al., 2013). Additional research could examine the accuracy of opioid risk assessment tools across multiple populations, including their role in improving outcomes related to misuse, overdose, and OUD, and test their use in clinical practice (Becker et al., 2013; Chou et al., 2015).

Given the potential to reduce dose-dependent risks, opioid dose reduction in the context of long-term opioid therapy is an area of ongoing research. Von Korff and colleagues (2016) report results from an interrupted time series analysis in Washington State examining changes between 2006 and 2014 in percentages of (1) patients being prescribed opioid therapy in doses exceeding 120 morphine-equivalent dose (MED)/day, and (2) patients receiving excess opioid days supplied. After release of a state-level chronic pain management guideline, as well as a health plan's initiative to reduce high-dose opioid prescribing, the authors found that while prescribers exposed to the state guideline alone decreased high-dose prescribing (from 20.6 percent to 13.6 percent) and excess opioid days supplied (from 20.1 percent to 14.7 percent), those prescribers additionally receiving guidance from the health plan initiative displayed significantly higher decreases on the same metrics (from 16.8 percent to 6.3 percent and 24 percent to 10 percent, respectively) (Von Korff et al., 2016). Similarly, research on an opioid dose reduction program in a U.S. Department of Veterans Affairs (VA) health care system found dramatic relative changes in prescribing of a variety of opioid medications before and after program implementation (notably, with a parallel increase in prescription of oxycodone immediate-release [IR]) (Westanmo et al., 2015). Importantly, the authors report that patient complaints were lower than they had anticipated, but stress that prescribers, despite believing that patient safety had improved, continued to express a need for more comprehensive pain management services. Becker and colleagues (2017) report similar success at an Opioid Reassessment Clinic to which high-complexity patients with pain (e.g., with co-occurring OUD) could be referred by primary care physicians.

Stepped Care

Stepped care is a patient-centered, multimodal approach to pain management that emphasizes treatment goals and a stepwise modification plan should goals fail to be reached or other complications arise (Cleeland et al., 2003). Research demonstrates improved outcomes for patients with chronic pain compared with usual care, including reduced pain-related disability, pain interference, and pain severity (Bair et al., 2015), and the approach also is associated with improved quality of life and cost savings (Hill et al., 2011). The Stepped Care to Optimize Pain Care Effectiveness (SCOPE) study showed success at integrating stepped care models into the primary care setting through the use of telehealth mechanisms (e.g., automated symptom monitoring via phone or Internet, with related optimization of analgesic management) (Kroenke et al., 2014).

Nonpharmacologic Pain Therapies

As discussed in Chapter 2, nonpharmacologic therapies are a promising option for various types of pain, and research has begun to formally establish associations with improved outcomes. For example, multiple studies have demonstrated the effectiveness of various nonpharmacologic therapies in chronic low back pain. Massage has been found to be superior for improving function and decreasing pain compared with usual care, with benefit extending many weeks after treatment (Cherkin et al., 2011). Similarly, Lamb and colleagues (2012) report durable improvement in pain and disability outcomes 1 year after group cognitive-behavioral therapy for low back pain; their long-term data indicate an average duration of effect of 34 months. Randomized trials studying other treatment modalities, such as tai chi, yoga, stretching classes, spinal manipulation, and physical therapy, also have demonstrated effectiveness for such conditions as low back pain, subacute neck pain, and osteoarthritis (Bronfort et al., 2012; Sherman et al., 2011; Wang et al., 2016).

Interventional Pain Therapies

Research in the area of interventional pain therapies, traditionally comprising small case series, observational studies, nonrandomized trials, and trials without controls, is slowly improving in quality. (See Chapter 2 for further discussion of these therapies.) Low back and neck pain account for the majority of medical visits for pain and the majority of disability in industrialized nations. Epidural steroid injections, most often administered for painful radiculopathy, are the most frequently performed of all pain procedures (Bicket et al., 2015), and epidural injections for chronic radicular pain have increased dramatically over the past 10 years (Manchikanti et al., 2013). The mechanism of pain relief from the injections remains unclear. Unlike NSAIDs, which are cyclooxygenase inhibitors resulting in prostaglandin reduction, steroids act via the lipoxygenase pathway, reducing leukotriene formation. Steroids also inhibit phospholipase A2, the enzyme responsible for arachidonic acid production (Baqai and Bal, 2009).

The data on efficacy for epidural steroid injections are varied despite more than 45 randomized controlled trials and many reviews. Review articles by interventional physicians tend to find more positive results relative to reviews by noninterventional physicians, and patient selection is important in the variability of the results (Cohen et al., 2013). A review of articles

published from 1953 to 2013 found that there was evidence of a positive result lasting less than 3 months from epidural steroid injections in more than half of the controlled studies in selected individuals, and the incidence of serious complications was rare if the injections were administered with proper precautions. More positive results were seen with use of transforaminal versus interlaminar or caudal techniques, and in radicular pain from lumbar herniated disc compared with spinal stenosis or axial pain (Cohen et al., 2013).

A systematic review of 3,641 patients in 43 studies evaluating control injections found that what is injected in the epidural space is not as important as previously thought, and injection of steroid may not be essential for pain relief. Epidural injection of local anesthetic only or even saline may provide similar results, a finding that may have relevance in diabetic patients with radicular pain (Bicket et al., 2013). Spine surgery rates also have increased significantly over the past 10 years, as has disability from spinal pain. A 2015 systematic review and meta-analysis of 26 studies, 22 of which were randomized controlled trials, provided unconvincing results regarding the surgery-sparing effect of epidural steroids. There was moderate evidence, falling short of statistical significance, that epidural steroid injections had a small effect on preventing surgery in the short term, and there was no effect on the need for surgery in the long term (Bicket et al., 2015).

An area in which research activity has recently increased is the field of neuromodulation for the treatment of pain. Spinal cord stimulation (SCS) has been used to treat neuropathic pain of the extremities for many years (Deer et al., 2014). A 2005 randomized controlled trial found that SCS provided superior analgesia and was more cost-effective relative to repeat surgery for failed back surgery patients with persistent lumbar radicular pain who were candidates for surgery (North et al., 2005).

A Cochrane review found that SCS provided better pain relief and analgesic sparing with decreased amputations compared with standard conservative treatment for nonreconstructable chronic critical leg ischemia (Ubbink and Vermeulen, 2013). Although lumbar radicular pain frequently is treated successfully with SCS, low back pain often is more challenging. Traditional SCS is at 40–60 Hz. High-frequency (10 kHz) SCS recently emerged as another form of SCS, and evidence for the claim of superior relief of low back and leg pain is discussed below.

With the emergence of new paresthesia-free SCS it is now possible to conduct placebo-controlled trials. In a randomized controlled trial of 198 patients with chronic back and leg pain, 84.5 percent of participants who received the 10 kHz SCS experienced 50 percent relief of their back pain and 83 percent relief of their leg pain at 3 months. By contrast, participants who received traditional SCS experienced 43.8 percent and 55.5 percent reductions in their back and leg pain, respectively (Kapural et al., 2015). Likewise, a multicenter randomized controlled trial showed that high-frequency stimulation provided at least 50 percent relief of low back and leg pain and was superior to traditional low-frequency SCS for 2 years (Kapural et al., 2016).

The new burst SCS, like high-frequency stimulation, is paresthesia-free. Burst stimulation (40 Hz burst with five spikes at 500 Hz/burst) is described as using both spinal and supraspinal analgesic mechanisms in relieving pain and suffering. Electroencephalogram (EEG) activity and current density were measured in the anterior cingulate and prefrontal cortex of patients with SCS with traditional tonic (40 Hz), burst, and placebo stimulation. Pain was reduced with tonic stimulation, then further reduced with burst stimulation, with EEG activity suggesting a supraspinal effect. Prior functional magnetic resonance imaging studies had demonstrated that tonic stimulation modulates the lateral pain pathways, whereas burst stimulation activates both the medial affective and lateral pain pathways (DeRidder et al., 2010).

A small randomized, placebo-controlled trial comparing tonic, burst, and placebo stimulation found that all types of SCS provided better analgesia relative to placebo. Burst stimulation improved back, limb, and general pain by more than 50 percent, versus 30–52 percent relief with tonic stimulation (DeRidder et al., 2013). More recently, spinal stimulation has been compared with a more selective targeting of the dorsal root ganglion (DRG) for the treatment of complex regional pain syndromes, with promising outcomes (Deer et al., 2017).

It is important to note that clinical research on interventional pain therapies often is observational and involves low numbers of patients. Nonetheless, some organizations are attempting to extract quality data from these studies that practitioners can apply to their practice. The Spine Intervention Society (SIS) has published guidelines on intervention for spine pain (SIS, 2014), and a few reviews suggest that adherence to these guidelines may improve outcomes.

Clinical interventions for the treatment of chronic headache also have been investigated. For example, cervical medial branch injections can be administered to provide analgesia for cervicogenic headache and neck pain. A 2016 systematic review of eight publications on radiofrequency denervation found that if performed as described by SIS guidelines, cervical radiofrequency neurotomy is effective, with minor risks. (One of the authors served in the standards division of SIS.) The majority of patients were pain-free at 6 months, and more than a third were pain-free at 1 year. The number of sessions needed to provide complete pain relief was two, and side effects were minor and temporary (Engel et al., 2016).

When peripheral nerve blocks are performed for headaches, they are most often occipital, particularly for posterior headaches. A review of five randomized controlled trials of greater occipital nerve blocks, four of which were double-blinded, found that all were small studies with 4- to 8-week follow-up that showed partial or complete relief of headache. The addition of a steroid to local anesthetic was not found to offer additional benefit (Ambrosini and Schoenen, 2016).

Botulinum toxin was FDA approved in 2010 for chronic migraine in patients who experienced at least 15 headaches per month for 3 or more months and whose headaches had migraine features for at least 8 of those days (Khalil et al., 2014). The largest double-blind placebo-controlled trials were all industry sponsored (Aurora et al., 2011).

Precision Health Care and Pain Management

Precision health care is focused on defining a true disease state/condition using pathophysiological mechanisms, congruent with the concept of clinical validity. In contrast, personalized health care applies to optimization of a therapeutic approach specific to an individual versus a population. This section highlights the differences in these concepts as applied to the state of the science on opioid prescribing for chronic pain management.

Diagnosis of Chronic Pain

Pain diagnosis currently depends on clinical examination and testing (laboratory, imaging) to identify the etiology of the pain. The pain condition is described in terms of the pain's location (e.g., orofacial pain, temporomandibular joint disorder, migraine, low back pain) and/or type (somatic pain is caused by injury to skin, muscles, bone, joints, or connective tissues and is nociceptive; visceral pain arises from the internal organs and is nociceptive; and

neuropathic pain is presumed to be caused by a demonstrable lesion or disease of the peripheral or central somatosensory nervous system). Duration of pain is commonly defined as acute (less than 6 weeks), subacute (6–12 weeks) or chronic (more than 12 weeks). In many instances, pain has no identifiable cause (i.e., is idiopathic), a feature that largely encompasses many of the pain syndromes diagnosed today, such as complex regional pain syndrome, fibromyalgia, and chronic pelvic pain. Even for the most common chronic musculoskeletal pain condition, chronic low back pain, more than 80 percent of cases have no identifiable etiology.

Studies suggest that genetics contribute substantially to the risk of developing chronic pain (Hocking et al., 2012; Nielsen et al., 2012). In an analysis of data from a Scottish cohort study (N = 7,644 people in 2,195 extended families), for example, the heritability of any chronic pain and severe chronic pain was found to be 16 percent and 30 percent, respectively, after adjusting for shared household effects, age, body mass index, occupation, and physical activity, among other factors (Hocking et al., 2012). A systematic review of more than 50 twin studies of pain showed heritability of 50 percent for migraine, tension-type headache, and chronic widespread pain; 35 percent for back and neck pain; and 25 percent for irritable bowel syndrome (Nielsen et al., 2012). Other than rare monogenetic familial pain conditions (e.g., familial migraine with aura or erythromelalgia), however, chronic pain does not follow the Mendelian transmission model but encompasses aggregates of endophenotypes, each of which may be governed by Mendelian law (Zorina-Lichtenwalter et al., 2016). Criteria for the endophenotype construct state that the endophenotypes must (1) be associated with the disease of interest, (2) be heritable, (3) be manifest in subjects independently of active pathology, and (4) cosegregate with disease in pedigree studies (Gottesman and Gould, 2003). Endophenotypes of chronic pain include the pain phenotype (location, severity, frequency, duration, presence of peripheral and central sensitization such as hyperalgesia and allodynia) and associated symptoms, including anxiety, depression, and sleep disturbance (Zorina-Lichtenwalter et al., 2016).

Precision health care could improve diagnosis of pain by using omic approaches (genomics, metabolomics) to understand the pathophysiology of specific pain conditions and symptom phenotypes, along with advanced imaging techniques to detect functional changes in pain processing. There is significant interest in this area with respect to the potential for improving the prediction and diagnosis of pain, as well as advancing preventive strategies. At present, however, studies using candidate gene approaches have largely failed in reproducibility.

In summarizing the literature on analysis of single nucleotide polymorphisms (SNPs) associated with chronic pain, more than 200 of which are known to exist, Crow and colleagues (2013) note that three (*GCH1*, which encodes GTP cyclohydrolase; *COMT*, an enzyme that eliminates catecholamines; and *OPRM1*, the MOPR gene) are particularly noteworthy for demonstrating the often contradictory findings in the field.

Studies of healthy volunteers and patients reporting persistent leg pain have shown associations between lower pain ratings and a *GCH1* haplotype (Campbell et al., 2009; Tegeder et al., 2006). In a larger cohort, however, neither the same association nor even the same haplotype was identified (Kim and Dionne, 2007), and similarly negative results were found in patients from a different ethnic population with HIV-associated neuropathy (Wadley et al., 2012). Likewise, research into the association between pain and *COMT* has thus far produced inconclusive and contradictory evidence. The first *COMT* SNP associated with pain was reported in 2003 (Zubieta et al., 2003) and has been confirmed in multiple patient and healthy volunteer groups (Diatchenko et al., 2005, 2006; Mukherjee et al., 2010), as well as animal models (Segall et al., 2010). Nevertheless, controversy exists over the importance of the original SNP

(Val158Met) (Kim et al., 2006), and the association between increased pain and other *COMT* variants does not replicate across populations. For example, no association was found between chronic pain and *COMT* SNPs in a large study of more than 7,000 people (Hocking et al., 2010). Rather, the authors found an entirely different haplotype within the *ADRB2* gene (responsible for encoding the beta-2 adrenergic receptor) that predicted both pain severity and duration, even after controlling for gender, social class, body mass index, and other confounding factors (Hocking et al., 2010). Finally, while relationships between pain and SNPs in *OPRM1* have been reported for more than a decade (Bond et al., 1988; Wendel and Hoehe, 1998), a larger meta-analysis was unable to confirm these findings (Walter and Lotsch, 2009).

Heterogeneity in chronic pain may explain this lack of consensus, as inter- and intracohort variability could confound results (Crow et al., 2013). Thus, moving toward a more mechanism-based pain syndrome classification, aided by rigorous phenotyping, is a promising next step (Maier et al., 2010). Another issue, common in genetic association studies, is the exceedingly population-specific nature of findings, resulting in varying results across different ethnic cohorts.

Moreover, genome-wide association studies often capture gene variants that are more common (e.g., with a minor allelic frequency of ≥5 percent). Discouragingly small effect sizes frequently are identified for most variants, which explain only a fraction of the genetic contribution to a particular condition (Hardy and Singleton, 2009). More successful approaches could include examining structural variation, such as copy number variation (WTCC, 2010), or even highly penetrant rare variants (e.g., those with a minor allelic frequency of less than 1 percent) (Gibson, 2011). Recent studies examining variants in European, South Asian, and African populations used exon sequencing across large cohorts and found the vast majority of variants (about 90 percent) to be rare (Nelson et al., 2012; Tennessen et al., 2012). In a healthy twin cohort study, an attempt to demonstrate an association between pain sensitivity and rare variants was inconclusive, but the authors (Williams et al., 2012) did identify a cluster of 30 genes within the angiotensin II pathway that segregated with thermal pain perception.

Better methods for precisely identifying the mechanisms underlying an individual patient's pain could improve pain management. If clinical research is focused on advancing the methods of pain phenotyping and classification of pain endophenotypes, therapeutics can be targeted to the individual's physiology. Such potential avenues being explored in patients with chronic pain include quantitative sensory phenotyping, imaging of peripheral nociceptors, study of pain mediators in bodily fluids (i.e., "inflammatory soup"), and the genetic and epigenetic approaches outlined above (Sommer, 2016).

Among patients with chronic pain, however, variability in the etiologies and types of pain and the high frequency of mental health comorbidities in this population (Campbell et al., 2015) make it difficult to determine whether long-term opioid analgesics are effective for improving pain severity, function, and quality of life (Chou et al., 2015; Knaggs, 2015; Robinson et al., 2015; Sehgal et al., 2013). Until researchers and clinicians have a better understanding of the mechanisms underlying chronic pain and improved diagnostic accuracy for chronic pain conditions is achieved, the treatment of chronic pain will continue to be driven by a hypothesis about the source of pain and traditional trial and error.

Pain Modulation Profile

Painful conditions can undergo modulation, either suppression or augmentation at the central nervous system. The inhibitory modulation system is known to be activated by painful stimuli, exercise, and muscle contraction (Nir and Yarnitsky, 2015). The exact mechanisms of pain modulation are not fully understood; however, it is widely believed that activation of the endogenous opioid system and release of peripheral and central beta-endorphins (Bement and Sluka, 2005; Stagg et al., 2011) play a major role in this phenomenon. Other suggested mechanisms include activation of neurotransmitters such as serotonin and norepinephrine (Dietrich and McDaniel, 2004) and involvement of the adenosinergic (Martins et al., 2013) and endocannabinoid systems.

A faulty pain modulation system has been shown to be associated with such chronic pain conditions as fibromyalgia (Graven-Nielsen et al., 2000; Price et al., 2002; Staud et al., 2003), tension-type headache, musculoskeletal pain (Ashina et al., 2006; Pielsticker et al., 2005), trigeminal neuropathies (Nasrin-Heir et al., 2015), migraine (Weissman-Fogel et al., 2003), chronic low back pain (Kleinbohl et al., 2006), irritable bowel syndrome (King et al., 2009a), and temporomandibular disorders (Maixner et al., 1998; Raphael et al., 2009; Sarlani and Greenspan, 2005; Sarlani et al., 2004). Among healthy subjects, pain modulation competence is reduced with age (Edwards et al., 2003), which may explain the increase in chronic pain among older adults.

Recent studies have shown that patients with less efficient pain modulation suffer more from chronic postsurgical pain (Yarnitsky et al., 2008) and experience greater therapeutic efficacy from certain medications, such as duloxetine, relative to patients with a normal pain modulation system (Yarnitsky et al., 2012). This finding may suggest that a pain modulation profile can be used as a tool for predicting the development of chronic pain and individualized pain management outcomes (Yarnitsky, 2015). Further research could examine the association among pain modulation profile, pain intensity, and treatment outcome in various chronic pain conditions and in response to various treatment options.

Relevance to Opioid Prescribing for Chronic Pain

Studies estimate that approximately 50 percent of the likelihood an individual will suffer from addiction has a genetic basis (Meshkin et al., 2015). The exposure to opioid medications in the health care setting could be a triggering event for some people (as noted in Chapter 2). In addition, individual differences in drug metabolism affect opioid efficacy. For instance, some opioids, such as hydrocodone and codeine, are known to be pro-drugs, and require metabolic conversion to an active metabolite (e.g., hydromorphone and morphine, respectively) for pharmacodynamic benefit. Genetic polymorphism of the enzyme CYP2D6 has been reported to lead to variable codeine and hydrocodone metabolism (Monte et al., 2014). Patients with deficient CYP2D6 activity produce very low concentrations of active drug, leading to suboptimal pain relief. In contrast, patients with duplication of active CYP2D6 genes are ultra-rapid metabolizers and produce relatively high concentrations of active drug, which can lead to toxicity. Therefore, testing the metabolic profile of the patient ahead of prescribing could assist with the selection of an opioid medication.

Genetic screening tests have been developed based on identified genes involved in opioid response, opioid metabolism, and addiction risk (Arthur, 2013; Deer et al., 2013). Further

research could determine whether these tools can guide pain management practice by providing prescribers with important information regarding patients' risk for opioid tolerance and OUD.

Summary

The movement toward pragmatic, practice-based trials is an important current trend in pain research. Many such trials are still under way, but they represent a critical step forward in clinical pain research. The ideal balance of opioid reduction in the context of more comprehensive pain management (e.g., stepped care models) continues to be investigated. Nonpharmacologic therapies can be effective, particularly for lower back pain, and can have long-lasting effects on such outcomes as pain intensity and disability. Interventional techniques to relieve pain hold promise, but research on these techniques is still developing. Precision health care (broadly defined) has the potential to improve clinical pain research and management. However, further research could better characterize the association among pain modulation profiles, pain intensity, and treatment outcomes in various pain conditions and in response to various treatment options.

INTERSECTION OF PAIN AND OPIOID USE DISORDER

As discussed briefly at the end of Chapter 2, pain and reward are processed within overlapping brain structures. Before this report turns in earnest from pain management and relevant research to addressing the opioid epidemic, this section addresses several key issues related to the critical intersection of the two. In keeping with the focus of this chapter, research gaps are identified that if filled could prove crucial to helping to resolve the current crisis.

Motivations for Initiating Misuse of Prescription Opioids

As indicated in the discussion of terminology in Box 1-2 in Chapter 1, this report uses the term "misuse" to refer to any use of prescription opioids outside the specifications of a prescription, whether by patients for whom the drugs have been prescribed or by other persons. This definition encompasses a heterogeneous cluster of situations, such as using medications without a prescription, using more medication than prescribed, combining prescribed drugs with other drugs or alcohol, and engaging in activities not recommended while taking the medication. A number of studies have found that misuse of prescription opioid medications is common (SAMHSA, 2013), although how common is difficult to determine in light of the wide range of motivations and behaviors encompassed by the term and the varied circumstances under which patients for whom opioids were lawfully prescribed initiate misuse. The purpose of this section is to anchor the dry term "misuse" in the diverse desires and frailties of humankind and the vicissitudes of social life, and to call attention to the need to operationalize various motivations and behaviors bearing on the transition from initiation of use of prescription opioids to misuse and subsequent problems.

Pervasiveness of Misuse

Any prescription medication that produces pleasurable effects or potential functional benefits poses an inherent risk of misuse. For instance, using leftover antibiotics to treat a self-

diagnosed sinus infection or using nonprescribed Adderall (indicated for the treatment of attention deficit hyperactivity disorder and narcolepsy) to facilitate studying for a school test constitutes prescription drug misuse. In addition to alleviating pain, opioid medications can produce feelings of pleasure, relaxation, and contentment (NIDA, 2017), and because of their broad effects, it can be challenging to determine specifically why people initiate misuse. As a consequence, some motives for misuse (e.g., the undertreatment of pain) may be difficult to recognize. How opioid medications are prescribed can further complicate the task of classifying misuse. Under the directive of a health professional to "take when necessary to control pain," patients have flexibility in determining how often they use a dose of a prescription opioid they have been prescribed. If patients are using opioid medications in a way they believe is necessary to control their pain, the concept of misuse may not apply or be impossible to distinguish from prescribed use. This can generally pose a challenge to prescribers because opioids can produce tolerance, meaning that with use over time, they become less effective. In an effort to control pain, a logical clinical outcome might be to increase the medication dose, something the patient may desire. It is therefore unsurprising that a number of studies have found that the most common type of opioid medication misuse involves users self-escalating the prescribed dose. Among an 85-patient sample being discharged from the emergency department, for example, Beaudoin and colleagues (2014) discovered that 42 percent self-reported misusing their opioid medications. Of those misusers, 92 percent reported escalating their dose without a health care provider's direction, while 36 percent reported using the drug for a reason other than pain.

Equally important, opportunities for misuse of opioid medications may arise as a benign consequence of a patient (or a patient's parent or guardian) not knowing the proper way to take or store the medication or dispose of medication that is unused. In large study (N = 501) of 8th and 9th graders, for example, Ross-Durow and colleagues (2013) found that 46 percent of the adolescents had been prescribed controlled medications, including pain medications, in the last 6 months, and the majority had unsupervised access to these drugs. Patients may even share their opioid medications in an honest effort to help others, such as family members, who are in pain (Kennedy-Hendricks et al., 2016).

Pain

The complexity of the relationship between pain and addiction is highlighted by the multiple trajectories of opioid misuse. Consider, for example, an all-too-common trajectory reported in open-ended/qualitative interviewing: a person is prescribed opioids for a legitimate pain condition and then starts using more than was prescribed after becoming tolerant to the drug's effects. Increases in level of use can also produce neurobiologic effects that, in turn, can create a new motive for increased use. Because patients are now taking higher doses, or after exhausting their supply have begun to experience symptoms of opioid withdrawal, a more potent form and/or route of administration (e.g., injecting) may become appealing, or heroin may become an alternative because it costs less and involves fewer barriers to use relative to opioid medications (Mars et al., 2014). The motive for misuse of opioid medication thus transitions from initial prescribed use to control pain, to misuse to manage pain, to nonmedical use, and then finally to heroin use. If a person is in acute pain from an injury, it is commonly believed that opioids will act to help relieve the suffering that follows, regardless of its duration and whether the source is prescribed or nonmedical. As this example illustrates, however, as use of opioids continues from days to weeks to months, the motivation to continue using them may become

more complex, going well beyond the drugs' original purpose or capability, and being in pain and not having legitimate (i.e., prescribed) or consistent access to opioids may motivate some people to seek and misuse these drugs.

Another common scenario is described by Rigg and Monnat (2015), who found that in rural areas of the country with large populations of laborers who worked in mining and other intensely physical industries, levels of untreated or undertreated chronic pain were high. Because of the limited numbers of health care facilities in these often-remote areas, prescribing large volumes of pain medicines was a common and efficient practice. It should also be noted that early in the opioid epidemic, these communities did not have local heroin markets to compete with pain medications, which allowed the demand for those medications to grow unabated and saturate the community.

Such scenarios may be attributable to a host of factors, such as difficulties in diagnosing and measuring pain, variations in prescribers' training and practices, and the maldistribution of health care facilities and health care providers. These localized factors may, in turn, be a product of much larger shortcomings of the health care system that have unintended consequences. Some studies have shown that people of color are less likely than whites to be prescribed opioids (Pletcher et al., 2008; Singhal et al., 2016), while others have shown that providers may have different expectations regarding the risk of opioid misuse based on a patient's race (Becker et al., 2011; Vijayaraghavan et al., 2011). Although on balance this observation may be equivocal with regard to the current opioid crisis, such structural barriers demonstrate why misuse may occur more frequently among certain groups than others.

Emotional Distress

The pain-relieving and other effects of opioids (e.g., the feelings of pleasure, relaxation, and contentment that opioids can induce) (NIDA, 2017) may give rise to use of these drugs to manage stress, depression, anxiety, or other acute psychological states or chronic mental health disorders (DiJulio et al., 2016; Feingold et al., 2017; Vorspan et al., 2015), which may be caused or worsened by social conditions (such as poverty, unemployment, lack of opportunity, and hopelessness). In these instances of misuse, the intended medical indications of opioids to alleviate physical pain may be coopted by treatment of these mental or social conditions. In the absence of a diagnosed medical condition verifying physical pain, this sort of misuse often is viewed as unacceptable. Nevertheless, people do use opioid medications to self-medicate. Even if this type of use is characterized as nonmedical use, users may perceive specific benefits in relieving some health-related conditions. Complicating this situation is the co-occurrence of mental health challenges and other chronic conditions, especially functionally debilitating pain. The inability to work, walk, or engage in enjoyable activities can greatly impact even the most resilient of patients with extensive coping skills and supports, leading to depression, anxiety, and potentially initiation or reinitiation of substance misuse. Data support the correlation between depression (Turner and Liang, 2015) and diagnosis of substance use disorder (SUD) (Zedler et al., 2014) among people prescribed opioids as a risk factor for overdose. Moreover, medications used to treat anxiety and depression (e.g., benzodiazepines) may be coprescribed with an opioid, contributing to an increased risk of overdose (Park et al., 2015; Sun et al., 2017). The ways in which the dynamics of hopelessness, lack of opportunity, poverty, undertreated pain (both physical and emotional), and reduced access to medical care have collided with nonmedical use of opioids are perhaps most obvious in the rural communities devastated by the

opioid epidemic discussed above. It should be noted, moreover, that during the time in which these communities were being inundated with these medications from pill mills and other legal and illegal suppliers, they were also suffering from the effects of an economic recession.

Nonmedical Use

As motives for the initiation of misuse of opioid medications become increasingly removed from or unrelated to the drugs' original or intended medical purpose, one could argue that the term "misuse" no longer applies. The final, and perhaps most important, group to consider here are the many people who misuse prescription opioids with no pretense, thought, or concern regarding their medical uses. Here the ability of these drugs to alter consciousness in a pleasurable way motivates use, and such misuse is simply another form of illegal recreational drug use. There is no intended medical purpose for the use, and the user is only seeking the euphoric condition these drugs produce. A major challenge for understanding the problems and consequences associated with the initiation of opioid misuse is identifying the different ways people might misuse these drugs while understanding that misusers may have multiple motives for their use and that their motives may change or adapt over time. Distinguishing empirically between motivations related to alleviation of pain or distress and reward seeking is a challenging but important task at both the neural and experiential levels.

Considerations for Research on Pain and Opioid Use Disorder

Much attention in the literature has been paid to pain as a potential precondition in some opioid misuse and addiction (Fishbain et al., 2008, Martell et al., 2007; Wasan et al., 2009). Pain is a trigger for self-medication, and is without question a significant risk factor for opioid misuse (Amari et al., 2011). As discussed above, however, one of the challenges hindering understanding of opioid risks in pain patients is the lack of consensus on the definition of terms such as "misuse," "problematic use," and "aberrant use" (as reflected in the COMM questionnaire; the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition [DSM-IV]; Portenoy's Prescription Drug Use Questionnaire [PDUQ]; the Brief Risk Interview; the Opioid Risk Tool; the Aberrant Drug Behavior Index; and the Prescription Opioid Therapy Questionnaire). Even if these assessments are used accurately, clinicians often are unable to predict misuse and addiction liability. For instance, chronic pain patients may develop tolerance and physical dependence, often in the absence of an OUD diagnosis, yet still resort to such aberrant behaviors as dose escalation to control poorly alleviated pain (Back et al., 2009). Even if there were universal agreement on the definition of misuse, efforts to use self-report assessments to identify pain patients who may be at risk for opioid misuse have been ineffective (Chou et al., 2014). An important first step in adequately identifying opioid risk is characterization of the neurobiological interaction between chronic pain and opioid use. Given the role of the brain's reward circuitry in opioid addiction (Martin-Soelch et al., 2001; Ross and Peselow, 2009), discussed earlier, this circuit is an ideal target for study of pain-induced vulnerability to opioid risk.

Treating chronic pain while avoiding misuse is particularly difficult in patients with a history of SUD. This is not an inconsiderable problem given that an estimated 5–17 percent of the U.S. population has a diagnosed SUD (Prater et al., 2002; SAMHSA, 2014; Warner et al., 1995). Unfortunately, nearly half of chronic pain patients with SUD diagnoses have reported that opioids prescribed to relieve their pain were the root cause of their disorder (Jamison et al.,

2000). It is well established that prior substance use (including use of nicotine and alcohol) is a strong predictor of opioid misuse (Novy et al., 2012; Turk et al., 2008). At the same time, however, there is a significant risk of undertreating people with serious pain, particularly if the SUD diagnosis involves opioids. In fact, 80 percent of methadone maintenance patients in one study reported recent pain, and 37 percent reported chronic pain (Rosenblum et al., 2003). It is this population in particular that is at greatest risk: the presence of pain creates a vicious downward spiral (described by Garland et al., 2013) whereby pain may trigger hypervigilance and catastrophizing and lead to self-medication. The relative low cost and abundance of heroin (compared with prescription opioid analgesics) is an important motivating factor when patients transition from prescription opioids to illicit drugs (Cicero et al., 2015). This cascade of events substantially increases the risk for misuse and overdose, given the unpredictable purity of illicit fentanyl and heroin (DEA, 2015; Mars et al., 2015). On the other hand, a recent meta-analysis (Dennis et al., 2015) suggests that pain may actually be a protective factor in the consumption of illicit opioids. These discrepancies in the literature further highlight the importance of mechanistic investigations into the neurobiology of opioid-treated pain in populations with prior opioid exposure.

Considerations Relating to Developmental Neuroscience and Adolescence

Exposure to opioids at a vulnerable point in time increases the potential for addiction, and younger age is a known vulnerability (85 percent of addictions are manifested by age 35 [Trigeiro et al., 2016]). Nonmedical use of opioids in adolescence has been classified into subtypes, including reward seeking (or sensation seeking) and self-treatment for various sources of pain. In the latter group, prescription opioids are thought to be used to self-treat physical pain and psychological symptoms following traumatic or stressful events (Young et al., 2012). In one survey of 7th to 12th graders, for example, the most common reason for nonmedical use was "to relieve pain" (n = 91, 62.8 percent), followed by "to get high" (n = 23, 15.9 percent) and "to experiment" (n = 16, 11.0 percent). Of this sample, 12.3 percent (n = 323) were identified as medical users, 2.7 percent (n = 70) as nonmedical self-treaters, and 2.5 percent (n = 66) as nonmedical sensation seekers. Thus, pain provides a pathway to adolescent misuse of opioids, which began to rise in the 1990s in concert with the development of stronger medications and more aggressive pain treatment (although rates for 12th graders are down significantly from a peak of 9.5 percent in 2004 [Johnston et al., 2017]). And high school seniors who misuse prescription pain medications are more likely to abuse other controlled substances as young adults (McCabe et al., 2013).

More generally, as noted earlier in this report, nonmedical use of opioids is most prevalent among young adults aged 18–25, and exposure to opioids represents a major risk for OUD. Risk taking, including experimentation with illicit drugs and alcohol, peaks in adolescence and young adulthood (IOM and NRC, 2011, 2015), laying the groundwork for substance misuse. During this developmental period, social, cognitive, and biological factors combine to create inordinate vulnerabilities to substance misuse and, ultimately, SUD (Casey et al., 2011; Reyna and Farley, 2006; Rudolph et al., 2017). Although many of these outcomes play out over a lifetime, increases in overdose deaths caused by heroin and synthetic opioids can be detected beginning at age 15 (Rudd et al., 2016a,b). Understanding these developmental factors is an essential part of designing effective risk communications, public health programs, and policies to combat nonmedical use of opioids. Moreover, prevention and intervention at this stage of life has tremendous potential for improving lifelong educational, economic, and health outcomes.

Specifically, behavioral and brain research indicates that adolescents are more responsive to rewards (e.g., food, money, and drugs) than are children or adults, and this is related to their risk taking (Bjork and Pardini, 2015; Galvan et al., 2007; Reyna et al., 2011; Romer and Hennessy, 2007). Neurodevelopmental theories of risk taking build on this finding and point to the earlier maturation of subcortical reward and emotional circuitry, especially in the amygdala and striatum, compared with emotional regulation and cognitive control areas of the brain (e.g., prefrontal cortex [Casey et al., 2015]). In addition, connectivity between these regions develops. For example, resting-state connectivity analyses have shown greater connectivity between the amygdala (an emotion area used as a seed region) and the prefrontal and parietal cortices (e.g., the right middle frontal gyrus, left cingulate gyrus, left precuneus, and right inferior parietal lobule) in risk-taking compared with non-risk-taking adolescents (Dewitt et al., 2014). (Note that greater rather than lesser connectivity between emotional and cognitive systems, as postulated in neural imbalance models, is associated with risk taking, a contradiction that could be resolved by further research.) Nevertheless, research supports the conclusion that the risk of addiction is present for young people without psychological disease because these drugs hijack the normal reward system, which is already primed and is less likely to be inhibited by cognitive control systems.

Neural imbalance between reward responsiveness and cognitive control appears to be an inevitable product of brain maturation. Although brain development is known to be shaped by experience, however, not enough is known about how experience (and what specific features of experience) sculpts the brain. For example, research could examine what kinds of experience lead to what kinds of brain growth, pruning, and neural connectivity and the functional implications of these developments for human behavior. Indeed, Feldstein Ewing and colleagues (2017) have shown that response to treatment for addiction in adolescents is associated with changing connectivity to the orbitofrontal part of the brain. Thus, considering research on risk taking as a whole, it is likely that adolescent brain development can be modified by specific experiences that reduce vulnerabilities to addiction.

In addition, effects of cognitive representation (i.e., how people "frame" or interpret the gist of their options) on risk taking have been established, and initial research has demonstrated that these mental representations can be modified and that doing so can reduce self-reported risk taking in adolescents (e.g., Fischhoff, 2008; Reyna and Mills, 2014). These effects illustrate the fact that pain, addiction, and other psychological phenomena are a function of subjective constructions rather than purely objective reality. Cognitive representations influence risk perceptions, risk preferences, and emotional responses, which in turn determine decisions to misuse substances. These decisions also occur in a social context that determines behavior, but is rarely understood beyond noting superficial differences in demographics or countries. Social norms are just one example of a highly relevant social factor. Social norms interact with developmental and individual differences in risk taking, changing the frequencies and kinds of risk taking manifested in adolescence (Mills et al., 2008; Rudolph et al., 2017; Steinberg et al., 2017). Therefore, cognitive representation, reward responsiveness, and cognitive control are likely modifiable—providing inroads for prevention and treatment—and their effects on vulnerability to addiction require a deeper mechanistic understanding of the interplay among social, cognitive, emotional, and neurobiological factors.

Basic Research on the Intersection Between Pain and Opioid Use Disorder

As discussed earlier, opioids, like other drugs that are misused, activate the structures within the mesolimbic reward pathway via MOPRs, DOPRs, and KOPRs. Binding of opioid agonists within this circuitry elicits the release of the neurotransmitter dopamine, which is critically involved in encoding reward and reinforcement. It is worth noting that pain relief itself is rewarding, a phenomenon that is attributed to the activation of this system (Becker et al., 2012). Data from both human and animal studies indicate that chronic pain induces dramatic changes in the functionality of the reward system, both directly through diminished dopamine neurotransmission and indirectly through dysregulation of the opioid receptor systems (Hipólito et al., 2015; Martikainen et al., 2015; Narita et al., 2004; Taylor et al., 2015). During inflammatory pain, MOPRs in this circuitry are desensitized, which may be due to a pain-induced increase in the release of endogenous opioid peptides (Schrepf et al., 2016). There is also top-down management of these processes by the hippocampus, given the role this structure plays in the reinstatement of drug-seeking behavior (Portugal et al., 2014). Pain-induced alterations in the reward pathway, including the altered value of reward and opioids (Loggia et al., 2014), could play a vital role in the vulnerability of patients to opioid misuse. Despite recent efforts to characterize pain-induced sensitivity to opioids, many unanswered questions remain. Although heroin use has recently been linked to several genetic polymorphisms (Hancock, 2015; Nelson, 2016), these have not been studied specifically in pain patients. The identification of "abuse-vulnerable" genetic markers or implementation of other biological screening tools would be of great utility, given the relative inadequacy of self-report and physician assessments of "abuse liability" (Chou et al., 2014).

The alterations in the dopaminergic system induced by either pain or stress can generate long-term modifications in the reinforcing values of opioids and thus lead to misuse. Therefore, it is important to elucidate how these modifications manifest at the cellular level in the mesolimbic pathway. To date, few studies have assessed the impact of pain and stress together on opioid intake in rodent models. One critical factor that is particularly pertinent when studying chronic pain–induced disorders is experimental/sampling time. Many preclinical models used previously were deemed failures (Yalcin and Barrot, 2014), but this may simply have been due to timing. Many of the same studies carried out during the first 3 weeks of pain induction versus after the first 3 weeks have shown strikingly opposite results (see the review by Yalcin and Barrot, 2014).

In addition to the importance of improving models of chronic pain and stress to assess their involvement in misuse liability, a deeper understanding of the intricate details of neuromodulation and signaling within key brain structures is critical. Recently, two studies revealed that KOPR activation in discrete regions of the NAc not only is anhedonic and aversive but also can be reinforcing (Al-Hasani et al., 2015; Castro and Berridge, 2014). Remarkably, these studies revealed the presence of both hedonic and anhedonic KOPR areas in the NAc in both mice and rats (Al-Hasani et al., 2015; Castro and Berridge, 2014). These findings enhance understanding of the complexity of the KOPR system in regulating the rewarding and aversive components of external stimuli and demand further study of how these newly identified systems modulate the pain experience.

There is clear comorbidity between chronic pain and stress-induced pathologies. Concomitant dysregulation of mesolimbic dopaminergic transmission is thought to increase vulnerability to opioid misuse. To reduce the misuse potential of opioid analgesics, a better understanding of the interactions between pain and stress systems is required. Stress-related

systems, such as the kappa opioid system, have been identified as key to the regulation of dopamine release during pain and stress. This system may be crucially involved in driving the pathological changes that result in misuse and potential fatalities.

Summary

A major challenge for understanding the problems and consequences associated with the initiation of opioid misuse is identifying the different ways in which people may misuse these drugs while understanding that misusers may have multiple motives that may evolve over time (e.g., pain relief; management of stress, depression, or anxiety). These complexities need to be borne in mind as this report reviews the scientific literature bearing on the use and misuse of prescription opioids and strategies for ensuring the public's health.

An important first step in identifying opioid risk is characterization of the neurobiological interaction between chronic pain and opioid use. Pain is a trigger for self-medication and a significant risk factor for opioid misuse. Treating chronic pain while avoiding misuse is particularly problematic for patients with a prior history of SUD, and more evidence could help determine the degree of risk for OUD when people with serious pain are undertreated.

During adolescence and young adulthood, social, cognitive, and biological factors combine to create inordinate vulnerabilities to substance misuse and, ultimately, addiction. Effective prevention and treatment of opioid addiction requires a deeper mechanistic understanding of how cognitive representation, reward responsiveness, and cognitive control interact in the developing brain; their interplay with pain; how these factors are shaped by the social context of risk taking in youth; and how these factors can be modified to reduce unhealthy risk taking.

A better understanding of the interactions among pain, reward, and stress systems, including pain-induced alterations in the reward pathway, will help inform and reduce the misuse potential of opioids.

SUPPORT FOR RESEARCH

In the absence of an institute dedicated to pain medicine, it appears that the National Institute on Drug Abuse (NIDA) has been the partner most willing to venture beyond its initial mandate in support of education and research for state-of-the-art pain management and prevention. This initiative has taken the form of various workshops, editorials, and position papers (Reuben et al., 2015; Volkow et al., 2016), but these have been mainly supportive efforts, valuable insofar as they help chart a course forward but unable to meet the need for a sustained research program. Moving forward, it will take a unified mandate across all National Institutes of Health (NIH) institutes to muster the resources needed to adequately address the area of pain medicine and, in turn, the opioid crisis. A recent commitment by NIDA and NIH to invest in overdose-reversal interventions, treatments for OUD, and nonaddictive treatments for chronic pain holds great promise (Volkow and Collins, 2017).

SUMMARY AND RECOMMENDATION

Chronic pain and OUD represent complex human conditions affecting millions of Americans and causing untold disability and loss of function. Helping individuals experiencing chronic pain regain meaningful function will require the development of therapies beyond new medications alone. Little is known about why individuals who use prescribed opioids to alleviate pain develop OUD, yet this outcome has become a driving force in the opioid epidemic. Research aimed at improving understanding of OUD and the relationships among pain, opioids, and the brain reward pathways is an essential prerequisite for developing successful treatments. Research is needed to improve understanding of the neurobiology of pain and support the discovery of innovative treatments, including nonaddictive analgesics and nonpharmacologic approaches at the level of the individual patient.

Recommendation 3-1. Invest in research to better understand pain and opioid use disorder. Given the significant public health burden of pain and opioid use disorder (OUD) in the United States, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, the U.S. Department of Veterans Affairs, industry, and other relevant research sponsors should consider greater investment in research on pain and OUD, including but not limited to research aimed at

- improving understanding of the neurobiology of pain;
- developing the evidence on promising pain treatment modalities and supporting the discovery of innovative treatments, including nonaddictive analgesics and nonpharmacologic approaches at the level of the individual patient; and
- improving understanding of the intersection between pain and OUD, including the relationships among use and misuse of opioids, pain, emotional distress, and the brain reward pathway; vulnerability to and assessment of risk for OUD; and how to properly manage pain in individuals with and at risk for OUD.

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PART II

ADDRESSING THE OPIOID EPIDEMIC

4

Trends in Opioid Use, Harms, and Treatment

Not since the HIV/AIDS epidemic has the United States faced as devastating and lethal a health problem as the current crisis of opioid misuse and overdose and opioid use disorder (OUD). Current national trends indicate that each year more people die of overdoses—the majority of which involve opioid drugs—than died in the entirety of the Vietnam War, the Korean War, or any armed conflict since the end of World War II. Each day 90 Americans die prematurely from an overdose that involves an opioid (Rudd et al., 2016b), leaving families and friends bereft. The opioid epidemic's toll is felt across the life span and in every sociodemographic group, but more heavily burdens vulnerable populations, such as those in economically depressed areas of the country. This chapter updates key statistics regarding use and misuse of prescription opioids, identifies risk factors for opioid-related harms, describes the recent increase in use of heroin and illicitly manufactured synthetic opioids and its relation to the prescription opioid epidemic, describes the impact of prescription opioids on illicit markets, reviews the current state of surveillance systems, and summarizes recent trends in treatment of OUD and use of naloxone to prevent overdose deaths. The committee selected these topics to discuss in particular for their relevance to the U.S. Food and Drug Administration's (FDA) exercise of its authority to regulate pharmaceutical opioid products (analgesics, agonists, and antagonists). Each aspect of this chapter identifies considerations that should be taken into account when weighing the societal perspective and public health impact relevant to these products when they are being considered for new drug approval or during post-market surveillance.

TRENDS IN PRESCRIPTION OPIOID USE AND MISUSE

Medical prescriptions for opioids started to increase sharply in the mid- to late 1990s (NIDA, 2014). Shortly thereafter, nonmedical opioid use also started to increase markedly, reaching a peak of 2.7 million new users in 2002 (Kolodny et al., 2015). The annual number of new nonmedical users slowly declined to about 1.8 million in 2012 (SAMHSA, 2013b), but the overall pool of people continuing to use nonmedically is very large. From 1999 to 2011, hydrocodone use increased more than two-fold, oxycodone use more than five-fold (Jones, 2013b), and the mortality rate of opioid-related overdose almost four-fold (Chen et al., 2014). Overdose mortality is the most dramatic consequence of increased opioid use, but it is not the only one; rates of emergency room visits for nonmedical opioid use (SAMHSA, 2013a), neonatal abstinence syndrome (NAS) (Patrick et al., 2012), and OUD treatment admissions all have soared since 2002 (SAMHSA, 2010).

While death rates associated with opioid overdose have increased for virtually every population group, the rates are highest among males under age 50 (CDC, 2015a). In Massachusetts during the period 2013–2014, 76 percent of opioid overdose deaths occurred among people under the age of 50, and men aged 18 to 34 had opioid-related death rates nearly three times higher than those of women of the same age (Massachusetts Department of Public Health, 2016). Opioid-related death rates also were higher among those who had recently been released from prison, those who obtained opioid prescriptions from multiple pharmacies, and those who obtained prescription opioids in combination with other scheduled medications.

The age group with the greatest past-year nonmedical use of opioids is young adults aged 18 to 25, yet the greatest use (i.e., exposure) of prescription opioids is among adults aged 26 and older. Substance Abuse and Mental Health Services Administration (SAMHSA) data indicate that most people who report prescription opioid misuse in current cohorts initiated use in their early to late 20s, which may explain why prescription opioid mortality disproportionately affects adults aged 25 to 54 (CDC, 2016c). More recent data show an overlap in these age-related demographics with respect to current use of heroin and, more disturbingly, the coincident increase in overdose deaths caused by heroin and synthetic opioids other than methadone among people aged 15 and older (Rudd et al., 2016). It is important to acknowledge that data on overdose deaths may be subject to misclassification with respect to intent (i.e., whether the overdose was intentional or unintentional), especially for older, medically ill patients prescribed medications, whose deaths may not be followed up with toxicology testing and may not be referred to a medical examiner as a drug-involved or suspicious death. Misuse and aberrant opioid use behaviors also may manifest differently in older adults (Beaudoin et al., 2016; Henderson et al., 2015), and given the aging U.S. population, the role of suicidal intent in prescription opioid poisoning in older adults is an area of active inquiry (Rocket et al., 2010; West et al., 2015).

The full extent of the public health consequences of prescription opioids is further complicated by the increased availability of heroin, which is less expensive than prescription opioids in the black market (DEA, 2013), and by the fact that so many who develop OUD from prescription opioids switch to heroin. In one study, about 80 percent of current heroin users reported that they began with prescription opioids (Muhuri et al., 2013). Therefore, the public health effects of prescription opioids and heroin are intertwined (Kolodny et al., 2015). Between 2001 and 2011, the rate of admission to treatment for OUD involving heroin doubled among non-Hispanic whites aged 20 to 34 (it stayed relatively constant for all other age groups among whites and for all age groups among non-Hispanic blacks), and the rate of heroin overdose deaths increased more than 2.5-fold among whites aged 18 to 44 (CDC, 2014; SAMHSA, 2013a). The cumulative effect is a 200 percent increase in opioid-involved overdoses from 2000 to 2014 (Rudd et al., 2016) concordant with increases in nonmedical prescription opioid use (Calcaterra et al., 2013; Cerdá et al., 2013; Kenan et al., 2013). In more recent years, national initiatives to reduce opioid prescribing have modestly decreased the number of prescription opioids dispensed (Dart et al., 2015). However, many people who otherwise would have been using prescription opioids have transitioned to heroin use, with a resulting three-fold increase in heroin-involved overdose deaths from 2010 to 2014 (Compton et al., 2016). Indeed, the overall frequency of heroin deaths has been accelerating since 2010 (see Figure 1-2 in Chapter 1).

Risk Factors for Prescription Opioid Misuse and Overdose

Despite the unsettling trends described above, a more nuanced examination indicates that not all prescription opioid medications confer similarly heightened risk. The causal pathways from the onset of pain to opioid exposure and to potential negative consequences such as misuse, drug seeking related to undertreatment of pain (Green and Chambers, 2015; Vadivelu et al., 2017), OUD, and overdose are difficult to disentangle, and represent an area of active research and investigation (Stumbo et al., 2017). Multiple post-marketing studies currently under way for extended-release (ER)/long-acting (LA) opioids (see Annex Table 6-1 in Chapter 6) may shed light on the timing and sequence of and precursors to the development of problem use and OUD and the incidence of nonfatal and fatal overdose among patients prescribed opioids for the treatment of chronic noncancer pain.

Characteristics of opioid medication and how they are prescribed can affect the risk of nonmedical use and other harms. Three key characteristics of opioid medications that have been found to influence the risk of harms include the chemical compound, the formulation, and the intended route of administration. Also salient are the number of pills prescribed and dosage, as well as other prescribing patterns.

Chemical Compound

Neuropsychological experiments demonstrate that "likability," and therefore "abuse liability," is greater for some compounds than others. In seminal work by Comer and colleagues (2008) among a sample of patients dependent on heroin, laboratory experiments compared the likability of oxycodone, fentanyl, buprenorphine, and morphine with that of heroin. Findings indicated that across several validated subjective scales, oxycodone scored most favorably among participants, while buprenorphine scored lowest. Translating data from laboratory-based, controlled abuse liability studies to the community and clinic to examine possible increased risk is more challenging. However, several studies provide insight into "real-world" abuse liability and risk variation by compound. One means by which demand for a compound can be deduced is through street price. Taking availability into account, one recent study found that the street price of buprenorphine/naloxone was lower than that of buprenorphine single-entity and of methadone (Larance et al., 2015). Interestingly, these findings are congruent with those of the laboratory-based abuse liability studies noted earlier.

Another indicator of a compound's risk is seen in mortality data. Unless the chemical entity is a novel one, it is difficult to differentiate branded from generic products as causal in an unintentional opioid poisoning death. Nevertheless, overdose death data show key compound-level trends, taking methadone as an example. Ray (2015) reports high overdose risk associated with use of methadone medications (for pain), and a 2017 analysis of methadone deaths and prescribing from 2007 to 2014 conducted by the Centers for Disease Control and Prevention (CDC) found that although methadone accounted for about 1 percent of all opioid prescriptions, overall methadone-related deaths accounted for 22.9 percent of all opioid-related mortality in 2014 (Faul et al., 2017). These findings have been replicated in other studies, suggesting that certain compounds are more likely to be misused and potentially lead to greater health consequences in the absence of preventive measures. Novel compounds, such as tapentadol (Nucynta), designed specifically to avoid tampering and reduce risk while achieving pain control, exhibit promising post-marketing epidemiologic data across a number of misuse and risk

indicators (Butler et al., 2015; Dart et al., 2016; McNaughton et al., 2015), findings that warrant further examination in longitudinal studies.

Formulation

Another characteristic of a medication that may influence the risk of harm is its formulation, specifically whether it is an ER/LA or immediate-release (IR) formulation. The FDA's Risk Evaluation and Mitigation Strategy (REMS) for ER/LA opioids anticipated that greater risks would be associated with opioids that increased the possible time of exposure through longer-time-release formulations. In fact, while further research is needed, available data show that ER/LA and IR formulations are associated with different types of elevated risk. ER/LA formulations are associated with increased risks of diagnosis of substance use disorder (SUD) and nonfatal and fatal opioid overdose (Braden et al., 2010; Miller et al., 2015; Zedler et al., 2014). However, limited data suggest that IR, short-acting opioid medications also may be associated with various morbidities and nonmedical use. Relative to ER/LA formulations, for example, these medications have been found to be indicated more often in poison center data as medications of misuse, and are associated with higher rates of nonfatal injury, including motor vehicle and pedestrian crashes and falls (Iwanicki et al., 2016). Moreover, an IR medication may be the first opioid of exposure over the course of one's lifetime (SAMHSA, 2016a), given the routine use of these drugs following dental and surgical procedures, as discussed in Chapter 2. These data suggest that both ER/LA and IR opioids warrant measures to reduce risks that can arise with their use. Indeed, the FDA plans to expand its REMS program for opioids to include IR formulations (FDA, 2017b).

Combination opioid products, especially those coformulated with naloxone (e.g., Targaniq [oxycodone/naloxone] and Suboxone [buprenorphine/naloxone]) may be associated with lower rates of misuse and nonmedical use by other than intended routes of administration (i.e., by injection or insufflation) compared with their single-entity counterparts (Davis et al., 2013; Larance et al., 2015; Walsh et al., 2016). Although coformulations may help prevent misuse and OUD (Raffa et al., 2014), epidemiologic studies to explore these differences further are needed, and some such studies are under way (Degenhardt et al., 2015).

Route of Administration

A final characteristic that may elevate the risk of an opioid medication is its intended route of administration. Many preparations are used in ways other than prescribed and may be manipulated to extract the active pharmaceutical ingredient. For instance, pills may be crushed in the mouth, insufflated, smoked, or injected with few physical barriers to use, and a transdermal patch's active pharmaceutical ingredients may be chewed, sucked, or extracted and prepared for injection. It is well substantiated that drugs used by insufflation and injection, in particular, enter the bloodstream and hasten the opioid's crossing of the blood–brain barrier, generating a faster onset of action, which in turn is associated with a greater risk of overdose and of developing OUD (EMCDDA, 2016).

Some prescription opioid preparations approved in recent years make crushing the pill more difficult or may be formulated to deter tampering. These abuse-deterrent formulations (ADFs) are reviewed more extensively in Chapter 5, but it is worth noting here that the level of tampering and prevalence of use by unintended routes associated with an opioid will influence its

public health consequences. For example, a new and comprehensive analysis by Alpert and colleagues (2017) shows that the reformulation of OxyContin from a non-ADF to an ADF prescription opioid was linked to higher-than-expected rates of subsequent heroin use, especially in places with persistently high rates of opioid misuse. The authors estimate that up to 80 percent of the increase in heroin use could be attributed to the formulation change. Likewise, the ADF Opana ER (oxymorphone ER) has been associated with several injection-related harms, linked to the same ADF preparation applied to OxyContin. Because of these injection-related harms, in June 2017 the FDA requested that Opana ER be removed from the market by its manufacturer (FDA, 2017a).

In a retrospective 24-month cohort study based on National Poison Data System data, Copelan and colleagues (2017) found intentional misuse and suspected suicidal intent to be significantly lower among patients using a 7-day buprenorphine transdermal system/patch than among those taking other ER/LA opioid analgesics examined. On the other hand, data from a recent Australian study showed that, 2 years after the introduction of a buprenophine-naloxone film, levels of injection and diversion were comparable between the film and methadone and buprenorphine-naloxone tablets among out-of-treatment people who inject drugs (PWID), but levels of injection and diversion were lower for mono-buprenorphine than for the film, after adjusting for availability (Larance et al., 2015). The ADF film was found to be easier to administer, which impacted clinician time and workflow. These data suggest a need for caution in reliance on ADF products as a regulatory strategy for improving opioid safety and the importance of weighing the public health impacts of all decisions. Tracking the prevalence of the intended and unintended routes of administration of a drug can provide signals of compromised safety and harmful consequences at the individual and societal levels.

Number of Pills Prescribed and Dosage

Emerging literature since the Institute of Medicine report *Relieving Pain in America* was issued (IOM, 2011) also suggests that potentially modifiable features of the prescription itself are associated with harm. The greater the number of days for which a prescription is written and the higher the dosage, the greater is the risk exposure. Unfortunately, the literature lacks clear consensus on the number of days after which risk increases (i.e., the threshold). The CDC's Guideline for Prescribing Opioids for Chronic Pain, released in 2016 (Dowell et al., 2016), urges prescribers to provide the lowest effective dosage and prescribe "no greater quantity than needed for the expected duration of pain severe enough to require opioids" (stating that "three days or less will often be sufficient"). Some states (e.g., Maine and Massachusetts) have recently legislated a supply limit for opioids prescribed for the treatment of noncancer pain, with far-reaching applications. (In Maine the law limits the number of pills that can be prescribed to a 7-day supply for acute pain and a 30-day supply for chronic pain [Traynor, 2016], while Massachusetts imposes a 7-day supply limit for first-time prescriptions for adults and a 7-day limit at any time for minors.[1]) More research in this area could better inform policy makers, patients, and providers.

A concept related to that of number of days' supply is daily morphine milligram equivalent (MME) dosing. Unlike the days' supply literature, the literature on this topic presents a clear and consistent finding that risk of overdose increases as dose increases (i.e., a dose-

[1]See https://malegislature.gov/Bills/189/House/H4056 (accessed May 15, 2017).

response relationship) (Baumblatt et al., 2014; Bohnert et al., 2011, 2016; Dunn et al., 2010; Gomes et al., 2011; Liang and Turner, 2015; Paulozzi, 2012; Zedler et al., 2014). Based on several early findings, some authors concluded—erroneously—that a specific threshold or MME cutpoint value (e.g., >100, >50, or >20 MME) could signify the point of elevated risk, below which opioids are safe but above which risk rises. Based on the existing literature and analysis of large clinical datasets, however, the risk of overdose and OUD increases as a function of dose (i.e., dose-response relationship) at any given level of exposure greater than none.

The FDA's required "abuse liability" studies attempt to anticipate and measure many of these drug-specific characteristics before a drug is approved. However, these studies are not designed to predict a fuller range of potentially harmful effects that one may want to consider in deciding whether to approve an opioid or other drug, such as unforeseen allergies, unanticipated side effects, co-use with other licit and illicit drugs, and ease of manipulation to prepare the product for misuse. For these effects, the current approach is to rely upon post-marketing surveillance to capture, in a proactive, preventive way, the cumulative effects of drug-specific characteristics as the drugs are actually used or misused in the population. Given heightened concerns about opioid misuse, OUD, overdose, and diversion, involving people who use drugs (or their representative organizations) in the review and discussion of post-marketing data may be informative.

Other Prescribing Patterns

Other patterns of prescribing and dispensing suggest additional risks for OUD and overdose. The timing of risk exposure, for instance, may contribute to iatrogenic overdose. Similar to the patterns of elevated risk of overdose mortality during the first 2 weeks after release from incarceration, circumstances defined by loss of tolerance (such as during hospitalization [Bird et al., 2016] or following detoxification [Strang et al., 2003]) or the establishment of tolerance, such as at the onset of treatment with opioid analgesics (Miller et al., 2015), all suggest that the timing of opioid exposure can affect patient safety and overdose risk. In addition to timing, obtaining opioids from multiple prescribers or multiple pharmacies and overlapping prescriptions have been associated with greater risk of overdose (Baumblatt et al., 2014; Hall et al, 2008; Yang et al., 2015). These patterns may ultimately reflect poor coordination of care for people with pain and OUD in the community rather than causal drivers of the epidemiology of nonmedical use of prescription opioids. In addition, a large body of health services literature indicates that a number of opioid analgesic prescribing behaviors contribute greatly to patient risk and prolonged opioid exposure. These include errors in MME calculations (e.g., during opioid rotation or conversion) (Paulozzi et al., 2009, 2011; Rich and Webster, 2011), underutilization of prescription drug monitoring programs (Starrels et al., 2011), and inconsistencies in monitoring of opioid use (Becker, 2011; Khalid et al., 2015), among others.

While the FDA-approved indications for use and labeling of opioids specify for whom and under what conditions the medications are intended to be used, prescribing and patient use patterns may differ from those envisioned at the time of approval. For instance, many opioid medications, such as IR products, are intended to be used to treat acute pain, such as postsurgical pain, over a short duration. However, a large proportion of patients continue to be treated with IR opioids far beyond the expected duration of healing (Bartels et al., 2016; Clarke et al., 2014), a phenomenon that could indicate failure to heal from an injury or surgery, progression or

persistence of pain to a chronic state, opioid dependence, onset of OUD, poor product labeling, or something else entirely. Still other patients may be prescribed an ER/LA opioid to treat an acute pain condition, a practice that runs counter to recommendations of the CDC guideline and from professional organizations.

With respect to chronic pain, ER/LA opioids are approved for use in the treatment of moderate to severe pain as may be needed to treat instances of failure to heal from injury or surgery or progression of acute to chronic pain, or in instances of treatment of other chronic conditions when moderate to severe pain occurs. As discussed in Chapter 2, however, there is a lack of long-term evidence (>1 year) from rigorous studies that opioid therapy is effective for improving pain and function for people with chronic pain (Dowell et al., 2016), while there is evidence that opioid therapy for chronic pain is associated with increased risk of OUD, overdose, and other adverse outcomes (Baldini et al., 2012; Chou et al., 2015; Dowell et al., 2016). For example, rates of iatrogenic OUD in studies in which OUD has been carefully diagnosed have averaged about 8 percent, while rates of iatrogenic misuse, OUD, and aberrant behaviors thought to be indicative of OUD have ranged from 15 to 26 percent (Volkow and McClellan, 2016). While the FDA does not regulate the practice of medicine, the committee recognizes the importance of prescribing practices in helping to curb opioid-related harms, and in Chapter 5 describes several interventions designed to promote more judicious prescribing.

One key aspect of opioid prescribing safety overseen by the FDA is drug–drug interactions, whereby concurrent use of certain medications may alter a patient's risk. Certain medications are coprescribed more frequently based on the co-occurrence of pain with other conditions, and it is also widely observed that patients may co-use other drugs with opioids to achieve heightened or prolonged analgesic or euphoric effects.

The co-use of opioid medications with one class of drugs, benzodiazapines, has been well established in preclinical, clinical, and epidemiologic studies, and contributes to up to one-third of fatal opioid overdoses in the United States (Jones and McAnich, 2015). Biological data indicate that these two drug classes have synergistic effects in producing sedation and respiratory depression, increasing the risk of overdose and death. Studies of opioid and benzodiazepine co-use in humans have demonstrated an elevated risk of overdose, especially in the context of misuse (Park et al., 2015; Sun et al., 2017). A large case-cohort study of U.S. veterans treated for chronic pain with long-term opioid analgesics, for example, showed that the risk of death from drug overdose increased in a synergistic, dose-response fashion as daily benzodiazepine dose increased, with risk being independent of dosing schedule (Park et al., 2015; see Figure 4-1). The safety concerns related to co-use of opioids and benzodiazepines led the FDA to require boxed warnings and patient-focused medication guides providing information about the risks associated with the concurrent use of these medications for more than 400 opioid and benzodiazepine products (FDA, 2016). These concerns also led to a recommendation in the CDC guideline urging caution in co-use or mitigation of the risk of respiratory depression with naloxone for patients coprescribed benzodiazepines and opioids

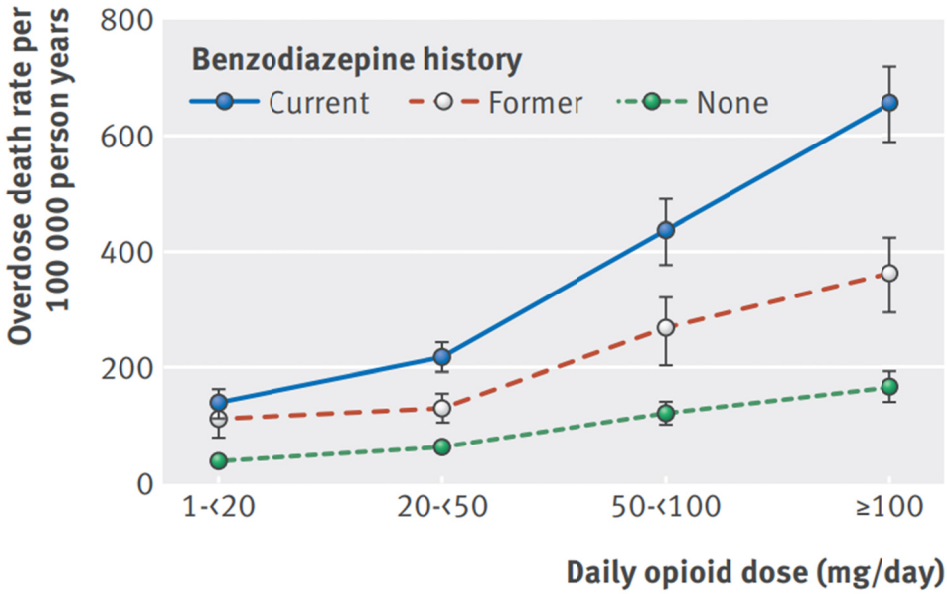


FIGURE 4-1 Benzodiazepine prescribing patterns and deaths from drug overdose among U.S. veterans receiving opioid analgesics: Case-cohort study. Overdose deaths rise sharply when opioid dose is 50 mg or greater and benzodiazepine is also used.
SOURCE: Park et al., 2015.

Summary

The level and type of risk to a patient from a given opioid are influenced by specific features of the medication iself, including the compound, formulation (whether the medication is an ER/LA, IR, and/or combination product), and route of administration. How opioids are prescribed (e.g., with other medications, days for which prescribed) also may influence the risk of overdose. Available studies consistently demonstrate that the risk of overdose increases in a dose-response fashion with increasing MME. While the FDA abuse liability studies capture several features of drugs that influence the risk of harm, including mechanisms of misuse and diversion, post-marketing studies and surveillance data could help to identify a comprehensive range of potentially harmful effects.

Vulnerable Populations

This section reviews recent trends in OUD among three especially vulnerable populations—pregnant women and neonates, persons involved with the criminal justice system, and injection drug users.

Pregnant Women and Neonates

According to a study by Patrick and colleagues (2015), the proportion of babies born with NAS in the United States increased five-fold from 2000 to 2012, concurrently with a significant increase in opioid use and misuse among pregnant women. Subsequent studies have found that the incidence of NAS varies significantly among states, that the geographic variations in NAS are consistent with the variations in opioid pain prescriptions, and that the incidence of NAS and

maternal opioid use increased disproportionately in rural relative to urban counties (Ko et al., 2016; Villapiano et al., 2017). Recent years have seen an unprecedented focus on NAS in the media; among policy makers; and among medical specialists in neonatology, pediatrics, and obstetrics. Strong disagreement among these interested groups is not uncommon as a result of poor understanding of and differences in opinion about the contexts and factors that affect NAS (Kaltenbach and Jones, 2016).

Recently the FDA has used the term "neonatal opioid withdrawal syndrome" on warning labels when referring to maternal use of opioids during pregnancy. It is understandable why this term is used on an FDA label pertaining to an opioid; however, the committee believes it is inappropriate for use in a clinical setting. When NAS occurs as a result of prenatal exposure to an opioid, it does so in various different contexts, and the presentation and severity are related to a number of factors in addition to maternal use of opioids. Accordingly, the discussion here uses the customary NAS terminology.

Although NAS was initially reported in 1865 as congenital morphism, with the first case of treatment reported in 1903, the focus of treatment and assessment over the past 50 years is based on work in the 1970s that established the definition of NAS and developed an instrument for measuring neonatal withdrawal. This work took place in response to the heroin epidemic and the resultant implementation of methadone pharmacotherapy for OUD (Jones and Fielder, 2015).

NAS generally is described as the occurrence of opioid withdrawal at birth after the discontinuation of prenatal opioid exposure. It is characterized by signs and symptoms of central nervous system irritability, including excessive crying, increased muscle tone, tremors, and sleep disturbances; gastrointestinal dysfunction, including poor feeding, vomiting, and diarrhea; respiratory distress; and autonomic symptoms, including sweating, sneezing, and mottling (McQueen and Murphy-Oikonen, 2016). It is a temporary phenomenon that may or may not require treatment. In general, available data do not suggest an association between NAS in particular and long-term adverse developmental outcomes, regardless of whether the NAS was severe enough to require treatment.[2] There is also no conclusive evidence that maternal dose is related to the severity of NAS (Cleary et al., 2010; Kaltenbach and Finnegan, 1986). In addition to factors discussed below, the presentation and severity of NAS are related to genetics (Wachman et al., 2013, 2014, 2015), maternal physiology (Jansson et al., 2007), and gestational age (Dysart et al., 2007; Gibson et al., 2017; Ruwanphthirana et al., 2015).

The current public focus on NAS does not take into account the context in which it occurs. The context encompasses whether the opioid is a medication taken under the care of a health care provider (e.g., a woman receiving medication under the care of a physician for pain management, or a woman being treated by a physician for OUD with methadone or buprenorphine), or whether the woman is misusing pain medications with or without a prescription and/or using illicit opioids such as heroin. Even though the risk of NAS is comparable across contexts, the overall risk to the fetus and neonate differ between women taking medications under the care of a qualified health care provider and those misusing medications and/or using illicit drugs. In particular, in contrast with diverted medications and illicit drugs of unknown purity, source, and quantity, the treatment of pain or OUD with opioid medications occurs within the safety of known doses of FDA-approved medications that have

[2]Although some babies with NAS may have other risks, such as low birth weight and/or parents with suboptimal caregiving capacity due to SUD, which are known to be associated with increased risk for adverse developmental outcomes.

been rigorously tested for safety and efficacy and obtained legally from a qualified pharmacy or dispensary. In the case of misuse and OUD involving black market prescription or illicit opioids such as heroin, in addition to the uncontrolled dose, quantity, and purity of the drugs, the pregnancy may be affected by stress, violence, and trauma surrounding illegal activity. Indeed, research shows that prenatal stress, depression, and trauma can influence birth outcomes and later development (Fatima et al., 2017; Su et al., 2015). Thus, although not altering the probability of NAS occurrence, shifting the opioid-exposed pregnancy from one that is untreated to one that is treated may improve overall health outcomes for both mother and baby.

The national and state data that have been used to report significant increases in NAS are based on hospital codes that do not differentiate between NAS occurring as a result of maternal opioid misuse and that due to the appropriate use of an opioid prescription. Additionally, the codes do not indicate whether an infant required treatment for NAS.

Complicating the understanding of NAS is that there are other medications that produce withdrawal symptoms similar to those associated with opioids and, when taken in conjunction with opioids, exacerbate NAS. When pregnant women receiving methadone or buprenorphine take selective serotonin reuptake inhibitors (SSRIs, i.e., antidepressants), for example, the SSRIs have been found to be related to both the presentation and treatment of NAS, with higher peak scores of NAS and higher doses of medication required for treatment (Jansson et al., 2010; Kaltenbach et al., 2012). A number of studies also have found that when pregnant women receiving methadone or buprenorphine take benzodiazepines, such concomitant use is related to prolonged length of treatment for NAS (Pritham et al., 2012; Seligman et al., 2008; Wachman et al., 2011). In addition, as noted earlier, this co-use of opioids and benzodiazepine increases the risk of overdose. Cigarette smoking also has been found to adversely affect NAS, including the total amount of medication required to treat it and the length of treatment (Jones et al., 2013).

With the exception of methadone and buprenorphine, no attention has been given to whether the incidence of signs and symptoms of NAS may differ by opioid. One study comparing the NAS profile before treatment or in the absence of treatment in infants exposed prenatally to methadone or buprenorphine found that the incidence of nasal stuffiness, sneezing, and loose stools was greater in the buprenorphine-exposed infants, whereas the methadone-exposed infants were found to have higher mean scores for hyperactive Moro reflex, disturbed and undisturbed tremors, failure to thrive, and excessive irritability (Gaalema et al., 2012). Such findings may explain reported differences in NAS incidence, severity, and treatment duration between methadone and buprenorphine. No information is available for other opioid pain medications regarding signs and symptoms of NAS, its incidence and severity, and the length of treatment. Importantly, little to no information is available regarding exposure to illicitly manufactured fentanyl or fentanyl analogs in pregnant women and its effect on the risk of fatal overdose; responsiveness to OUD treatment; the maternal medication-assisted treatment (MAT) dose; or NAS incidence, severity, or treatment duration.

The issue of assessment, which determines the diagnosis and severity of NAS and thus directs the course of treatment, is another area of misunderstanding. No objective, biological index or marker exists for the determination of NAS. Neonatal metabolic alterations such as hypocalcemia, hypoglycemia, hypomagnesemia, and hypothermia can mimic NAS and need to be ruled out before treatment for NAS is initiated. The most widely used assessment tool consists of 21 items with 31 possible scores (e.g., “mild tremors when disturbed” and “marked tremors when disturbed,” “loose stools” and “watery stools,” “hyperactive Moro reflex and markedly hyperactive Moro reflex”) (Finnegan and Kaltenbach, 1992). Making such distinctions requires

extensive reliability training, and even with such training, it can be difficult to score some items with a high degree of accuracy. Additionally, neither the incremental validity of the differential weighting of the tool nor its sensitivity and specificity have been examined. Such limitations have led to calls to reexamine the assessment of NAS and the need for an objective measure derived from a rigorous psychometric approach (Jones and Fielder, 2015).

Although a standard of care for NAS has been developed over the past 50 years, aggregate data across several hospital/fellowship program surveys suggest significant variability in both diagnosis and treatment protocols (Jones and Fielder, 2015). Effectiveness evidence for medications used to treat NAS is limited. Currently, oral morphine solution and methadone are recommended by the American Academy of Pediatrics for the treatment of NAS (Hudak and Tan, 2012). Morphine has been found to have shortcomings under some dosing and weaning regimens, and no data from randomized controlled trials comparing methadone with morphine are currently available. Although not yet used in clinical settings, randomized controlled trial data comparing buprenorphine and morphine show buprenorphine to be more effective than morphine, requiring less medication and shorter length of treatment (Kraft et al., 2011). In a recent randomized trial involving 63 infants with NAS, those treated with buprenorhine had significantly shorter treatment duration compared with those treated with morphine. The median between-group difference in treatment duration was 13 days (Kraft et al., 2017).

Medication dose regimens for NAS are traditionally determined by the infant's weight, but some institutions and research protocols use a symptom-based approach in which the dose is based on the severity of the infant's symptoms. To date, no systematic studies have evaluated these differing regimens.

The lack of protocols has recently been identified as impacting the duration of NAS treatment, the length of inpatient stay, and the rate of adjunctive therapy. Other recent changes in hospital practices, such as supporting breastfeeding and integrating mothers as partners in care, have been found to decrease the need to treat NAS and reduce the length of hospital stay (Holmes et al., 2016).

It should be reemphasized that these data are specific to women maintained on methadone or buprenorphine for OUD. To the committee's knowledge, no data specific to other opioid pain medications are available. Infants undergoing NAS would be assessed and treated the same, but mothers receiving opioids for chronic pain who wished to breastfeed would require a safety evaluation, including type of medication, length of time on medication, and rapid increases in dose (Sachs, 2013).

The incidence of NAS in relation to the opioid epidemic has been identified as a major concern. Regrettably, strategies to address NAS are often punitive and excessive and applied disproportionately to vulnerable populations. The identification of NAS as fetal harm calls into question the ability to adequately parent their children for both women who use opioid medications as prescribed by their health care providers and those who misuse opioid medications or use illicit opioids (Terplan et al., 2015). Some state legislatures have required surveillance of NAS prevalence for both prescribed and illicit drugs. Judges and prosecutors have implemented punitive approaches with women who use both prescribed and nonprescribed opioids during pregnancy, including arrest, civil commitment, detention, prosecution, and loss of custody. The Child Abuse Prevention and Treatment Act of 2010[3] requires states to have policies and procedures in place for notifying child protective services about children affected by

[3]Public Law 93-247.

withdrawal symptoms from exposure to prenatal drugs, and the Comprehensive Addiction and Recovery Act of 2016 requires that a plan of safe care be implemented. Neither law differentiates among the highly varied contexts in which NAS occurs. While there may be situations that call for action to prevent child abuse and neglect, caution is warranted in designating NAS as a proxy for risk of abuse and neglect.

In summary, only by disentangling NAS due to the use of an opioid medication as prescribed by a health care provider from that due to misuse of these medications and/or the use of illicit opioids can prevention and treatment approaches for NAS be better refined. A more comprehensive response to NAS and treatment of OUD in pregnant women would be enabled by better understanding of the signs and symptoms of NAS for specific opioid medications and illicitly manufactured fentanyl and its analogs, including the development of an objective diagnostic tool, better understanding of the effectiveness of various medications and protocols for treatment of NAS, and the development of treatment protocols specifically for pregnant women using fentanyl.

Persons Involved with the Criminal Justice System

Another population heavily affected by the opioid epidemic and with unique risks consists of people within the criminal justice system. Drug-related crimes and seizures of illicit drugs point to a sharp rise in the opioid crisis. As the opioid epidemic shifts rapidly from prescription opioids to heroin, illicitly manufactured fentanyl, and other illicit drugs, more individuals, many of whom live with OUD, are coming into contact with the criminal justice system. Authors of a 2006 study analyzing data on arrests, incarcerations, and heroin use estimate that 24 to 36 percent of all people with OUD involving heroin pass through U.S. prisons and jails each year (Boutwell et al., 2006), although this figure may be different today owing to changes in the heroin-using population. People recently released from incarceration experience the highest risk of fatal opioid overdose of any subpopulation (Binswanger et al., 2007, 2011, 2013; Farrell and Marsden, 2008; Merrall et al., 2010) because of their loss of tolerance, social isolation, and extraordinarily high relapse rates. Examining data from the Arrestee Drug Abuse Monitoring II Program, Hunt and colleagues (2015) found that those with a history of heroin use had higher drug use and severity and higher rates of treatment utilization relative to those reporting use of other drugs. Only one-third (34 percent) of arrestees with drug use histories had received SUD treatment during their lifetime, and only 14 percent had obtained such treatment during the year prior to their arrest. Receipt of mental health treatment services also was extremely low in this population despite a high prevalence of mental health problems (Hunt et al., 2015).

As is the case for pregnant women with OUD, there are important opportunities to identify and treat people in the criminal justice system who are at risk of progressing to more severe OUD and overdose. However, the most effective evidence-based approaches for addressiknng OUD and reducing overdose risk (Connock et al., 2007) have historically been inaccessible to people who are incarcerated in the United States. The social, medical, and economic benefits of providing MAT in correctional settings have been well documented (Deck et al., 2009; Dolan et al., 2003, Heimer et al., 2006; Kerr et al., 2007; Kinlock et al., 2009; MacArthur et al., 2012; Mattick et al., 2009; McKenzie et al., 2012; Rich et al., 2015; Zaller et al., 2013). Although the World Health Organization (WHO, 2009) and SAMHSA (Miller and Hendrie, 2008) have strongly endorsed the use of MAT to treat OUD in criminal justice settings,

there has been little to no implementation or routine use of MAT in U.S. jail and prison settings (Lee et al., 2015; Vestal, 2016).

National household-based surveys exclude people who are incarcerated and other institutionalized populations. Thus, trends in the epidemiology of opioid use and misuse, OUD, and overdose in this large, underserved, and particularly vulnerable population often are missed, as is the chance to provide lifesaving treatment and medications to a high-risk population at a high-risk point in time. When new medications are approved for the treatment of OUD and overdose, it will be important for those drugs to be made available to individuals who are incarcerated. In addition to the enormous potential public health benefit of doing so, people involved in the criminal justice system are in contact with community corrections and thus could provide key surveillance data points, thereby improving post-marketing surveillance and public health data capacity.

In summary, OUD is prevalent in criminal justice settings, and improved access to effective treatments and collection of surveillance data with which to track opioid use and associated harms in these settings are needed. The status of surveillance systems for collecting data on drug use among individuals involved in the criminal justice system and other populations is discussed later in this chapter.

People Who Inject Drugs

PWID are subject not only to the harms related to the drug itself but also to the harms related to injection. In particular, PWID are at risk of abscesses, tissue infections, ulcers at the site of injection, and endocarditis (Smith et al., 2014), and those who share syringes and other injection equipment also are at risk of contracting bloodborne infections such as hepatitis C virus (HCV) and HIV.

HCV, which can cause liver scarring and liver cancer, is spread primarily through blood contact, with the primary risk factor in the United States being injection drug use. In 2014, there were an estimated 30,500 cases of acute HCV infection in the United States and an estimated 2.7 to 3.9 million people living with chronic HCV (CDC, 2016a). HCV is now responsible for nearly 20,000 deaths annually in the United States—more than the number due to 60 other infectious conditions combined (Ly et al., 2016). The number of acute HCV infections had been declining steadily in the United States but reversed course and began to increase in the mid-2000s; since 2005, the estimated number of acute infections has more than doubled (CDC, 2016b). This increase in infections has been particularly pronounced among young, nonurban white people (Suryaprasad et al., 2014). Between 2006 and 2012, there was an estimated 364 percent increase in HCV infection among people under age 30 in Kentucky, Tennessee, Virginia, and West Virginia, for a total of 1,377 reported cases (Zibbel et al., 2015). Among the 265 cases for which risk information was available, 73 percent of infected persons reported injection drug use (Zibbel et al., 2015). The authors of this study note that during the same period, there was a surge in the number of young people in these states seeking treatment for OUD related to use of prescription opioids and heroin, suggesting that "the increase in acute HCV infections in central Appalachia is highly correlated with the region's epidemic of prescription opioid abuse and facilitated by an upsurge in the number of persons who inject drugs in these four states" (Zibbel et al., 2015, p. 457). An analysis of national surveillance data showed similar trends, with 75 percent of young persons newly infected with HCV reporting that they had ever injected drugs and 75 percent reporting that they had ever misused prescription opioids (Suryaprasad et al., 2014).

The authors conclude that all "available information indicates that early prescription opioid abuse and addiction, followed by initiation to IDU [injection drug use], is fueling increases in HCV infection among young persons" (Suryaprasad et al., 2014, p. 1417).

HIV attacks a person's immune system and can lead to infections, cancers, and death. It is spread primarily through sexual activity, but 6 percent (2,392) of new diagnoses in the United States in 2015 were attributable to injection drug use, and another 3 percent (1,202) were due to injection drug use in addition to male-to-male sexual contact (CDC, 2017a). It is estimated that more than 171,000 people in the United States are living with HIV that is attributable to injection drug use (CDC, 2017a). In general, HIV diagnoses among PWID are on the decline, down 48 percent between 2008 and 2014 (CDC, 2017a). However, an increase in injection drug use in nonurban areas and in new populations has created new challenges in monitoring and preventing HIV transmission. High-risk practices—sharing needles, syringes, and other injection equipment—have declined among black and Hispanic PWID, but have not declined among their white counterparts. Young (under 30 years) and new (injecting less than 5 years) PWID are more likely than other PWID to share equipment (CDC, 2017a). High-profile HIV outbreaks have been seen in areas that were previously considered low-risk for HIV. In southeast Indiana, for example, a region that normally saw about 5 new cases of HIV annually, 169 people were diagnosed with HIV in the first half of 2015 (Strathdee and Beyrer, 2015). Most of these people were young and white and lived in rural communities, and the infections were linked directly to the preparation of the newly reformulated ADF Opana ER (oxymorphone ER) for injection (Strathdee and Beyrer, 2015). This development represents a major shift. Since the beginning of the HIV epidemic in the United States, most PWID who became infected with HIV were black men older than 35 who lived in urban areas, and most infections were associated with the injection of street drugs, not prescription medications (Strathdee and Beyrer, 2015). Effective interventions for reducing harm associated with bloodborne disease have a strong evidence base and include the provision of new syringes and needles through syringe access programs and point-of-sale pharmacy access to this equipment (CDC, 2015b; Hagan et al., 2011; Logan and Deutsch, 2015); however, many states recently affected by HIV and HCV increases, including Indiana, do not provide legal access to safe injection equipment. Further discussion on policies related to injection equipment is included in Chapter 5.

New data presented by the CDC at a March 13–14, 2017, advisory committee meeting reviewing ADF Opana ER (oxymorphone ER) suggest that ADF strategies and specific formulation components common to the ADF versions of OxyContin and Opana ER had harmful effects on PWID and drove outbreaks of HIV, HCV, and thrombotic thrombocytopenic purpura-like illness (TPP)[4] in this population (Brooks, 2017). Data from quantitative (case-control) and qualitative (focus group and interview) studies were analyzed to understand how the characteristics of drugs—and their subsequent use—influenced risks of infection and TPP. Findings indicated that in these communities, which had endemic prescription opioid misuse (with little heroin use), diverted prescription opioids were used in multiple injection events per day. Oxymorphone (the active ingredient in Opana), which is 10 times more potent than the equivalent morphine dose, led to more intense withdrawal in people who had developed OUD involving use of the drug. Opana ER—like Oxycontin ER—is formulated with a crush-resistant coating, which drove many users who had been snorting their Opana to inject the drug. The

[4]TPP is a rare but serious blood disorder characterized by microangiopathic hemolytic anemia and thrombocytopenia (low blood platelet count). Intravenous drug use is a known risk factor for TPP (CDC, 2013).

reformulation, however, required multiple steps to be prepared for injection, and the preparation methods used involved the use of more solvents, which ultimately diluted the injection so that more injections occurred during the same injection episode. Also unique to preparation of Opana ER ADF (compared with injection use of other prescription opioids or heroin, for instance) was the use of "rinse shots" to extract all possible drug from the leftover materials. The increased street cost of Opana ER in the community incentivized cooperation and collaboration among people injecting the drug, creating more opportunities for transmission of HIV and HCV (Brooks, 2017). Additional data reported from a 2011 outbreak of HCV in New York State traced transmission to injection of prescription opioids, and in this case, Opana ER and OxyContin ER were the two most frequently injected opioids. These three instances illustrate well the risks of specific drug characteristics and drugs developed to treat pain that can be expected to be misused, diverted, and repurposed.

In summary, PWID are vulnerable to harms related to drug use. It is predictable that new medications with abuse liability will be used by people with established patterns of injecting drugs. Tracking the toll of expected nonmedical use of specific products on the health of people who inject drugs is of public health importance. For new formulations of opioids and other drugs that may be manipulated and injected, it is prudent to anticipate and fully examine the possible harms to health that might occur via injection routes. Data on harms can be collected through surveillance, but ethnographic and qualitative research also is required to understand use behaviors. When harm arises, involving PWID and their health advocates in interventions that affect them can improve public health outcomes. Harm to this population can be minimized and treatment entry improved through safe access to injection materials.

HEROIN USE AND ITS RELATION TO PRESCRIPTION OPIOID USE

It is now abundantly clear that heroin use and trends in illicit drug markets have a substantial influence on the public health impact of prescription opioid use and misuse and OUD. One cannot weigh the importance of new therapeutics without taking full account of unintended harm from diversion and transition to illicit opioid use.

Trends in Heroin Use

Heroin, also known as diamorphine, is a synthetic derivate of the opium plant that can produce intense feelings of euphoria. Its use by humans traces to 1874, when it was synthesized from morphine and subsequently marketed as a medication. Now considered an illegal drug with no medical applications in the United States, diamorphine is currently used in some countries in palliative care or as medication treatment for people with OUD who have not responded successfully to other opioid agonist therapies (Strang et al., 2015).

Data indicate that heroin use has been rising in the United States in recent years among both men and women, in most age groups, and across all income levels (see Figure 4-2). The CDC notes that some of the greatest increases have occurred in demographic groups with historically low rates of heroin use, including women, the privately insured, and people with higher incomes. Of note, heroin use among people aged 18 to 25 more than doubled in the past decade (Jones et al., 2015).

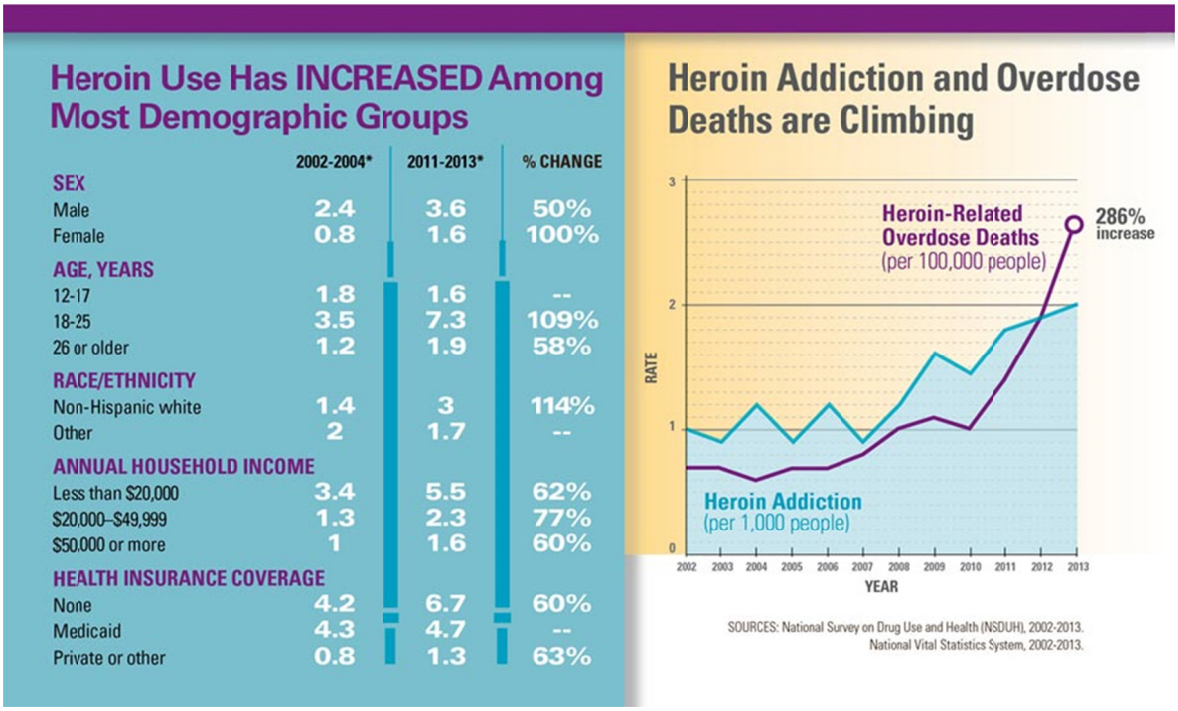


FIGURE 4-2 Public health impact of heroin use.
SOURCE: CDC, 2015c.

Concomitant with increased heroin use over the past decade have been increases in heroin-related overdose deaths, heroin-related emergency department visits, and help seeking through treatment admission for OUD. Heroin-related overdose deaths have more than quadrupled since 2010, totaling more than 12,989 in 2015. Demographically, the highest rate for heroin overdose death (7.0 per 100,000) in 2013 was among non-Hispanic whites aged 18 to 44, a demographic that one decade earlier had been heavily affected by nonmedical use of prescription opioids, as reviewed earlier in this chapter. Importantly, there are geographic differences in heroin overdose rates, with the greatest burden being exhibited in the Northeast (6.3 per 100,000) and Midwest (6.1 per 100,000) (see Figure 4-3).

Trends in heroin use among those entering treatment have changed radically and quickly. A study of patients entering SUD treatment programs for OUD involving heroin nationwide examined retrospective reports on past drug use patterns (Cicero et al., 2014). Findings indicate significant changes in the profile of heroin users over the last several decades, from a previously predominantly inner-city, minority-centered problem to one that has more widespread geographic distribution. Users now comprise white men and women in their late 20s living outside of large urban areas who were introduced to opioids through prescription drugs and progressed to heroin in part because of its lower cost and greater availability (Cicero et al., 2014).

FIGURE 4-3 Age-adjusted heroin overdose death rates per 100,000 population from 2014 (light blue) to 2015 (dark blue), by census region of residence.
*Statistically significant at $p < 0.05$ level.
SOURCES: Adapted from Rudd et al., 2016.

Interactions and Transitions from Prescription Opioids to Heroin

One of the most urgent concerns posed by the widespread increase in prescription opioid use and consequent misuse beginning in 2000 is how this epidemic is influencing current trends in the use of heroin and fentanyl and mortality due to overdose involving these drugs. A number of studies have yielded evidence strongly supporting the conclusion that the recent prescription opioid epidemic has resulted in a significant increase in domestic heroin use and associated overdose deaths (Al-Tayyib et al., 2017; Jones, 2013a; Muhuri et al., 2013). The rate of heroin overdose increased moderately from 2006 to 2010 but more than tripled from 2010 to 2014 for all age groups (see Figure 4-4), with the greatest increase occurring among those aged 25–34 (CDC, 2017b). Data for 2015 indicate that the rate of heroin overdose continued to climb, reaching a rate of 4.1 per 100,000 population, more than four times the rate in 2010 (Rudd et al., 2016). Furthermore, from 2007 to 2013, rates of past-year nonmedical use of or OUD involving heroin increased nearly 150 percent (Jones et al., 2015). While societal factors have certainly contributed to this trend, a major concern is how prescription opioids contributed to this problem both by serving as "gateway" drugs to heroin use (Muhuri et al., 2013) and by "squeezing the balloon" through focused efforts to reduce their misuse (e.g., the development of ADFs), leading to illicit sources and drugs such as heroin (Unick et al., 2013).

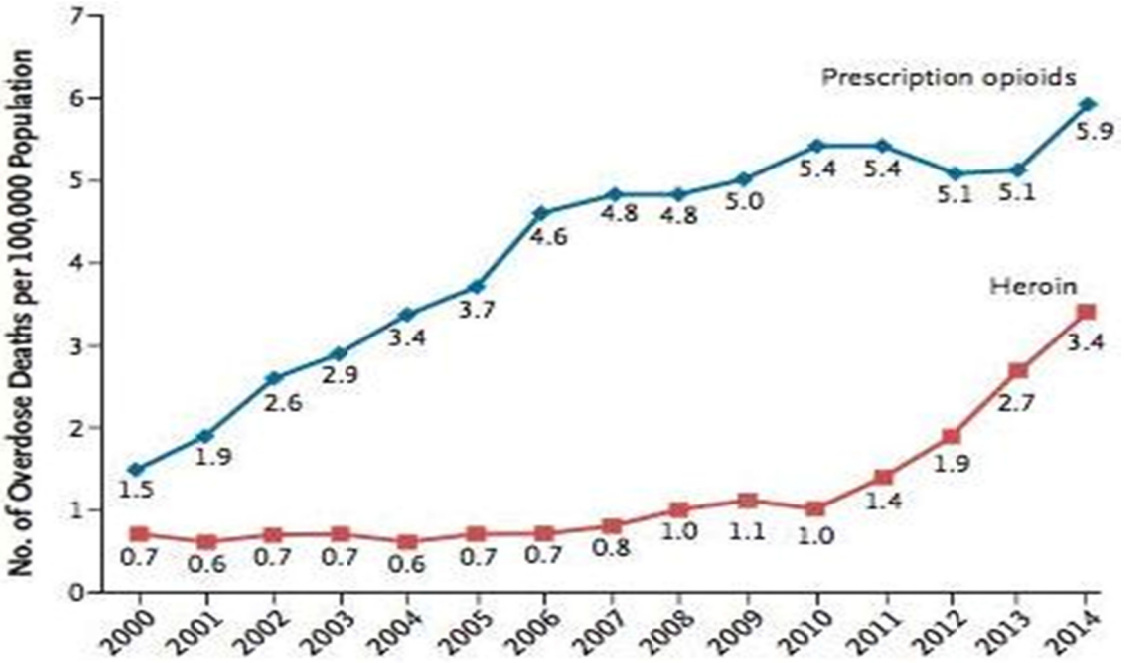


FIGURE 4-4 Age-adjusted rates of death related to prescription opioids and heroin drug poisoning in the United States, 2000–2014.
SOURCE: Adapted from Compton et al., 2016.

One issue to keep in mind in this discussion is the relative size of the heroin and prescription opioid epidemics. Heroin historically has attracted only a small number of chronic users in the United States. In terms of the number of people regularly using opioid medications (for pain or nonmedical reasons), the prescription opioid epidemic is many orders of magnitude larger than the endemic level of heroin use. This means that an unprecedented number of people are potentially vulnerable to meeting their opioid use needs with heroin. Understanding how the dynamics of these two current epidemics overlap and the motives of people switching from pills to heroin is a critical challenge.

Prescription Opioids as a Gateway

The gateway theory of the movement of prescription opioid users to heroin is predicated on the fact that opioid medications produce the same neuropharmacologic effects as heroin, so the substances are natural substitutes. Use of both heroin and prescription opioids involves tolerance, cross-tolerance, and withdrawal. Yet heroin is, on balance, more potent than the most common low-dose prescription opioids (e.g., codeine, Vicodin, Percocet). This is true of even fairly low-purity (<30 percent) heroin, but has become even more evident with recent increases in heroin purity rates in some cities (Gray, 2014). The implication is that as people become tolerant to a dose (i.e., level) of opioid medication and no longer feel the desired effects of the drug, they may use heroin and thereby feel more intensely and rapidly effects that pills once may have produced. As discussed in Chapter 3, anyone consistently using these medications is likely to experience tolerance, which may lead to taking opioid medications in amounts greater than prescribed (Webster and Webster, 2005).

Moreover, initial use of opioids to treat pain may shift to chronic use. In an analysis of linked health care claims, Shah and colleagues (2017) found that the probability of long-term prescription opioid use increased markedly in the initial period of therapy, especially after 5 days or 1 month. Over this initial course of care, tolerance develops and can, if the patient is not tapered off the drug and cared for safely, lead to dependence and OUD. While other factors may influence the transition to heroin use, the point is that the risk of this transition is great for people prescribed opioids, and those initially prescribed the drugs for longer periods or in larger doses (i.e., ER opioids) tend to stay on opioids.

For many people who misuse opioids, switching to heroin also involves an associated transition to a more potent route of administration—e.g., injecting—either before or in conjunction with initiation of heroin use. It is true that most prescription opioids are swallowed, but depending on their formulation (and the knowledge of the person misusing) they also can be sniffed, smoked, chewed, sucked, or injected. In the United States, heroin is most commonly injected—the fastest route of administration—which introduces a host of additional public health consequences (discussed earlier regarding PWID). Heroin (along with fentanyl) is more potent than opioid analgesics (NIDA, 2016), and the potency of opioid analgesics is influenced by the route of administration. The differences in potency and onset of effects among orally ingested opioid medications, snorted or injected prescription opioids, and injected heroin places a person making the switch away from oral routes at much higher risk for overdose. Moreover, to someone tolerant to and misusing prescription opioids, ER opioid formulations and heroin offer a much more rapid onset of effects relative to prescription IR formulations. In this manner, ER opioids and heroin can reset the reward pathway, giving people who make this switch a powerful incentive to continue using them. Efforts to make ER opioid formulations less accessible and/or "abuse-deterrent" and black market efforts to make heroin more readily available, then, may tilt the reward mechanism in favor of seeking heroin.

It is important to acknowledge that an overwhelming majority of people who use prescription opioids do not continue to use them chronically (Shah et al., 2017), and so are not at risk of switching to using heroin. However, for those that do use chronically and then move to heroin through this pathway, the movement is typically one-way. Once a person has begun using heroin consistently, returning to a pattern of primary use of prescription opioids is unlikely for a variety of reasons, including heightened scrutiny by health care providers and the relative expense (see below for discussion of opioid markets) (DEA, 2013). Chronic users of heroin seldom consume prescription opioids and typically do so only to delay withdrawal when heroin is episodically unavailable; when informally seeking to reduce their heroin intake; or, more recently, when protecting themselves against fentanyl-contaminated heroin.

Further promoting such transitions to heroin among persons previously using prescription opioids is the financial incentive for switching, since heroin is considerably cheaper than street-available pain medications (DEA, 2013). In locations where both illicit prescription opioids and heroin are available, drug users consistently report that prices are lower for heroin. This price difference has always existed. Heroin also has a much lower initial market entry price than that of opioid pills for new users (e.g., a bag of heroin sells for $10, while a pill might cost $20), but few people start with heroin because its use is stigmatized.

Market Effects and the Transition to Heroin

Differences in drug prices are complex and often a consequence of how the markets operate. For instance, the supply of legal prescription opioids is controlled and can therefore be restricted—for example, when a pill mill is shut down or an opioid is reformulated with abuse-deterrent properties (see discussion on OxyContin reformulation below and related discussion in Chapter 5). These medications also are sold in what can be described as a secondary market, meaning the drug is first diverted from some legitimate source to be resold illegally, which is costly and raises the price. As discussed further in the next section, these markets are now growing. Even within expanding markets for counterfeit opioid medications and illicitly manufactured synthetic opioids, moreover, the latter products remain less expensive to purchase than most opioid analgesics, both diverted and counterfeit.

Part of the reason for the price difference between illicit prescription opioids and heroin is that heroin supplies coming into the United States are largely unrestricted (other than by the sorts of supply-related control measures that may restrict opioid medications). In many places where heroin is sold, sales are well-organized and have the support of an established black market infrastructure. Therefore, all other things being equal, once a person starts using heroin, acquiring it consistently may become easier and less expensive relative to pills. As tolerance increases and if OUD progresses, evidence-based treatment may be the only intervention able to disrupt this cycle.

The important regional variations in the numbers of people switching to injection use and to heroin from prescription opioids noted earlier reflect such market factors. One reason especially high rates of prevalence of prescription opioid use did not immediately lead to extensive heroin use in rural communities may be that heroin was not yet as entrenched and available in these locations. For instance, consistently low rates of heroin use have been seen in a cohort of rural Appalachian injectors in Hazard, Kentucky, even after reformulation of OxyContin and Opana (Havens et al., 2014). But more recent state and local data on overdose deaths, treatment entry, and arrests indicate that heroin is now surging in these same areas. The substantial delay in heroin uptake in these areas may be linked to shifts in drug trafficking patterns, localized interventions to reduce the supply of diverted opioid medications, or changes in the social structure created alongside the pill-based economy (Jonas et al., 2012).

Quantifying the Degree of Overlap

Although a number of factors have prompted people to move from use of opioid medications to use of heroin, quantifying precisely how many people have made this switch is difficult. Yet a number of studies suggest that an alarming overlap has occurred, and is still occurring, between these two epidemics. Authors of a national study of people who use heroin (Cicero et al., 2014) note that an important demographic shift has occurred in recent years. Over the past 50 years, the population of people using heroin has transformed to mirror the population of people using and misusing prescribed opioids. People who use heroin now are primarily younger and non-Hispanic white. Those who have an OUD involving heroin today are very different from their counterparts only 10 years ago, but much more like the people affected by the prescription opioid epidemic. In asking whether people who use heroin begin doing so before or after using prescription opioids, these authors identified a complete reversal from the 1960s:

almost all people who initiated heroin use in the 1960s started with heroin, whereas almost all those who began using heroin in the 2000s began with the use of prescription opioids.

One large cohort study and a number of regional studies confirmed that a majority of people who had recently started using heroin began by misusing opioid medications. In the first published study on this topic, Siegal and colleagues (2003) found that 50 percent of young persons (aged 18–33) in Ohio who had recently started using heroin reported first having misused opioid medications, primarily OxyContin. A number of similar studies yielded a similar finding, although rates of prior opioid misuse varied. A large study of illicit and prescription drug misuse in young urban people in New York and Los Angeles in 2008 and 2009 found that 73 percent had a lifetime history of obtaining a prescription for opioids and initiated prescription misuse at a younger age relative to use of heroin, suggesting that nonmedical opioid misuse may serve as a gateway to initiation of heroin use (Lankenau et al., 2012). Studies of heroin users in San Diego (Pollini et al., 2011), Seattle (Peavy et al., 2012), and New York City (Mateu-Gelabert et al., 2015) found that 40 percent, 39 percent, and 77 percent of heroin users, respectively, were users of nonmedical opioids before initiating heroin use. In a more recent sample of PWID in Denver (2015), 32 percent reported being "hooked" on prescription opioids before injecting, and the primary drug they injected was heroin (Al-Tayyib et al., 2017). Finally, in a large, matched cohort of aging U.S. veterans who reported no previous history of nonmedical prescription opioid or illicit opioid use, Banerjee and colleagues (2016) found that nonmedical use of prescription opioids was associated positively and independently with subsequent initiation of heroin use.

An analysis of data from the National Survey on Drug Use and Health (NSDUH), the only nationally representative study of self-reported drug use behavior in the United States, supports the conclusions of the above cohort and regional studies, although it is important to note that household surveys have unavoidable limitations for use in assessing high-frequency use of drugs such as heroin (Caulkins et al., 2015b). Using NSDUH data pooled from 2002 through 2011, Muhuri and colleagues (2013) noted that, among individuals aged 12–49, four of every five recent heroin initiates (79.5 percent) (i.e., those who had initiated heroin use within the last 12 months) were previous self-reported users for purposes of nonmedical pain relief (NMPR) (see Figure 4-5).

The analysis by Muhuri and colleagues (2013), which included approximately 609,000 respondents at risk for heroin initiation and 524,000 respondents at risk for NMPR use, is notable because it found that only a small percentage (3.9 percent) of NMPR users initiated heroin within 5 years after first using NMPR. The NSDUH, however, is a household-based sample that excludes institutionalized populations, homeless individuals, and others, and thus likely underestimates these outcomes. The small incidence rate also is deceptive because of the large annual number of new heroin users it represents. As others have noted, "given the large number of nonmedical users, even a small percentage who initiate heroin use translates into several hundred thousand new heroin users" (Compton et al., 2016, p. 158). Applying the 3.9 percent incidence rate to the 25 million Americans who ever initiated NMPR use between 2002 and 2011 (SAMHSA, 2012) indicates that the prescription opioid epidemic created nearly 1 million new heroin users in this 10-year time frame, or roughly 100,000 annually. Given underreporting, the correct number may be considerably higher still.[5]

[5]It is important to note that until 2015, the NSDUH instrument posed questions regarding "misuse" in terms of two behaviors: using the medication in ways other than prescribed and using it for the way it makes one feel. In 2015 the

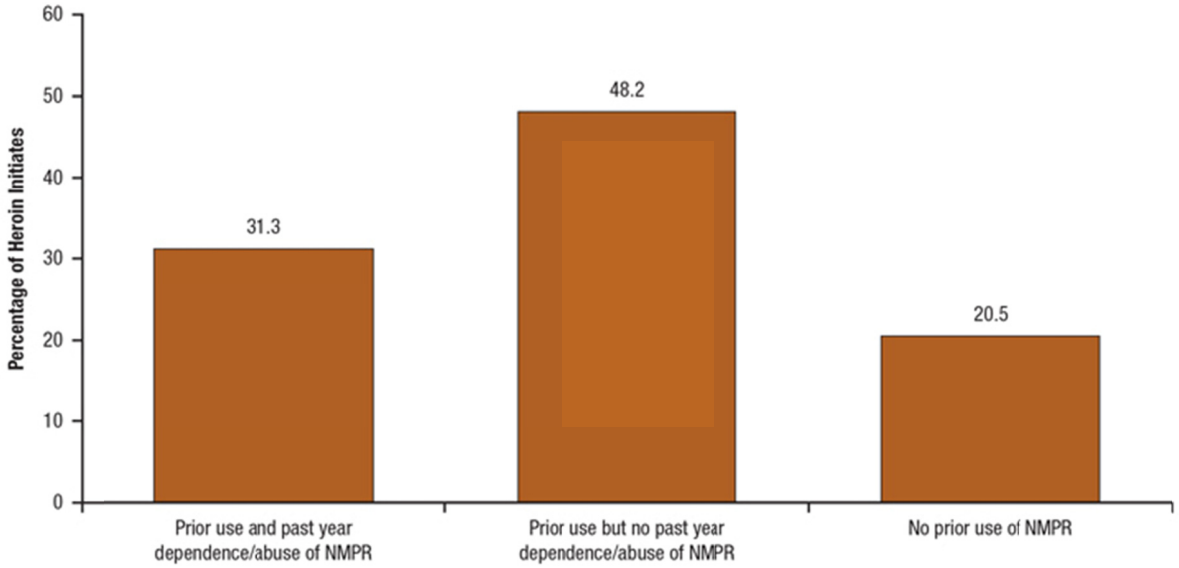
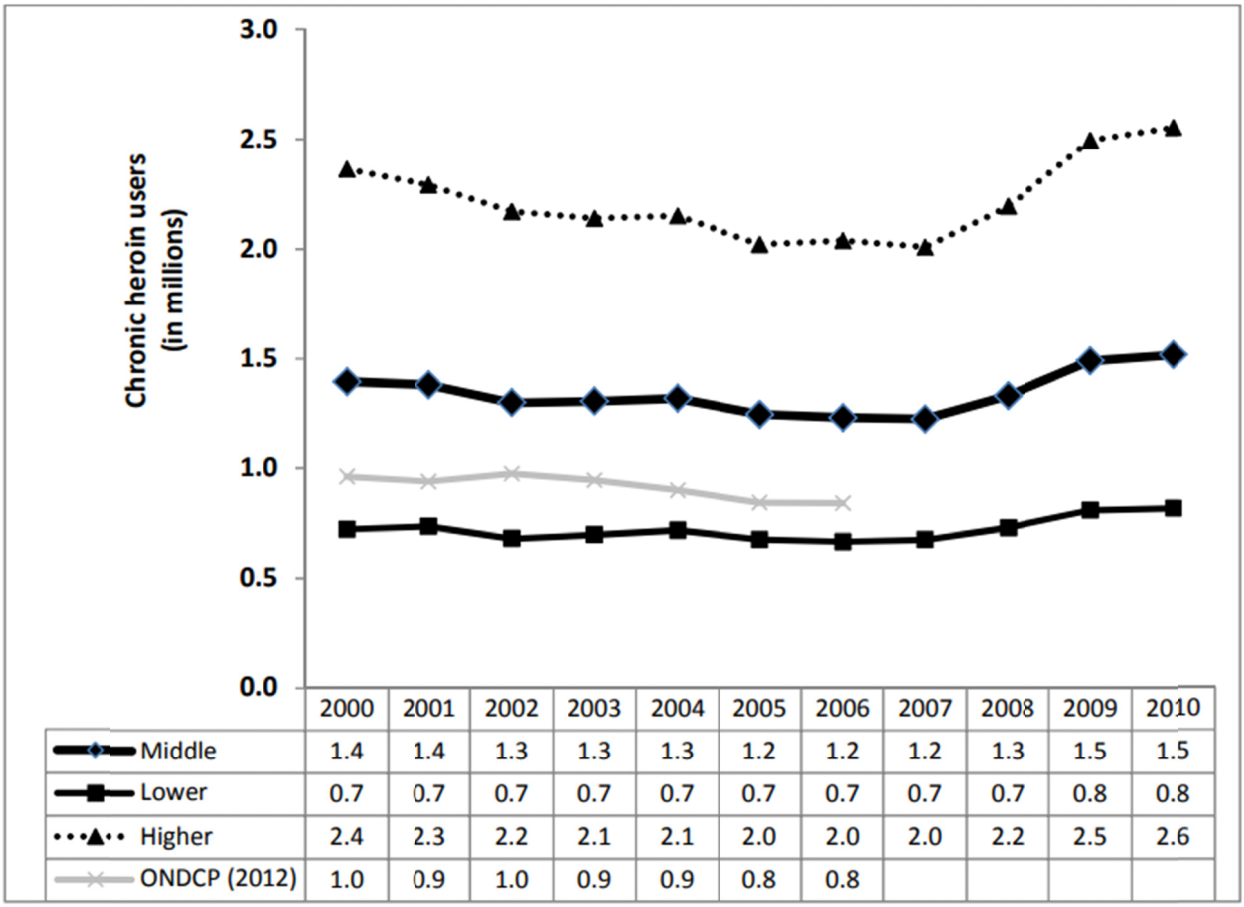


FIGURE 4-5 Percentage of heroin initiates among persons aged 12–49, by prior and past-year dependence on/abuse of nonmedical pain relievers (NMPRs), 2002–2011.
NOTES: Past-year NMPR users are those who had initiated NMPR use prior to initiation of heroin use in the past 12 months. Past-year NMPR users who initiated NMPR use subsequent to initiation of heroin use in the past 12 months are not included. Dependence or abuse is based on self-reported problems and definitions found in the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV).
SOURCE: Muhuri et al., 2013.

Alarmingly, data from other sources are consistent with this projection. The most recent estimate from a RAND Corporation report prepared for the Office of National Drug Control Policy (ONDCP) suggests there were 1.5 million chronic heroin users in the United States in 2010 (the latest year estimated) (Kilmer et al., 2014). Based on this "high" projection, 400,000 more chronic heroin users existed in 2010 than in 2002. The estimated number of chronic heroin users remained fairly stable between 2000 and 2007, but from 2007 to 2010 increased 25 percent (see Figure 4-6). During 2007–2010, the rate of new chronic heroin users was >100,000 annually, keeping in mind that these calculations are conservative because they are based on the noted underestimates of the rate of initiation of heroin use from the NSDUH. Based on these estimates, starting from 2010 and assuming 100,000 new heroin users annually, the prescription opioid epidemic could at least double the number of heroin users in the United States by 2025.

A preponderance of evidence suggests that the major increase in prescription opioid use beginning in the late 1990s has served as a gateway to increased heroin use. Two questions remain: How costly, in terms of heroin mortality, has this connection been? and What does this mean if prescription opioid supplies are curtailed? As in the findings cited above, the year 2010 is an important turning point for addressing these issues.

latter query was eliminated. Because of this change, estimates of misuse from the NSDUH before and after the change was made are not entirely comparable.



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Middle	1.4	1.4	1.3	1.3	1.3	1.2	1.2	1.2	1.3	1.5	1.5
Lower	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8	0.8
Higher	2.4	2.3	2.2	2.1	2.1	2.0	2.0	2.0	2.2	2.5	2.6
ONDCP (2012)	1.0	0.9	1.0	0.9	0.9	0.8	0.8				

FIGURE 4-6 Estimated number of chronic heroin users, 2000–2010 (in millions).
SOURCE: Kilmer et al., 2014.

Marketed aggressively in a campaign that began in 2000, OxyContin—developed by Purdue Pharma in 1996 and the most popular opioid medication in history—is widely regarded as the drug that initiated the current opioid medication misuse epidemic. A critical factor in the initial epidemic was that many people were able to misuse OxyContin by crushing, dissolving, and injecting the drug. All routes of administration were available, and presumably, early in this epidemic, many individuals who misused the drug were particularly vulnerable to using heroin (if locally or regionally available) because they had progressed beyond barriers posed by injection. This trend in OxyContin misuse progressed unabated until August 2010, when at the request of the FDA, an ADF of OxyContin was introduced, after which it became more difficult for people to crush, snort, and inject the drug. Yet the reformulation of OxyContin to an ADF led some users to abandon the drug entirely (e.g., for treatment), while others moved to other drugs or routes of administration and still others switched to heroin. Cicero and Ellis (2015) found that 33 percent of nonmedical OxyContin users had adapted to the OxyContin ADF by using other drugs, and 70 percent of that group had switched to heroin.

The importance of OxyContin and the change to its ADF formulation offered Alpert and colleagues (2017) an opportunity to conduct a unique analysis to assess how this policy influenced both opioid medication misuse and heroin mortality. Notably, using NSDUH data (again noting the limitations of this household survey described earlier) and comparing states with high and low rates of OxyContin misuse, the authors found that before 2010, no correlation

existed between trends in heroin mortality and opioid misuse; death rates for heroin during this time period were stable. By contrast, in the years after the reformulation (2010–2013), "each additional percentage point of pre-reformulation OxyContin misuse is associated with a relative decrease in OxyContin misuse of 0.8 percentage points and an additional 2.5 heroin deaths per 100,000 through 2013" (Alpert et al., 2017, p. 5). In other words, the reformulation decreased opioid medication misuse as intended but substantially increased heroin mortality. This finding led the authors to conclude that for each percentage point reduction in misuse of OxyContin generated by its reformulation, there was an increase in heroin-related deaths of 3.1 per 100,000. When the authors applied their calculation to increased heroin mortality rates between 2010 and 2014, 80 percent of the increase in those rates was explained by OxyContin's reformulation. As noted by the authors, the reformulation of OxyContin to an ADF had different short- and long-term outcomes. In the short term, the change increased heroin-related overdose deaths, while in the long term it reduced (or at least leveled) prescription opioid misuse, which could potentially reduce heroin deaths down the road.

Finally, increases in the numbers of individuals who use heroin over the last decade of the prescription opioid epidemic entail important independent dynamics. With more new heroin users entering the market every year, it has become much easier for people to start using heroin directly, without first using prescription opioids. Thus in addition to individuals who formerly misused prescription opioids, individuals whose heroin use began recently include those who were not influenced by the gateway effect of prescription opioid medications. As a result, heroin may become much more mainstream, appearing to have crossed a threshold that has historically restricted its popularity, so that the movement to direct use of heroin is occurring in the context of a social contagion fueled by the many heroin users produced by the prescription opioid epidemic. In short, the demographic shift in heroin use among persons who are rural, white, and geographically isolated as well as those who are suburban, young, white, more educated, and from middle-class backgrounds may be facilitating the popularity of heroin by slowly eroding long-standing stigmas that have prevented people from using this drug in the past. The potential waves of new heroin users naïve to opioids are particularly alarming and may explain why heroin and synthetic opioids (fentanyl) have been increasing exponentially the numbers of heroin-related overdose deaths since 2010. Thus in addition to initiating and continuing to directly feed the current heroin epidemic by facilitating people's switch to heroin, the prescription opioid epidemic may have mutated into a new and independent heroin epidemic.

Summary

The prescription opioid and heroin epidemics are intertwined. One of the consequences of increased prescribing of opioid analgesics has been increases in the use of heroin; in associated overdose deaths; and in the incidence of HIV, HCV, and other injection-related harms. In addition to prescription opioids serving as a gateway to use of heroin, market forces and efforts designed to reduce harms associated with use of prescription opioid medications (e.g., ADFs) may be contributing to increased heroin use. And given the comparatively small population of heroin users relative to that of prescription opioid users, there is currently an unprecedented potential market for heroin use.

ILLICIT OPIOID MARKETS

While it is reasonable to presume for many prescription medicines that consumption is limited substantially to those to whom the drugs were prescribed, this is not the case for all medications, including prescription opioids. Prescription opioids may be diverted (e.g., through resale, theft, or other means) to illicit markets that are the proximate cause of considerable harm (OUD and overdose). Furthermore, these markets for diverted prescription opioids interact with purely illegal markets for opioids that are not supplied through the U.S. health care system (Unick et al., 2013), as well as with the dark web of vibrant online drug cryptomarkets (Aldridge and Décary-Hétu, 2016). Traditionally, markets for purely illegal opioids pertained primarily to heroin, but they have been expanding to encompass new psychoactive substances, most recently and infamously synthetic opioids such as fentanyl and its analogs (e.g., acetyl fentanyl, ocfentanil, carfentanyl) that are packaged and sold in bulk from abroad to drug trafficking organizations or even as counterfeit pills made to look like popularly diverted prescription opioid medications. Thus, part and parcel of creating the supply of prescription opioids for treatment of chronic pain are increases in the supply to and demand for black markets for opioids, with all of their attendant harms, including violence, corruption, and incarceration.

History of Illicit Opioid Markets

Prescription opioids did not create the black markets for illegal opioids. The illicit opioid markets already had a long history in the United States. In fact, their prominence is reflected in the very names of such institutions as the Bureau of Narcotics and Dangerous Drugs (the predecessor of today's Drug Enforcement Administration [DEA]) and in the fact that "narc" is a slang term for a drug enforcement officer. However, large-scale misuse of prescription opioids created new demand that substantially reinvigorated, expanded, and diversified those markets.

The illegal opioid markets saw ebbs and flows before the expansion of prescription opioid misuse. A surge of use occurred after World War II, but it had been largely contained by the 1960s (President's Commission on Law Enforcement and Administration of Justice, 1967). Another, larger epidemic of heroin use took place in the late 1960s and early to mid-1970s, but that, too, was quelled by a combination of interventions on the demand side (early deployment of methadone) and supply side (Turkish poppy ban and breaking of the "French Connection") (DuPont, 1971, 1973, 1974; DuPont and Greene, 1974; Kaplan, 1983).

The heroin market was not completely stable between the mid-1970s and mid-1990s. The source of supply shifted markedly, from Mexico to Southwest Asia to Southeast Asia to South America (DEA, 2016b, p. 47). Heroin purity rose between the 1980s and 1990s, and purity-adjusted prices fell sharply (DEA, 2016c). But initiation was low, and use had remained substantially confined to an aging group of mostly men in major urban centers, predominantly in the Northeast and Southwest. Notably, availability was quite limited in most small cities and rural areas.

The heroin market was revived in the mid-1990s by a new source of initiation in the form of people whose opioid misuse had started with prescription opioids who transitioned to cheaper, and riskier, black market opioids (see Figure 4-7). This influx changed the demographic composition of the user base (Cicero et al., 2014; Muhuri et al., 2013), roughly doubled initiation into heroin use, and much more than doubled demand because all of these new initiates were experienced opioid users.

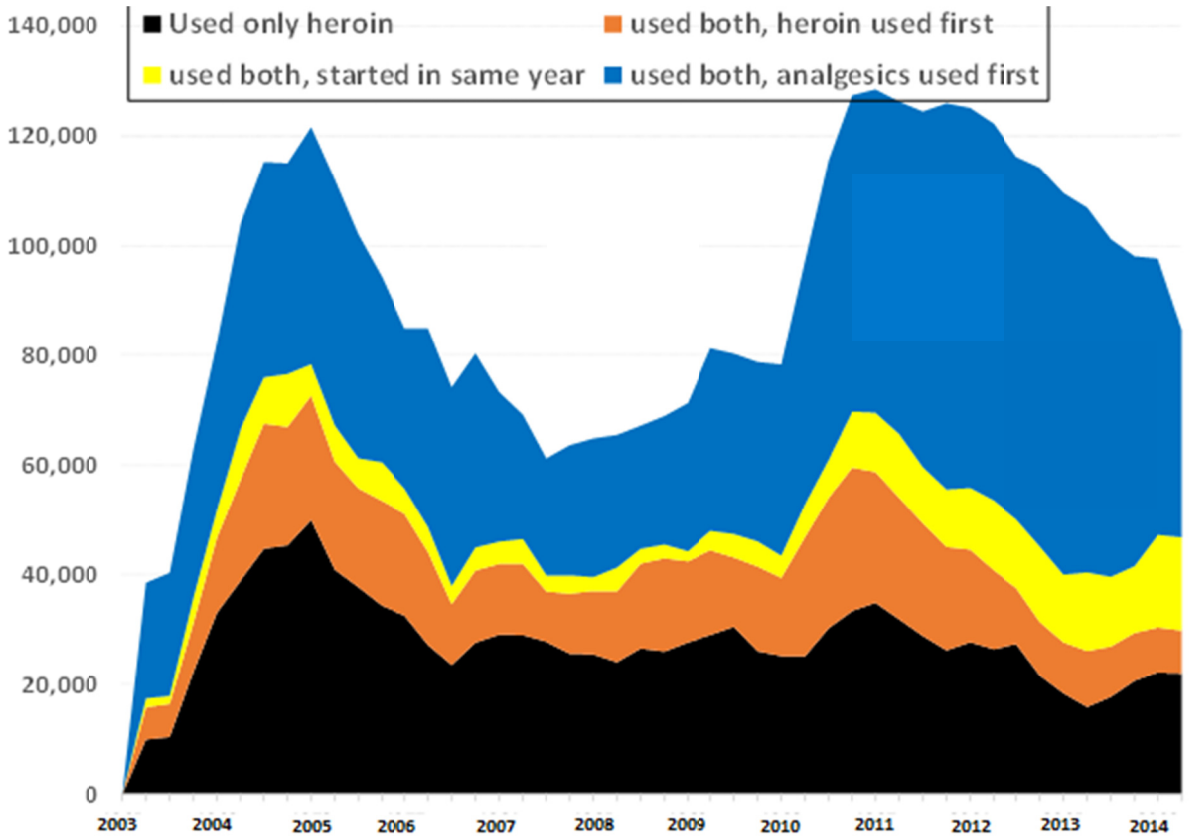


FIGURE 4-7 Heroin initiation reported in the 2003–2014 National Survey on Drug Use and Heroin (NSDUH), broken down by whether analgesics were used nonmedically before heroin.
SOURCE: Committee analysis of 2003–2014 National Survey on Drug Use and Health (NSDUH) data.

The effects can be seen not only on initiation but also on the ages of those seeking treatment. Among those the Treatment Episodes Data Set (TEDS) records as seeking treatment for heroin as their primary drug of use, in 1993 two-thirds were between the ages of 30 and 44. Twenty years later, in 2012, that proportion had fallen to one-third. The absolute numbers had declined by 20 percent (from 124,000 to 98,000), whereas the corresponding numbers for those under the age of 30 had grown by 150 percent (from 49,000 to 124,000) (SAMHSA, 2013b).

A further shift in supply occurred as well, with heroin produced in Mexico eclipsing that produced in South America. Seizures of heroin along the Southwest border of the United States began to increase sharply after 2007 (DEA, 2016b, p. 46). Importantly, retail distribution expanded into smaller cities and rural areas and to parts of the country, such as the Midwest, that previously had had lower availability. It is unclear whether that expansion in availability was demand-driven (supply reached out to where the new users lived), supply-driven (heroin distribution from other countries piggy-backing on networks that already had broad geographic reach for the delivery of cocaine and methamphetamine), or both.

In the last few years, two "new" and potentially very important product forms—fentanyl and counterfeit opioid pills—have proliferated in North American black markets for illegal opioids. The word "new" is in quotes because little that happens in black markets is truly unprecedented (Baum, 1985). Rather, what is new is that these products are becoming common, not exceptional. For example, the DEA (2016a) reports that before 2014, the National Forensic Laboratory Information System (NFLIS) recorded more than 1,000 fentanyl exhibits only in a

single year—2006, when a fentanyl "crisis" was associated with production tracked primarily to a clandestine lab in Toluca, Mexico. Yet by 2015, NFLIS recorded 13,002 fentanyl exhibits, more than 8 times the 1,594 exhibits observed during the 2006 crisis.

Present-Day Illicit Opioid Markets

Today's illicitly manufactured fentanyl may have multiple sources that are diversifying and expanding. Much illicitly manufactured fentanyl is reputedly produced in the same areas (and perhaps even the very same factories) that produce legal medications for distribution by pharmaceutical companies (DEA, 2016a). Black market drugs often move through complex pathways, but the DEA believes a common pathway is bulk shipments from China to drug trafficking organizations in Mexico and thence across the Southwest border, although some of the drugs may also be produced in Mexico. The fentanyl may be sold straight up at retail, but also is mixed into heroin as an extender and increasingly into other drugs such as cocaine. This practice is facilitated because trafficking organizations now distribute various powdered forms of heroin, not just the traditional "black tar" heroin, which cannot as easily be adulterated with fentanyl.

An economic incentive exists for trafficking organizations to "extend" heroin with fentanyl or to sell fentanyl outright. Fentanyl is thought to be 25 to 50 times more potent than heroin (DEA, 2016d). As a synthetic opioid, it is more economically appealing than natural opioids such as heroin. The Western States Information Network (WSIN) (2016) reports kilogram prices of heroin ranging from $17,000 to $30,000 for Mexican brown and $20,000 to $46,000 for Colombian white (which is also distributed by Mexican drug trafficking organizations), two forms that can readily be cut with fentanyl (Southeast Asian heroin is somewhat more expensive, but has a very minor market share in the United States, especially in the West). While fentanyl manufactured in a lab could be purchased at prices below that of heroin per kilo (DEA, 2016a), fentanyl's potency allows it to be diluted more and still deliver a dangerous dose. In this way, a kilo of drug can be multiplied into 10 to 20 kilos or more of drug for street sale with the addition of fentanyl products. There exist at present only anecdotal reports of wholesale fentanyl prices, but the DEA (2016a, p. 8) cites instances of a distributor selling fentanyl for $3,500 per kilogram, while the DEA's Miami Field Division reports that fentanyl could be purchased for $1,700 per kilogram (DEA, 2016a, p. 8).

The other factor that affects relative price is competition and the presence of substitute products. As with many new synthetic psychoactive products, manipulation of fentanyl contributes to the creation and proliferation of fentanyl analog products in the illegal drug trade and cryptomarkets (Quintana et al., 2017) and a ready source of replacement chemicals.

If fentanyl in wholesale markets costs about one-tenth as much as heroin but is 10–25 times as potent on a pure milligram basis, then heroin "per unit of intoxication" from the customer's perspective is 10–25 times more expensive for drug traffickers. Thus there is an incentive to adulterate heroin (and other drugs) with fentanyl to reduce the costs of materials.

Prices in illegal markets adjust slowly, perhaps because of poor information flows, but they are competitive, and in the long run prices tend to fall in parallel with production costs, at least if one understands costs broadly to include compensation for the various risks involved in distributing drugs (Caulkins and Reuter, 2010; Reuter and Kleiman, 1986). One should not be surprised, then, if over the next half-dozen years, fentanyl continues to displace heroin in illegal opioid markets, and its prices continue to fall, perhaps very substantially.

A related phenomenon is the selling of counterfeit prescription opioid pills, often laced with or containing only fentanyl. The logic for the fentanyl adulteration is compelling. Fentanyl, as noted, is cheaper than heroin, and heroin is cheaper than prescription opioids, so fentanyl-laced counterfeit pills are markedly cheaper than are diverted pharmaceuticals. That this is so is not really surprising, given that production costs for many pharmaceuticals are just a tiny fraction of their sales price in the United States.

Pressing pills is not difficult. Pill presses are not regulated and can be purchased openly in some countries. (It is illegal to bring presses into the United States without notifying the DEA, but criminal organizations ignore that law or do the pressing in other countries.) The DEA (2016a, p. 9) cites prices of under $1,000 for a press that can produce 5,000 pills per hour and die molds selling for a little over $100, so the equipment costs are negligible given that pills often sell for $20 apiece at retail, and perhaps $6.50 per counterfeit pill in bulk. And while it may be difficult to meet the exacting standards for legal pharmaceutical pills, it is not difficult to make counterfeit pills that are potent and indistinguishable from true pharmaceutical pills to the casual observer. Moreover, the street-based purchase environment for the illicit drug consumer often is not conducive to thorough inspection of pills to verify indicia, color, weight, and shape (Green et al., 2015a). Counterfeit pills may serve a purpose for suppliers as well: they may be a relatively safe means of transporting some of the most potent fentanyl analogs (e.g., carfentanyl), and may be perceived as a more economically efficient and controlled dosing mechanism than powdered fentanyl or contaminated illicit powder drugs (if the fentanyl quantity contained in the pill is known to the supplier or purchaser) (Green and Gilbert, 2016). The proliferation of a counterfeit prescription opioid market into the foreseeable future is likely.

Whether the trafficker is pressing it into pills, dividing it to sell outright, or using it to adulterate other powdered illicit drugs, fentanyl's chemical properties leave little room for error. Its potency means that very small quantities can be lethal, and it is sometimes difficult for black market producers to mix and dilute powders with sufficient precision to avoid inadvertently selling quantities that contain a lethal dose. (It is easier to reliably dilute and prepare fentanyl solutions, which can be delivered via metered dose, either intranasally or intravenously, as is typically performed by anesthesiologists in hospitals.)

Again, while prices in illegal markets do not always arbitrage away price gaps swiftly, they tend to do so over time. So as with fentanyl displacing heroin, one can envision counterfeit pills displacing diverted pharmaceutical pills in the coming years, at least for those who have developed OUD. It will be important to track the public health implications of the fentanyl and counterfeit market displacements on the symptoms, prevalence, and severity of OUD.

Smaller-Scale Diversion to Illicit Markets

Thus far, this section has been addressing traditional black markets that involve long distribution chains through which organized criminal groups connect users to (mostly) overseas production. There exists another form of illegal market in which smaller quantities of prescribed medications are diverted and sometimes even sold. This is a sort of retail-to-retail distribution more akin to heavy cannabis users growing their own and selling to other users on the side.

It has long been understood that prescription drugs get diverted into illegal markets in multiple ways (Inciardi et al., 2007), but solid estimates of the relative magnitude of these channels are lacking, for reasons that also have long been understood (Inciardi et al., 2009). It appears that most of the diversion is carried out by individuals who receive prescriptions

lawfully rather than through robberies of pharmacies or delivery trucks and other diversion from the legal, wholesale supply chain.

To understand why, it is important to get a sense of scale. It has been estimated that the United States consumes 39,487 defined daily doses (DDDs)[6] of opioids per million inhabitants per day (Häuser et al., 2016). Multiplying by the U.S. population of 320 million and by 365 days per year indicates that there are approximately 4.6 billion DDDs of opioids per year in the United States.

Respondents to the 2014 NSDUH self-reported 564 million days of use of prescription pain relievers that were not prescribed for them or were taken "for the experience or feeling it caused." As an aside, the majority (61 percent) of those days was among respondents who self-reported enough problems with drugs or alcohol to be judged as meeting the criteria of the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV), for abuse or dependence on drugs or alcohol, and 43 percent was among respondents who met those criteria specifically for "abuse or dependence on prescription pain relievers."

Surveys, moreover, can underestimate drug consumption as a result of respondents' social desirability concerns or inability to recall, among other reasons. Even for alcohol, it has been found that survey self-reports account for only about half of the alcohol known to be sold based on tax records (Cook, 2007). Thus the 564 million self-reported days in the NSDUH may correspond to more like 1 billion actual days. If the average dose per day for NSDUH respondents equals the DDDs underpinning the 39,487 DDDs per million figure, then dividing that 1 billion by the 4.6 billion DDDs posited above, one might speculate that very roughly 20 to 25 percent of prescription opioids in the United States are used nonmedically.

The DEA (2016b, p. 34) reports that in recent years, distributors in the United States disbursed 12–15 billion dosage units of opioid narcotics to retail-level purchasers, suggesting that total diversion is on the order of 2.5–4.0 billion dosage units. By contrast, the DEA (2016b) reports that in the entire country in 2015, only 9.1 million dosage units of opioid narcotics were lost to diversion from the supply chain (e.g., from robberies of pharmacies), while another 1.9 million dosage units were "lost in transit." Those are small numbers compared with the 12–15 billion dosage units disbursed to the retail level and the speculation of something like 2.5–4.0 billion units diverted.

A small number of high-volume, corrupt prescribers can provide substantial supply. ProPublica, for example, reported on Medicare's top 20 OxyContin prescribers for 2010.[7] The 12 prescribers who were charged, were fined, and/or had their medical licenses revoked wrote 17,000 OxyContin prescriptions and more than 56,000 prescriptions for narcotics of all kinds in 2010. Those are prescriptions, not dosage units, and there are many more than just a dozen corrupt doctors. Still, it is not clear that a handful of extreme prescribers can account for a number of dosage units in the billions.

There is slightly better information from the other direction on where people obtained the analgesics they used nonmedically. It is clear from the NSDUH and other sources that most people who use prescription analgesics nonmedically obtain them for free from friends or family,

[6]DDD refers to "the assumed average maintenance dose per day for a drug used for its main indication in adults." It does not necessarily correspond to the recommended or prescribed daily dose for a given patient, which will often differ from the DDD based on such characteristics as age and weight, as well as pharmacokinetic considerations (WHO, 2003).

[7]See https://projects.propublica.org/checkup/oxycontin (accessed January 30, 2017).

and it is believed that in turn, most of those friends and family obtained those drugs from a single doctor (DEA, 2016b; Kennedy-Hendricks et al., 2016). However, for drugs, and for that matter many other consumer goods, a minority of heavy users account for a disproportionate share of consumption. In the 2014 NSDUH, two-thirds of those answering the question about where they most recently had obtained pain relievers for nonmedical use reported use on 50 or fewer days in the past year (i.e., less than weekly), and those users accounted for just 14 percent of the self-reported days of use. To the extent that frequent users also tend to use more per day of use, their share of market demand was even smaller. Conversely, the 8 percent of those respondents who said they had used on 180 or more days in the past year (so every other day or more often) accounted for almost half of the days of use, and presumably well more than half of the consumption. This means that statistics based on numbers of users can differ sharply from those based on a measure related more closely to market demand. For example, people who reported in the 2014 NSDUH that they had obtained nonmedical analgesics most recently by purchasing them—whether from a friend, relative, dealer, or other stranger—tended to be heavy users. So even though they represented just 14 percent of respondents who had used analgesics for nonmedical reasons, they accounted for 25 percent of the self-reported days of use (SAMHSA, 2014).[8]

It is also worth noting that some people who had acquired the drugs most recently by some relatively innocuous means may also have purchased them or obtain them by fraud at other times. Respondents who reported use within the last 30 days account for the majority of days of use, and the NSDUH asks respondents to "Please enter all of the ways that you got the prescription pain relievers you used in the past 30 days." In 2014, fully 39 percent of those individuals reporting days of use indicated that they had bought the drugs at some point in the past month, from a dealer, friend or relative, or the Internet. Another 5 percent denied purchasing but admitted to other illegal behavior (stealing, obtaining fake prescriptions, or taking from a friend or relative without asking), and a further 5 percent had neither bought nor scammed, but had obtained from multiple doctors. Based on these findings, perhaps roughly half of current nonmedical consumption is among people who engage in such tactics at least some of the time. To be clear, this does not mean that half of nonmedical analgesics are obtained using these tactics. Even among the 500,000 respondents who reported buying from drug dealers, 20 percent said they also had obtained in the past month from a single doctor.

This pattern is not new. Figure 4-8 shows that if anything, the proportion of current demand attributable to people who buy analgesics for nonmedical use at least occasionally has been greater in previous years.

Furthermore, all of these statistics apply to those who responded to the questions on this household survey, and household surveys fail badly at capturing the behavior of most problematic users. Caulkins and colleagues (2015a), for example, observe that the NSDUH suggests there were only 60,000 daily or near-daily heroin users in the United States, whereas Kilmer and colleagues' (2014) more comprehensive estimate, drawing on the Arrestee Drug Abuse Monitoring (ADAM) system, among other sources, puts the figure closer to 1,000,000.

[8]Committee calculations. Variable ANLLTS2 = 6 or 8.

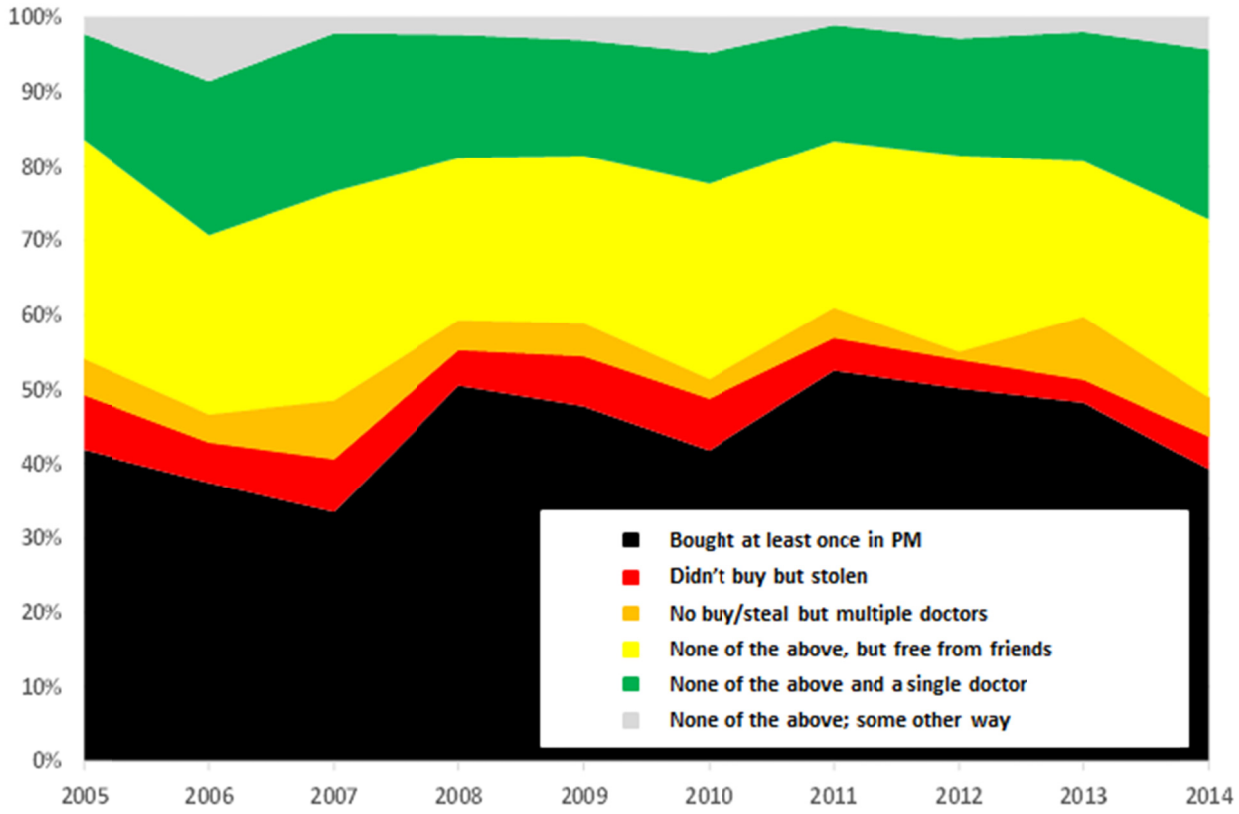


FIGURE 4-8 Proportion of past-month (PM) users' days of use, broken down by whether those individuals reported ever participating in diversion.
SOURCE: Committee analysis of 2005–2014 National Survey on Drug Use and Health (NSDUH) data.

If the people who fell outside the NSDUH's sampling frame were unwilling to complete the survey, skipped these questions, or did not respond truthfully were more heavily involved in diversion relative to those who answered the survey questions forthrightly, then the extent of diversion may be even greater than is suggested by this discussion. Omitted and untruthful responses by individuals within the NSDUH's sampling frame also are a potential source of bias. What is clear is that the scale of diversion is sufficient to enable such organizations as StreetRx.com (Dasgupta et al., 2013) and WSIN (2016, p. 27) to quote black market prices with high geographic specificity not only for such staples as oxycodone, methadone, and hydromorphone (Dialaudid) tablets, but also for buprenorphine (with and without naloxone) and 25, 50, 75, and 100 mcg/hour fentanyl patches.

Trends indicate that for more than a decade, opioid-related harms, including OUD and unintentional overdose, have been growing problems across the country (Calcaterra et al., 2013; Paulozzi, 2012) and the world (EMCDDA, 2015a,b), and are now negating indicators of public health advances and altering both life expectancy (Olshansky et al., 2012) and the very demography of the American populace. The implications of these extensive illicit markets for the evaluation of post-marketing or other policy interventions for prescription opioids, given the current paucity of suveillance capacities (discussed in the section on surveillance below), cannot be overstated.

Summary and Recommendation

Several distinct, well-established markets for opioids exist with overlapping demand in the United States that are likely to persist for the foreseeable future. The products they supply include opioids prescribed, dispensed, and used by patients as medically intended; those prepared as a prescription but not used as intended, including opioids dispensed and misused, as well as those that are diverted before being dispensed (i.e., diverted from lawful channels of commercial distribution, such as wholesalers and pharmacies); and those supplied by drug trafficking organizations, mostly from international sources. Conditions appear ripe for fentanyl and counterfeit prescription pills to continue to spread, with potential effects not only on heroin and other illicit drug markets but also on markets for diverted prescription drugs. These markets are both well established and likely to persist for the foreseeable future. **The committee recommends that, in designing and implementing policies and programs pertaining to prescribing of, access to, and use of prescription opioids, the U.S. Food and Drug Administration, other agencies within the U.S. Department of Health and Human Services, state agencies, and other stakeholders consider the potential effects of these interventions on illicit markets—including both the diversion of prescription opioids from lawful sources and the effect of increased demand for illegal opioids such as heroin among users of prescription opioids—and take appropriate steps to mitigate those effects (Recommendation 4-1).**

THE CURRENT STATE OF SURVEILLANCE SYSTEMS

Since the Institute of Medicine report *Relieving Pain in America* (IOM, 2011) was issued, a remarkable loss of publicly available data sources on drug-related trends has occurred. Four major publicly funded data sources (discussed later in this section) were phased out during this period, and only one has been replaced with a new system; still others remain in validation stages for redesign. In the void created by the defunding of these data sources, proprietary and specialized post-marketing surveillance systems have gained immense importance. The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System and the National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO*)* are two such multimodal data systems. They provide product-level real-time post-marketing surveillance at cost to the pharmaceutical industry, which then uses these data to respond to the FDA REMS and other FDA-related post-marketing reports and inquiries.

RADARS originated as part of Purdue Pharma's risk management activities and was subsequently incorporated into the Rocky Mountain Poison and Drug Center, a division of the Denver Health and Hospital Authority. Its real-time, product-specific data collection includes a survey of key informants across the country, a survey of methadone treatment program attendees, analysis of news and social media mentions, drug diversion investigator surveys, a college student survey, street price analysis, and poison control reports. NAVIPPRO operates a similar system, with real-time data collection via a version of the well-known Addiction Severity Index (ASI), amended to collect product-level information about misuse, route of administration, and drug source. NAVIPPRO is a proprietary dataset owned by Inflexxion, Inc., which created the system through a series of Small Business Innovation Research (SBIR) grants from the National Institute on Drug Abuse (NIDA). NAVIPPRO includes data collected from a national

sample of both adults and young adults attending substance use treatment centers. The data are compiled for analysis together with poison control data and text-based analysis of drug-related online message boards and chatter from drug-use discussion forums. Although both systems have published extensively on their creation, validation, and product-level analyses and are used by pharmaceutical companies, they have not been widely used by public health practitioners and researchers. Sources that report drug-related data are catalogued in Appendix C; those no longer operating since 2011 to date are discussed immediately below.

The Drug Abuse Warning Network (DAWN) was a public health surveillance system created in 1972 that monitored drug-related hospital emergency department visits (DAWN-ED) in order to report on the impact of drug use in metropolitan areas and nationally. While DAWN was never designed to be nationally representative, the system generated estimates at the metropolitan area level and was later used to produce nationwide estimates. In addition, the system was expanded to encompass drug-related deaths investigated by medical examiners or coroners (DAWN-ME) in a selected sample of metropolitan areas. After 2003, DAWN included a real-time data access portal called DAWN Live. The site facilitated quicker access to data for participating sites and public health organizations, with clear indicators of reporting completeness and attendant caveats.

The agent (i.e., product and compound)-level specificity of the data reported in DAWN meant that the pharmaceutical industry and the public had access to product-level information and could compare product impacts, including morbidity and mortality trends, interactively. DAWN was initially overseen by the DEA, then NIDA, and finally SAMHSA, but both DAWN-ED and DAWN-ME were discontinued in 2011 (SAMHSA, 2016b). Thus this resource was unavailable as the opioid epidemic unfolded. In retrospect, the product-level detail in DAWN could have informed decision makers across institutions of the nature and challenge of the prescription opioid and illicit drug crises.

In researching the reasons for the defunding of DAWN, the committee learned of several factors, including frustrations with the sampling frame, incompleteness of data, concerns among industry about the product-level data, cost, and the lack of representation of small-town and suburban communities. In the absence of DAWN, it has become more difficult to track drug-related emergency department visits (Rowe et al., 2016). SAMHSA's new Emergency Department Surveillance System (SEDSS) is intended to serve as the new source of data on drug-related emergency department visits, and will combine aspects of DAWN with the National Center on Health Statistics' (NCHS) National Hospital Care Survey. The timeliness of reporting, geographic specificity, and product-level details of the new system are unknown.

In 2014, two additional key data sources were phased out. First, funding for the Arrestee Drug Abuse Monitoring survey (ADAM II), which had been funded since 2007 by ONDCP, was cut for budgetary reasons (before 2007, an earlier version of the system had been housed in the National Institute of Justice) (Kilmer and Caulkins, 2014; NIJ, 2014). ADAM collected self-reported data and biological samples from arrestees admitted to booking facilities, inquiring about drug use trends and street prices and examining their urinalysis results. The value of the ADAM data was evident in information on trends of illicit drugs other than marijuana, which generated strikingly different estimates from those extrapolated from the NSDUH (Caulkins, 2015a; Kilmer et al., 2014). These data were useful for policy makers, law enforcement, and treatment resource planners. To date, this data source has not been replaced or reinvigorated.

Also phased out was NIDA's Community Epidemiology Work Group (CEWG), a network of local experts in drug-related topics, which had met semiannually to report on drug

trends and emerging issues in sentinel sites from 1976 to 2014. The CEWG experts created metrics and indicators of drug use trends, collaborated on annual reports, and conducted field research on emerging trends. The CEWG was replaced by the National Drug Early Warning System (NDEWS) (NIDA, 2015), which coordinates a listserv, hosts webinars, tracks online media mentions of various drug-related terms and trends, and convenes a virtual network of sentinel sites that conduct local area data collection as requested. Only 3 years into its existence, the NDEWS is not equal to its predecessor in terms of representation, participation, and reach; however, its role and purpose continue to evolve, providing a crucial platform for questions and discussion related to drug use trends for its online and invited membership.

Notably, few of the public and proprietary datasets that have collected self-reported data from people who use drugs have asked respondents about their overdose history. Those that have inquired about overdoses have tended to employ wording that conflates unintentional and intentional (i.e., suicide attempt) overdose or failed to specify or ask separately about overdose on opioids (heroin, pain medication, or MAT medications). More recent efforts to better apply and report emergency department International Classification of Diseases (ICD) E-codes in order to standardize and improve the reporting of hospital-treated overdoses are laudable, but will underestimate the true rate of nonfatal overdose in a community. Capturing the many nonfatal overdose experiences in which the person is not transported to the hospital requires a valid and reliable direct inquiry encompassing all people who use these drugs.

It has been said that one cannot see what one does not count. The absence of agent-specific, real-time, drug-related data has contributed to the severity of the current opioid crisis. The timing of these data losses exacerbated the inability to detect changes in misuse and mortality driven by prescription opioids, and it continues to hinder the nation's capacity to track illicit drug trends and their public health consequences. Cost-effective and nimble data collection systems may be reliable and even timely, but need to be examined rigorously for validity. More critically, the pervasiveness and lethality of illicit synthetic drugs heighten the need to capture agent-level information and concurrent and subsequent drug-using behaviors.

As discussed in Chapters 2 and 3, gaps exist in the reporting of data that can be used to accurately describe the epidemiology of pain and OUD in the United States, including how these conditions relate to one another and how often they co-occur. This chapter has reviewed the interrelated nature of the prescription and illicit opioid epidemics and the limitations of current salient surveillance systems. Closing these data gaps would improve understanding of pain, OUD, and overlapping illicit use, and enable more effective and measurable policy interventions. **The committee recommends that the Substance Abuse and Mental Health Services Administration, the U.S. Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention collaborate to identify best practices and reporting formats that portray the epidemiology of both pain and opioid use disorder accurately, objectively, and in relation to one another (Recommendation 4-2).**

The committee recommends that the National Institute on Drug Abuse and the Centers for Disease Control and Prevention invest in data collection and research relating to population-level opioid use patterns and consequences, especially nonmedical use of prescription opioids and use of illicit opioids, such as heroin and illicitly manufactured fentanyl (Recommendation 4-3). The research proposed in Recommendation 4-3 could include transitions to and cessation of use of heroin and fentanyl; motivations for use; social determinants underpinning misuse and illicit use; and differences arising by sex, gender, race, and ethnicity.

RECENT DEVELOPMENTS IN PHARMACEUTICAL TREATMENT OF OPIOID USE DISORDER

This section highlights the use of pharmacotherapies in the treatment of OUD, with an emphasis on new research and treatment approaches that have emerged since the 2011 IOM report was issued. A review of current trends in access to, utilization of, and outcomes of treatment services is presented in Chapter 5.

The Centrality of Pharmacotherapies in Treatment of Opioid Use Disorder

Medications are central to the treatment of OUD. The three medications approved by the FDA for treatment of OUD are methadone, buprenorphine, and naltrexone (see Table 4-1). There continues to be some debate in the field regarding whether, and under what circumstances, use of these medications should be regarded as necessary or sufficient, a debate that is reflected in the terms used to refer to treatment with these medications. For example, recovery community advocates encourage the use of the term "medication-assisted recovery" to describe the combination of pharmacotherapy and counseling and/or recovery work that they believe patients should undergo. They argue that remission of SUD achieved through use of medication alone is not genuine because without counseling, the person may not have achieved the interpersonal and spiritual changes deemed necessary for lasting recovery. The assumption is that only by participating in regular counseling and adjunctive treatment services can people attain signficant recovery achievements. As an alternative, WHO uses the term "psychosocially assisted" pharmacotherapy, to capture the central role of medications in the treatment of OUD (WHO, 2009). It is both critical and convenient for the purposes of this report that the most effective approaches for treating OUD are those within the purview of FDA.

The committee has chosen to use the acronym MAT to refer to the use of pharmacotherapies in treatment of OUD. As explained in Box 1-2 in Chapter 1, MAT may be defined to refer either to "medically assisted treatment" (use of medications in combination with counseling and behavior therapies to treat OUD) or to "medication for addiction treatment" (implying that medication may be used alone, but need not be). The committee has chosen to use MAT to embrace this ambiguity instead of opting for one definition or the other. For purposes of this report, the only material scientific conclusion is that medications should play a central (if not exclusive) role in treatment of OUD, a view strongly supported by the scientific literature.

A 2009 Cochrane systematic review found that opioid agonist treatment without counseling is more effective than being waitlisted for treatment or receiving psychosocial treatment with or without placebo (Mattick et al., 2009). These findings were affirmed by recent results from the NIDA Clinical Trials Network's Prescription Opioid Addiction Treatment Study (POATS), in which a randomized controlled trial examined buprenorphine-naloxone treatment of varying durations and counseling of varying intensities among patients dependent on prescription opioids. It was found that patients receiving individual counseling for OUD in conjunction with the medication (weekly 45- to 60-minute sessions with a trained mental health or substance abuse professional) showed no additional benefit over those receiving standard medical management (15- to 20-minute visits with a physician certified to prescribe the medication) (Weiss et al., 2011). Similarly, a study of more intensive counseling in the setting of office-based buprenorphine prescribing compared with medication only showed no superior patient outcomes (Fiellin et al., 2006). On the other hand, one study in a veteran population showed superior

outcomes for patients receiving methadone coupled with counseling compared with medication-only treatment (McLellan et al., 1993).

The central importance of medication treatment is further affirmed for patients with prescription OUD in a recent evidence synopsis by Nielsen and colleagues (2017, p. 967), who found that "long-term maintenance of opioid agonists is associated with less prescription opioid use and better adherence to medication and psychological therapies for opioid dependence compared with opioid taper or psychological treatments alone." In addition, no differences in efficacy were observed between methadone and buprenorphine maintenance therapies (Nielsen et al., 2017). While the studies across this literature were not exhaustive in the psychological therapies tested, and therefore should not be construed as suggesting that all such approaches are ineffective, the data consistently indicate clinical utility and improvements in quality of life for people with OUD who receive medication treatment.

Instistence on provision of counseling is an important factor in access to burprenorphine. According to state regulations and accrediting standards, opioid treatment programs are required to provide a minimum of counseling services each month. Yet the literature shows that counseling may help engage people in their recovery, but may not be necessary or effective beyond the provider–patient clinical sessions. The inability to provide the recommended OUD treatment services alongside prescription buprenorphine does not indicate inferior treatment, and withholding prescription buprenorphine from a patient with OUD if these services are unavailable, as may be the case as a result of insurance companies' prior authorization requirements for buprenorphine—may be lethal.

Data from studies of methadone treatment programs provide a compelling rationale for medication-only treatment when this is the only available option. Schwartz and colleagues (2012), for example, compared mortality rates among patients with OUD treated with methadone in a treatment program providing counseling services with similar patients on a waitlist for the program treated only with medication (i.e., interim dosing) and with waitlisted patients not receiving interim dosing. Mortality rates were comparably reduced for patients receiving MAT with or without supportive counseling, but were significantly higher among patients who received no medication (Schwartz et al., 2012). In a randomized trial, patients receiving MAT without counseling also showed lower HIV risk behaviors, suggesting that this approach could reduce the risk of bloodborne virus transmission (Wilson et al., 2010). A recent systematic review of interim methadone dosing studies concluded that this approach helped bridge gaps due to treatment shortages, improved patient outcomes, and warranted expansion to assess generalizability (Sigmon, 2015). And in a small randomized pilot study, participants assigned to interim dosing with buprenorphine combined with technology-assisted components to support adherence showed a statistically significant reduction in the use of illicit opioids and intravenous drugs compared with waitlist controls, indicating that interim therapy may be suitable when treatment options are limited. The authors note that additional studies with larger samples and longer follow-up periods are needed (Sigmon et al., 2016).

Notably, other countries that provide pharmacotherapies to treat patients with OUD do not impose counseling and psychotherapy as a requirement for receipt of treatment; indeed, the provision of medication in combination with counseling is not common. In the United Kingdom, for example, pharmacotherapies are dispensed daily or less frequently to patients through community pharmacies, and patients with OUD are managed by general practitioner–assisted teams of SUD treatment specialists (NICE, 2007). Counseling and psychological therapies may be used, but are not a condition or expectation for receipt of medication.

The literature is consistent in finding that the longer a person with OUD is treated and maintained on medication for the disorder, the better are their health outcomes. This consistent finding argues against the application of a tapering approach, a detoxification model, and the expectation that short-term courses of therapy can treat OUD effectively. It further supports a long-term, maintenance model of provision of pharmacotherapy and the need for a more diverse product environment for FDA-approved medications for treatment of OUD. In fact, short-term treatment for OUD, especially in the case of abstinence-based treatment, but also with medications, is associated with increased mortality risk (Woody et al., 2008).

The following subsections briefly describe the medications available for treatment of OUD, whose characteristics are summarized in Table 4-1.

TABLE 4-1 Characteristics of Medications for the Treatment of Opioid Use Disorder

Characteristic	Methadone	Buprenorphine	Naltrexone
Selected Brands	Dolophine, Methadose	Subutex,* Suboxone, Zubsolv	Depade, Revia, Vivitrol
Class	Agonist (fully activates opioid receptors)	Partial agonist (activates opioid receptors but produces a diminished response even with full occupancy)	Antagonist (blocks the opioid receptors and interferes with the rewarding and analgesic effects of opioids)
Use and Effects	Taken once per day orally to reduce opioid cravings and withdrawal symptoms	Taken orally or sublingually (usually once per day) to relieve opioid cravings and withdrawal symptoms	Taken daily orally or monthly by injection to diminish the reinforcing effects of opioids (potentially extinguishing the association between conditioned stimuli and opioid use)
Advantages	High strength and efficacy as long as oral dosing (which slows brain uptake and reduces euphoria) is adhered to; excellent option for patients who have no response to other medications	Eligible to be prescribed by certified physicians, nurse practitioners, and physician assistants, which eliminates the need to visit specialized treatment clinics and thus widens availability; lower risk of overdose	Not addictive or sedating and does not result in physical dependence; a recently approved depot injection formulation, Vivitrol, eliminates the need for daily dosing
Disadvantages	Mostly available through approved outpatient treatment programs, which patients must visit daily; respiratory depression; abuse liability	Subutex* has measurable abuse liability; Suboxone diminishes this risk by including naloxone, an antagonist that induces withdrawal if the drug is injected; for Subutex and Suboxone, withdrawal in patients dependent on methadone or short-acting prescription opioids	Poor patient compliance with the oral form (but Vivitrol should improve compliance); initiation requires attaining prolonged (e.g., 7-day) abstinence, during which withdrawal, relapse, and early dropout may occur; overdose fatality due to self-discontinuation and hypersensitized μ opioid receptors

*Subutex (a single-agent buprenorphine product) is no longer on the market in the United States. However, multiple other generic single-agent buprenorphine products are available.
SOURCE: Adapted from Volkow et al., 2014.

Methadone

Response to methadone appears to be dose related. Mean response at 1 year is approximately 60 percent, but differs based on a host of patient factors and adherence to evidence-based dosing practices (Bart, 2012). Methadone is a full opioid agonist that was invented in Germany in the late 1930s for use during World War II as a cheaper and easier-to-manufacture analgesic alternative to the opioids available at the time (Strang and Tober, 2003). It was approved for use in the United States shortly after the end of the war and started being used to treat opioid withdrawal within 1 year (Isbell et al., 1947). A few decades later, in the 1960s, it began to be investigated for maintenance therapy for OUD (Dole and Nyswander, 1965). For reasons that may have to do with its antagonism at the NMDA (N-methyl-D-aspartate) receptor, tolerance does not increase for methadone the way it often does for other opioids (Davis and Inturrisi, 1999). This feature, along with its low cost, makes methadone an ideal medication for long-term maintenance therapy for OUD.

In the 50 years since first being used to treat OUD, methadone has been the subject of hundreds of studies evaluating its efficacy and safety. Several large-scale studies in the 1970s and 1980s showed that 25–45 percent of people with OUD who were treated with methadone remained drug-free after 1 year (Hubbard and Marsden, 1986; IOM, 1995; Sells et al., 1979). Modern reviews confirm these findings, and observe further that retention in treatment is greater for people on methadone than for those in treatment who are not receiving pharmacotherapy (Mattick et al., 2009).

Methadone's safety also has been well established, having been documented extensively for at least 40 years (Kreek, 1973). While methadone can, like all opioids, lead to respiratory depression, most cases of overdose involving methadone stem not from its use to treat OUD but its less tightly regulated use as a pain medication (SAMHSA, 2007). Among patients with OUD, it has been shown that more intensive monitoring of medication dosing is associated with decreased mortality (Bart, 2012; Strang et al., 2010).

Buprenorphine

Buprenorphine was the first opioid medication to become available in the United States since 1914 that could be used for OUD maintenance treatment in primary care settings. FDA approval of buprenorphine came in 2002. Since that time, several forms of buprenorphine have been approved, as a single entity or formulated in combination with naloxone to protect against tampering (see Box 4-1), in pill form and as sublingual film, and in varying flavors. A systematic review of 16 randomized controlled trials on the efficacy of buprenorphine found that it is associated with improved outcomes compared with placebo for individuals and pregnant women with OUD (Thomas et al., 2014).

The Drug Addiction Treatment Act of 2000 (DATA 2000) broadened the types of clinical settings where MAT for OUD could be provided. In the two decades prior to its passage, only opioid treatment programs could dispense Schedule III–V medications used to treat OUD. DATA 2000 specified that qualified providers are permitted to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications (medications with a lower risk for misuse, such as buprenorphine) in settings other than an opioid treatment program (SAMHSA, 2017b).

BOX 4-1
Buprenorphine-Naloxone

Buprenorphine-naloxone (Suboxone) is an effective treatment for opioid use disorder (OUD). Accessing the drug, however, has proven problematic. For example, a 2003 survey revealed that 31 percent of 814 private health plans did not cover it. Of those that did, 80 percent placed it in tier three of their formulary, requiring the highest level of patient copayment. One reason for this was the drug's high price, set initially by Reckitt Benckiser at almost $300 per month.

In addition, using a combination of tactics, Reckitt kept the price of buprenorphine-naloxone artificially high over time by forestalling generic competition. First, as the end of market exclusivity approached for the original tablet formulation, the company introduced a sublingual film version of the drug. Following the U.S. Food and Drug Administration's (FDA's) approval of this modified formulation in 2010, Reckitt ceased producing the tablets. With Abbreviated New Drug Applications (ANDAs) for generic buprenorphine-naloxone tablets pending before the FDA, Reckitt then submitted a Citizen Petition requesting that the agency reject such products, claiming that tablets were less safe than film. The FDA denied the petition 5 months later but was forced to delay its approval of the ANDAs over this time.

Finally, Reckitt capitalized on a relatively new FDA post-market safety program: Risk Evaluation and Mitigation Strategies (REMS). Possible REMS components include medication guides for patients; communication plans for physicians; and—for drugs raising the most serious safety concerns—elements to assure safe use (ETASU), such as mandatory prescriber or pharmacy certification and patient follow-up testing. Brand-name and generic manufacturers of a drug must generally use a shared ETASU REMS. However, in the case of the ETASU REMS for buprenorphine-naloxone, Reckitt refused to cooperate on a shared system. As alleged in a complaint filed by 37 states in 2016, Reckitt "merely feigned cooperation with the shared REMS development process and used deceptive tactics for months to hide its true intent, which was to delay the generic industry from obtaining" approvals.

These strategies effectively forestalled generic competition for several years, keeping the drug's price artificially elevated and reducing access to this OUD treatment.

SOURCE: Sarpatwari et al., 2017.

While expanding the types of health professionals and the places where people with OUD could find treatment, DATA 2000 also specified a cap on the number of patients per prescriber who could be treated, as well as the requirements of providers who opted to provide office-based treatment. Providers must apply to SAMHSA to provide buprenorphine treatment beyond a 30 patient limit for up to 100 patients with OUD (SAMHSA, 2017a). In 2016, two changes aimed at improving access to buprenorphine treatment were announced. First, providers who have prescribed buprenorphine to 100 patients for at least 1 year can apply to increase their patient limit to 275 (SAMHSA, 2017a). Second, the 2016 Comprehensive Addiction and Recovery Act extended buprenorphine prescribing privileges to physician assistants and nurse practitioners for 5 years (until October of 2021) (ASAM, 2017), with rigorous training requirements in place to ensure consistent and careful prescribing.

Importantly, DATA 2000 did not require prescribers with a waiver to prescribe buprenorphine for OUD to provide other treatment services (i.e., counseling, group therapy) as well. Rather, the act states only that it is recommended that such services be provided or

coordinated. While many providers prescribing buprenorphine are SUD specialists, and many others recognize the importance of ensuring coordination of SUD treatment services, many do no more than prescribe medication. As discussed earlier, many believe that optimal care for OUD involves providing medication accompanied by supportive counseling and other treatment services.

Since buprenorphine may be dispensed within an office-based practice and methadone can be dispensed only within an opioid treatment facility, buprenorphine has the potential to provide better access to treatment. Many areas of the country have limited numbers of opioid treatment facilities or facilities that lack the capacity to meet demand (see Figure 4-9). Additionally, although methadone regulations require that opioid treatment facilities give priority to pregnant women, facilities are not always compliant. Preference for an office-based system of care also often makes buprenorphine preferable since the requirements for onsite dosing differ significantly from those for an opioid treatment facility. However, the delivery system for buprenorphine functions well below capacity. A recent study found that the majority of physicians with waivers to prescribe buprenorphine were doing so well below the limits allowed by law, with fewer than 10 percent prescribing to at least 75 patients (Stein et al., 2016). How this gap impacts special populations such as pregnant women is unknown, but anecdotally, many pregnant women report they were discharged from care for OUD upon becoming pregnant, and many prescribers report being unwilling to provide care to pregnant women. It is possible that for many pregnant women with OUD, the context and structural challenges of receiving MAT contribute substantially to the severity of NAS. (See the section below on pharmacotherapies for treatment of pregnant women with OUD.)

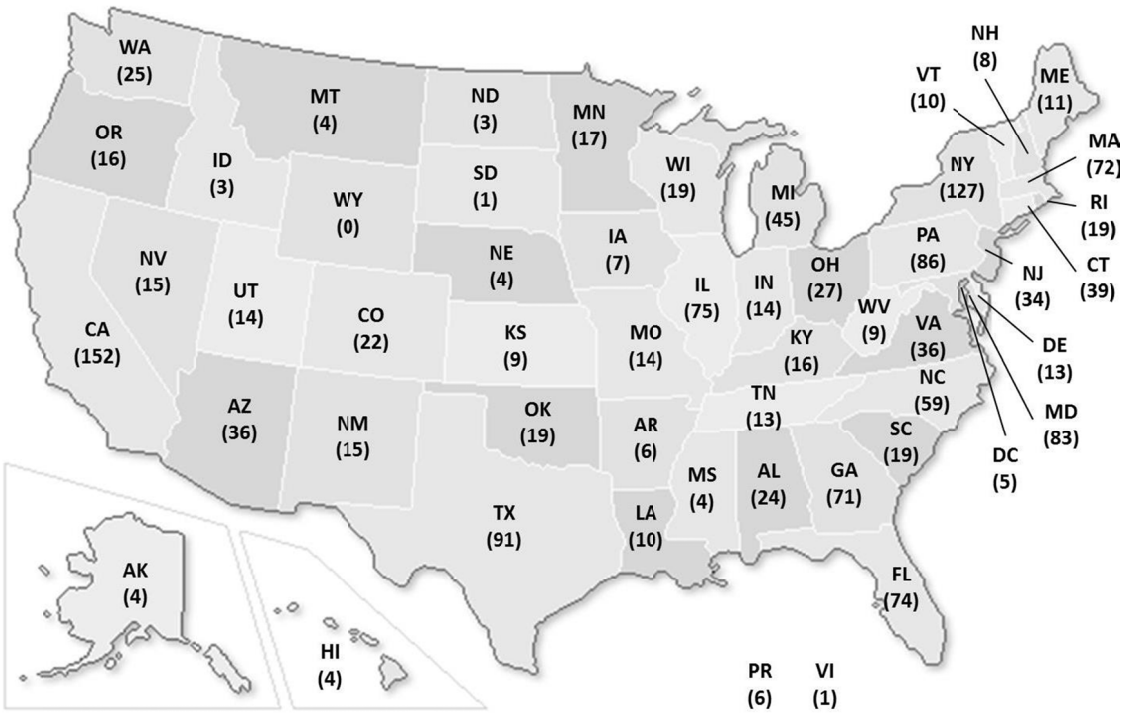


FIGURE 4-9 Number of opioid treatment programs certified by the Substance Abuse and Mental Health Service Administration (SAMHSA) by state, 2016.
SOURCE: SAMHSA, 2016b.

In addition, significant disparities in the use of buprenorphine have been documented. A recent review of the literature found that buprenorphine patients are largely white, are employed full time, are seeking treatment for heroin or prescription OUD, are treated in private physician practices, and pay out of pocket or are privately insured (Duncan et al., 2015). Furthermore, a study in New York City found neighborhood-level disparities, with the highest buprenorphine prescription rates being in high-income residential areas with low percentages of African American and Hispanic residents (Hansen et al., 2016). The authors note that these disparities may be attributable to buprenorphine marketing to the private sector (primary care physicians represent 65 percent of buprenorphine maintenance providers) and perceptions that this form of treatment is most appropriate for employed patients. Despite increased numbers of buprenorphine providers, moreover, 43 percent of U.S. counties had no buprenorphine-waivered physicians as of 2011 (Stein et al., 2015). The authors argue that because of buprenorphine's greater effectiveness relative to methadone in the treatment of OUD; its suitability for varying therapeutic settings, including public health care systems; and its additional advantages (e.g., less required oversight, potential to reduce stigma, increase in treatment of comorbid health and psychiatric conditions), its accessibility in such settings should be promoted as a first line of treatment.

Naltrexone

Naltrexone is a μ opioid receptor antagonist, and when formulated as naltrexone ER has been shown to be safe and effective in treating OUD. Accordingly, the FDA approved the naltrexone ER product in 2011. The evidence for oral naltrexone's effects on craving in OUD is less clear than that for its effects on craving in alcohol addiction (Bart, 2012), and the oral formulation is not recommended or widely used for treating OUD. However, the long-acting form of naltrexone, which is implanted under the skin, is more effective than a daily pill because it eliminates problems with adherence (Comer et al., 2006; Krupitsky and Blokhina, 2010; Krupitsky et al., 2012). Patients using long-acting naltrexone are three times more likely than those using oral naltrexone to remain relapse-free after 6 months (Krupitsky et al., 2012).

Some have questioned the findings of pivotal efficacy studies of naltrexone and raised additional safety concerns about naltrexone ER related to overdose (Wolfe et al., 2011). A meta-analysis of cost and utilization outcomes between naltrexone ER and other pharmacotherapies for treatment of OUD found that patients with OUD taking naltrexone ER had lower inpatient substance misuse–related utilization relative to those taking other agents, and had $8,170 lower total costs relative to those taking methadone (Hartung et al., 2014). With respect to clinical outcomes, however, it is unclear whether naltrexone ER is as effective as methadone and buprenorphine in reducing the risk of fatal overdose and other drug-related health and quality-of-life outcomes. Lee and colleagues' (2015) study of outcomes in jail-initiated naltrexone ER found reductions in opioid use and increased abstinence, while findings on secondary outcomes suggested lower risk of overdose compared with controls. Another trial examined naltrexone ER compared with treatment as usual for the prevention of opioid relapse among individuals in the criminal justice system. No overdoses occurred in the naltrexone group compared with seven in the usual treatment group. Individuals assigned to naltrexone ER also had significantly lower rates of relapse than those in the usual treatment group (43 percent versus 64 percent) (Lee et al., 2015). While promising, these findings have not been replicated in other populations and settings.

Other Alternatives

In Europe, Canada, and Australia, other opioids have been used successfully for opioid maintenance treatment to reduce the risks of injection of illicit opioids. For example, several trials using slow-release morphine (Ferri et al., 2013), heroin (Ferri et al., 2011), and hydromorphone (Oviedo-Joekes et al., 2016) for patients who had not done well with methadone showed positive outcomes (Strang et al., 2015).

Prescription of heroin also is integrated into the treatment systems of several European countries (Uchtenhagen, 2010). Supervised injectable heroin (SIH, or diamorphine) may be an effective treatment for heroin dependence refractory to standard treatment, although it is less safe than methadone maintenance treatment and therefore requires more clinical attention to manage safety issues (Strang et al., 2015). A systematic review and meta-analysis identified six randomized clinical trials of SIH and concluded that among patients with OUD involving heroin, those receiving SIH compared with control groups (most often receiving methadone maintenance treatment) demonstrated better outcomes with respect to greater reduction in use of illicit heroin (Strang et al., 2015).

Pharmacotherapies for Treatment of Women with Opioid Use Disorder Who Are Pregnant

The use of MAT for the treatment of women with OUD who are pregnant has a long history, beginning with the implementation of methadone pharmacotherapy in the late 1960s. Initially, the FDA mandated methadone-assisted withdrawal for pregnant women, but it quickly reversed this decision following the occurrence of adverse pregnancy events (Blinick et al., 1969; Jones et al., 1999). Currently, questions often arise about exposure of the fetus to the medication as the newborn may experience withdrawal that requires treatment, and there have been calls recently for pregnant women wth OUD to be withdrawn from all opioids, including treatment medications. However, the risk of withdrawal is deemed much less important than the benefits of treatment. The 1993 and 2004 SAMHSA Treatment Improvement Protocols for OUD, the 1997 National Institutes of Health Consensus Panel on Effective Medical Treatment of Opioid Addiction, the 2012 American College of Obstetricians and Gynecologists and American Society of Addiction Medicine Joint Opinion, the WHO 2014 Guidelines for the Identification and Management of Substance Use and Substance Use Disorders in Pregnancy, and the 2016 SAMHSA Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders all recommend MAT for pregnant women as the standard of care. The underlying principle behind the use of MAT during pregnancy is that it prevents erratic maternal opioid levels and protects the fetus from repeated episodes of withdrawal. In addition, it ensures that the woman is engaged in the health care system and promotes prenatal care, which results in healthier outcomes for both mother and infant (Kaltenbach et al., 1998).

The emergence of the implementation of methadone pharmacotherapy for pregnant women with OUD coincided closely with the creation of NIDA. One of NIDA's first endeavors was to fund a number of research demonstration projects in 1974 implementing treatment programs for pregnant women with OUD. This research provided the foundation for the model of care that emerged in the 1980s. Another major contributor to the development of treatment for this population was the funding source created by SAMHSA's Pregnant and Postpartum Women's project, initiated in the early 1990s, which is still part of the agency's portfolio.

The treatment options that exist today are an extension of the original model, which began with the premise that services for pregnant women must be comprehensive, to include not only treatment of OUD but also obstetrical, medical, and psychiatric care. Research has shown that women with SUD, including OUD, have a complex array of biopsychosocial problems that must be addressed if treatment is to be successful and recovery sustained (Comfort and Kaltenbach, 1999).

The framework for treatment is grounded in the premise that the treatment should be woman-centered (i.e., responsive to the specific needs of the individual); trauma-informed (i.e., recognizing the role of trauma and violence in the lives of women); strengths-based (i.e., focusing on strengths rather than deficits); and culturally competent (i.e., acknowledging the role of culture, ethnicity, race, racism, and sexual orientation) (SAMHSA, 2009). The treatment approach should be multidisciplinary and include pharmacotherapy with methadone, buprenorphine, or buprenorphine-naloxone. Initiation of naltrexone currently is not recommended in pregnant women.

At present, the field is for existing recommendations to reflect new data. The current recommendation that the combination product buprenorphine-naloxone not be used was published in 2004 and was based on a lack of data on infant exposure to naloxone. And although there have been no salient randomized controlled trial data to date, several studies have shown no difference in infant outcomes between the single-entity and combination products, with the latter being used by many providers (Debelak et al., 2013; Lund et al., 2013; Wiegand et al., 2015). In addition to pharmacotherapy supports, a multidisciplinary approach would involve not only obstetrical, medical, and psychiatric services but also individual and family therapy, trauma services, case management, parent–child services, and liaison relationships with the department of human services. Treatment modalities encompass traditional levels of care, including outpatient, intensive outpatient, and women and children residential care.

Although the efficacy of comprehensive treatment for pregnant women with OUD has been well established, the number of programs available to provide such services is extremely limited. Nationally, there exist only 20 residential treatment programs for pregnant and parenting women funded under the SAMHSA portfolio, and of those, only three provide treatment specific to OUD. Among the 1,450 opioid treatment programs (see Figure 4-9), it is estimated that no more than 12 programs provide specialized treatment for pregnant women. Moreover, treatment for pregnant women often is fragmented and may be impeded when collaboration is lacking among the opioid treatment facility, obstetrician, pediatrician, and hospital.

In light of these limited services, newer models of collaboration among multiple systems of care have emerged within the past few years to provide comprehensive care to pregnant women with OUD. Excellent examples of collaboration among the state, medical providers, and treatment providers are the Vermont Children and Recovering Mothers (CHARM) Collaborative and the Ohio Maternal Opiate Medical Support (MOMS) project. CHARM involves 10 organizations, including hospitals, treatment providers, state agencies, maternal and child health programs, and the visiting nurse association aimed at providing comprehensive care coordination for pregnant women with OUD.[9] The MOMS project, funded by the state of Ohio, employs a maternity care home (MCH) model in four sites across the state. Each site is unique, but all utilize the MCH team-based care delivery model, which emphasizes coordination of

[9]See SAMHSA's Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders (SAMHSA, 2016c) for a detailed description.

community services and treatment for OUD, including pharmacotherapy, case management, and prenatal care.[10] Additionally, a new model based on Project ECHO (Extension for Community Healthcare Outcomes)[11] is currently being examined to provide support and improve care in treatment programs for pregnant and postpartum women with SUD. Project ECHO is based on an approach in which telemonitoring utilizes case-based learning to focus on best practices. The ECHO model is based on a hub-and-spoke knowledge-sharing network led by a team of "experts" using video conferencing to conduct virtual clinics with community providers.

Other treatment matters to be addressed for this vulnerable population are centered on the medications used. Since the FDA approved buprenorphine in 2002, there have been two medications to use in treating pregnant women with OUD. The two have different benefits and disadvantages, but the basic tenets of treatment are the same.

The efficacy criterion for the choice of medication for pregnant women with OUD (i.e., methadone or buprenorphine) has not yet been established. However, data from a multisite randomized controlled trial that compared maternal and infant outcomes among women maintained on methadone with those of women maintained on buprenorphine often are cited as a determining factor. The study found that, although there was no difference in the number of infants that required treatment for NAS, infants exposed prenatally to buprenorphine required 89 percent less morphine to treat NAS, spent 58 percent less time in the hospital being medicated for NAS, and spent 43 percent less time in the hospital overall relative to infants exposed prenatally to methadone (Jones et al., 2010).

A systematic review and meta-analysis of 12 studies, including the above-cited randomized controlled trial, found that infants explosed prenatally to buprenorphine had better outcomes than methadone-exposed infants with respect to treatment duration, morphine dose, birth weight, length, and head circumference (Brogley et al., 2014). These findings have led some practitioners to recommend always that buprenorphine rather than methadone be used for pregnant women. Ideally, however, treatment will be based on what is best for both the mother and child; each woman's medical, psychological, and substance use history must be considered in any treatment decision. As a partial agonist, for example, buprenorphine may not be as effective as methadone for certain women. Without data to guide decisions, however, the current recommendation is that women with OUD who are naïve to agonist treatment may be good candidates for buprenorphine. If women do not respond to buprenorphine, transfer to methadone can easily be initiated. In any case, it is recommended that women successfully stabilized on methadone or buprenorphine who become pregnant remain on their current medication (Jones et al., 2012). And the 2012 Joint Opinion of the American College of Obstetricians and Gynecologists and American Society of Addiction Medicine recommends the use of either methadone or buprenorphine.

Although withdrawal often is cited as a way to reduce NAS, there is no evidence based on an intention-to-treat analysis that withdrawal without medication is beneficial to the mother, fetus, or infant. In addition, limited data suggest that infant treatment outcomes with buprenorphine may be similar to those of withdrawal. A long history of concern regarding withdrawal during pregnancy also merits consideration. Adverse fetal events that occurred in the

[10]See www.momsohio.org for further information.

[11]Project ECHO, developed at the University of New Mexico to address hepatitis C, is now used throughout the United States and other countries to address 40 different subject areas. There are 14 institutions in the United States conducting pain management ECHOs. See http://echo.unm.edu for more information.

1970s as a result of withdrawing pregnant women from methadone led to recommendations that withdrawal be initiated only in the second trimester because of safety concerns, such as fetal demise in the first trimester of pregnancy and prematurity in the third trimester. In the 1990s, however, research indicated that with appropriate fetal monitoring, women could be withdrawn safely at anytime during pregnancy (Jarvis and Schnoll, 1994). Yet the question is not whether withdrawal can be done safely but whether it should be done at all. A summary of the recent literature on medication-assisted withdrawal during pregnancy indicates that it can be safe and may be associated with less NAS and improved birth weights. When given a choice, however, approximately 50 percent of women choose medication treatment rather than withdrawal, and among those who are undergoing withdrawal, the risk of relapse is high (Bell et al., 2016; Dashe et al., 1988; Jones et al., 2008; Lund et al., 2012; Stewart et al., 2013). A recent commentary by Jones and colleagues (2017) speaks to the lack of evidence supporting a clear benefit of medication-assisted withdrawal for the maternal–infant dyad, as it increases the risk of poor treatment engagement and relapse for the mother and does not improve the health of or significantly reduce the occurance of NAS in the infant. The WHO 2014 *Guidelines for the identification and management of substance use and substance use disorders in pregnancy,* the 2012 American College of Obstetricians and Gynecologists and American Society of Addiction Medicine *Opinion No. 524: Opioid Abuse, Dependence, and Addiction in Pregnancy*, and SAMHSA's 2016 *A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders* all recommend treatment rather than withdrawal because of the high rate of relapse that places the fetus at additional risk.

Access to care for pregnant women with OUD also is driven by state policies. Office-based provision of buprenorphine is covered by Medicaid in all states and the District of Columbia, but provision of methadone is covered only in 31 states and the District of Columbia. A recent study by Angelotta and colleagues (2016) found that fewer than 50 percent of pregnant women with OUD received MAT. The most important factors associated with lack of MAT were referral source, geographic location, Medicaid funding for methadone, and state laws permitting child abuse charges for illicit drug use in pregancy. Pregnant women referred to treatment by the criminal jusctice system were the least likely to receive MAT, especially in states with prenatal child abuse laws (Angelotta et al., 2016). As might be expected, lack of Medicaid coverge also was a factor, but there was a high correlation as well between lack of Medicaid funding for methadone and state prenatal child abuse laws. Absent better coordination between medical standards of care and public policy at both the national and state levels, the provision of effective treatment for this at-risk population will continue to be fragmented at best.

Summary

Three underutilized, efficacious medications are available for the treatment of OUD. Few new products for treatment of OUD have entered the market, although several new modes of medication delivery have emerged. Even for special populations such as pregnant and postpartum women, medication therapy is the standard of care. Expected side effects of opioid exposure in utero, such as NAS, can be treated and symptoms abated with no current evidence of long-term effects.

TRENDS IN TREATMENT OF OPIOID OVERDOSE WITH NALOXONE

The term "overdose" is used to describe the poisoning event that occurs when opioid exposure results in respiratory depression, morbidity, or mortality. The onset of respiratory depression caused by exposure to opioids may progress to severe, life-threatening symptoms within a matter of minutes to hours depending on a number of factors, including the drug involved (e.g., rapid-onset medications such as fentanyl), the presence of other drugs in the individual's system, the route of administration (i.e., injection hastens delivery of opioids to the bloodstream and speeds crossing of the blood–brain barrier, bringing on respiratory depression, among other physiological reactions), and the individual's health condition (e.g., a respiratory condition or metabolic distrubance can worsen symptoms more rapidly) (EMCDDA, 2016). Therefore, although a single large dose can cause severe respiratory depression and death, overdoses occur at varying opioid doses in individuals with compromised breathing, metabolic conditions, or altered opioid tolerance (Sporer, 1999), and even at therapeutic levels when used in combination with other central nervous system depressants such as benzodiazepines (as reviewed above) or alcohol.

Use of Naloxone to Treat Overdose

Naloxone, a synthetic N-allyl derivative of oxymorphone and an opioid antagonist, was first synthesized in 1961 by Jack Fishman and investigated by Harold Blumberg. The discovery was the first of its kind, an antagonist with the ability to avoid agonistic activity through prevention or elimination of agonistic narcotic binding. Also related to its antagonistic activity, naloxone uniquely reverses opioid-induced respiratory depression and may precipitate withdrawal. Naloxone was approved by the FDA in 1971 as a diagnostic and therapeutic agent for the treatment of opioid-induced respiratory depression and is currently on the WHO Model List of Essential Medicines (WHO, 2015).

Adverse reactions and consequential events associated with naloxone are well established in the literature. Serious complications (seizure, pulmonary edema, asystole, cardiac arrest) following naloxone administration are reportedly rare (occurring in between 0.3 and 1.6 percent of individuals) (Buajordet et al., 2004; Osterwalder, 1996; Yealy et al., 1990) and could be related to the overdose itself as opposed to the naloxone. Opioid withdrawal symptoms (confusion, headache, nausea or vomiting, aggressiveness, tachycardia, sweating, and tremor) are expected in opioid-dependent persons (Buajordet et al., 2004; Osterwalder, 1996; Terman, 2012; Yealy et al., 1990). Also reported in postoperative patients are hypotension, hypertension, ventricular tachycardia and fibrillation, and pulmonary edema. Naloxone is light-sensitive, is recommended to be stored at room temperature, and typically has a shelf life of 18 to 24 months. It is safe, effective, and nonaddictive and lacks contraindications except for a possible rare allergic reaction (Hardmann et al., 2001; Sporer, 1999, 2003).

While use of naloxone over the past 40 years has been primarily by trained health professionals in research, hospital, and prehospital settings, community activism since the late 1990s on the part of harm reduction organizations and people who use drugs has moved it to the forefront of efforts to address the opioid crisis. As of 2014, 136 opioid overdose prevention and response programs collectively managed 644 naloxone distribution sites throughout the United States, distributing naloxone kits to 152,283 laypersons and reporting 26,463 overdose reversals (between 1996 and 2014) (Wheeler et al., 2015). In addition to the pharmacologic and extensive

clinical application literature, the evidence base for expanded community access to naloxone is growing. Data show that educating and providing naloxone to people who are at risk of witnessing or experiencing overdose is associated with reduced heroin consumption (Seal et al., 2005), fewer opioid-related emergency department visits (Coffin et al., 2016), and a 30–45 percent decrease in opioid overdose death rates at the community and individual levels (Bird et al., 2016; Walley et al., 2013). Increasing the availability of naloxone, therefore, is a central component of population-level efforts to prevent opioid overdose deaths, as illustrated by the U.S. Department of Health and Human Services having identified access to naloxone as one of three main strategies for addressing the national opioid epidemic (HHS, 2016).

In the United States, naloxone is available only by prescription, although many states and locales have implemented innovative models of expanded community access to naloxone, such as standing orders (whereby pharmacists are permitted to offer the medication broadly under a prescriber's order and according to the prescriber's stipulations); collaborative pharmacy practice agreements (whereby pharmacists are permitted to manage the medication on behalf of a prescriber after fulfilling certain training and documentation requirements); or other regulatory changes (Green et al., 2015b) designed to enable more first responders and laypersons to obtain naloxone from community organizations or pharmacies, to carry the medication, and to use it to reverse a witnessed overdose. Additional laws and policies aimed at providing broader access to naloxone at low or no cost to people at risk of opioid overdose are emerging across the country (see Chapter 5 for discussion of these policies). In addition, the trusted, privileged, and critical access to people who use drugs afforded by these programs is particularly important as the opioid epidemic becomes dominated more by illicit than by prescribed opioids.

Naloxone is a known and established medication. Its generic status has meant that the FDA would consider novel delivery devices or alternative routes of administration along the 505(b)(2) regulatory pathway (discussed in Chapter 6). Indeed, the past 2 years has seen entry into the U.S. market of two new, FDA-approved naloxone products. Patients now can choose among prescribed naloxone products, allowing them to factor in their living situation; type of opioid of exposure; comfort level with syringes; and other factors, such as preference for little to no instruction or voice-activated instructions upon administration. Across all products and access points, instructions stress that training a family member, friend, or caregiver to use naloxone is recommended.

The cost of naloxone is a key consideration for most people (Beletsky et al., 2009) and a major impediment for the branded naloxone products. The community-based and volunteer capacity of many naloxone distribution programs depends on innovations in pricing, donations, billing, and other distribution factors to sustain low- or no-cost naloxone. It is unclear whether the emergence of multiple new naloxone products will benefit patients, family members, and community-based programs. Unless covered by insurance, the out-of- pocket cost of $40 to $150 for naloxone makes it inaccessible for most people, especially if it is being administered in larger quantities or more frequently in the presence of potent opioids such as fentanyl. Prescription formulary coverage of the different prescription naloxone products varies, but with time and increasing demand (Jones et al., 2016), greater coverage is expected. Indeed, public and private insurers increasingly include naloxone in their formularies, thereby creating a sustainable and accessible source of the medication through medical and pharmacy routes. When naloxone is covered by insurance, its uptake improves, and states such as Rhode Island that have instituted both statewide pharmacy access to naloxone and broad insurance coverage of multiple products have seen the emergence of sustainable models of naloxone access as a complement to

community-based programs. However, the new products, and increasingly the generic ones as well, are beyond the financial reach of most community-based programs, many of which have had to rely upon small grants or donations. In the face of unprecedented numbers of opioid overdoses and the infiltration of fentanyl into the illicit drug supply, the FDA and other federal agencies would be well advised to take steps to ensure that organizations and institutions with privileged access to those with high overdose risk have free (or lowest-cost) naloxone so as to maximize the reach and sustainability of their efforts. Examples of such steps include novel pricing, alternative models, or price controls.

Finally, several FDA public meetings have considered the prospects and requirements for making naloxone an over-the-counter (OTC) product. A first public meeting in 2012 featured presentations from researchers in naloxone and overdose, the FDA, and others on the state of the science and regulatory requirements for an OTC naloxone product. Absent a branded product, few to no current naloxone manufacturers were willing or able to undertake the studies necessary to achieve that status. Three years after this initial public meeting, a new FDA-approved naloxone product was available, joined by another the following year. At this time, no naloxone product has attained OTC status, and in the meantime, as discussed above, states have greatly expanded access to naloxone through pharmacies, emergency departments, community-based organizations, and first responders using various implementation models. Research is needed to understand the impact and reach of these models. Given the variety of settings in which naloxone providers and programs operate and the unique access of many programs to populations at high risk of overdose, it is unclear how an OTC naloxone product would improve the accessibility and availability of naloxone at the community level.

Summary

Medication to treat a pernicious side effect of opioid exposure and overdose is available, and two new FDA-approved medications join several generic naloxone products. The provision of naloxone to overdose victims by health professionals in the prehospital setting is the standard of care, and in response to rising community overdose rates, community-based programs and first responder agencies have adopted this protocol for treating opioid overdose. Mechanisms for increasing naloxone prescribing and dispensing and equipping of first responders, and possibly enabling direct patient access (e.g., an OTC status), are warranted, but are impeded by high and unpredictable costs for the medication.

SUMMARY AND RECOMMENDATIONS

While it is unrealistic to expect that the diversion and misuse of pain medications can be entirely eradicated, the effects of these drugs on public health need to be acknowledged, tracked, and mitigated. The interrelated nature of the prescription and illicit opioid epidemics means that one cannot be addressed separately from the other. Moreover, there are both iatrogenic and predictable consequences of opioid exposure at the individual patient and societal levels that can be anticipated and actively mitigated. The downstream effects and societal impact of these intertwined epidemics require consideration by the FDA and other agencies with authority to affect the flow of prescription opioid medications and illicit opioids before, during, and after the introduction of new, similar opioid products into the marketplace. Important research gaps exists

in such areas as surveillance; ethnographic studies of drug use behaviors; epidemiologic studies of exposure, natural histories describing transitions in routes of administration and use, and risk of new illicitly manufactureed synthetic opioids; evolving OUD treatment trajectories; changes in opioid markets; and measurement of the impact of use of opioids, particularly heroin and illicit fentanyl, on society and the economy.

Recommendation 4-1. Consider potential effects on illicit markets of policies and programs for prescription opioids. In designing and implementing policies and programs pertaining to prescribing of, access to, and use of prescription opioids, the U.S. Food and Drug Administration, other agencies within the U.S. Department of Health and Human Services, state agencies, and other stakeholders should consider the potential effects of these interventions on illicit markets—including both the diversion of prescription opioids from lawful sources and the effect of increased demand for illegal opioids such as heroin among users of prescription opioids—and take appropriate steps to mitigate those effects.

Recommendation 4-2. Improve reporting of data on pain and opioid use disorder. The Substance Abuse and Mental Health Services Administration, the U.S. Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention should collaborate to identify best practices and reporting formats that portray the epidemiology of both pain and opioid use disorder accurately, objectively, and in relation to one another.

Recommendation 4-3. Invest in data and research to better characterize the opioid epidemic. The National Institute on Drug Abuse and the Centers for Disease Control and Prevention should invest in data collection and research relating to population-level opioid use patterns and consequences, especially nonmedical use of prescription opioids and use of illicit opioids, such as heroin and illicitly manufactured fentanyl.

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5

Evidence on Strategies for Addressing the Opioid Epidemic

Years of sustained, coordinated, and vigilant effort will be required to contain the present opioid epidemic and ameliorate its harmful effects on society. At least 2 million people have an opioid use disorder (OUD) involving prescription opioids, and almost 600,000 have an OUD associated with heroin (HHS, 2016). These numbers are likely to increase in the coming years, regardless of what policies are put in place. Follow-up studies of individuals receiving treatment for OUD involving heroin (e.g., Hser et al., 2001) find very high rates of premature mortality (in the neighborhood of one-third) due to overdose or other complications of the disorder. Thus, even if the nation ramps up treatment availability substantially and immediately, death rates will climb and quality of life will be dramatically reduced for many people for years to come. Likewise, the continued progression of still more people from prescription opioid use to OUD will demand sustained and coordinated effort to establish and implement the scientifically grounded policies and clinical practices necessary to reshape prescribing practices and reduce the occurrence of new cases of prescription opioid–induced OUD.[1]

What should be done to contain the opioid epidemic and to prevent new cases of iatrogenic addiction and associated overdose, death, and other harms? The purpose of this chapter is to review available evidence on strategies that have been used to address the problems of opioid misuse, OUD, and related deaths. The chapter begins with prefatory sections addressing (1) the nature of the evidence on policies implemented at the jurisdictional level (typically a state or a nation), as opposed to clinical interventions operating at the level of an individual patient; and (2) the need for a systems approach, including the importance of recognizing the potential effects that interventions focused on misuse of prescription opioids have on misuse of opioids more generally. Next the chapter reviews the evidence on the effectiveness of strategies for addressing the opioid epidemic in four categories: (1) restricting supply, such as by regulating the types of products approved for use (e.g., abuse-deterrent opioids) and regulating/restricting conditions of lawful access to approved drugs; (2) influencing prescribing practices, such as through provider education and the issuance of prescribing guidelines; (3) reducing demand, such as by educating patients about opioids and increasing access to treatment for OUD; and (4) reducing harm, such as through provision of naloxone to prevent opioid overdose and needle exchange programs for people who use injection drugs.

[1]Vigilance will also be needed to reduce the risk of similar problems in the future with other classes of medications for which there exists demand for clinical uses other than the indicated conditions and/or active black markets for their resale.

NATURE OF THE EVIDENCE

Theoretically, the comparative effectiveness of different opioid-related policies could be quantified through use of randomized controlled trials (RCTs). For example, consider a clinical strategy that eschews prescribing opioids to treat noncancer chronic pain if the patient scores high on a scale used to measure risk of developing opioid addiction. The effectiveness of this strategy for preventing opioid addiction could be evaluated in an RCT in which patients were assigned to either that policy intervention or an alternative one with fewer restrictions on opioid prescription. An RCT is the preferred source of evidence for causal inference because the random assignment is expected to result in comparable groups of individuals assigned to each strategy. In a large RCT of different approaches to opioid prescribing for preventing opioid addiction, for example, one would expect patients in each group to have, on average, the same risk factors for developing addiction. That is, any future differences between the groups in the frequency of opioid addiction could be ascribed to the different treatment strategies to which they were assigned rather than to differences in the characteristics of the individuals receiving each strategy. As a result, the outcome distribution in each group could be interpreted as the counterfactual outcome distribution that would have been observed in that population under the corresponding strategy.[2]

RCTs, however, are rare for policies that require implementation at the level of an entire jurisdiction, nor are they ethically permissible in many policy contexts. In the absence of RCTs, other sources of evidence are needed to estimate the counterfactual outcome distribution under different strategies. One such source of evidence is the collection of data on individuals who happen to receive the strategies of interest as part of their routine care, often from electronic health records. The so-called observational analyses based on such data are attempts to emulate the RCT that cannot be conducted (the target trial). In these observational analyses, however, the comparability of the groups receiving each strategy is not guaranteed. In the real world, for example, the restricted opioid prescription policy might more likely be applied to individuals visiting providers in urban health care settings who also received other interventions to reduce the risk of addiction. As a result, a direct comparison of the outcome distribution between those who received each strategy would be confounded by the concomitant interventions.

Observational analyses attempt to eliminate bias due to confounding by adjusting for all measured prognostic factors that are distributed differentially between the groups. For example, the comparison might be conducted separately among individuals in urban and rural health care settings. If all confounding factors are appropriately measured and adjusted for, the observational analysis will adequately emulate the target trial and correctly estimate the counterfactual scenarios under each strategy. But even if confounding is eliminated in an observational analysis, this source of evidence is inherently limited with respect to the counterfactual scenarios it can recreate. Analyses of observational data may be helpful for estimating the comparative effects of different treatment strategies applied to a clinical population, but may not capture population-level effects under different policies. For example, an observational analysis of patients of

[2]Of course, even RCTs are not perfect. For example, they may overlook indirect effects on people other than those participating in the study. Parmar and colleagues (2017) describe an RCT of the distribution of naloxone to heroin injectors being released from prison in which only one-third of the naloxone administrations in the treatment group were to the ex-prisoners in the study themselves; the majority of the administrations were to others who were outside the scope of data collection. The trial was closed prematurely as a result of this and related problems.

certain health care providers will not quantify effects due to scaling up a treatment strategy as a policy applied to the entire health system.

In fact, this chapter typically investigates the effects of strategies that operate at the level of a jurisdiction, such as a locality or state, or that of the country as a whole. Because random assignment is exceedingly rare in such circumstances (no one, for example, is authorized to randomly assign New Hampshire and 24 other states to receive one policy or to freeze policy in the other 25 states so they can serve well as controls), and observational analyses of clinical populations cannot capture system-wide effects (even if they could successfully adjust for confounding), other approaches are needed. All of these approaches will lack physical randomization of the strategies being examined and therefore will be subject to confounding, but they nonetheless are essential sources of evidence for estimating the effectiveness of various strategies.

Before–After Comparisons

A common nonrandomized source of evidence is before–after comparisons, or the comparison of population outcomes before and after a strategy has been implemented in a single population. Because of underlying trends, however, this comparison may provide a biased estimation of the counterfactual scenarios. For example, the strategy might have been implemented in a population precisely because conditions in that population had been deteriorating. If the underlying factors that gave rise to this trend persisted, conditions might continue to worsen after the strategy was implemented even if the strategy was helpful because it diminished but did not reverse the rate of deterioration. Or the implementation process might move so slowly that the strategy did not take effect until the underlying problem had already exhausted its momentum, and a sort of regression to the mean thus created the illusion that the policy was more effective than it truly was. Therefore, a before–after comparison may not correctly identify the counterfactual of how the world would have looked in the absence of the strategy's implementation.

Ecological Comparisons

Another nonrandomized source of evidence is ecological comparisons, or comparison of outcomes between two different populations, only one of which has received the strategy. Again, however, this comparison may provide a biased estimation of the counterfactual scenarios because the policy may have been implemented in one of the populations precisely because conditions had been deteriorating, or other important between-population differences in prognostic factors may have affected the outcome.

An additional challenge for nonrandomized sources of evidence is that many strategies may exert effects that extend across jurisdictional boundaries or manifest only with a considerable lag. For example, even a successful intervention might noticeably reduce the incidence of overdose only many years after being implemented. Indeed, some interventions that successfully reduced diversion of prescription opioids might, at least in theory, initially *increase* rather than decrease the number of overdose deaths, even if they reduced deaths in the long run, as the result of an initial surge in deaths among people already dependent on prescription opioids who turned to black market substitutes, whose potency is more variable. Furthermore, some interventions may have different effects depending on the metric employed; thus, for example,

distributing naloxone might reduce the number of fatal overdoses but—particularly if there were some risk compensation or other behavioral adaptation—increase the total number of overdose events. Strang and colleagues (1999), for instance, found that 6 percent of individuals in treatment for opioid addiction who were interviewed (9 of 142) reported that access to naloxone might lead them to increase their heroin dosage.

Another problem is that of nonlinear response in systems that have their own internal dynamics. For example, resale or other diversion of prescription opioids by people who had already "traded down" to cheaper black market opioids might cause others to initiate misuse of prescription opioids, others who themselves might later trade down, divert, and supply still others. This problem is illustrated by the difficulty of talking about the number of cases of an infectious disease that are prevented per vaccination as if it were a universal constant, whereas that number in fact depends on the number of other vaccinations being given and the current prevalence of the disease.

THE NEED FOR A SYSTEMS APPROACH

A complementary approach to evaluating intervention strategies implemented at the jurisdictional level in systems with lags and nonlinearities is to use some model of the system in question to project what might be expected with and without the intervention of interest. This approach has been used in a variety of contexts, including air traffic control (Bertsimas and Patterson, 1998; Long et al., 1999; Terrab and Odoni, 1993), fisheries management (Bjørndal et al., 2004; Clark, 1990; Megrey, 1988), vaccination (Goldstein et al., 2005; Kaplan et al., 2002; Medlock and Galvani, 2009), and tobacco control (IOM, 2007, 2015; Levy et al., 2005), among many other important policy domains.

The dynamics of prescription opioid misuse are complicated, particularly when one takes into account the markets for diverted and purely illegal opioids, but a simple sketch helps clarify the value of a systems approach. A typical clinical trajectory that policy changes would like to prevent starts with medically appropriate use of prescription opioids, escalates to misuse and then to OUD, and then evolves to trading down to cheaper black market opioids before manifesting in overdose. Thus a leaky prescription drug system increases the flow of people into the state of having OUD. People tend to remain in that state for a very long time, an average of 10 to 20 years, with modest flows out of that state through overdose death, death from other causes, or permanent cessation of use.[3]

The number of overdoses per year might be roughly proportional to the number of people who currently had an active OUD, but this number would *not* be proportional to the current inflow of new people developing OUD, which is what many interventions aimed at controlling the misuse of prescription opioids would affect most directly. Those interventions would not instantly change the prevalence of OUD and hence would generally not have an immediate effect on overdose. By contrast, interventions that reduced the likelihood that an overdose would occur, or that it would be fatal, might reduce fatalities right away. A fair comparison of the effectiveness of interventions designed to reduce diversion with those designed to reduce the frequency or lethality of overdoses requires a true systems model, not just simple statistics.

[3]More sophisticated models will have a second pool consisting of people who have temporarily ceased use but are vulnerable to relapse.

Wakeland and colleagues (2015) provide an example of such a systems model, reproduced in Figure 5-1.

Constructing such models is a major research endeavor in its own right, and the committee is unaware of any existing model that incorporates all of the strategies discussed in this chapter; therefore, the relative effectiveness of these strategies cannot be compared. Creating such models would have important advantages: it would guide and strengthen surveillance and research, foster a common policy vocabulary among all agencies with decision-making authority over opioid regulation and enforcement (federal, state, and local), and facilitate the exchange of information among them. Investing in research and possible development of such a model is worthy of consideration by the U.S. Food and Drug Administration (FDA) and other agencies. In any event, since no formal systems model now exists, the committee provides an overview of the key conceptual features and implications of a systems approach (without a formal model) to identify some of the considerations that need to be taken into account in reviewing the possible impact of alternative strategies. However, empirical analysis of the various strategies reviewed in this chapter relies on the traditional statistical methods outlined in the previous section.

A Systems Approach to Opioid Misuse

The boundaries delineating governmental agencies' respective responsibilities do not always align with the real boundaries of markets or behaviors concerning OUD and resulting overdose. While the FDA's regulatory authority may give it a particular interest in reducing addiction and mortality caused by prescription opioids, the nation's overall public health interest lies in reducing addiction and mortality caused by opioids of all sorts. A person with prescription opioid–related OUD may escalate his or her opioid misuse, and an overdose leaves a grieving family wondering whether or not the person's last dose was obtained through a prescription.

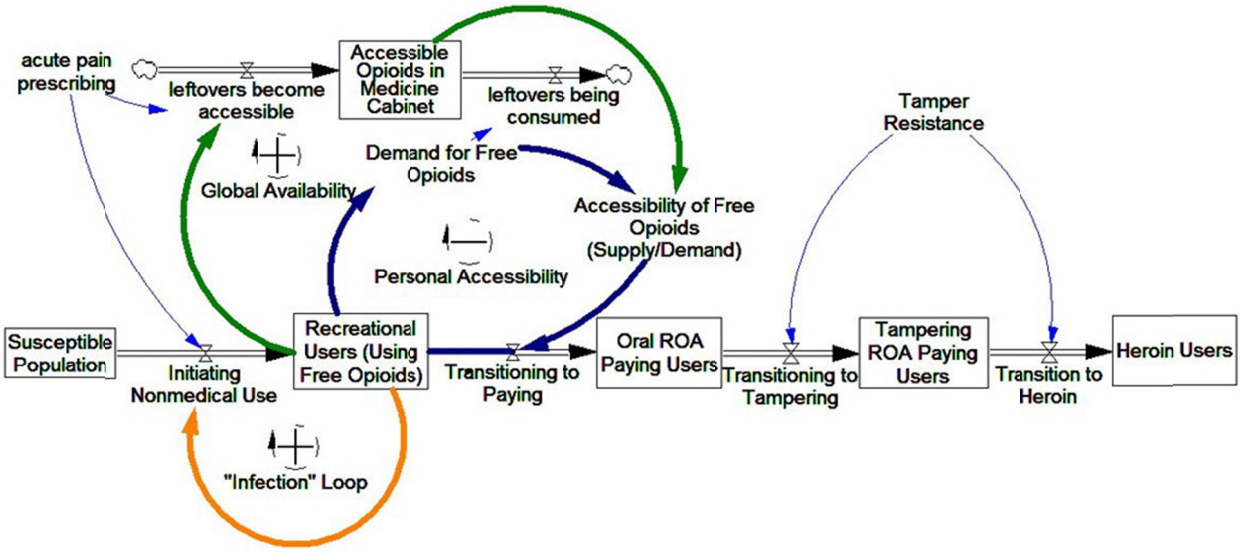

FIGURE 5-1 A systems model of the opioid misuse problem.
SOURCE: Reprinted from Wakeland et al., 2015.

Prescription and nonprescription opioids intertwine on both the demand and supply sides of the market because all opioids belong to one family of chemicals that operate on similar molecular pathways; the molecules bind to a neuroreceptor regardless of whether they are associated with a prescription. In addition, as shown in Chapter 4, the prescription opioid epidemic is interwoven with the illegal drug market. Therefore, this chapter considers policy options for reducing OUD, mortality due to opioid overdose, and other opioid-related harms among people who have ever used prescription opioids, rather than focusing exclusively on options for reducing misuse of or overdoses from prescription opioids alone.

In the economic sense of the term, all opioids are substitutes (as opposed to complements) in the same sense that oil, gas, coal, nuclear, solar, and hydro are substitute sources of energy for producing electric power. Substitutes are not identical and interchangeable; a molecule of morphine is different from a molecule of fentanyl, just as a barrel of oil differs from a ton of coal. There are distinguishable groupings within broad families of substitutes. Energy policy distinguishes fossil fuels from sources with lower carbon footprints; in this context, one can distinguish partial from complete opioid agonists. But just as one cannot develop a sensible response to global warming by changing only policies toward oil, one cannot develop a sensible response to the nation's opioid problem by adjusting only policies concerning prescription opioids.

The central economic idea about substitutes is that people will tend to use more of item A and less of item B when the price of A falls relative to the price of B, where price is construed broadly to mean the total cost of obtaining and using the item. For opioids, that total cost includes not only the dollar price, but also the time and inconvenience of obtaining the drug and all relevant risks in terms of health and possible criminal justice sanctioning (Moore, 2013; Reuter and Kleiman, 1986; Rocheleau and Boyum, 1994). A related concept is substitution driven by changes in income; as people become poorer, they may substitute hamburger in place of steak and heroin in place of prescription opioids (Petry and Bickel, 1998).

As noted earlier and discussed in greater depth in Chapter 4, in the case of the opioid epidemic, one common pathway to death over the past 20 years has been becoming addicted to prescription opioids, no longer being able to sustain that habit financially, and so trading down to cheaper black market opioids before dying of an overdose or suicide. Trading down can also involve beginning to inject drugs, since that is a more efficient mode of ingesting psychoactive substances. Therefore, additional opioid-relevant public health outcomes include morbidity and mortality stemming from bloodborne infection (e.g., hepatitis C virus [HCV], HIV), both for the individuals injecting and for others (e.g., sexual partners). These outcomes remain relevant even if, for example, no prescription opioids were taken during the month preceding death due to AIDS.

Conversely, finding large amounts of a prescription opioid in the decedent's body does not imply that the person had a prescription. It is common for people who have traded down to black market drugs to retain their prescriptions for purposes of reselling those drugs on the black market. In 2016, typical street prices were $10–$30 for a 30 mg tablet of oxycodone, $5–$20 for a methadone tablet, $3–$8 for Vicodin, and $1 per mcg per hour for fentanyl patches (WSIN, 2016). Thus, diverting to the black market a prescription for two 30 mg tablets per day can produce revenues of $7,300–$21,900 over the course of 1 year. That income is tax-free and mostly pure profit because the copays for those prescriptions are typically small, as is the case for those filled through Medicaid, for example.

Thinking beyond prescription-related misuse becomes all the more important when one recognizes that the same chemicals that appear in prescription drugs are increasingly reaching users not only through diversion but also via distribution chains that are illegal from top to bottom. So even when an autopsy shows that the decedent's body contained a drug that is available by prescription, this does not mean that the fatal dose was obtained through a prescription by the decedent or anyone else.

In particular, drug trafficking organizations increasingly use fentanyl to adulterate black market heroin and counterfeit pills that have been stamped to look like prescription drugs. This black market fentanyl is produced in the same countries—perhaps even in the same laboratories—that sell fentanyl to pharmaceutical companies that supply prescription fentanyl in lozenges and transdermal patches. Likewise, the pill presses and dyes that these firms sell to the drug trafficking organizations that press the powdered fentanyl into counterfeit tablets of opioid painkillers (e.g., oxycodone) and benzodiazepines in North America are the same as those used by other firms to make the tablets sold to the pharmaceutical companies (DEA, 2016, p. 7). Thus, not only is black market fentanyl the same chemical compound as pharmaceutical fentanyl, but it may even have the same provenance. That in turn means there is no practical way to count precisely how many overdose deaths are due to prescription opioids even in the narrow sense that the proximate cause of death was a dose that had been prescribed.

It is worth noting that black market fentanyl is a relatively recent phenomenon. Until 2014, the number of fentanyl exhibits reported by the National Forensic Laboratory Information System (NFLIS) remained below 1,000, except for a spike to 1,594 in 2006, when a single clandestine lab in Toluca, Mexico, fueled the fentanyl outbreak. The number of exhibits soared in 2014, accompanied by sharp increases in deaths despite no comparable increase in prescribing (Gladden et al., 2016), and reached 13,002 in 2015 (DEA, 2016).

Price data suggest this trend may continue to intensify. The Drug Enforcement Administration (DEA) reports that traffickers can buy powdered fentanyl from suppliers for a few thousand dollars per kilogram when buying in bulk (e.g., 20 or 40 kg lots) (DEA, 2016). Since a counterfeit tablet contains only about 0.9–6.9 mg of fentanyl, the active ingredient can cost high-level traffickers just a penny or two for a pill that wholesales for $6.50 and retails on the street for $10–$20. By comparison, over the last decade, black market retail prices were roughly $500 for a gram of powder 30 percent heroin by weight. So while black market heroin has been much less expensive than (real) diverted prescription opioids, fentanyl is now much less expensive per morphine-equivalent dose than has been the case for black market heroin.

Drug markets are often characterized by substantial price increases as one moves down the distribution chain, but in the case of opioids these increases can be comparatively extreme (in some locations) (Caulkins et al., 2016), which suggests that the current price structure is unstable (Caulkins et al., 2016; Reuter and Kleiman, 1986). The situation is unprecedented, so it is difficult to know how it will develop, but it would not be entirely surprising if the market for counterfeit prescription pills were to undermine the market for real prescription pills. Should this occur, it might reduce the prescription drug overdose problem in its narrowest form, but it would not decrease the total number of opioid-related deaths.

The desire to root opioid policy making in an integrated systems perspective has three corollaries that bear discussion: (1) an ongoing research program is needed to continuously improve understanding of how the various opioids in all their combinations are used and misused in fact, as opposed to just as intended; (2) investment is warranted in an underlying data infrastructure, as opposed to piecemeal efforts local to particular considerations; and (3) the

capability to monitor, understand, and model that behavior can be shared among all agencies that have decision-making authority over opioid policy (federal, state, and local), as not all agencies can or should invest in model building within their own silos.

Need for a Formal Quantitative Model

Ideally, an integrated framework for regulatory decision making, discussed further in Chapter 6, would rely on an explicit model of the opioid ecosystem. This is because, as discussed above, decisions made about complex systems with endogenous feedback can be myopic in the absence of a formal model. It would be sensible for the FDA, in collaboration with the Centers for Disease Control and Prevention (CDC), to commission a panel of experts to develop a quantitative model of prescribed and illicit opioid use and distribution and establish the data infrastructure needed to support and apply that model. With such a model, the FDA and other government agencies could predict the effects of changes in policy or other changes in the opioid ecosystem.

If a model capturing the relevant outcomes in the opioid ecosystem were to be developed, that effort would not be accomplished overnight. The process would take time, and important decisions regarding opioids would have to be made in the interim. For now, then, agencies will need to integrate and weigh data from multiple sources and consider the multiple complex feedback processes without the benefit of a formal model. In Chapter 6, the committee outlines some key attributes of any sound framework for decision making involving opioid regulation. At the very least, these attributes will help in making judgments transparent, highlighting areas of uncertainty and the nature of the qualitative judgments that were made.

In sum, when evaluating past policies and estimating the effects of future interventions, it is necessary to use a comprehensive approach that takes full account of the interactions between prescription and black market opioids. Ideally, this approach could take the form of a quantitative model, although developing such a model would itself be an ambitious research undertaking.

Categorizing Strategies for Addressing the Opioid Epidemic

In traditional policy discourse relating to use of addictive drugs, analysts typically categorize available strategies (including specific policies and interventions) as aiming either to (1) reduce supply or the availability of the addictive drug, (2) reduce demand for the addictive drug, or (3) reduce the likelihood that use of the drug will have *harmful consequences* (see Box 5-1 for a list of strategies discussed in this chapter). Like all typologies, this one presents challenges of classification, but it will serve well enough in the present context by enabling the committee to summarize the evidence on the effectiveness of the wide range of policies and interventions now being deployed to address the opioid epidemic.

BOX 5-1
Strategies for Addressing the Opioid Epidemic

Reducing Supply

Regulating the approved product (e.g., abuse-deterrent formulations)

Restricting lawful access
- Scheduling
- Penalizing diversion
- Drug take-back programs
- Other state and local policies restricting access

Influencing prescribing practices
- Provider education
- Prescribing guidelines
- Electronic medical records and decision support
- Insurer policies
- Prescription drug monitoring programs

Reducing Demand

Patient and public education

Increasing access to and utilization of medical treatment for opioid use disorder

Reducing Harmful Consequences

Use of naloxone to reverse overdose

Reducing disease transmission
- Syringe exchange
- Supervised injection facilities
- Drug checking
- Behavioral interventions

Several preliminary observations are necessary to avoid misunderstanding. First, each strategy has its own costs and entails trade-offs. Obviously, one of the key trade-offs at the heart of this report is the tension between reducing the supply of opioids to reduce harms associated with their misuse and making opioids available to provide pain relief for individuals who have no satisfactory alternative. Second, strategies cannot be fully evaluated in isolation from one another. Sometimes they are seen, mistakenly, to be in tension with one another, as in the example that making naloxone available to prevent a fatal overdose (harm reduction) can counteract policies aiming to discourage opioid misuse. In other cases, different strategies may have additive effects or even potentiate one another, such that each is stronger and more effective than it otherwise would have been; for example, some observers have pointed out that one way in which some tobacco control interventions are effective is through synergy of multiple

intervention components (Green and Kreuter, 2010). In still other cases, successful implementation of some strategies (and the effectiveness of a jurisdiction's overall approach) may require that strategies be implemented in tandem with one another. A good example is that a strictly enforced supply reduction strategy may cause substantial harms to individuals with OUD (and to society) unless treatment opportunities are aggressively increased.

Finally, it is important to note that very little research has addressed the relationship among strategies. Thus strategies A, B, and C may each have a small effect, but what would happen if they were all implemented simultaneously and vigorously is unknown. This limitation is critically important in the context of this report. The data reviewed in this chapter suggest that many strategies might each have a small effect in reducing opioid misuse and related harms, but simultaneous and vigorous implementation of all of these strategies would still leave a huge reservoir of people misusing and addicted to opioids for years if not decades to come.

Another important point to make at the outset is that the strategies reviewed in this chapter have been adopted and implemented by a wide variety of public and private entities at the national, state, and local levels. The literature reviewed in this chapter demonstrates that there is currently no national strategy. Nor is there a lead agency responsible for crafting and implementing such a strategy or integrating efforts across levels of government (local, state, or national). While formulating a national strategy and suggesting which agencies should implement it are beyond this committee's charge, this approach is worthy of consideration.

STRATEGIES FOR RESTRICTING SUPPLY

As discussed previously, the responsible clinical use of prescription opioids can be a powerful tool for pain management under some circumstances. The area of continuing concern relates to long-term use of opioids to alleviate chronic noncancer pain. A constellation of policies related to lawful access and judicious clinical decision making can help ensure that opioid-related harms are minimized while providing access to these drugs for patients with appropriate clinical indications. This section reviews such supply-side strategies, including regulation of legal access to opioids for legally approved uses. The next section addresses legal regulations and professional policies aimed at reducing lawful access by discouraging unnecessary opioid prescribing or promoting safe prescribing practices. Although both types of strategies aim to control access to opioids, the former focuses on legal restrictions on distribution, while the latter focuses on efforts to influence the decisions of health care providers as the gatekeepers to lawful access by patients.

Regulating the Approved Product: Abuse-Deterrent Opioids as a Case Study

The FDA's decision to approve a new drug follows a rigorous review of product- and indication-specific benefits and risks. In the case of opioids, a drug is reviewed for its ability to provide analgesia, weighed against the potential risk of adverse effects (e.g., dependence, addiction, nausea and other side effects to the patient). Often, the benefit calculus includes product-specific features, such as high-dose extended-release (ER) formulations for pain that is long-lasting and especially severe. The drug is then ultimately approved for use in a specific population for a specific clinical indication, based on the totality of evidence considered by the

FDA for that particular population and indication (see Chapter 6 for a suggested approach for FDA decision making on and post-market monitoring of opioids).

However, one consequence of early ER opioid formulations was unexpectedly high misuse. In response, a new product feature—designated abuse-deterrent formulations (ADFs)—has been a focus of FDA policy for addressing the opioid epidemic. ADFs are opioid medications that have been reformulated to reduce the possibility or the likelihood that the medication will be "abused." While users may misuse opioid medications by swallowing pills whole, the misuse often involves manipulation of the pills. For example, a user may crush the pill and then swallow, snort, or smoke it, or dissolve and inject it. Many ADFs are designed to discourage manipulation either by making the pill difficult to manipulate or by rendering it ineffective or unpleasant once manipulated. Abuse-deterrent technologies include the following (FDA, 2015a):

- Physical designs that are crush/extraction-resistant—For example, OxyContin, a form of ER oxycodone, incorporates a hard polymer matrix that makes crushing or chewing the pill difficult and that transforms into a viscous gel when dissolved in water (which prevents extraction). Formulations that integrate such physical barriers often are referred to as "tamper-resistant opioids."
- Chemical barriers that prevent extraction of the opioid with solvents.
- Agonist/antagonist combinations that interfere with the euphoria associated with opioid abuse—These ADFs include coformulations of opioids with sequestered naltrexone or naloxone. Inadequate pain relief and even acute opioid withdrawal are concerns with the use of these formulations.
- Aversion formulations that include a substance that produces an unpleasant effect if the medication is abused.
- Delivery systems that are resistant to "abuse," such as subcutaneous implants.
- New molecular entities and prodrugs that have novel effects, such as becoming active only when the pill reaches the gastrointestinal (GI) tract.
- Combinations of these technologies.

The development of ADFs is an evolving area of research, and introduction and regulatory consideration of additional methods are expected.

An industry-sponsored review by Michna and colleagues (2014) found that, relative to placebo, ADFs and non-ADFs were comparably effective and safe for individual patients with noncancer pain. However, it is important to understand that none of the available formulations is designed to prevent all types of misuse—for example, excessive oral ingestion is not prevented by an ADF designed to limit intravenous misuse. Interestingly, currently marketed ADF products do not claim on their labels that they are abuse-deterrent; rather, information on the label describes the studies that suggest abuse deterrence to inform prescribers. The reason is that there is no long-term evidence on the products' real-world impact on reducing misuse, which the FDA would require for such a claim. Indeed, an FDA advisory committee recently voted to remove a particular formulation of oxycodone hydrochloride from the market, citing unexpectedly high potential for intravenous misuse (and associated public health harms) despite attempts to render the drug resistant to insufflation (FDA, 2017a). Thus, while ADFs represent a potentially promising area of opioid drug development, it remains aspirational.

For this reason, the FDA requires that manufacturers of all currently approved ADF products gather data demonstrating the magnitude of the products' effect on real-world misuse relative to existing comparator products and the broader opioid ecosystem (FDA, 2015a). Multiple factors will determine the impact of any given ADF on public health through reduced prescription opioid misuse, addiction, and subsequent misuse of black market opioids. These include prescribing uptake and resulting market share, whether substitutions are made for other comparably harmful prescribed or illicit opioids, and whether ADFs are delivered to those patients with the highest risks of misuse. ADFs may do little to prevent misuse by determined individuals (or actions by a minority of dishonest prescribers), but may play an important role in preventing escalation to misuse. If evidence showed that abuse-deterrent opioids presented truly effective barriers to misuse and that patients with high risk of misuse or diversion were identifiable, one can envision clinical guidelines recommending the prescription of these formulations for such high-risk patients. It remains to be seen whether the FDA's post-market research requirements for opioid manufacturers (see Annex 6-1 in Chapter 6), along with the ADF-specific data gathering mentioned previously, will eventually serve this purpose and reduce the misuse liability of individuals being prescribed opioids.

Another important question is whether the existence of relatively cheap heroin or fentanyl should be taken into account in deciding whether to phase out non-abuse-deterrent opioids, as has been strongly advocated by many analysts. While Severtson and colleagues (2013) report reductions in OxyContin-associated misuse and diversion following introduction of an ADF reformulation, Cicero and colleagues (2012) observe that indicators of fentanyl, hydromorphone, and heroin use went up during roughly the same period. Coplan and colleagues (2013) raise similar concerns based on National Poison System data, as do Cassidy and colleagues (2014) using data on 232,874 individuals assessed for substance use disorder treatment in 2008–2011. Coplan and colleagues (2016) examined the harms associated with reformulated OxyContin compared with other comparator prescription opioids, reporting a noticeable relative decrease for OxyContin, although this study did not specifically examine collateral outcomes such as potential transition to heroin and related harms. A recent state-by-state analysis suggests that the introduction of ADF OxyContin in 2010 resulted in reduced OxyContin misuse, but with a trade-off of increased heroin-related deaths and evidence of an overall trend of increased opioid overdose deaths (Alpert et al., 2017).

Black market exchange could play an additional role for individuals misusing prescription opioids whose access to non-abuse-deterrent formulations was replaced with ADFs. Even if such a person did not know how to defeat the abuse-deterrent technology, he or she could still sell the ADF drugs for cash and use the cash to buy heroin or other black market opioids. ADFs such as the new formulations of OxyContin sell for a moderate discount compared with the non-abuse-deterrent formulations,[4] but markets for them nonetheless still exist.

There is also at least the theoretical possibility of "boomerang" effects. Andrew Kolodny, chief medical officer at Phoenix House, has echoed concerns in the field that the abuse-deterrent information on the label might lull some doctors into thinking that these formulations are not misusable and/or are not addictive and so be less cautious in their prescribing (Arlotta, 2016). Also, some attempts to defeat abuse-deterrent properties could create uncertainty as to the actual dose ingested, which might in certain circumstances increase the risk of overdose. Such perverse

[4]Severston and colleagues (2013) describe prices that are 22 percent lower. RADARS System Technical Report, 2014-Q2 describes declines closer to 33 percent.

effects do not necessarily have the potential to outweigh the beneficial effects of ADFs, but that they are readily imagined does underscore the point that no clinical trial finding an ADF to be safe and effective when the unit of analysis is the individual patient necessarily indicates that the ADF will have a net positive effect on public health. In summary, although ADFs of opioids would be expected to reduce some opioid-related harms, it is necessary to consider whether these benefits are offset by their potential effect on movement to illicit markets (either for diverted non-ADF prescription opioids or for illegal drugs such as heroin) among people who misuse opioids or have OUD.

Given the complexity discussed above (and also in Chapter 4), the committee views the evidence surrounding ADFs as not compelling enough to warrant a recommendation at this time. The potential for benefit remains counterbalanced by recent examples of unexpected harm, and ongoing studies will help to clarify the optimal role for ADFs as a strategy for reducing misuse of prescription opioids. The FDA's current cautious approach appears to be well advised. Further discussion of ADFs in the context of the FDA's regulatory oversight of prescription opioids can be found in Chapter 6**.**

Regulating/Restricting Conditions of Lawful Access to Approved Drugs

Once the FDA has approved an opioid formulation (or other controlled substance) for therapeutic use, federal and state agencies have the authority to control the amount, storage, and distribution of the drug at every stage in the course of commerce. One key purpose of these restrictions is to limit access to and use of the drug to the amounts and indications for which it was lawfully prescribed and to curtail its distribution outside of lawful channels of commerce. This section reviews evidence regarding the effects of the federal and state controlled substances acts and their enforcement on access to approved drugs (i.e., in deterring diversion) and, ultimately, on use (either legal or illegal) of these drugs and associated harms.[5] It should be noted that curtailing illegal production and distribution of unapproved/illegal drugs (i.e., heroin and other Schedule I drugs and illegally manufactured versions of legally available drugs) lies outside the scope of this study (see the committee's statement of task in Box 1-1 in Chapter 1). The discussion here also encompasses so-called "take-back" programs that facilitate the return or destruction of lawfully obtained but unneeded medication, as well as additional state and local restrictions on amounts that can be dispensed or prescribed within specific periods. Related tools include licensing and limiting the class of persons or entities authorized to manufacture, ship, distribute, dispense, and prescribe the approved drugs. The DEA license confers a considerable benefit and provides a source of leverage for regulation and enforcement. Restricting the pool of physicians and other practitioners who are licensed/authorized to prescribe opioids under state or federal law is discussed in the next section. It should be emphasized that all of these efforts to control legitimate access will involve complex policy choices because they may trade off reduced relief from pain and be accompanied by illegal access/use.

[5]Enforcement and punishment strategies for curtailing illegal production and distribution of unapproved/illegal drugs (i.e., heroin and other schedule I drugs and illegally manufactured versions of legally available drugs) lies outside the scope of this study. However, see the National Research Council report Informing America's Policy on Illegal Drugs: What We Don't Know Keeps Hurting Us (NRC, 2001).

"Scheduling" Drugs Under the Controlled Substances Act

In the United States, "controlling" a drug with a "potential for abuse" means placing it within one of the five schedules defined by the Controlled Substances Act (CSA) or shifting it between schedules. (Schedule I is for substances with no "accepted medical use,"[6] while Schedules II–V apply to substances with recognized medical value, depending on their potential for abuse. See Chapter 6 for a more specific discussion of the CSA as it relates to opioid regulation.) A moderately large empirical literature exists on the effects of "scheduling" or "rescheduling" a substance under the CSA. This section also refers to studies regarding analogous actions by regulatory authorities in other countries, but the names and particular definitions of the categories differ. Most of these studies are simple "before and after" or interrupted time series comparisons, sometimes with one or multiple outcome indicators (e.g., calls to poison centers).

Scheduling of hydrocodone Perhaps the single most relevant example of opioid rescheduling is the DEA's moving hydrocodone products from Schedule III to Schedule II on October 6, 2014,[7] but evidence concerning this event is still emerging. Early studies document clear reductions in prescribing of hydrocodone and increases in prescribing of other opioids, but none examined effects on health outcomes such as death or OUD on the one hand or deficits in pain control on the other.

Oehler and colleagues (2016), for example, document that among emergency department patients in one academic tertiary hospital who received a pain-related prescription, the proportion receiving a prescription for hydrocodone-containing products fell from 58.1 to 13.2 percent following the rescheduling. Seago and colleagues (2016) examined the effects on dispensing by 14 pharmacies in central Texas. They found pronounced reductions in prescriptions for hydrocodone/acetaminophen combinations offset by sharp increases in prescriptions for alternative analgesics, including tramadol and codeine/acetaminophen, leaving total morphine equivalents dispensed after rescheduling only slightly below what they were before rescheduling. The authors conclude that "this study demonstrates several shortcomings of the federal rescheduling of hydrocodone products" (p. 270). However, the ultimate goal of scheduling drugs under the CSA is to reduce misuse and diversion and the addiction, deaths, and other adverse effects associated with misuse. Seago and colleagues do not assess effects on any of those outcomes. Similarly, Haynes and colleagues (2016) report reductions in hydrocodone exposures reported to Texas poison control centers, but increases in mentions of codeine, oxycodone, and tramadol that may reflect substitution. However, this study used no control group, and opioid poisonings may have been increasing for other reasons as well.

Scheduling of other substances in the United States There are other reports of sharp declines in single drug–related indicators after a drug's classification as a controlled substance. Loeffler

[6]This section addresses restrictions on drugs that have been approved by appropriate authorities for medical use, i.e., that are not allowed for nonmedical use. Different policy challenges arise in the design and implementation of regulatory schemes that control access to and use of a drug for nonmedical purposes. Prominent examples are alcohol and marijuana. It is possible to have separate legal regimes for medical and nonmedical uses. All of these issues are beyond the scope of this report.

[7]21 C.F.R. Part 1308.

and Craig (2013) note an 89 percent decline in calls concerning bath salts in the United States after the DEA's October 11, 2011, decision to "control" the substance under the CSA. Likewise, Stogner and colleagues (2012) report that self-reported current and past-year use of salvia fell after Florida classified it as a Schedule I drug on July 1, 2008. Spiller and colleagues' (2010) study of the effects of the scheduling of tramadol by Kentucky and Arkansas is particularly relevant, since it involves an opioid and takes advantage of comparison with two control states (Ohio and West Virginia) that did not schedule the drug. Poison control center cases mentioning tramadol increased in all four states before the scheduling policy intervention, and thereafter continued to increase in the control states but fell in Kentucky and Arkansas.

An older example concerns paregoric. Lerner (1966) documents a geometric rise in the number of paregoric-related arrests in Detroit from 0 in 1955 to 713 in 1963. Michigan ended nonprescription sales of the drug in April 1964, whereupon arrests collapsed, falling to 10 by 1965.

Restrictions on precursor and essential chemicals A related literature explores the effect of adding legal restrictions on precursor and essential chemicals used in the production of controlled substances. McKetin and colleagues (2011) review 10 studies of 13 regulations (plus two enforcement operations) directed at precursors for methamphetamine production in the North American market. Most of these studies found reductions in methamphetamine-related outcomes (of 12 to 77 percent), with no evidence of shifts to other types of drug use; the exceptions were instances in which substitutes for the restricted chemicals were readily available. However, the authors of one of the studies (Dobkin and Nicosia, 2009), while acknowledging short-term effects of that size, stress the impermanence of the reductions as other methods of production were developed over the longer term.

Cunningham and Liu, the lead authors of the majority of the papers reviewed by McKetin and colleagues (2011), also studied regulation of chemicals essential to the production of cocaine. They again report evidence of reductions in various indicators of production and consumption (Cunningham et al., 2015, 2016). In particular, they attribute the dramatic reduction in U.S. cocaine consumption between 2006 and 2010 to regulation of sodium permanganate implemented on December 18, 2006. That decline is significant because it is among the largest in an illegal drug market in recorded history (Caulkins et al., 2014). Thus key regulatory tools of controlled substance legislation—especially tightening controls (in particular through Schedule II of the CSA) and banning precursor substances to prevent illicit manufacture—can be effective in accomplishing their purposes.

Preventing and Penalizing Diversion of Controlled Drugs

A key element of a regulatory system for controlling dangerous drugs is preventing and penalizing diversion of the drugs from the channels of distribution that have been authorized for medical use. Prescription drugs are diverted to nonmedical use in myriad ways, but it is useful to distinguish three categories: (1) diversion *before* a prescription has been filled (e.g., theft from production facilities or retail pharmacies), (2) diversion *via* the filling of a prescription, and (3) diversion *after* a prescription has been filled.

While the first category undoubtedly occurs, it appears to be of quite modest scale. As noted in Chapter 4, the DEA (2016b, p. 34) reports that in recent years, 12–17 billion dosage units of opioid narcotics were dispensed at the retail level. By contrast, the DEA (2016b, p. 35)

reports that in the entire country in 2015, only 9.1 million dosage units were lost to robbery of pharmacies or otherwise "lost in transit." Those are very small numbers relative to the 12–17 billion dosage units disbursed at the retail level.

By contrast, the third category, diversion *after* a prescription has been filled, is much more common. One recent survey found that about one in five adults with an opioid prescription self-reported having shared those opioids with another person, most frequently for the purpose of helping to manage pain (Kennedy-Hendricks et al., 2016). However, such individual-level actions generally are not the concern of federal law enforcement, which focuses on misbehavior by DEA registrants and large-scale diversion by industry (Sapienza, 2006).[8]

Some diversion within the second category, diversion *via* the filling of a prescription, also falls outside the priorities of federal law enforcement—notably diversion that is driven by the patient (e.g., doctor shopping), facilitated by at most inattention or carelessness by the prescriber but not with criminal intent. The portion of this diversion category that is more likely to attract the attention of federal law enforcement is that which involves the knowing misbehavior of DEA registrants, such as with so-called "pill mills."

Some of these actions are civil, not criminal. For example, the DEA has pursued action against CVS in multiple states for filling forged prescriptions or knowingly dispensing to individuals without a legitimate medical need (DOJ, 2016; Wang, 2016). Such action has led to agreements to pay fines in Massachusetts ($3.5 million) and Maryland ($8 million), among other states. The sanction in many DEA cases against practitioners is simply revocation of prescribing privileges, although some of those revocations stem from personal circumstances and errors, such as a practitioner who develops an OUD and is prescribing to him- or herself, not the more egregious cases. The largest criminal case involving prescription drug diversion, Operation Piluted, led to 280 arrests, including 22 doctors and pharmacists, for illegally prescribing and distributing controlled substances, including oxycodone and hydrocodone (DEA, 2015a). One of the doctors charged is accused of selling prescriptions for $500 each, which subsequently yielded profit from sale of the pills on the black market (e.g., selling 100 pills from a prescription at $30 each would gross $3,000).

In a series of investigative journalism stories, *New York Times* reporter Katie Thomas (2014a,b, 2015, 2016a,b) documented the criminal activity of InSys Therapeutics. Employees were indicted for offering bribes and kickbacks to doctors and nurses in exchange for their prescribing more of the company's fentanyl product, Subsys, and several of the company's former executives have been charged under the Racketeer Influenced and Corrupt Organizations (RICO) Act. Two doctors who were paid more than $100,000 in "speaking fees" in 2014 were each responsible for prescriptions that generated more than $1 million in Medicare reimbursements.

Drug Take-Back Programs

The DEA, among other agencies and organizations, also tries to reduce the supply of prescription opioids by facilitating the return of unused medications through drug take-back programs. Typically, these are ad hoc or occasional events that allow individuals with unused medications to bring them in to be disposed of properly. Perhaps the best-known is an annual program sponsored by the DEA since 2010 (Stewart et al., 2015).

[8]The actions of organized criminal groups also apply here, but they generally are not involved in prescribing.

These programs are popular, and the literature on them is generally favorable, although all but devoid of high-quality evidence concerning effects on final outcomes, such as overdose (Haegerich et al., 2014). Rather, the literature finds that the programs raise awareness (e.g., Yanovitzky, 2016) and that substantial quantities of drugs are brought in for collection (DEA, 2015b; Stewart et al., 2015)—for example, 69.6 million unit doses of medication (of all kinds) brought back in to Operation Medicine Drop in North Carolina (Fleming et al., 2016) over 4 years. However, while the quantities may be substantial in absolute terms, they represent a very small proportion of the total dispensed. Egan and colleagues (2017), for instance, found that over 4 weeks in one community, 21 million units of controlled medication were dispensed, but only 21 thousand were collected.

Furthermore, evaluations of such programs generally cannot assess directly effects on such outcomes as OUD and mortality. Moreover, the reduction in harm may be even smaller than the reduction in volume of medications in circulation if the doses that are voluntarily surrendered are not the ones that would have caused OUD and death had they not been collected. One might speculate that people struggling with OUD or selling pills on the black market would be among those least likely to surrender pills voluntarily.

On the other hand, it is important to note that asking whether take-back programs are an effective way to ameliorate problems with prescription opioids is a very narrow framing. Opioids are one of many categories of medications, and the literature is concerned as much with environmental harms from improper disposal as with harms from nonmedical use.[9]

Despite the effort invested in occasional take-back programs, proper disposal of unused medications is relatively rare in the United States (Glassmeyer et al., 2009; Law et al., 2015; Maeng et al., 2016), and surveys find that many prescribed drugs are not used (e.g., Kennedy-Hendricks et al., 2016). Maughan and colleagues (2016) found that this was the case for a majority of opioid pills dispensed to patients who had undergone surgical tooth extraction. Likewise, Harris and colleagues (2013) found that one-third of patients prescribed opioids after dermatology surgery did not fill their prescriptions, and 86 percent of those who did had leftover pills. And Welham and colleagues (2015) found that among opioid prescriptions returned for disposal, the majority of the dispensed amount was unused. A large proportion of respondents report keeping medications around, even when they are not needed, and then disposing of them improperly, whether in the trash or down the drain.

Reducing misuse may not be sufficient motivation for members of the public at large to go much out of their way to return drugs; in one study, far fewer participants were motivated by concern about accidental poisoning (14 percent) than by environmental considerations (45 percent) or a simple desire to clean house (68 percent) (Gray and Hagemeier, 2012). The literatures on other environmental problems conclude that getting the public to do what is right (e.g., to recycle) depends on making it very convenient. The United States has largely failed in this regard with respect to disposing of unused medications. Once-per-year take-back programs

[9]There can be some tension between these objectives. While both interests agree that the first-best outcome is for unused medications to be returned to pharmacies or other institutions that can dispose of them properly, that is the exception, not the norm, and there can be disagreement about what is the best fallback. Some who are concerned about misuse urge that leftover drugs be flushed down the toilet, but that is arguably the worst option from an environmental perspective because sewage treatment plants seldom remove medications from water, and those concerned about environmental consequences may prefer that leftover drugs be disposed of in the trash (Daughton, 2007).

do not meet that test, and the patchwork of state, local, and pharmacy-specific programs may confuse and deter the public.

By contrast, many peer nations have simple systems whereby most people can return any drug to any pharmacy on any day of the year. Australia's Return Unwanted Medicines program gets high marks in this regard, as do the programs in several of Canada's provinces, including British Columbia's Medications Return Program (Daughton, 2003). Glassmeyer and colleagues (2009) report that many countries in Europe offer a similar service. Sometimes these programs are funded by taxpayers, sometimes by the pharmaceutical industry, and sometimes by a mix of the two. Regardless of who pays, the basic idea of disposing of unwanted materials by operating the standard distribution system backward has many advantages and is a cornerstone of reverse logistics. Box 5-2 provides further detail on one example of a national-level take-back program. It is also important to note that many unused medications are in institutions, such as nursing homes, so ensuring that take-back programs are available to them, not just individual consumers, is important.

Ironically, both environmental and drug control laws make implementing convenient drug take-back programs challenging in the United States (Glassmeyer, 2009). The Resource Conservation and Recovery Act exempts household hazardous wastes from many regulations, but when they are collected, they are regulated. So it is perfectly legal for 1,000 individual consumers to dispose of their unused drugs in the worst possible manner, but if an organization collects those unused drugs and disposes of them in a much better but not ideal way, the organization performing that service may run afoul of the law.

BOX 5-2
An Example of a National Drug Take-Back Program: France's Cyclamed

Cyclamed is a nonprofit organization in France tasked with collecting and disposing of unused drugs. It began operating in 1993, originally focusing on the collection of waste packaging materials and expanding in 2007 following passage of a law requiring pharmacists to collect unused drugs. Cyclamed is funded entirely by the pharmaceutical industry through a tax on boxes of medication distributed (€0.0022 per box). A network of more than 22,000 pharmacies helps recover drugs from French households, supported by a robust communication campaign aimed at both providers and the general public with the tagline, "Medicinal drugs are useful, let's not make them harmful."

Research on public awareness of the program has found that three-quarters of French people return some amount of unused medication, with 70 percent of that number claiming to "always" do so. As a result, in 2014 more than 15,000 metric tons of waste (including both packaging and medication) was processed and, when necessary, incinerated, resulting in the recovery of energy sufficient to power 7,000 homes for 1 year according to Cyclamed's estimates. Through its partnership with industry, the program aims to refine its efficiency and improve uptake, and thereby maximize the return on investment to the benefit of all stakeholders and the public.

SOURCE: Cyclamed, 2014.

Historically, an even greater problem was a requirement of the CSA that scheduled drugs be under the control of law enforcement. Thus a pharmacy could run afoul of the CSA if it allowed consumers to bring back opioids at any time unless law enforcement personnel were present (Glassmeyer et al., 2009). On September 9, 2014, the DEA published new guidelines allowing certain DEA registrants to become authorized collectors of returned controlled medications (DEA, 2014), although it is unclear whether full advantage is being taken of that new flexibility.

Certainly some organizations find ways to overcome the obstacles and create permanent drop-box options (e.g., Gray et al., 2015), and the committee is not expert in either the legal challenges or logistical practicalities of such programs. However, the advantages of allowing consumers to return medications on any day of the year to any of many locations they visit regularly (e.g., all pharmacies) are clear. As one example of early success, a U.S. pharmacy chain reports that the first year of a program establishing secure dropboxes for unwanted medication (in 600 of its pharmacies across 44 states) has resulted in the collection of 72 tons of medication (Walgreens, 2017).

Education for patients as to why safe disposal is important also is needed. Kennedy-Hendricks and colleagues (2016) report that almost half of survey respondents who were prescribed opioids said they did not recall receiving any instructions regarding safe storage or disposal.

The available evidence suggests that drug take-back programs in the United States can increase awareness about the safe disposal or return of many unused drugs, but effects of these programs on such downstream outcomes as diversion and overdose are unknown. As noted, moreover, many drug take-back programs in the United States are once-per-year events, and the patchwork of state, local, and pharmacy-specific programs may confuse the public. Nevertheless, international examples and the recent success of a year-round disposal program at one pharmacy chain support policies expanding such programs to reduce the amount of unused opioids in the community. **The committee recommends that states convene a public–private partnership to implement drug take-back programs allowing individuals to return drugs to any pharmacy on any day of the year, rather than relying on occasional take-back events. (Recommendation 5-1).**

State and Local Policies Restricting Access

States vary widely in rates of prescribing opioids (e.g., Zerzan et al., 2006), and not surprisingly, evidence indicates that such policy interventions as mandating coverage and reimbursement can affect prescribing of pharmaceuticals generally (Green et al., 2010). There is, after all, a long history of published concern that misinformed and exaggerated fears about liability related to dependence on opioids lead regulators to stifle the prescribing of these medications for patients who need them for pain relief (e.g., Hill, 1996). What is less clear is whether one can infer from the variation among states or other evidence whether particular state policies are effective at reducing diversion and misuse of opioids without adversely impacting their availability for pain control. Meara and colleagues (2016), for example, find no association over a 7-year period between opioid-related outcomes in Medicare administrative data and states' adoption of controlled substance laws of the sort described further below.

Haegerich and colleagues (2014) provide a useful review of English-language MEDLINE articles in this literature. Unfortunately, they conclude that the available empirical studies are

generally of low quality, and that the outcomes studied are often intermediate, such as prescribing practices, and not final, such as overdose. The largest number of studies uncovered pertained to prescription drug monitoring programs (PDMPs), naloxone, and clinical guidelines, all of which are addressed separately in this chapter; the others are briefly discussed here.

Haegerich and colleagues describe the literature evaluating state policy actions pertaining to regulation of pain clinics (which when they are sources of large numbers of prescriptions may be referred to as "pill mills") and doctor shopping as "extremely limited." The pain clinic laws coincide with reductions in the number of clinics and the supply of drugs, but the nature of the evidence is weak. Florida is a special case, discussed further below. Studies of doctor shopping interventions are no better in terms of enabling causal inference concerning health outcomes.

One might say the literature documents that these policies exist and have been implemented, and in a dog-not-barking sense, infer that they can be implemented without resulting in obvious catastrophic failures. Furthermore, there are clear logic models for why one might expect these policies to have some beneficial effect. However, these studies are unconvincing if one adheres to the standards of scientific skepticism and disbelieves that interventions have any bottom-line effect unless clear evidence from high-quality empirical studies demonstrates this to be the case. A Maine law that went into effect January 1, 2017, for example, limits prescriptions for opioids or opioid-containing medications to 100 morphine milligram equivalents (MME) per day. In addition, the law limits the number of opioid pills that can be prescribed to patients (except in cases of inpatient, cancer-related, palliative, and end-of-life care, as well as treatment for substance use disorder) to no more than a 7- and 30-day supply for acute and chronic pain, respectively (Traynor, 2016). In Massachusetts, a new law places a 7-day supply limit on first-time opioid prescriptions for adults and a 7-day limit at any time for minors.[10] Yet it remains to be seen what impact these types of restrictions will have on curbing opioid-related harms, particularly for individuals that do not have OUD.

One particular case study merits discussion: Florida's experience circa 2010–2012. Multiple policy interventions were being implemented simultaneously at that time, so it is impossible to use this case study as evidence concerning any one of them. Nonetheless, the changes in adverse outcomes were so abrupt both in absolute terms and relative to other states that it appears highly plausible that some combination of those interventions was responsible for the changes, and hence for averting thousands of premature deaths (Chang et al., 2016; Gau and Brooke, 2016; Johnson et al., 2014; Meinhofer, 2016; Rutkow et al., 2015; Surratt et al., 2014).The interventions were predominantly on the supply side, including closing approximately 600 pain clinics, revoking medical licenses and/or DEA certificates of registration, and placing restrictions on physicians dispensing (as opposed to prescribing) Schedule II–IV controlled substances.[11] A PDMP was implemented about 1 year later. The law enforcement component ("Operation Pill Nation") was led by DEA but heavily involved state and local law enforcement as well, and targeted not only providers, pain clinics, and pharmacies but also four wholesale distributors.

Meinhofer (2016) shows that these supply reduction measures more than tripled street prices for oxycodone and sharply reduced oxycodone-related mortality and hospitalization with apparently minimal spillover effects on other states, suppliers, or drugs—the only exception

[10]Massachusetts Public Law H.4056.

[11]The ADF of OxyContin ER also emerged around this time, but this was a national not a state-specific intervention and so cannot account for the peculiar trajectory of outcomes in Florida.

being some substitution of heroin, which was small relative to the reductions in oxycodone use. She observes that in the years preceding the operation, 2007–2010, Florida's oxycodone supply per capita had risen from close to the national average to quadruple the national average. After the intervention, it fell back to the national average. Consumption of various substitutes never departed appreciably from national averages, and no other state experienced a spike in oxycodone supply even close to the same magnitude as that experienced in Florida. The effects were dramatic, with the time trajectory of oxycodone deaths mirroring that of oxycodone supply.

On the one hand, this circumstantial evidence suggests that supply-side interventions against prescription opioids can have dramatic effects. On the other hand, Florida may have been experiencing a uniquely bad baseline situation in 2010 that may never again be replicated. Examining Texas's pill mill law, for example, Lyapustina and colleagues (2016) found reductions in the number of opioid prescriptions, number of pills dispensed, opioid volume, and average morphine-equivalent dose per transaction, but the reductions were 8–24 percent, not the enormous reductions seen in Florida. Overall, although further research is warranted, limited evidence suggests that state and local interventions aimed at reducing the supply of prescription opioids in the community may be effective. It should be emphasized, however, that none of these studies investigated the impact of reduced access on the well-being of individuals suffering from pain whose access to opioids was curtailed.

STRATEGIES FOR INFLUENCING PRESCRIBING PRACTICES

Reducing prescribing of opioids is at once a tool both for reducing lawful supply (by limiting the indications for prescribing them or otherwise reducing the number of patients holding prescriptions) and for reducing demand, or aggregate desire for using or misusing the drugs. Reduced prescribing can affect demand in two ways: first, by reducing patients' reliance on opioids to manage pain by satisfying their needs through other forms of pain management; and second, by reducing the number of patients or others who develop OUD and increasing the incentive for treatment among patients with OUD. This section describes a range of formal and informal policies, interventions, and tools designed to shape, guide, and regulate the prescribing practices of physicians and other health care professionals (the gatekeepers) authorized to prescribe these drugs.

Provider Education

The relief of pain represents one of the primary responsibilities of the practice of medicine (Federation of State Medical Boards, 2013). As detailed in this section, the breadth and depth of educational efforts to train physicians, nurses, pharmacists, occupational/physical therapists, and other health professionals have often fallen short of their goals for developing appropriate clinical competencies in pain management. Compared with the progressive advancement of medical education surrounding such fields as cardiology and oncology, advances in pain management education are entirely absent or minimally developed—often limited to a few hours of didactic lectures over multiple years of training.

Although detailed protocols have been developed through rigorous clinical trials for specific conditions (e.g., in the treatment of chest pain as a result of ischemic heart disease), the management of chronic noncancer pain has no equivalent foundation. Moreover, no single entity

or organization has overall jurisdiction for the development of pain management guidelines, clinical pain competencies, or opioid prescribing practices. What exists appears to be a group of loosely aligned efforts sponsored by federal, state, and local agencies surrounded by professional organizations and private industry influences. These efforts are summarized below for their respective agencies and organizations.

U.S. Food and Drug Administration

Known by its modern name since 1930, the FDA is the oldest consumer protection agency in the U.S. federal government (FDA, 2015b). Building on its key milestone, the 1906 legislation that outlawed adulterated and misbranded food and drugs, the FDA has grown in scope and size to ensure the health and safety of a broad range of therapeutics, including opioid and nonopioid analgesics. As detailed in Chapter 6, the FDA reviews and approves new and reformulated drugs for use for defined medical indications. Importantly, it can also serve as a hub for advanced training (FDA, 2016a), including the opioid-specific Risk Evaluation and Mitigation Strategy (REMS), as part of an effort to reduce "risks of serious adverse outcomes including addiction, unintentional overdose, and death" (p. 2) from prescription opioid analgesics (FDA, 2017b). Notably, provider participation in the educational component of the opioid REMS is currently voluntary, with unclear evidence of reduction in opioid-related harms or impacts on opioid prescribing (FDA, 2016b). See Chapter 6 for further discussion of the role the FDA's REMS can serve in ensuring that the benefits of prescription opioids continue to outweigh their risks.

Centers for Disease Control and Prevention (CDC)

The publication of the CDC Guideline for Prescribing Opioids for Chronic Pain (Dowell et al., 2016) may well represent a watershed moment in the education of health care providers in the management of chronic pain, and specifically with respect to the prescribing practices for opioid analgesics. As discussed later in this chapter, this guideline, in whole or in part, is being integrated into a wide range of educational resources (e.g., guidance from state-level medical boards). It is too early to understand its impact on changes in the quality of pain management or on opioid analgesic prescribing practices. Directed research could track such outcomes, especially as components of the guideline are incorporated into various educational materials at the undergraduate and postgraduate levels, as well as for the public at large. Concerns exist surrounding the proper interpretation of certain aspects of the guideline, especially with respect to the potential restriction of opioids for acute and/or chronic painful conditions. As discussed later in this chapter, patient-centered management, aided by patient educational materials explaining the risks and benefits of long-term opioid use, could be useful in optimal clinical use of the guideline.

National Institutes of Health (NIH)

As discussed in Chapter 3, NIH support for research and educational aspects of pain management is disproportionately small relative to, for example, HIV research. However, in the face of this disparity in resources to support the development of advanced pain care and address

the opioid epidemic, small but determined efforts exist within NIH in support of pain research and education.

As a result of a 1996 congressional mandate, for example, the NIH Pain Consortium, including representatives from 24 NIH institutes and centers, was established to coordinate pain research and disseminate its findings. Subsequently, the consortium held a workshop in 2010 on the state of pain education in the United States to help establish a way forward for the future of education for health care providers (medical, dental, nursing, and pharmacy). The findings of this meeting were as alarming then as they are now: the consortium concluded that the nation is failing to properly educate and train the next generation(s) of health care providers entrusted with relieving pain. Then as now, medical students were receiving on average only 8 hours of training in how to measure, diagnose, and treat pain. A consequence of this failure in education is that pain often goes poorly treated, with some patients receiving the wrong treatment and/or medications. Some may receive too little, while others receive more than is warranted, for unspecified durations, and without the benefit of long-term follow-up to abate the risks of addiction or ensure that the plan is safe and effective. Sometimes, unfortunately, the result is OUD and its sequelae.

In response to this systematic failure, an NIH initiative, the Centers of Excellence in Pain Education (CoEPEs) (NIH, 2017), led by the National Institute on Drug Abuse (NIDA), was launched to increase pain education in medical, nursing, pharmacy, and dental schools across the nation. The plan for these centers was intended to support "pain education champions" and their teams in health care schools who have previously demonstrated a commitment to increasing pain education in their institutions. One of the key elements of this initiative is the production of interactive teaching tools, which other institutions can freely download and use to teach their students about pain and its treatment. An example of these modules can be found on the Pain Consortium website.[12] While these efforts are ongoing and were initially met with great enthusiasm, budgetary restrictions and inconsistent funding sources have progressively undermined the initiative's strength and productivity. Strengthening and expanding this critical effort represents a key opportunity for NIH to support education surrounding opioid analgesia.

The challenge of supporting a national strategy for pain education is surprising in the face of the current opioid epidemic, as well as the recommendations of the Institute of Medicine (IOM) report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (IOM, 2011). Resulting from a study conducted shortly after the passage of the Patient Protection and Affordable Care Act (ACA), that report offers specific recommendations to (1) improve curriculum and education in pain management for health care professionals, and (2) increase the number of health professionals with advanced expertise in pain care. Collaborative actions with other government agencies—for example, the Substance Abuse and Mental Health Services Administration (SAMHSA), which has developed treatment improvement protocols such as Treatment Improvement Protocol 54 (TIP 54), Managing Chronic Pain in Adults with or in Recovery from Substance Use Disorders—could provide synergy for such educational efforts (SAMHSA, 2012).

[12]See http://painmeded.com/wp-content/uploads/adobe_captivate_uploads/EdnaUpdate081616/multiscreen.html.

Public and Private Universities/Professional Schools

Medical school education has been undergoing a transformation nationwide, requiring a complete redesign of curriculum to incorporate the early integration of clinical encounters, development of an interdisciplinary team approach to care models, and development of clinical competencies prior to graduation (Satterfield et al., 2004). Despite this redesign, however, the tradition of pain management education in undergraduate curriculum has often been more robust in other disciplines, such as pharmacy, dentistry, nursing, and veterinary schools, relative to medicine. In fact, according to one study, topics related to pain pathophysiology and management appear to be more developed in the training of physician assistants than in that of physicians (Doorenbos et al., 2013).

In the past, the limited hours dedicated to pain management education in medical schools have been restricted to a series of didactic lectures given in the first year. This approach has been evolving in recent years so that students are increasingly challenged with clinically relevant reenactments. An example is the "Danovic" case at the University of California, San Francisco, which is presented early in the first-year curriculum (UCSF, 2017). In this case, Mr. Danovic has a history of chronic low back pain that provides multiple opportunities to develop longitudinal interdisciplinary links for his pain management throughout the subsequent 4 years of training and to integrate aspects of other pain management learning. Additional curriculum advances include the Bridges program, based on "inquiry" (i.e., posing questions or scenarios to students as opposed to presenting facts), which emphasizes a systems approach to care. Numerous similar innovations, such as the learning models developed by the Academy of Medical Educators (AoME, 2017), are occurring across the country. These integrated programs represent a broad opportunity for the expansion of pain curriculum at the nation's medical schools. They may also partially offset the influence of industry representatives that often inadvertently fill gaps in undergraduate medical education around prescribing practices (Relman, 2001).

Taken together, undergraduate medical education that integrates longitudinal, inquiry-based curriculum and that stresses interactive sessions over large lecture formats has the potential to greatly improve clinical care delivery for pain through improved communication and clinical competencies. Additionally, the development of integrated topic pathways may improve the teaching of and competency in pain management by replacing traditional topic silos during the third-year core clerkships (Poncelet et al., 2011). Such approaches are intended to break down traditional communication barriers and empower health care providers to embrace an interprofessional model of care that includes pain management—a model that increases the likelihood that all members of a treatment team will advise clinicians to use both pharmacologic and nonpharmacologic alternatives, including multimodal adjuvant therapies (e.g., physical therapy, acupuncture, manipulation or massage, ice, and music therapy). In addition to efforts sponsored by individual professional schools, it may be hoped that modules developed through the NIH CoEPEs (discussed above) will allow additional pain education resources to be made available and introduced throughout any professional health care program.

Professional Societies

Despite the prominence and availability of web-based patient care guidelines for the management of pain, whether issued by national or international professional societies (e.g., American Pain Society, American Academy of Pain Medicine, International Association for the

Study of Pain), the under- and overtreatment of pain remains a widespread challenge. Although such societies may provide a wealth of information through online modules, annual meetings, and seminars, they are often targeting health care providers who are already engaged in pain management and/or the treatment of OUD. Primary care physicians, often represented by such organizations as the American Academy of Family Physicians, care for the vast majority of patients with acute and chronic pain, but may not be directly connected to or engaged in these pain society resources and thus must develop and provide their own educational resources for pain management (see, for example, AAFP, 2017).

Depending on their participation in such educational initiatives, the majority of physicians likely have practice and knowledge gaps that include inadequate understanding of pain assessment and diagnosis, especially in the context of chronic pain; inappropriate use of analgesic medications; failure to assess and reassess pain systematically and in the context of opioid use; and the inability to distinguish among opioid tolerance, physical dependence, and OUD (Murnion et al., 2010). Just as interprofessional approaches to undergraduate education have emerged, pain and addiction societies could work more closely with organizations supporting primary care providers, as well as seek to find the correct balance of industry sponsorship that does not unduly bias their educational content (Relman, 2001).

State Medical Boards (SMBs)

SMBs are the primary regulatory authority governing physician prescribers of opioids, through the provision/renewal of medical licensure and related functions (e.g., disciplinary actions related to inappropriate prescribing). To varying degrees, SMBs also serve as an educational resource for clinicians in their state through the publication of relevant legal information (e.g., the statutory obligations for prescribers of controlled substances) or the dissemination of best practice guidelines (discussed later in this chapter). In the context of pain management and opioid prescribing practices, this constellation of state-level oversight represents both a powerful tool to assist physicians in providing safe and effective care and a potential source of variability in the broader guidance to physicians across the country.

Summary

Current efforts to improve prescriber pain education and knowledge about prescription opioid misuse, such as the NIH CoEPEs, are inadequate and at risk of collapsing. Providers managing pain are often left to pick and choose from weakly supported alternatives. Addressing this lack of alternatives is a topic discussed in Chapter 3. However, any meaningful effort to improve pain management will require a fundamental paradigm shift in the nation's approach to mandating pain-related medical education; completion of a brief online module will not be sufficient (Holliday et al., 2017). **The committee recommends that state medical schools and other health professional schools coordinate with their state licensing boards for health professionals (e.g., physicians, nurses, dentists, pharmacists), the National Institutes of Health's Pain Consortium, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the Drug Enforcement Administration to develop an evidence-based national approach to pain education encompassing pharmacologic and nonpharmacologic treatments and educational materials on opioid prescribing. (Recommendation 5-2).**

Prescribing Guidelines

As summarized in a Chapter 2, there are many medical situations in which opioids might be considered an appropriate treatment option. The most common indications include (1) acute pain management, such as after injury; (2) management of pain in the context of cancer or the end of life when accompanied by pain; and (3) management of chronic pain not due to a malignancy. Federal, state, and professional organizations have issued clinical guidelines for the use of opioids (e.g., initiation, dosing, monitoring, discontinuation) in each of these situations. The issuance of these guidelines often is accompanied by such efforts as educational outreach, including continuing medical education (CME), to foster implementation (Haegerich, 2016).

Opioids and Acute Pain Management

Acute pain is experienced commonly after surgical or dental procedures, traumatic injuries, and some normally transient medical conditions (e.g., acute low back pain) when its resolution is expected over a time course of hours to several weeks. Depending on the specific situation, opioids, nonopioid medications, nerve blocks, topical medications, and other measures might be used individually or combined in a multimodal approach (see Chapter 2). As discussed in previous chapters, understanding and controlling opioid use in these situations is important as these routes of exposure may lead to long-term use, particularly in certain populations (Sun et al., 2016; Webster et al., 2007). Additionally, as detailed earlier, unused medications provided by hospitals, emergency rooms, and clinics may leak into the community and be used for nonmedical purposes (Inciardi et al., 2007).

The subject of guidelines for acute pain management currently revolves primarily around use rather than dosage or duration. Dosage guidelines are widely available and fairly widely accepted. However, opioids prescribed for acute pain syndromes have too often been provided at doses and dosing intervals and for durations unlikely to yield optimal effects (Humphries et al., 1997). One attempt at providing general guidelines for the use of opioids for acute pain was made by the Utah Department of Health,[13] and portions of these guidelines have been incorporated into the guidelines used by other states. The process of developing the guidelines involved broad representation of stakeholders on advisory and working groups. These guidelines call for opioids to be used only when nonopioid alternatives are deemed inappropriate, and for the drugs to be issued in carefully limited amounts (in dosage and duration) and after education of the patient concerning appropriate use and storage.

Various groups have independently developed guidelines for the prescribing of opioids for management of acute pain in emergency rooms (del Portal et al., 2016) and for the management of pain in acutely injured workers (Mai et al., 2015). In one study, del Portal and colleagues (2016) found that opioid prescribing decreased significantly in an acute care setting (from 52.7 percent before the guideline was issued to 29.8 percent immediately after its introduction, and to 33.8 percent 12 to 18 months later) based on retrospective chart review for more than 13,000 patient visits. There do not appear to be any widely accepted guidelines for postoperative opioid prescribing, although one study found that the amount of opioid provided often was much larger than the amount required (Hill et al., 2017). The suggestion recently was

[13]See http://www.health.utah.gov/prescription/guidelines.html (accessed April 17, 2017).

made that postoperative opioid prescribing be based on the specific surgical procedure, type of anesthesia used, patient age, and other variables (Kim et al., 2016).

Guidelines for the management of back pain issued in 2017 by the American College of Physicians suggest using nonpharmacologic approaches for treatment of acute and subacute back pain, given that this type of pain often resolves on its own over time. When pharmacologic treatment for acute and subacute back pain is desired, the guidelines suggest the use of nonsteroidal anti-inflammatory drugs (NSAIDs) or skeletal muscle relaxants (Qaseem et al., 2017).

Opioids and Pain Management in the Context of Cancer and End of Life

The use of opioids for the treatment of pain in the context of cancer and end of life is broadly supported by outcome studies. While not adequately effective as sole analgesic agents in every patient, opioids, including morphine, oxycodone, fentanyl, and others, can reduce pain due to malignancies, including so-called breakthrough pain, a sometimes severe form of cancer pain of very rapid onset (Zeppetella and Davies, 2013). The use of opioids for cancer pain is codified in the World Health Organization's (WHO's) analgesic ladder, one of the oldest and most widely accepted sets of opioid treatment guidelines (WHO, 1986). Regrettably, 10–20 percent of cancer patients experience pain that is refractory to standard opioid management. For these patients, a number of opioid- and non-opioid-based options have been described, but evidence is not yet sufficient to develop guidelines for their use (Afsharimani et al., 2015).

A number of studies have estimated compliance with cancer pain management guidelines. The results suggest that, despite the existence of various guidelines, pain assessment and reassessment and some other provisions of the guidelines are not always adhered to, and that pain control can be improved when guidelines are followed (Du Pen et al., 1999; Mearis et al., 2014; Miaskowski et al., 2001). On the other hand, many more people are surviving cancer treatment than was the case during the development of the WHO guidelines. It is unclear what role opioids should play in the management of persistent pain after successful cancer treatment that might be due to surgery, chemotherapy, radiation, or other related causes.

Opioids and Pain Management in the Context of Chronic Pain

The controversial nature of the practice of using opioids to treat chronic pain, as well as growing recognition of its adverse consequences for both individual patients and society, has prompted the development of numerous prescribing guidelines. These guidelines have been sponsored and promulgated by professional societies; SMBs (such as the Federation of State Medical Boards); and federal agencies, such as the CDC.

Of the sets of opioid prescribing guidelines currently available, that developed by the CDC is the most recent, comprehensive, and influential (Dowell et al., 2016). The CDC's inclusive process for developing the guideline emphasized the use of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology to rate the quality of the evidence used in constructing the guideline, as well as the strength of the resulting recommendations. This process further involved the engagement of federal partners that included representatives from SAMHSA, NIDA, the FDA, the U.S. Department of Veterans Affairs (VA), the U.S. Department of Defense (DoD), and others. The development process further involved constituents, including clinicians and patients. Peer review of the guideline was solicited, as were

public comments. The 12 key provisions of the resulting guideline (see Box 5-3) emphasize consideration of nonopioid options prior to or in addition to opioids, careful pre-prescribing risk stratification, conservative dosing, careful follow-up, and appropriate discontinuation/tapering.

BOX 5-3
Centers for Disease Control and Prevention's Recommendations for Prescribing Opioids for Chronic Pain Outside of Active Cancer, Palliative, and End-of-Life Care

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

SOURCE: Excerpted from Dowell et al., 2016, p. 1638.

Because the CDC guideline was issued only recently, its impact on prescribing practices remains unknown. Some have questioned the strength of the data behind some of the recommendations, such as the overall emphasis on improvement in function, as well as in pain control, in the consideration of whether benefits of using the drugs are expected to outweigh risks to the patient (Pergolizzi et al., 2016).

With respect to other guidelines for chronic pain management that have been in the field longer than the CDC guideline, researchers have found modest improvement in practice behaviors, such as use of urine drug screens and referral for specialty evaluation, and modest impacts on overall opioid prescribing rates, as well as overdose rates (e.g., Barber et al., 2017; Beaudoin et al., 2016; Chen et al., 2016). Moreover, strong state-level guidelines were associated with a reduction in the number of patients receiving high doses of opioids (Garg et al., 2013; Sullivan et al., 2016). Notably, multipronged efforts that include guidelines as well as other educational information for providers on how to prescribe opioids safely have been found to be associated with decreases in emergency department visits and deaths from opioid overdose (Cochella and Bateman, 2011; Paone et al., 2015). These findings suggest that guidelines may be able to moderate the most aggressive opioid prescribing but are unlikely to be sufficient on their own to ensure the application of optimal medical practices in all cases, and that multipronged educational interventions and changes in reimbursement for pain management are required.

State Medical Board Guidelines

In an attempt to provide educational resources on the topic of pain management and opioid prescribing practices, many SMBs have either developed their own best practices preceding the release of the CDC guideline in 2016 or subsequently responded by incorporating foundational components of that guideline addressing key decisions encountered during clinical pain management. Although the CDC guideline was intended to serve as a broad resource for primary care physicians, it is being adapted and largely interpreted at the state level for all practicing physicians across the nation. A brief review of three key CDC topic areas across the web-based resources of five SMBs (California, Florida, Kentucky, Ohio, and Washington) on pain management and opioid prescribing practice reveals examples of content variability:

- **Determining when to initiate or continue opioid treatment**—California's guidance on initiation of opioid therapy for chronic pain references carefully defined, 90-day opioid trials (MBC, 2014), whereas Ohio's SMB cautions against using opioids to treat chronic pain but advises clinician vigilance should they be deemed necessary (GCOAT, 2013).
- **Opioid selection, dosing, and duration**—Advice generally echoes the CDC's "start low and go slow" approach; however, different morphine-equivalent doses are specifically cited by different SMB documents. California mentions 80 mg/day as a threshold above which caution should be used (MBC, 2014), while a joint publication from the Washington State Agency Medical Directors' Group urges caution at any dose, and additionally recommends referral to specialists for cases necessitating doses above 120 mg/day (WSAMDG, 2015).
- **Follow-up, monitoring, and discontinuation of opioid treatment**—Other areas of variation include whether and how to use treatment agreements and screening tools for OUD risk (discussed in Chapter 2), as well as considerations for monitoring patients on long-term opioid therapy and conditions necessitating treatment discontinuation. Perhaps most important is the degree to which guidance regarding tapering of opioid treatment is provided. SMBs vary in the depth to which this issue is addressed, from simply recommending referral to addiction or pain specialists (Ohio), to describing the risks, benefits, and management of withdrawal symptoms associated with various weekly reductions in opioid use (California and Washington).

Most of the selected SMBs that provide opioid guidance documents recommend consideration of nonopioid/nonpharmacologic pain management strategies prior to initiation of opioid therapy, and contain appendixes varying in number and length providing supplemental data for prescribers and patients. Many of the documents also recommend that opioids for acute pain be prescribed in limited amounts and doses consistent with the expected clinical course of the case (such as postsurgical pain). Such state-to-state variation is to be expected, and often is due to the goal of the particular guidance document (e.g., Washington's guidance focuses on pain management broadly, whereas Ohio has separate documents for chronic and acute pain, with comparatively little emphasis on patient education or other "wraparound" services). States also may vary in the degree of autonomy that is customary among their physicians.

Unfortunately, in some cases, SMB guidance for opioid pain management can be quite limited, describing only the statutory obligations of physicians prescribing controlled substances

for pain, although reference also may be made to the CDC guideline (FBM, 2010; KBML, 2003). In short, there are wide disparities in the availability and comprehensiveness of SMBs' prescribing guidance. In April 2017, the Federation of State Medical Boards (FSMB) released a revised "model policy" for chronic use of opioid analgesics (FSMB, 2017), for use by SMBs seeking to evaluate physician management of patients with pain. This guidance is largely consistent with (if not as broad and comprehensive as) the CDC guideline. Notably, FSMB stresses at the outset that "effective means of achieving the goals of these Guidelines vary widely depending on the type and causes of the patient's pain, the preferences of the clinician and the patient, the resources available at the time of care, and other concurrent issues beyond the scope of these Guidelines" (FSMB, 2017, p. 2).

In summary, prescribing guidelines may be able to improve provider prescribing behavior but may be most effective when accompanied by provider education and other measures designed to facilitate implementation.

Electronic Medical Records and Decision Support

The use of electronic medical record (EMR) systems is expanding rapidly in both inpatient and outpatient medical settings. Use of EMRs was led by the VA, but aggressive federal policies have prodded many offices, clinics, hospitals, and integrated health care systems to employ the technology. Clinic notes, study results, laboratory values, pharmacy information, and other key data may be included. Compared with more traditional paper-based systems, EMRs offer potential improvements to health care delivery, including but not limited to increased efficiency, better adherence to guidelines and regimens, and fewer medical errors and related events (Campanella et al., 2016).

These advantages could contribute to safer and more effective opioid prescribing for several reasons. First, notes documenting treatment and follow-up plans may be more easily located by consulting an EMR than by sorting through paper files, and delays in accessing the records are minimized when providers need patient information quickly. Importantly, EMR systems containing sections for current medications, allergies, and other pharmacy-related information, (e.g., last medication refill dates and tablet quantities) may aid greatly in managing higher-risk patients. The electronic format is conducive to the use of treatment templates in which opioid follow-up assessments and ongoing prescribing plans can be included.

At present, a modest amount of information helps inform the utility of EMRs and opioid prescribing in different settings. A pre/postimplementation analysis concluded that the implementation of an EMR system may have contributed to higher rates of signed opioid treatment agreements, use of urine drug screens, and documentation of assessment of functional status (Anderson et al., 2016). Another study demonstrated that the inclusion of electronic alerts for the presence of opioid-use care plans within an EMR system may reduce opioid prescribing by emergency departments for high-frequency emergency department patients (Rathlev et al., 2016). Use of EMRs, however, may not always discourage opioid prescribing. A regression analysis to analyze the prescribing behavior of primary care physicians with and without EMR systems showed that visits to physicians with EMRs were more likely to result in opioids being prescribed relative to visits to physicians using more traditional systems (Harle et al., 2014).

Evidence on the effectiveness of clinical decision support systems (CDSSs) for opioids, incorporated within EMRs, is similarly conflicting. Trafton and colleagues (2010) describe a commendable attempt to iteratively improve and deploy a CDSS for primary care physicians

treating chronic pain with opioids. In the end, while the CDSS did overcome some perceived barriers to guideline adherence (e.g., medication selection, dosing calculations), remaining systemic barriers at the health care system level (e.g., lack of time, competing clinical demands) appear to have blunted the beneficial impact of the CDSS on patient outcomes (Trafton et al., 2010). Thus, the impact of electronic and other types of record-keeping systems on pain management or opioid prescribing, whether positive or negative, is not yet fully understood.

Insurer Policies for Pain Management

Insurer policies have a large and logical impact on health care delivery through their considerable financial leverage with respect to covering and reimbursing for specific clinical services or restricting access to others. In pain management, for example, a policy may or may not require specified indications before reimbursement for prescription opioids is authorized; in contrast, other policies may have more stringent requirements for authorization of nonopioid pain therapies and/or inadequate reimbursement structures. These policies, in turn, may result in marked differences in access to services and in desired outcomes. Insurers, including sources of publicly funded health care coverage and pharmacy benefit managers, therefore can play a critical role in shaping clinical practices related to opioids and nonopioid alternatives for pain management. As a result of increasing recognition of the role such policies can play in improving analgesic care, examples are emerging of both reductions in inappropriate opioid prescribing and enhanced access to more comprehensive models of pain management.

Opioid Prescribing Policies

Haegerich and colleagues (2014) reviewed eight studies examining the effect of patient review and restriction (PRR) (i.e., "lock-in") programs on opioid use. PRRs, used by public and private insurance plans, may require patients suspected of misusing controlled substances to obtain prescriptions from a specified prescriber and/or pharmacy. Overall, the findings of this review are impressive. Four of the studies considered both cost savings and health outcomes. These studies generally found that in the four respective programs studied (in Louisiana, Ohio, Oklahoma, and Washington), PRRs were associated with reductions in opioid use of one-third to one-half and with reductions in the number of patients able to successfully access multiple providers or pharmacies. The Washington study, which followed up patients 1 year later, also found significant reductions in emergency department and physician visits and in hospital costs (Haegerich et al., 2014). PDMP data can be used to determine whether a PRR is needed. In a survey of state Medicaid agencies, however, 48 percent (22 states) reported that their fee-for-service PRR program does not have access to the state PDMP (Pew Charitable Trusts, 2016).

Four studies reviewed by Haegerich and colleagues (2014) examined drug utilization review (DUR) programs that review claims data to identify and notify providers of potentially problematic use patterns. Although none of these four studies evaluated health outcomes, all found reductions in drug utilization, and one RCT found reductions in numbers of prescribers and pharmacies used. In a later study, Qureshi and colleagues (2015), utilizing pharmacy claims data from 980 members enrolled in a commercial health plan who met DUR criteria, found a 28.1 percent reduction in potentially unsafe combination therapy involving opioids and other central nervous system drugs (benzodiazepines or antidepressants). State Medicaid programs have implemented the use of DUR to curb inappropriate opioid prescribing.

Finally, Haegerich and colleagues (2014) also examined studies on prior authorization (PA) and quantity limit (QL) programs. PA requires review of medical justifications before drugs are covered by an insurer, while QL limits the amount of a drug that can be dispensed in a given time frame. Haegerich and colleagues (2014) summarize the finding of Morden and colleagues (2008) that the 21 states that implemented PA in their Medicaid programs saw 34 percent reductions in oxycodone use over the study period, whereas those with more lenient PA policies witnessed a slight (but nonsignificant) increase. Three studies of PA and QL by Oregon State University are described as finding significant reductions in use of long-acting (LA) opioids and carisoprodol, but no significant impact on sedatives/hypnotics (Haegerich et al., 2014).

In summary, insurance-based policies, such as those involving PRR, DUR, PA, and QL, have substantial potential to reduce the use of specific prescription drugs, although their impact on health outcomes remains uncertain.

Coverage and Reimbursement of Nonopioid Pain Management

As discussed in Chapter 2, there are multiple nonopioid pharmacologic (e.g., NSAIDs) and nonpharmacologic (e.g., physical therapy, cognitive-behavioral therapy) options available for patients with chronic pain. Nevertheless, insurer policies affect access to and uptake of these treatment options. The IOM report *Relieving Pain in America* specifically points to misaligned incentives in fee-for-service insurance systems as a primary obstacle to comprehensive and effective pain management, citing lower (or absent) reimbursement of psychosocial or nonprocedural treatments (IOM, 2011).

In part in response to the growing opioid epidemic, some insurers and state Medicaid agencies are working to expand access to nonopioid pain management services for common clinical indications, such as back pain (Cigna, 2016; McLaughlin, 2015; Oregon Health Plan, 2016). This is occurring despite the relatively lower cost of opioid prescriptions, which carry an average out-of-pocket cost of $10 per prescription (although the cost of extended-release [ER] formulations can be more than double that of immediate-release [IR] formulations) (Craig and Strassels, 2010). While relatively more expensive in the short term, integrated or multidisciplinary pain treatment programs have demonstrated long-term cost-effectiveness and increased functional improvement for patients (Turk and Burwinkle, 2005). Promising clinical research into opioid dose reduction programs, more comprehensive pain management, and the effectiveness of nonopioid treatments for pain is discussed further in Chapter 3.

The judicious deployment of insurer policies related to opioid prescribing, outlined above, would logically benefit from a commensurate increase in coverage of and access to nonopioid pain management. This broader approach to pain management is consistent with the guidelines of the CDC (discussed earlier in this chapter), the American College of Physicians, and FSMB, among others, that recommend careful initiation of opioids in the context of a comprehensive pain management plan (Dowell et al., 2016; FSMB, 2017; Qaseem et al., 2017). Accordingly, **the committee recommends that public and private payers develop reimbursement models that support evidence-based and cost-effective comprehensive pain management encompassing both pharmacologic and nonpharmacologic treatment modalities (Recommendation 5-3)**.

Prescription Drug Monitoring Programs

PDMPs, currently authorized in every U.S. state except Missouri,[14] as well as in the District of Columbia and the U.S. territory of Guam (Brandeis PDMP TTAC, 2017), are statewide electronic databases designed to prevent diversion and misuse of controlled substances. They require pharmacies and sometimes dispensing physicians to submit to a central office data on controlled substances prescribed and dispensed (e.g., drug type, dose, amount dispensed) (Haegerich, 2016), as well as insurance/payment and patient information. These data can be monitored for patterns in prescribing and dispensing. This monitoring for patterns includes the identification of possible "doctor shoppers" (individuals who visit multiple prescribers or pharmacies to obtain multiple prescriptions), as well as need for treatment, unsafe drug combinations, and inappropriate provider prescribing practices (Brandeis PMP COE, 2012, 2013, 2014; Jann et al., 2014; Patrick et al., 2016). Because PDMPs include virtually all data on prescriptions dispensed to a patient regardless of payment method, they allow for more complete monitoring than claims databases, which often are limited to data on payments for prescriptions within a particular network (Brandeis PMP COE, 2013).

States vary somewhat in terms of authorized users and recipients of PDMP data (NAMSDL, 2016). In most states, PDMPs are administered by health departments, boards of pharmacy, or a single state authority. Other states' programs are administered by law enforcement agencies, boards of pharmacy in conjunction with other agencies, professional licensing boards, or departments of consumer protection/affairs. As of May 2016, however, in only a handful of states (New Mexico, New York, Ohio, Oklahoma, Utah, and Vermont) were departments of health or commissioners of public safety authorized users of PDMPs, meaning that they are permitted to request and receive information on behalf of agency activities (Davis et al., 2015; Haegerich, 2016; NAMSDL, 2016). Prescribers and dispensers and physician assistants/medical residents/nurse practitioners are authorized recipients of PDMP data in every state, and law enforcement officials are authorized recipients in all but one state (Nebraska). Table 5-1 shows other types of professionals who are authorized users by state. As is shown, several states do not permit access for mental health and substance abuse and other types of professionals who could potentially use the data to monitor opioid use and related harms.

Although they have operating PDMPs, some states have laws that do not expressly mandate that prescribers and/or dispensers access PDMP information.[15] Most states are permitted to share PDMP data with other state PDMPs and/or with authorized users in other states (NAMSDL, 2016).

[14]Several counties and other localities within Missouri have established their own PDMPs.
[15]As of May 2016, these states included Alabama, Alaska, Georgia, Illinois, Indiana, Iowa, Kansas, Minnesota, North Dakota, Oregon, South Carolina, South Dakota, Wisconsin, and Wyoming (NAMSDL, 2016).

TABLE 5-1 States Authorizing Use of PDMP Data, by Selected Professions (as of May 2016)

State	County Coroners, Medical Examiners, and/or State Toxicologists	Medicare, Medicaid, State Health Insurance Programs, and/or Health Care Payment/Benefit Providers or Insurers	Mental Health/Substance Use Professionals	Worker's Compensation Specialists
Alabama	X	X		
Alaska	X	X	X	X
Arizona	X	X	X	
Arkansas	X			
California				
Colorado	X		X	
Connecticut	X	X		
Delaware	X	X	X	
District of Columbia	X	X	X	
Florida		X	X	
Georgia		X		
Hawaii	X	X	X	
Idaho	X	X		
Illinois	X			
Indiana	X	X	X	
Iowa				
Kansas	X	X	X	
Kentucky	X	X		
Louisiana		X		
Maine	X	X		
Maryland	X	X	X	
Massachusetts	X	X		
Michigan		X		
Minnesota	X	X	X	
Mississippi	X	X		
Missouri	NA	NA	NA	NA
Montana	X	X		X
Nebraska				
Nevada		X		
New Hampshire	X	X		
New Jersey	X	X	X	
New Mexico	X	X		
New York	X	X		
North Carolina	X	X		
North Dakota	X	X	X	X
Ohio		X		X
Oklahoma			X	
Oregon	X			
Pennsylvania	X	X	X	

Rhode Island	X	X		
South Carolina		X		
South Dakota		X	X	
Tennessee	X	X	X	
Texas	X			
Utah	X	X	X	X
Vermont	X	X		
Virginia	X	X	X	
Washington	X	X		X
West Virginia	X	X		
Wisconsin	X		X	
Wyoming				

SOURCE: NAMSDL, 2016.

With respect to effects on prescribing practice and patient receipt of drugs from multiple health care providers, PDMPs are currently considered promising strategies based on before–after studies and time series analysis (Haegerich, 2016). A contextual review conducted to support development of the CDC's Guideline for Prescribing Opioids for Chronic Pain concluded that there is indirect evidence for the utility of PDMP data for identifying indicators of risky opioid-taking behaviors and prescribing practices (Dowell et al., 2016). A recent analysis of Medicaid data suggests that mandatory prescriber registration with state PDMPs (as opposed to mandatory use of them) can lead to decreased prescribing of Schedule II opioids, although whether this resulted in safer prescribing or limited access to legitimate pain relief could not be assessed (Wen et al., 2017). In patients for whom a decision is made to initiate or continue opioid therapy, the CDC guideline recommends that clinicians review PDMP data for high-risk drug combinations or dosages (see Box 5-3, presented earlier). Further, the guideline states that PDMP data should be reviewed "when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months" (Dowell et al., 2016, p. 1639).

Research on the effectiveness of specific features of PDMPs is currently limited (Patrick et al., 2016). The Brandeis Prescription Monitoring Program Center of Excellence identified PDMP best practices based on a systematic review of articles published through November 2011 (Clark et al., 2013). None of the studies met criteria for the highest level of evidence (RCT or meta-analysis). Best practices based on the next level of evidence (observational study with comparison group) included using serialized prescription forms and sending unsolicited reports and alerts to prescribers, pharmacists, investigative agencies, and other relevant parties regarding questionable activity (Clark et al., 2013). Current laws in most states allow for unsolicited reporting but vary somewhat in terms of the parties to whom the reports may be provided (NAMSDL, 2016) (see Figure 5-2). Generally, these data support the effectiveness of PDMPs in reducing the supply of prescribed controlled substances in the community, which is one, but not the only, causal factor in the risk of opioid use disorder and overdose.

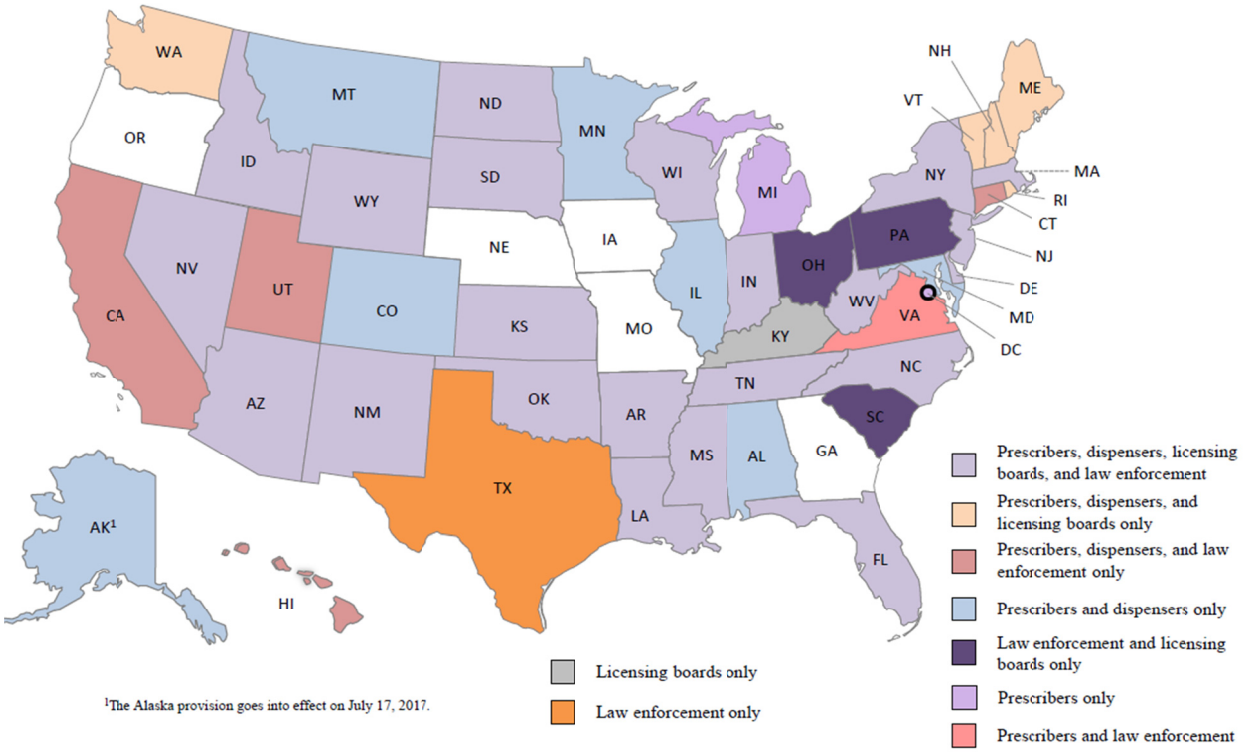

FIGURE 5-2 Unsolicited reporting of prescription drug monitoring program (PDMP) data to prescribers, dispensers, licensing boards, and law enforcement (as of May 2016).
SOURCE: NAMSDL, 2016.

Some states have worked to share PDMP data with other programs to support monitoring of prescribing patterns. Washington State's PDMP, for example, shares data with state Medicaid and workers' compensation programs to provide a more complete picture of controlled substances prescribed to patients. State program administrators reported that this effort supported improved identification of and early intervention for patients at risk for substance use disorder and overdose, led to reductions in costs associated with unnecessary prescription drug use and diversion and uncoordinated care, and improved education of prescribers about PDMPs, among other positive effects (Brandeis PMP COE, 2013). These findings are not specific to opioids, however. In Ohio and other states, a risk score (the NARxCHECK) that provides an assessment of patients' history of use of controlled substances based on PDMP data is incorporated into EMRs to support intervention efforts.

As noted above, states also utilize PDMP data to address at-risk prescribing through use of such tools as prescriber report cards and reports to licensing boards and law enforcement. Data on how these reports impact prescribing practices are currently limited, however. In Arizona, report cards summarizing prescribing over the last year were sent to outlier prescribers (those for whom PDMP data indicated that the number or total dosage units prescribed were 1 standard deviation above the average in their specialty and county). Preliminary findings for a county 1 year following implementation of the report cards show that the percentage of outlier prescribers fell from 19.2 to 14.2 percent (Brandeis PMP COE, 2014). In such states as Kentucky and Texas, provision to investigators of information regarding problem prescribers is believed to have helped identify and address this problem, both through removal and by providers being encouraged to modify their prescribing practices (Brandeis PMP COE, 2014).

As noted earlier, some states allow substance use and mental health professionals to access PDMP data. In treatment settings, the data may be used to check whether patients are being prescribed controlled substances. Limited evidence suggests that such access by these professionals may play a role in reducing opioid use by individuals in treatment (Brandeis PMP COE, 2015). It is worth noting that federal law itself may pose an additional obstacle related to treatment for substance use disorder: 42 C.F.R. Part 2 prohibits PDMP data from including any information related to substance use disorder services (e.g., receipt of methadone from an opioid treatment program). This provision carves out an additional area of patient privacy, often a contentious issue surrounding PDMPs, but necessarily excludes potentially relevant information from the PDMP.

By reducing the availability of opioids from medical sources in the community, one might reasonably expect that PDMPs would reduce mortality from opioid overdose. Yet relatively few studies have evaluated the impact of PDMPs on opioid-related mortality, and the results of available studies are mixed (Delcher et al., 2015). An analysis of observational data for the period 1999 to 2005 found no significant differences in rates of opioid overdose mortality and rates of opioid drug use between states with and without PDMPs (Paulozzi et al., 2011). However, PDMPs vary so widely in their legal requirements that little effect would be expected in a "yes or no" comparison. Until recently, for example, PDMPs were used primarily for law enforcement rather than public health purposes in most states, so an effect on drug overdose mortality might not be expected unless their use for this purpose had been articulated (Green et al., 2011). Additionally, utilization of PDMPs by health care providers was not included when the impact of PDMPs on overdose mortality or opioid use was assessed in two studies (Green et al., 2011; Kerlikowske et al., 2011). In another study that evaluated mortality data in states and the District of Columbia with and without PDMPs during 1999–2008, implementation of PDMPs was found not to be associated with reductions in drug overdose mortality in most states (Li et al., 2014).

A time series, quasi-experimental study of Florida's PDMP found that oxycodone-caused mortality declined by 25 percent in the month after implementation of the PDMP in 2011. This finding was significant after controlling for declines in mortality associated with the introduction, before implementation of the PDMP, of tamper-resistant oxycodone hydrochloride (HCL) controlled-release tablets to the market; law enforcement efforts to crack down on pill mills; and stricter rules and regulations related to prescribing of controlled substances (Delcher et al., 2015). However, even the study authors acknowledge the complex interrelationship among variables in the study, and specifically mention their lack of an explanation for the PDMP's mechanism of influencing their reported outcome, calling it an "important [remaining] empirical question" (Delcher, et al., 2015, p. 65). This may be because Florida circa 2010, as discussed earlier in this chapter, may have been a unique case study that does not generalize well to other states. Another recent analysis that included all state PDMPs found that implementation of a PDMP was associated with a reduction in opioid-related overdose deaths of 1.12 per 100,000 people in the year after implementation. Greater reductions in opioid-related overdose were observed in states where PDMPs included robust features, such as monitoring of greater numbers of drugs with abuse potential and at least weekly updating of PDMP data (Patrick et al., 2016). As of April 2017, the interval for PDMP data collection was within a week or less in all states except Alaska, which will go to weekly reporting starting in July 2017, and Montana (which reports data every 8 days). Only one state—Oklahoma—had real-time PDMP reporting as of April 2017 (NAMSDL, 2017).

Some researchers have noted that while PDMPs may have an important role to play in preventing opioid overdoses, a multipronged approach that includes PDMPs is needed to foster significant reductions by addressing multiple correlates (Davis et al., 2014). Explicit and public articulation of the application and role of PDMPs in overdose prevention may increase their effectiveness and use for this purpose (Green et al., 2015a).

In summary, evidence suggests that PDMPs can help address the opioid epidemic by allowing prescribers, dispensers, and other stakeholders to track prescribing and dispensing information. State laws differ widely in who has access to PDMP data, with some states denying access to certain stakeholders (e.g., substance use and mental health professionals, health departments) that could use the data to monitor opioid use and related harms. As noted earlier, some states do not require prescribers and/or dispensers to check PDMP information, assuming that a mandate would be overly burdensome and that the PDMP's availability is sufficient to enable responsible prescribing. As a result, PDMP data currently are not being used to their full potential.

The committee recommends that the U.S. Department of Health and Human Services, in concert with state organizations that administer prescription drug monitoring programs, conduct or sponsor research on how data from these programs can best be leveraged for patient safety (e.g., data on drug–drug interactions), for surveillance of policy and other interventions focused on controlled substances (e.g., data on trends in opioid prescribing, effects of prescriber guidelines), for health service planning (e.g., data on discrepancies in dispensing of medications for treatment of opioid use disorder), and for use in clinical care (i.e., in clinical decision making and patient–provider communication). (Recommendation 5-4).

STRATEGIES FOR REDUCING DEMAND

This section reviews strategies aimed at reducing aggregate desire and need for opioids, including both reducing patients' reliance on opioids for pain management and reducing the occurrence and prevalence of untreated OUD. Accordingly, the discussion encompasses two main strategies: education programs focusing on alternatives to opioids for pain management and prudent and limited use of opioids if they are prescribed; and health policies bolstering and improving access to and utilization of evidence-based treatment for OUD.

Patient Education

This section addresses targeted patient education programs as well as mass media campaigns for the general public.

Targeted Patient Education Programs

Patients' understanding of the potential benefits and risks of and alternatives to opioids can be influenced by targeted patient education programs, provider initiatives mediated by professional education, and disclosures by manufacturers mandated by the FDA. Unfortunately, research on the effectiveness of patient education in reducing the risk of harms from prescription opioids is lacking. In the review of evidence conducted to support development of the CDC

Guideline for Prescribing Opioids for Chronic Pain, investigators found no studies evaluating the effectiveness of patient education as a risk mitigation strategy. However, evidence suggests that many patients lack knowledge about opioids, indicating a need for patient education (Dowell et al., 2016). The CDC guideline recommends that before initiating opioid therapy, clinicians and patients weigh the known risks and benefits, available alternatives, and mutual responsibilities for optimal therapy. In connection with its prescribing guideline, the CDC has prepared a number of informational materials for patients on opioids and the risks associated with their use, as well as pharmacologic and nonpharmacologic alternatives for pain management (CDC, 2016b).

Other organizations also have developed informational materials for patients to promote safe opioid use and awareness of alternative therapies, although studies have not been conducted to assess the effectiveness of these materials. In 2016, the FDA issued guidance for patients on what to ask their providers before taking opioids (FDA, 2016c). The guidance recommends that patients ask their providers why they might need the medications (including asking whether there are alternative medications they can take to help with pain relief), how long they should take them, and whether they should have a prescription for naloxone (FDA, 2016c).

The potential value of patient education for reducing opioid-related harms also is supported by a number of health care organizations. The VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain recommends education about opioids for both patients and family members (VA and DoD, 2010). Pharmacists are trained to educate patients and others on the disposal of prescription medications, and the American Society of Health-System Pharmacists encourages pharmacists to educate patients about the storage, handling, and disposal of prescription medications (ASHP, 2011). A number of states' opioid prescribing guidelines also recommend education for patients on the risks and benefits of opioid therapy, alternative treatment options, and safe storage and disposal.

Part of the committee's charge was to describe education for patients (as well as prescribers) about safe storage and disposal of opioid medications as a means of curbing opioid-related harms. As discussed earlier in this chapter, many patients do not safely store and dispose of their prescription opioid medications, which can lead to misuse (Binswanger and Glanz, 2015; Reddy et al., 2014). Available studies that include a specific focus on the role of education in promoting safe storage and disposal of opioids are preliminary and have small sample sizes.

A pilot study of a brief, web-based educational intervention found significant improvements in knowledge about safe storage and disposal of prescription opioids postintervention and at 1-month follow-up. The study also found reductions in self-reported misuse (e.g., saving pills, lending medications to others) 1 month postintervention (McCauley et al., 2013). The intervention, which presented safety information in an interactive multimedia format, was administered to 62 adult outpatients who presented for treatment of chronic pain at pain management and dental clinics (McCauley et al., 2013). Likewise, in a prospective study of 300 adult cancer outpatients, those provided with educational material on safe opioid use, storage, and disposal each time they received an opioid prescription were significantly less likely to have unused medication at home (38 versus 47 percent) and significantly more likely to keep their medications in a safe place (hidden, 75 versus 70 percent; locked, 14 versus 10 percent) relative to patients who did not receive such material. The study found further that patients receiving the intervention were significantly more aware of proper opioid disposal methods (76 versus 28 percent) and less likely to share their opioids with others (3 versus 8 percent) (de la Cruz et al., 2017). Finally, a brief behavioral intervention was associated with a 22 percent increase in the proportion of patients who reported disposing of, or intent to dispose of, unused

opioids in a pilot RCT involving cancer patients (N = 79), but this finding was nonsignificant (Maughan et al., 2016). The downstream effects of this education, such as effects on opioid misuse and opioid-related morbidity and mortality, are unknown.

In summary, studies evaluating the effectiveness of patient education about prescription opioids are generally lacking. However, evidence does indicate that patients lack information about opioids, suggesting the need for such education. Information about the risks and benefits of opioids and alternative strategies for managing pain is being provided by several organizations, but because these efforts have not been evaluated, their impact is unclear. Preliminary research suggests that patient education on safe storage and disposal of opioids is associated with self-reported improvements in measures of these outcomes.

Mass Media Campaign for General Public

In parallel with the committee's recommended changes to provider education and payer policy is the need to effect a major change in patient expectations in the treatment and management of chronic pain. The committee was struck particularly by the relative lack of attention to the impact of education of the general public (i.e., all potential patients) about the risks and benefits of opioid therapy and the comparative effectiveness of opioid and nonopioid analgesics and nonpharmacologic interventions. Therefore, **the committee recommends that the nation's public health leadership, including the surgeon general, the Centers for Disease Control and Prevention, and heads of major foundations and professional organizations, convene a body of experts in communication and in pain and opioid use disorder to evaluate the likely impact (and cost) of an education program designed to raise awareness among patients with pain and the general public about the risks and benefits of prescription opioids and to promote safe and effective pain management (Recommendation 5-5).**[16]

Increasing Access to and Utilization of Medical Treatment for Opioid Use Disorder

As discussed in Chapter 4, medication-assisted treatment (MAT) is the central component of evidence-based treatment for OUD, regardless of whether it is combined with behavioral therapy. The use of medication can help patients cope with withdrawal symptoms, and may relieve drug cravings without producing the "high" of opioids. The medications that are used in MAT are opioid agonists, partial agonists, or antagonists, and include methadone, buprenorphine, naltrexone, and combination buprenorphine-naltrexone (Suboxone®). Research is ongoing into new MAT drug products, including implantable and "vaccine"-type medications.

Delivery Models

Integrating buprenorphine maintenance therapy (BMT) into federally qualified health centers (FQHCs) has been shown to be feasible, to increase access to evidence-based treatment for OUD, to expand the scope of patient-centered medical homes (a model of primary care under

[16]A logical complement to all patient and public education efforts is a substantial effort to counteract and possibly restrict direct-to-consumer advertising and other promotional efforts by pharmaceutical manufacturers aimed at increasing the use of opioids. This topic is addressed in Chapter 6.

the ACA that is patient-centered, comprehensive, accessible, and focused on quality), and to reduce illicit opioid use (Haddad et al., 2013). Integrating BMT into FQHCs also resulted in improved engagement of patients in primary care, preventive screening for other health conditions, and quality health care indicators beyond treatment of OUD. Additional strategies may be needed for women and those retained in treatment for less than 3 months, as they were less likely than their counterparts to receive preventive screening, which resulted in lower-quality health care indicator scores for these populations (Haddad et al., 2015).

An RCT comparing three approaches used in emergency department–initiated buprenorphine-naloxone treatment for OUD found that those who received screening, brief intervention, and referral to primary care for 10-week follow-up had superior outcomes relative to two comparison conditions (screening and treatment referral; and screening, brief intervention, and facilitated referral to community-based treatment services). Superior outcomes were noted for engagement in treatment 30 days postrandomization and reduced days of self-reported illicit opioid use per week. The rate of negative urine screens did not differ by study condition (D'Onofrio et al., 2015).

With regard to criminal justice settings, an RCT of prison-initiated buprenorphine treatment for inmates who were heroin-dependent prior to incarceration found significant effects favoring the buprenorphine treatment compared with counseling only (99 versus 80.4 percent) and for entry into treatment in a community setting compared with an opioid treatment center (47.5 versus 33.7 percent). Women were significantly more likely than men to complete treatment (85.7 versus 52.7 percent) (Gordon et al., 2014). A study of the impact of opioid treatment therapy in correctional settings in Australia found high treatment retention during incarceration (82 percent), prescriptions for MAT provided at release (90 percent), and presentation at community clinics for MAT postrelease (94 percent) (Larney et al., 2016).

State and Local Initiatives

Several state and local initiatives have been undertaken to increase access to and utilization of medical treatment for OUD. A buprenorphine initiative in Baltimore, Maryland, reduced opioid treatment waitlists and heroin overdose deaths by using a team of health care workers to support patients while they were in short-term treatment at a substance use disorder treatment facility, help them access Medicaid coverage, and refer them to outpatient providers for continuing care (Schwartz et al., 2013).

The Massachusetts Department of Public Health has implemented a nurse management model that encompasses initial assessment; referral to treatment; adherence monitoring; and communication with prescribing physicians, addiction counselors, and pharmacists. This model allows physicians with buprenorphine waivers to take on more patients (Alford et al., 2011). The expansion of this collaborative model for delivery of opioid agonist therapy with buprenorphine to 14 community health centers in Massachusetts led to a 375 percent increase in the number of waivered physicians (enabling their prescribing of buprenorphine) within 3 years (LaBelle et al., 2016).

Vermont's regional infrastructure for treatment of substance use disorder utilizes both geographic area–specific centers ("hubs") to provide comprehensive services to individuals with OUD and teams of clinicians ("spokes") to provide treatment, counseling, and other services to individuals who are less clinically complex. A cross-sectional study conducted during 2008 to 2013 evaluated outcomes for Vermont Medicaid beneficiaries with OUD, comparing those

receiving MAT with those receiving treatment without medication. Results suggest that MAT is associated with reduced general health care expenditures and utilization, such as inpatient hospital admissions and outpatient emergency department visits. The costs of treatment therefore were offset by these savings (Mohlman et al., 2016).

Treatment Utilization

State Medicaid policies influence enrollees' access to and use of opioid agonists (e.g., methadone and buprenorphine) for treatment of OUD. Most states cover such treatment for Medicaid enrollees, and the number of enrollees covered increased from 2004 to 2013. However, some states do not cover both methadone and buprenorphine. Furthermore, obstacles to utilization of opioid agonists exist, such as prior authorization requirements; copayments; and requirements for concurrent counseling, which if not available can act as a barrier to the treatment (Burns et al., 2015). State policies regarding coverage of the treatment have been associated with an increase in buprenorphine-waivered physicians (Stein et al., 2015) and with use of opioid agonist therapies and buprenorphine in substance use disorder treatment facilities (Bauhoff et al., 2014; Ducharme and Abraham, 2008). Mark and colleagues (2015) found that while 12 percent of Medicaid recipients had substance use disorders, only 13 state Medicaid programs included all medications approved for treatment of alcohol and opioid substance use disorder on their preferred drug lists. The drugs that were most commonly excluded were ER naltrexone, acamprosate, and methadone. Forty-eight Medicaid programs required prior authorization for combined buprenorphine-naloxone treatment, and 11 had 1- to 3-year lifetime treatment limits (Mark et al., 2015).

Availability of Providers and Treatment

Insufficient numbers of providers for treatment of OUD have been noted as a significant barrier to the availability of such treatment. In a state-level analysis of the supply of physicians waivered to prescribe buprenorphine for OUD, Knudsen (2015) found that the average state had 8.0 waivered physicians per 100,000 residents. In addition, large regional differences were found between states in the Northeast and states in the Midwest, South, and West. The supply of physicians waivered to prescribe buprenorphine was positively associated with the percentage of residents covered by Medicaid, the population-adjusted availability of opioid treatment programs, and the number of substance use disorder treatment programs. The supply of waivered physicians was positively correlated with states' numbers of overdose deaths, suggesting that physicians may seek waivers in response to the level of the opioid problem in their state (Knudsen, 2015). Recent steps to expand the number of waivered providers include increasing the upper limit of patients that can be treated by waivered physicians, expanding the type of prescribers permitted to be DATA[17] waivered, and integrating the required training into the health care professional educational curriculum (ASAM, 2016). For instance, the state of Rhode Island has taken steps to expand access to OUD treatment by incorporating the required training into existing medical school curriculum (McCance-Katz et al., 2017).

Significant gaps exist between the need for MAT and capacity. Jones and colleagues (2015) report that in 2012, the national rate of opioid misuse or dependence was 891.8 per

[17]Drug Abuse Treatment Act of 2000.

100,000 people aged 12 or older, while the treatment capacity was 420.3 for buprenorphine and 119.89 for methadone. Forty-eight states and the District of Columbia had past-year opioid misuse or dependence rates higher than their buprenorphine treatment capacity. While states varied significantly in their treatment need and capacity gap, most states (77.6 percent) reported that at least 75 percent of their treatment programs were operating at 80 percent capacity or greater. Although capacity for MAT increased markedly between 2003 and 2012, driven largely by the increase in the number of waivered physicians, the large gap between treatment need and capacity did not close significantly. The authors call for national and state practice and policy strategies to increase treatment capacity, such as improving training of health care professionals in the diagnosis and treatment of addiction; removing insurance, administrative, and payment-related obstacles; raising the limit on the number of patients physicians can treat with buprenorphine; and expanding the types of providers who can prescribe buprenorphine under the Drug Addiction and Treatment Act (Jones et al., 2015).

Increases in the availability of methadone and buprenorphine treatment have been linked to decreases in overdose deaths (Schwartz et al., 2013). However, MAT has been adopted in fewer than half of private-sector treatment programs, and when offered, only about one-third of patients receive it (Knudsen et al., 2011). Volkow and colleagues (2014) note that contributors to low access to and utilization of treatment with medication include the paucity of trained providers; negative attitudes regarding this form of treatment among providers, patients, and the general public; policy and regulatory barriers, such as utilization management techniques that place limits on dosages; treatment length; cumbersome paperwork for authorization and reauthorization; and minimal counseling coverage.

Treatment-Related Disparities

Studies show disparities in access to and utilization of treatment for substance use disorder in general and OUD in particular by race, ethnicity, and income.

Data from the National Epidemiologic Survey on Alcohol and Related Conditions show that both U.S.-born and immigrant Hispanic people who use drugs are less likely than their non-Hispanic white counterparts to have used any type of substance use disorder treatment (Mancini et al., 2015). The relationship between nativity and utilization of substance use disorder services varied among Hispanic groups, with utilization by Puerto Ricans being higher among those born on the island of Puerto Rico relative to those born in the continental United States. The authors point to several documented barriers to substance use disorder treatment among Hispanics, such as family factors, insurance/costs, linguistic and cultural factors, and the fit of service need with existing programs. The lifetime prevalence of use of heroin (as well as other drugs) was greater among U.S.-born relative to immigrant Hispanics after controlling for confounders, a finding that corroborates those of previous studies (Mancini et al., 2015). Data from an urban sample of the Treatment Episode Data Set-Discharges, a national census of annual discharges from substance use disorder treatment facilities, indicate that Hispanics and blacks are less likely to complete outpatient treatment relative to their white counterparts. Among heroin users, Hispanics were only 75 percent as likely as whites to complete a treatment episode (Mennis and Stahler, 2016).

For OUD specifically, a study of geographic and demographic differentials in uptake of buprenorphine compared with methadone treatment in New York City neighborhoods between 2004 and 2013 found that buprenorphine treatment had increased in all social areas over time, but that increases had been significantly higher in areas with the highest income and lowest

percentages of Hispanics, blacks, and low-income residents. Overall, methadone treatment had remained stable over time (Hansen et al., 2016). Another study (the RAPiDs study) examined variables affecting enrollment in treatment among Rhode Island young adult users of nonmedical prescription opioids. This study found that nonwhite race and low income, as well as previous incarceration and having experienced drug-related discrimination by medical providers, were associated with significantly lower rates of treatment enrollment (Liebling et al., 2016).

In an analysis of the demographic characteristics and behavioral health of persons aged 12 and older that met criteria for past-year OUD (N = 6,125) in the 2005–2013 National Surveys on Drug Use and Health, Wu and colleagues (2016) found that more than 80 percent of those with OUD had another substance use disorder, and 28.7 percent had experienced a major depressive episode. Among persons with OUD, 26.2 percent had used any treatment for alcohol or drug use, and 19.4 percent had used opioid-specific treatment. Opioid-specific treatment was especially underutilized by adolescents, the uninsured, blacks, Native Hawaiians/Pacific Islanders/Asian Americans, persons with prescription OUD only, and persons without major depressive episodes or substance use disorder (Wu et al., 2016).

Individuals involved in the criminal justice system also face barriers to effective treatment. While these individuals have high rates of substance use disorder (60–80 percent), their treatment utilization is low. Examining data from the Arrestee Drug Abuse Monitoring II program, Hunt and colleagues (2015) found that those with a history of heroin use had higher drug use and severity and higher rates of treatment utilization than those reporting use of other drugs. However, a minority (34 percent) of arrestees with drug use histories had received substance use disorder treatment during their lifetime, and only 14 percent had obtained such treatment during the year prior to their arrest. Receipt of mental health treatment services also is extremely low in this population despite a high prevalence of mental health problems.

More than 53 percent of state prison and local jail inmates meet diagnostic criteria of the *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition (DSM-IV) for drug abuse or dependence, and 19 percent have a lifetime history of heroin use (Belenko et al., 2013). However, a low proportion of those who could benefit from treatment receive it. When treatment with medication is offered, it is typically limited to detoxification, and often is provided only to pregnant women. Moreover, about half of drug courts have a specific policy against use of treatment with medication. Yet studies have demonstrated the efficacy of treatment with medication (i.e., methadone, buprenorphine, injectable sustained-release naltrexone) in criminal justice populations. Lack of treatment uptake in the criminal justice system may reflect state and local regulations, security concerns, institutional philosophy, and availability and resources. Additional research is needed on strategies for how best to integrate treatment into the criminal justice system at all stages (Belenko et al., 2013).

Summary

MAT for OUD has been found to be effective in a number of delivery models and settings but is greatly underutilized. This underutilization is driven by a combination of factors that include policies related to insurance coverage, payment, and approval and reimbursement limitations; lack of availability of eligible providers; negative attitudes toward treatment with medication among providers, patients, and the general public; insufficient training in OUD and its treatment among medical providers; and disparities in access and utilization. Aside from its immediate benefits to individuals with OUD, a strategy of increasing access to and utilization of

treatment for OUD can be expected to diminish the risk of public health harms in the broader community by lowering the number of individuals engaging in opioid misuse. State and local governments are well positioned to take responsibility for ensuring universal access to treatment of OUD, using whatever financial and technical assistance is available from the federal government. To enhance these benefits, additional research could examine several relevant areas, such as (1) development of new medications; (2) testing of the efficacy of combination drugs (e.g., combining buprenorphine and naloxone to decrease potential for misuse); testing of the efficacy of approaches for increasing utilization in various key treatment settings, reducing negative side effects (including those related to inappropriate opioid/benzodiazepine prescribing), and reducing disparities in utilization; (3) testing of the efficacy of therapies combining medication and behavioral treatment; and (4) testing of alternative pain management methods for reducing the iatrogenic effects of pain management on opioid addiction. See Chapter 3 for the committee's formal research recommendation.

The enormity of the current opioid crisis necessitates an immediate and massive expansion of treatment capacity to provide evidence-based treatment and recovery to millions of individuals. More than 2 million people have a prescription opioid–related OUD, and almost 600,000 have a heroin-related OUD (HHS, 2016). To address the gap between the availability of and demand for treatment, **the committee recommends that states, with assistance from relevant federal agencies, particularly the Substance Abuse and Mental Health Services Administration, provide universal access to evidence-based treatment for opioid use disorder (OUD), including use of medication, in a variety of settings, including hospitals, criminal justice settings, and substance use treatment programs. Efforts to this end should be carried out with particular intensity in communities with a high burden of OUD. State licensing bodies should require training in treatment for OUD for all licensed substance use disorder treatment facilities and providers (Recommendation 5-6).**

The committee recommends that schools for health professional education, professional societies, and state licensing boards require and provide basic training in the treatment of opioid use disorder for health care providers, including but not limited to physicians, nurses, pharmacists, dentists, physician assistants, psychologists, and social workers (Recommendation 5-7).

The committee recommends that the U.S. Department of Health and Human Services and state health financing agencies remove impediments to full coverage of medications approved by the U.S. Food and Drug Administration for treatment of opioid use disorder (Recommendation 5-8).

STRATEGIES FOR REDUCING HARM

Drug use can have a number of negative consequences, including lowered quality of life, transmission of disease through intravenous needles, and increased morbidity and mortality. Many of the tools of drug policy are aimed at reducing or ending the use of drugs. These tools utilize a variety of methods, including individual rehabilitation and treatment, enforcement of criminal sanctions against drug use or distribution, and public communication campaigns aimed at preventing drug use. The priority of the harm reduction approach, in contrast, is minimizing the negative consequences of drug use instead of focusing solely on reducing drug use itself.

Harm reduction encompasses multiple strategies tailored to the needs of particular individuals and communities, and may focus on encouraging safer drug use, managed use, and/or abstinence.

Two of the most significant harms of opioid use are overdose and transmission of bloodborne infections due to injection drug use. As discussed in Chapter 4, opioid-related overdoses have soared in recent years; in 2015, more than 33,000 people died from opioid overdoses, nearly half of which involved a prescription opioid (Rudd et al., 2016). Harm reduction strategies for opioids are aimed primarily at these two harms. Strategies for reducing the harms of opioid use may include dispensing naloxone for use in reversing overdose, providing services that facilitate safer drug use (syringe exchange, supervised injection facilities, and drug checking), and implementing behavioral interventions. Changes in drug laws also can be effective (see Box 5-4 for an international example). Often, harm reduction strategies are implemented together (see Box 5-5 for an example). Thus, naloxone is provided along with training in how to use it, and syringe exchange facilities also facilitate treatment admission or other services, educate users about overdose prevention and abscess and wound care, and provide training in the use of naloxone.

BOX 5-4
Outcomes Associated with a Harm Reduction Strategy in Portugal

In Portugal, spearheaded by a multidisciplinary group led by a physician, intentional and aggressive steps were taken to focus on the health of the citizens and effect a shift in attitude from viewing drug use as a crime to viewing it as a health problem to be addressed as a disease. As a result, people who use drugs are considered “physically ill or sick,” not “criminal” (Laqueur, 2014). Treatment of the substance use disorder was aggressively emphasized (Bushak et al., 2016). Possession of a small amount (up to a 10-day supply) of drugs is now dealt with by the local Commission for the Dissuasion of Drug Addiction, composed of an attorney, physician, and social worker.

Approximately 90 percent of antidrug resources in Portugal is now spent on prevention and treatment, with the rest going to incarceration and other punishment. The increased health care costs are thought to be offset by cost reductions in the penal system. Portugal did not keep statistics on drug use or misuse until after 2001, but drug use has not increased since then as was predicted at the time of the change in the law, and has remained relatively unchanged. What did decrease was the negative effects of drug use, such as the number of cases of infection-related morbidity associated with drug misuse, the rate of substance use disorder, and drug-related mortality. The burden on the Portuguese criminal justice system also has significantly decreased. What is unique about the Portugal experience is the combination of decriminalization and an aggressive focus on health care (Bushak, 2016; EMCDDA, 2015; Hughes and Stevens, 2010; Laquer, 2014).

BOX 5-5
Harm Reduction Strategies in Huntington, West Virginia

West Virginia has been hit hard by the opioid epidemic. The state had the highest rate of opioid overdose deaths in the nation in 2015, with 41.5 deaths per 100,000 people (Rudd et al., 2016). Between 2010 and 2016, drug wholesalers shipped millions of opioid pills to West Virginia—433 pills for every man, woman, and child in the state (Eyre, 2016).

In August 2016, paramedics and police officers in the town of Huntington responded to 26 heroin overdoses in one afternoon alone. However, the paramedics and police officers were equipped with naloxone and were experienced in dealing with overdoses, and all 26 people survived. Huntington has responded to its opioid problem by "throwing everything we know at the problem," including harm reduction strategies such as providing naloxone, medication-assisted treatment, and syringe exchange. The town began equipping its police officers with naloxone in spring 2016, and changes to state laws have enabled naloxone distribution to the public and protection of those who report overdoses. The town has eight medically assisted detox beds, which are always full, and a long-term recovery facility with peer mentors. West Virginia's first syringe exchange program opened in Huntington in 2015, and in less than 1 year distributed 150,000 clean syringes to more than 1,700 people. The program also offers medical assessments and referrals to recovery options.

Huntington's groundbreaking programs "have been models for the rest of the state," but unfortunately, the money needed to conduct these programs is running out. Dr. Michael Kilkenney of the Cabell-Huntington Health Department says that the town has "programs ready to launch, and we have no resources to launch them with. We're launching them without resources, because our people are dying, and we can't tolerate that" (Joseph, 2016).

Use of Naloxone to Reverse Overdose

As discussed in Chapter 4, naloxone is an opioid antagonist of the μ opioid receptor. When administered, it blocks the effects of opioids and reverses depression of the respiratory and central nervous systems, preventing death by overdose. Naloxone can be administered via intravenous, intramuscular, subcutaneous, or intranasal routes. In 2014, the FDA approved a naloxone autoinjector system that provides the administrator with voice and visual guidance, and in late 2015, the FDA approved a naloxone nasal spray, which is easy to administer and eliminates the risk of a contaminated needle stick. Naloxone is not a controlled substance and has no abuse potential, but when administered to people who are dependent on opioids, it may cause acute withdrawal symptoms, including vomiting.

Overdoses can occur among all groups of opioid users—those who use illicit opioids, those who misuse prescription opioids, and those who use opioids to manage pain as prescribed by a doctor. Naloxone training and distribution programs have historically been targeted at users of illicit opioids, particularly people who use drugs intravenously, because they are at high risk and are also most likely to report using the medication to reverse an overdose (Rowe et al., 2015). However, there is growing interest in translating these programs into clinical settings for patients who take prescription opioids (Mueller et al., 2015). Because anyone who uses opioids is at risk of overdose, various strategies are used to make naloxone available in a variety of settings. These strategies can be divided roughly into community-based, systems-based, pharmacy-based, and prescriber-based.

There are a number of barriers to the use of naloxone to prevent overdose. First is a simple logistical barrier: the person who is overdosing cannot self-administer naloxone, so there must be someone nearby who can recognize the symptoms of overdose, can quickly access naloxone, and knows how to administer it. There also are legal and regulatory barriers. For example, naloxone requires a prescription in some states, a nonmedical person who administers naloxone can face potential liability, and people who use drugs who summon aid for an overdose can face potential legal ramifications. Most states have passed laws to address these various barriers. New Mexico, for example, passed the first law protecting lay administrators of naloxone in 2001 and the first "Good Samaritan" law to protect users who summon help in 2007 (Network for Public Health Law, 2016). Dozens of states have followed suit. Rhode Island has made particular progress in eliminating the legal barriers to the use of naloxone (see Box 5-6). The adoption of these laws has been shown to be associated with a decrease in opioid-related deaths. Rees and colleagues (2017) examined the effect of naloxone access laws and Good Samaritan laws. They found that the adoption of a naloxone access law is associated with a 9–11 percent reduction in opioid-related deaths, while the adoption of a Good Samaritan law appears to be associated with a similar reduction, although this association is not statistically significant. The authors note that the naloxone access laws most strongly associated with a decrease in deaths are those that remove criminal liability for possession of naloxone (Rees et al., 2017).

BOX 5-6
Improved Access to Naloxone in Rhode Island

Rhode Island is among the top five states in per capita opioid overdose deaths (Rudd et al., 2016); drug overdoses kill more people in the state than motor vehicle crashes (Green et al., 2015b). In the past decade, Rhode Island has been a leader in innovative programs aimed at reducing overdose deaths, including by improving access to naloxone through a variety of avenues. In 2006, Miriam Hospital began a pilot program called Preventing Overdose and Naloxone Intervention (PONI), which provides naloxone kits and training to individuals. PONI also collaborates with the department of corrections to train incarcerated individuals on overdose prevention and distribute naloxone prior to release. In 2012, Rhode Island passed a Good Samaritan law to shield bystanders who administer naloxone and overdose victims from prosecution or civil liability. The same law provides limited drug-related immunity to victims and responders of an overdose. Also in 2012, Walgreens Pharmacy entered into a collaborative practice agreement that permitted it to distribute naloxone without a prescription.

Pharmacy-distributed naloxone evolved into a statewide endeavor with the help of a 2014 emergency regulation that expanded access further by allowing all pharmacists to dispense naloxone to a patient without their having to see a prescriber for a prescription. In addition, the law permitted all licensed prescribers to dispense naloxone to organizations and to anyone at risk of overdose, as well as to a friend or family member of such an individual (i.e., a "third party"). In 2017, new legislation furthered access to naloxone by mandating insurance coverage of generic naloxone products for both insured individuals and third parties. Today, naloxone distribution in the state has reached optimal community uptake shown to reduce mortality (Bird et al., 2016).

Making changes to the legal landscape requires, of course, some level of public support for the changes, and the public does not always support the provision of naloxone, despite its obvious and immediate benefits (see Box 5-7 for a review of state laws regarding naloxone). Critics of naloxone programs argue that the availability of naloxone will encourage increased drug use because users will rely on it to save them from overdose, or that using naloxone is futile because people who overdose and are saved will only overdose again in the future. This latter example is supported by modeled evidence: overdose predicts subsequent overdose (Coffin and Sullivan, 2013). However, the same could be said of myocardial infarction (MI) predicting MI and a corresponding argument made against the use of coronary catheterization, the difference being that the underlying OUD is stigmatized more than underlying obesity or other clinical predictors of MI. This is an important point, because the public's low level of knowledge about or familiarity with naloxone and lack of sympathy for people who use drugs impact the level of support for naloxone distribution (Bachhuber et al., 2015). However, one study showed that these perceptions could be changed through exposure to messaging, particularly that which included factual information along with a sympathetic narrative about an individual who could have been saved with naloxone (Bachhuber et al., 2015). The final barrier is cost. Demand for naloxone has risen dramatically as the opioid epidemic has worsened and as states have facilitated and promoted the lay use of naloxone. Companies recently have raised the price of naloxone; in one case, Kaleo Pharma raised the price for its specific pack of two single-dose injectors from $750 to $3,750 (Silverman, 2016). Lack of widespread insurance coverage further exacerbates the cost issues of naloxone, particularly for third-party prescriptions (currently legal in 44 jurisdictions; see Box 5-7).

Community-Based Programs

Overdose education and naloxone distribution programs are designed to train people in the community who are most likely to witness an overdose—people who use drugs and their friends and family. Training programs that provide information about recognizing and responding to an overdose have existed since the mid-1990s, but in recent years have increasingly focused on providing naloxone to trainees (CDC, 2012). The trainings are often offered in conjunction with other services aimed at people who use drugs, such as syringe exchange programs; as a result, the trainees tend to be largely users of illicit opioids (e.g., heroin), despite the fact that nearly half of opioid overdoses involve a prescription drug (Clark et al., 2014).

A 2014 systematic review of community-based overdose education and naloxone distribution programs found that they are effective at increasing bystander knowledge about recognizing and responding to an overdose, and that this increased knowledge results in the successful use of naloxone and a high survival rate among those treated (Clark et al., 2014). Among the studies that measured knowledge before and after the training, many found a statistically significant increase in knowledge, although retention of this knowledge was variable. The primary components of the training included information about recognizing and preventing overdose; risk factors for overdose; and appropriate response to overdose, including naloxone administration.

BOX 5-7
State Laws on Naloxone

In a 2016 report, the Network for Public Health Law tracks multiple questions regarding state laws on naloxone aimed at increasing access among nonprofessional responders, including the following:

- Does the jurisdiction have a naloxone access law?
- Do prescribers have immunity from criminal prosecution for prescribing, dispensing, or distributing naloxone to a layperson?
- Do prescribers have immunity from civil liability for prescribing, dispensing, or distributing naloxone to a layperson?
- Is a layperson immune from criminal liability when administering naloxone?
- Is a layperson immune from civil liability when administering naloxone?
- Are prescriptions of naloxone authorized to third parties?
- Is prescription by a standing order authorized?
- Does the law remove criminal liability for possession of naloxone?

The report states that as of June 2016, 48 states and the District of Columbia had passed naloxone access legislation (Kansas, Montana, and Wyoming were the exceptions, and all three subsequently passed naloxone laws, in April and May 2017). Specific legal provisions in those 48 jurisdictions vary: the laws allow for layperson possession of naloxone without a prescription in 17 jurisdictions; prescribers have immunity from criminal prosecution in 37 jurisdictions and from civil liability in 33; laypersons who administer naloxone are immune from civil liability in 42 jurisdictions and from criminal liability in 36; prescriptions to third parties are authorized in 44 jurisdictions; and prescriptions by standing order are authorized in 39 jurisdictions. Prescribing to third parties is permitted in 44 jurisdictions.

The report also summarizes “Good Samaritan” laws, which provide varying levels of immunity from prosecution for those summoning emergency responders in the event of an overdose, including

- immunity from prosecution for possession of controlled substances, and
- immunity from prosecution for possession of drug paraphernalia.

Some form of “Good Samaritan” law had been passed in 37 jurisdictions, with all 37 providing immunity from prosecution for possession of controlled substances, and 25 additionally providing immunity from prosecution for possession of drug paraphernalia.

SOURCE: Network for Public Health Law, 2016.

According to an analysis of 19 Massachusetts communities adopting overdose education and naloxone distribution programs, rescue with naloxone was attempted 327 times between September 2006 and December 2009. The reported survival rate of overdose victims was high—98 percent overall—and the authors suggest that these trainings were associated with reduced mortality from opioid overdose at the population level (Walley et al., 2013). In addition to information about naloxone, trainees in these programs often receive information about other

appropriate responses to overdose, including placing the person in the "recovery position," using cardiopulmonary resuscitation (CPR), and contacting emergency medical services (EMS). Yet while some studies report that training improved the use of appropriate responses, many trainees continued to use inappropriate responses (e.g., throwing water on the victim), and most did not contact EMS. The failure to contact EMS often was due to a fear of negative consequences, although those who did contact EMS generally reported positive experiences (Clark et al., 2014).

While many users of naloxone obtain the drug through a formal training program, one retrospective cohort study in Massachusetts suggests that people who obtain naloxone through other means (e.g., their social networks) can and do use it successfully to reverse overdoses. Nor do their responses to overdose differ significantly from those of people who have been trained in the provision of naloxone (Doe-Simkins et al., 2014).

Systems-Based Programs

Naloxone distribution and training can also be conducted through health systems such as the Veterans Health Administration (VHA). Veterans are at particular risk of opioid-related harms, as many suffer from chronic pain and take opioids to treat it. About 68,000 veterans—roughly 13 percent of the total population of veterans who take opioids—have OUD, and veterans are twice as likely as nonveterans to die from accidental opioid overdoses (Childress, 2016). To address these issues, the VHA launched its Opioid Safety Initiative in October 2013. This initiative has reduced the use of opioids among veterans while seeking to manage their pain in other ways, and monitors the VHA's opioid dispensing practices systemwide. The VHA also launched the Opioid Overdose Education and Naloxone Distribution program in May 2014 to reduce opioid-related morbidity and mortality. This program encourages VA providers to consider providing education and naloxone to veterans who are at risk of opioid overdose, and gives providers tools for identifying such veterans using such information as opioid dosage, history of overdose, and other substance use disorder (VA, 2016).

Pharmacy-Based Programs

Research has shown that pharmacists are in an excellent position to train patients and their families on the use of naloxone kits (Bachyrycz et al., 2016; Bailey and Wermeling, 2014; Green et al., 2015b), although availability of the kits is not universal, and attitudes toward their use currently vary (Nielsen et al., 2016). Many states allow pharmacists to distribute naloxone over the counter without a prescription from a doctor. As of December 2016, this was the case in 33 states and the District of Columbia, with plans to expand to 7 more states in 2017 (see Walgreens, 2016). Pharmacists' knowledge, training, and position of trust put them in an ideal position to provide naloxone and counsel patients in when and how to use it. In the course of their work, most pharmacists "likely [are] serving some people who are misusing" prescription or illicit opioids (see APhA, 2015), and "can serve as invaluable instruments in identifying high-risk patients" (Bailey and Wermeling, 2014). Pharmacists interact daily with patients who are filling prescriptions for opioid analgesics, and in states that permit over-the-counter sales of syringes, with people who inject drugs. Because pharmacies are spread throughout neighborhoods and visited frequently by community members, the provision of naloxone through pharmacists greatly expands its accessibility, potentially enabling it to reach communities that are not served by other naloxone distribution programs (Green et al., 2015b).

Provider-Based Programs

Health care providers have an important role to play in reducing the harms of opioid use, both for users of illicit opioids and for patients who use opioid analgesics. Health care professionals can identify patients who are at risk of OUD or overdose, and can prescribe naloxone for patients who are taking opioids. Coprescription of opioids and naloxone is a fairly new practice, but some research suggests that it is well received by patients and can actually result in safer opioid use behaviors. Phillip Coffin, who oversees a project in which California clinics prescribe naloxone to any chronic pain patient who has used opioids for more than 3 months, says he is "looking for a change in the way that people interact with their opioid. The naloxone is there and will hopefully never be used, but I hope it helps people recognize the real risk of prescription opioids" (Alcorn, 2014). A nonrandomized study of such clinics compared those patients who were and were not prescribed naloxone along with their opioid prescription. Patients who had previously had an opioid-related emergency department visit or who were prescribed higher doses of opioids were more likely to be offered naloxone. Compared with patients who did not receive a naloxone prescription, those who did had 63 percent fewer opioid-related emergency department visits after 1 year. Among those who were prescribed naloxone, 82 percent filled the prescription successfully, and 37 percent reported safer opioid use behaviors after receiving the prescription. Patients generally had a favorable opinion of naloxone: 97 percent said they believed that patients who are prescribed opioids for pain should also be offered naloxone, and 79 percent had either a positive or neutral response to being offered naloxone (Behar et al., 2016; Coffin et al., 2016). While this study was observational and may not be generalizable to other settings, it suggests that coprescription of naloxone is acceptable and may have additional benefits.

Coe and Walsh (2015) argue that while providing naloxone to all prescription opioid users is "probably unnecessary and perhaps not practicable," providers should consider making it available to patients who are at high risk, including those who

- have a diagnosis of alcohol or drug use disorder;
- maintain on a high dose of opioids;
- are initiating or receiving methadone;
- use other prescription medications, particularly benzodiazepines;
- have comorbid psychiatric disorders and are at greater risk for suicide by overdose; and
- have cognitive impairments that could lead to accidental overingestion.

The CDC guideline for prescribing opioids recommends naloxone coprescription in similar cases, with an additional recommendation for those patients who are at risk of returning to high doses and who are no longer tolerant (e.g., patients recently released from prison) (Dowell et al., 2016).

Despite the benefits of coprescription of naloxone, however there are significant barriers to this strategy. Providers may lack knowledge about naloxone and its use to prevent overdose, may be unaware that their patients are at risk for overdose, or may be hesitant to prescribe naloxone for fear that patients will be offended or will treat naloxone as a safety net and take more risks with opioids (Binswanger et al., 2015). One qualitative study of primary care staff who prescribed opioids to patients revealed that many staff had significant gaps in their

knowledge about naloxone and were uncertain as to which patients were at risk of overdose. The staff in the survey suggested that naloxone prescribing could be facilitated through standardized guidelines for prescribing, efforts to reduce the stigma of naloxone, and improved communication from emergency departments about overdoses and guidance for follow-up (Binswanger et al., 2015).

Patients who are at risk for overdose due to illicit drugs face an even greater barrier to obtaining naloxone or other harm reduction medications from their physicians. One study showed that 54 percent of physicians "would never consider prescribing naloxone to a patient who injected drugs" because of discomfort, lack of knowledge, or a belief that providing naloxone may condone risky drug use (Mueller et al., 2015). Health care professionals are in a prime position to identify and assist patients who are at risk for overdose, but stigma reduction efforts, education, and training are needed to capitalize on this opportunity.

Summary

Naloxone is a safe and effective method for reversing overdoses, and can easily be administered by bystanders. However, a number of barriers prevent it from being as widely used as it could be. These barriers include laws that do not allow community members to access naloxone or pharmacists to distribute it, its rising cost, and a lack of knowledge about it among health care providers. **The committee recommends that state medical and pharmacy boards educate and train their members in recognizing and counseling patients who are at risk for opioid use disorder and/or overdose, and encourage providers and pharmacists to offer naloxone when an opioid is prescribed to these patients or when a patient seeks treatment for overdose or other opioid-related issues (Recommendation 5-9).**

Reducing Disease Transmission

Syringe Exchange

Sharing syringes and drug injection equipment puts people who inject drugs at high risk of being infected with HIV and HCV, as well as hepatitis B virus. Unsafe drug use is responsible for about 8 percent of new HIV infections in the United States and has contributed to a recent 150 percent increase in HCV infections (CDC, 2015). Because such infections as HIV and HCV also can be spread through sexual activity or from mother to baby, reducing infections among people who inject drugs can help protect the whole community (CDC, 2015). Syringe exchange programs, whether in a community setting or through pharmacies, have proven an effective method for reducing the risk of infection. In addition to providing clean injection equipment, these programs can facilitate a number of other services that are useful for people who use drugs, including helping them find treatment options, HIV testing and counseling, access to naloxone, and education about safer injection practices and safer drug use. Because syringe exchange programs often are just one of a broader set of harm reduction interventions, it is difficult to determine the extent to which they reduce the risk of infection for people who inject drugs. Research does suggest, however, that syringe exchange programs are an effective strategy for reducing HCV seroconversion (Hagan et al., 2011) and are effective at encouraging and facilitating entry into drug treatment (SAMHSA, 2011). In late 2016, the CDC called on state and local health departments to improve access to syringe exchange, citing a CDC report noting

that only one in four people who use injection drugs always use sterile injection equipment (Abbasi, 2017). Additionally, a CDC brief cites multiple studies demonstrating the cost savings resulting from legalized syringe exchange programs, primarily through reducing the prevalence of HIV, HCV, and related health care costs (CDC, 2016a).

In some communities, safe injection equipment is available directly from pharmacies. The sale of syringes through pharmacies is regulated by a patchwork of laws and regulations, including state laws that require a prescription for syringes and state drug paraphernalia laws that forbid the sale of items intended to be used to consume illegal drugs (see Box 5-8 for a summary of state laws regulating the possession or distribution of injection equipment).[18] However, some states have taken steps to improve access to clean syringes by exempting syringes from such laws. The American Pharmacists Association is supportive of these efforts; it "encourages state legislatures and boards of pharmacy to revise laws and regulations to permit the unrestricted sale or distribution of sterile syringes and needles by or with the knowledge of a pharmacist in an effort to decrease the transmission of blood-borne diseases" (APhA, 1999).

BOX 5-8
Laws Concerning Injection Equipment

State laws affect the ability of a person who uses drugs to access clean syringe equipment. Laws that make it difficult to access equipment make it more likely that a user will share or reuse equipment, leading to infectious disease or infection. The Policy Surveillance Program tracks three primary questions regarding syringe access:

- Does state law prohibit the sale or distribution of drug paraphernalia?
- Does state law regulate the retail sale of syringes?
- Is syringe exchange explicitly authorized by state law?

Every state except Alaska criminalizes the sale or distribution of drug paraphernalia, but many jurisdictions have some exemptions for drug injection equipment: 7 jurisdictions explicitly exclude injection equipment from these laws, while 17 jurisdictions define syringes as illegal drug paraphernalia but have exceptions to allow for distribution of syringes to prevent bloodborne diseases. Twenty-four states have no such exceptions to their drug paraphernalia laws.

Twenty-five states have state laws that regulate the retail sale of syringes. Regulations include limits on the number of syringes that may be sold, the requirement that the buyer have a prescription for syringes, or requirements for the seller to collect specific information from the buyer. Eighteen jurisdictions explicitly authorize syringe exchange.

For much of the last 30 years, a ban on the use of federal funds for syringe exchange programs has been in place, but this ban was partially lifted in January 2016. Federal funds may not be used directly for syringes or needles, but may be used for program and staff expenses.

SOURCE: Policy Surveillance Program, 2012.

[18]See http://www.temple.edu/lawschool/phrhcs/otc.htm (accessed April 17, 2017).

Making syringes available from pharmacies has great potential to expand the geographic reach of access to clean syringes (Logan and Deutsch, 2015). Pharmacists also can counsel users and facilitate other services; in fact, a 2015 California law mandates that pharmacies selling nonprescription syringes provide written or verbal counseling at the time of sale about accessing drug treatment, accessing HIV and HCV testing and treatment, and safely disposing of used injection equipment.[19]

Supervised Injection Facilities

Supervised injection facilities (SIFs) provide users a safe space to inject drugs (that are obtained elsewhere) under clinical supervision. The facilities often offer clean injection equipment; information about safer drug use; referrals for medical care, testing, and treatment; and other services (We are the Drug Policy Alliance, 2017). Research has shown that SIFs are associated with safer injection practices and higher uptake of treatment services (Beletsky et al., 2008). In addition to the benefits for people who use drugs, SIFs reduce drug-related public nuisances, such as public drug use and discarded syringes (Beletsky et al., 2008). There are more than 100 SIFs operating in 11 countries worldwide, but none in the United States (*ScienceDaily*, 2016). Efforts are under way to implement SIF pilot projects in the United States; a 2016 study estimated that a single SIF in San Francisco could generate $3.5 million in health savings per year (*ScienceDaily*, 2016). The city of Ithaca, New York, has developed a comprehensive drug plan that calls for the exploration of a SIF. The plan explains that a SIF could "prevent fatal and non-fatal overdose, infectious disease, and bacterial infections; reduce public drug use and discarded needles; and provide primary care and referrals to basic services, housing, and substance use services and treatment" (City of Ithaca, 2016, p. 7). In light of these initiatives, it appears likely that severely affected localities will seek to establish SIFs. If they do so, however, legal questions may arise about whether states or local governments could authorize the facilities and operate them without violating federal law. Such facilities could be established on an experimental basis for the purpose of estimating the effectiveness and cost of such programs.

Drug Checking

The heroin that the individuals in Huntington, West Virginia, had injected, as described earlier in Box 5-5, was found to be mixed with fentanyl (an opioid 50–100 times stronger than morphine) and carfentanil (an opioid used for tranquilizing elephants that is 10,000 times stronger than morphine) (Joseph, 2016). Drug checking services are designed to avert these kinds of tragedies by analyzing the purity of drugs and identifying the presence of adulterants; in addition, the services use this information to monitor the drug market and identify new or lethal drugs. Drug checking services have existed in Europe for several decades but are scarcer in the United States, consisting of only a handful of online services that test anonymously sent drug samples or provide at-home test kits (Johnson, 2016).

[19]See http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140AB1743&search_keywords= (accessed April 17, 2017).

Behavioral Interventions

The medications and services discussed above often are offered in tandem with behavioral interventions, although the latter interventions may also be offered solo. Evidence suggests that behavioral interventions—such as trainings, education about safe injection practices, and motivational counseling—can result in increased knowledge, safer and/or reduced drug use, and lower risk of overdose or transmission of disease. Research has shown, for example, that opioid overdose training that includes information about how to recognize an overdose and administer naloxone significantly increases knowledge and confidence in administration (Ashrafioun et al., 2016).

Behavioral interventions can be delivered in a variety of settings, including the community, syringe exchange facilities, clinics, and pharmacies. One particularly promising setting for such interventions is the emergency department. People who seek help at an emergency department for opioid-related issues, including overdose, are in a prime position to be receptive to behavioral interventions, including education and treatment. Intervention in the emergency department is a fairly new strategy, so data on its effectiveness are limited, but early research suggests that this strategy can result in long-term behavior changes. A program begun in August 2014, for example, targets patients presenting with an opioid overdose in Rhode Island hospitals. Patients in the emergency department are given a naloxone kit and overdose prevention education, and are paired with a peer recovery coach who offers support and referral to addiction treatment (Samuels et al., 2014). The coaches are trained and certified by the Anchor Recovery Community Center, a peer-to-peer recovery support organization. Since the program's inception, 82 percent of people who have overdosed and been seen in Rhode Island hospitals have accepted a recovery coach, and 87 percent of them have remained engaged at the 30-day mark. Six months after their emergency department visit, 33 percent were still engaged and on the path to recovery (Goyer, 2016). Other emerging models for these types of interventions include the following:

- Safe Stations (Manchester, New Hampshire)—Fire stations are designated safe spaces for individuals who are seeking assistance on a path to recovery. Such individuals who arrive at fire stations are asked to dispose of needles, paraphernalia, and illegal substances, and then are medically assessed and may speak with recovery coaches and obtain further information about treatment.[20]
- Angel Program (Gloucester, Massachusetts): This program allows individuals to turn in their drugs to the police (without threat of arrest) and assigns them an "angel" to guide them through recovery. Early numbers suggest that the program saves money and may facilitate recovery. Of 100 program participants who answered a survey question, 60 had not returned to using drugs. Similar programs have begun in Chicago and North Carolina (Hasan, 2016).

Summary

Harm reduction strategies such as syringe exchanges, SIFs, and drug checking can not only facilitate safer drug use practices but also serve as a conduit for users to access treatment,

[20]See https://www.manchesternh.gov/Departments/Fire/Safe-Station (accessed April 17, 2017).

medical care, and basic services. Unfortunately, while some strategies have been shown to reduce morbidity and mortality among people who use prescription and/or illicit opioids, there are significant barriers to access to safe injection equipment, most notably state laws.

To reduce the harms of opioid use, including death by overdose and transmission of infectious diseases, the committee recommends that states implement laws and policies that remove barriers to access to naloxone and safe injection equipment by

- **permitting providers and pharmacists to prescribe, dispense, or distribute naloxone to laypersons, third parties, and first responders and by standing order or other mechanism;**
- **ensuring immunity from civil liability or criminal prosecution for prescribers for prescribing, dispensing, or distributing naloxone, and for laypersons for possessing or administering naloxone; and**
- **permitting the sale or distribution of syringes, exempting syringes from laws that prohibit the sale or distribution of drug paraphernalia, and explicitly authorizing syringe exchange. (Recommendation 5-10)**

SUMMARY AND RECOMMENDATIONS

Each of the above strategies involves costs and trade-offs. Every policy that aims to curtail opioid-related harms by reducing access to opioids (including reducing "overprescribing") involves a potential therapeutic loss to patients in pain who have no satisfactory alternatives to opioids. The committee believes the restrictions, policies, and practices recommended in this report leave adequate space for responsible prescribing and reasonable access for patients and physicians who believe that an opioid is medically necessary. Another likely effect of restrictions on lawful access to prescription opioids is that some proportion of persons who have developed OUD will seek to satisfy their needs on the illicit market. One way of thinking about the policy trade-off is that curtailing access on the legal market to reduce the incidence of future iatrogenic OUD (and other harms) will drive persons who already have OUD to the illegal market. The committee regards the need to couple the long-run public health gain of reduced access with an investment in treatment for the millions of individuals with OUD as an ethical imperative.

Strategies for Restricting Supply

Recommendation 5-1. Improve access to drug take-back programs. States should convene a public–private partnership to implement drug take-back programs allowing individuals to return drugs to any pharmacy on any day of the year, rather than relying on occasional take-back events.

Strategies for Influencing Prescribing Practices

Recommendation 5-2. Establish comprehensive pain education materials and curricula for health care providers. State medical schools and other health professional schools should coordinate with their state licensing boards for health professionals (e.g., physicians, nurses, dentists, pharmacists), the National Institutes of Health's Pain Consortium, the U.S. Food and Drug Administration,

the Centers for Disease Control and Prevention, and the Drug Enforcement Administration to develop an evidence-based national approach to pain education encompassing pharmacologic and nonpharmacologic treatments and educational materials on opioid prescribing.

Recommendation 5-3. Facilitate reimbursement for comprehensive pain management. Public and private payers should develop reimbursement models that support evidence-based and cost-effective comprehensive pain management encompassing both pharmacologic and nonpharmacologic treatment modalities.

Recommendation 5-4. Improve the use of prescription drug monitoring program data for surveillance and intervention. The U.S. Department of Health and Human Services, in concert with state organizations that administer prescription drug monitoring programs, should conduct or sponsor research on how data from these programs can best be leveraged for patient safety (e.g., data on drug–drug interactions), for surveillance of policy and other interventions focused on controlled substances (e.g., data on trends in opioid prescribing, effects of prescriber guidelines), for health service planning (e.g., data on discrepancies in dispensing of medications for treatment of opioid use disorder), and for use in clinical care (i.e., in clinical decision making and patient–provider communication).

Strategies for Reducing Demand

Recommendation 5-5. Evaluate the impact of patient and public education about opioids on promoting safe and effective pain management. The nation's public health leadership, including the surgeon general, the Centers for Disease Control and Prevention, and heads of major foundations and professional organizations, should convene a body of experts in communication and in pain and opioid use disorder to evaluate the likely impact (and cost) of an education program designed to raise awareness among patients with pain and the general public about the risks and benefits of prescription opioids and to promote safe and effective pain management.

Recommendation 5-6. Expand treatment for opioid use disorder. States, with assistance from relevant federal agencies, particularly the Substance Abuse and Mental Health Services Administration, should provide universal access to evidence-based treatment for opioid use disorder (OUD), including use of medication, in a variety of settings, including hospitals, criminal justice settings, and substance use treatment programs. Efforts to this end should be carried out with particular intensity in communities with a high burden of OUD. State licensing bodies should require training in treatment for OUD for all licensed substance use disorder treatment facilities and providers.

Recommendation 5-7. Improve education in treatment of opioid use disorder for health care providers. Schools for health professional education, professional societies, and state licensing boards should require and provide basic training in the treatment of opioid use disorder for health care providers, including but not limited to physicians, nurses, pharmacists, dentists, physician assistants, psychologists, and social workers.

Recommendation 5-8. Remove barriers to coverage of approved medications for treatment of opioid use disorder. The U.S. Department of Health and Human Services and state health financing agencies should remove impediments to full coverage of medications approved by the U.S. Food and Drug Administration for treatment of opioid use disorder.

Strategies for Reducing Harm

Recommendation 5-9. Leverage prescribers and pharmacists to help address opioid use disorder. State medical and pharmacy boards should educate and train their members in recognizing and counseling patients who are at risk for opioid use disorder and/or overdose, and encourage providers and pharmacists to offer naloxone when an opioid is prescribed to these patients or when a patient seeks treatment for overdose or other opioid-related issues.

Recommendation 5-10. Improve access to naloxone and safe injection equipment. To reduce the harms of opioid use, including death by overdose and transmission of infectious diseases, states should implement laws and policies that remove barriers to access to naloxone and safe injection equipment by

- permitting providers and pharmacists to prescribe, dispense, or distribute naloxone to laypersons, third parties, and first responders and by standing order or other mechanism;
- ensuring immunity from civil liability or criminal prosecution for prescribers for prescribing, dispensing, or distributing naloxone, and for laypersons for possessing or administering naloxone; and
- permitting the sale or distribution of syringes, exempting syringes from laws that prohibit the sale or distribution of drug paraphernalia, and explicitly authorizing syringe exchange.

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6

Opioid Approval and Monitoring by the U.S. Food and Drug Administration

As the federal agency responsible for protecting the public's health by assuring the safety, efficacy, and security of drugs, the U.S. Food and Drug Administration (FDA) has a central role to play in addressing the opioid epidemic. The agency is responsible for approving new drugs and reformulations, giving it an important gatekeeping function, and also, along with the Drug Enforcement Administration (DEA), helps monitor the use of available opioid products. In this chapter, the committee provides recommendations aimed at improving the FDA's regulation of opioid analgesics, including by informing the agency's development of a framework for opioid approval and monitoring that takes into account the range of benefits and harms associated with the use of opioid analgesics, incorporating both the needs of pain patients and the relevant public health considerations.

Federal regulation of opioid medications has a long history. The original Pure Food and Drug Act of 1906—the first piece of U.S. federal legislation regulating the pharmaceutical marketplace—was passed in part because of widespread use of morphine in the so-called patent medicines of the 1800s, particularly in products aimed at children, such as Mrs. Winslow's Soothing Syrup, which was promoted for treating colic. The Pure Food and Drug Act required that products containing morphine indicate the quantity of the drug on their labels. The 1938 Food, Drug, and Cosmetic Act (FDCA) built on these rules by additionally requiring manufacturers to test their products for safety in human patients prior to approval. In the 1962 Kefauver-Harris Amendments, the FDA was given the further authority to ensure that drugs showed substantial evidence of efficacy from adequate and well-controlled investigations prior to approval.

As the FDA's authorities have evolved over the past century, so have the types of opioids available to U.S. patients. After the first synthetic opioid medications were developed in the 1910s, manufacturers continued to develop new products and formulations. In the 1960s and 1970s, the FDA approved short-acting combination products such as oxycodone/acetaminophen (Percocet, 1976). In the late 1980s and early 1990s, the FDA approved long-acting formulations of older opioid products, such as morphine (MS Contin in 1985) and oxycodone extended-release (ER) (OxyContin, 1995). Most recently, starting around 2010, the FDA has approved a cohort of opioids with supposedly abuse-deterrent properties, including tapentadol ER (Nucynta ER, 2011) and hydromorphone ER (Exalgo ER, 2010), although controversy arose when the agency approved hydrocodone ER (Zohydro ER) around this time without an abuse-deterrent formulation (ADF) (see Box 6-1).

BOX 6-1
Approval of Zohydro Extended-Release

The first stand-alone hydrocodone product approved by the U.S. Food and Drug Administration (FDA), hydrocodone extended-release (ER) (Zohydro) was approved on the basis of a single randomized, placebo-controlled, double-blind pivotal trial lasting 12 weeks and involving 183 subjects with moderate to severe chronic lower back pain. The primary endpoint was mean change in average 24-hour pain scores (at 12 weeks compared with baseline) with hydrocodone ER, leading to a statistically significant mean decrease of less than 1 point on an 11-point scale (the overall pain scores in both groups worsened over the 12-week period). The safety of the drug was studied in 1,512 subjects, both inside and outside the trial, 332 of whom were exposed for more than 6 months. Adverse events consistent with other ER opioid analgesics, such as constipation and somnolence, were noted, as were some episodes of study drug diversion and hoarding, despite the particular care taken to minimize such events. The FDA convened an outside expert advisory committee, which voted 11-2 (with 1 abstention) against approval of the drug given the high probability of opioid use disorder and diversion for a hydrocodone-containing product without an abuse-deterrent formulation (ADF). Nonetheless, the FDA approved the product in 2013, instituting a post-approval Risk Evaluation and Mitigation Strategy that included voluntary prescriber education and close surveillance. An ADF version of hydrocodone ER was introduced to replace the original version in 2015.

SOURCE: FDA, 2017b.

Throughout all of these approvals, as well as other regulatory actions, the FDA generally has reviewed opioids through the same lens used for other drugs. The committee believes that the preceding chapters of this report establish a scientific and epidemiological basis for special treatment of opioids by the FDA that would involve greater integration of public health considerations at the time of preapproval testing, during regulatory review and approval, and during routine post-approval oversight.

In making the case for this approach, this chapter begins with an overview of the FDA's current regulatory oversight of prescription drugs. This overview is followed by a discussion of public health dimensions of FDA drug regulation, which includes examples of previous cases in which the agency has successfully incorporated public health considerations into its regulatory decision making and an examination of those public health considerations specifically relevant to the approval and monitoring of opioids. Next, the chapter lays out the key elements of an integrated framework for opioid regulation that incorporates these considerations. Finally, the chapter presents the committee's recommendations for the implementation of such a framework; these recommendations are summarized at the end of the chapter.

OVERVIEW OF THE FDA'S REGULATORY PROCESS FOR PRESCRIPTION DRUGS AND ITS APPLICATION TO OPIOIDS

This section of the report briefly reviews the key principles of FDA drug regulation and their application to opioids.

FDA Review and Approval of Prescription Drugs

Drug development often begins with the identification of cellular targets and corresponding candidate compounds, with the most promising compounds moving on to preclinical studies. Preclinical in vitro and in vivo animal studies seek to establish initial pharmacologic activity and, importantly, potential for toxicity. FDA oversight at this stage is limited,[1] although the agency has promulgated requirements for good laboratory practice.[2]

Once a compound has demonstrated sufficient preclinical activity to warrant investigation in humans, an Investigational New Drug (IND) application is filed with the FDA. Information required in an IND application includes drug chemical and manufacturing information, pharmacologic and toxicologic information from preclinical data, a summary of any prior human data, a protocol for each planned study, and a brief outline of the clinical study plan. The FDA reviews the application, which goes into effect 30 days after being submitted unless the FDA imposes a clinical hold. Once the IND has gone into effect, clinical studies may proceed, typically occurring in three phases. Phase 1 studies usually enroll a few, often healthy, volunteers to explore pharmacokinetic and pharmacodynamic parameters of the drug based on a small number of doses. Phase 2 studies begin to test the drug's optimal dosage in patients with the condition of interest, and may provide a first look at the drug's therapeutic potential.[3] Phase 3 studies (if they are performed) enroll hundreds or thousands of patients and may require years to complete, although one review found that two-thirds of all new drugs are approved on the basis of trials lasting 6 months or less (Downing et al., 2014). These latter studies account for the majority of the spending on drug development, and "are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling."[4] While the manufacturer controls the organization and execution of the trials, manufacturers can, and frequently do, consult with FDA staff at various times to receive advice on trial design and outcomes.[5]

At the conclusion of the clinical trials, the manufacturer submits a New Drug Application (NDA). There is a 60-day filing review period during which the FDA ensures that all the necessary information is organized within the NDA. The drug is reviewed under a standard 10-month pathway; however, drugs that appear to represent therapeutic advances may be granted a 6-month priority review schedule (FDA, 2014c). The raw data and the study reports submitted in the NDA are reviewed by teams of FDA staff with expertise in chemistry and manufacturing, pharmacology, toxicology, statistics, clinical medicine, and any other relevant fields to determine whether the data show that the drug is safe and that there is substantial evidence of its

[1] 7 U.S.C. § 2131.

[2] See http://www.ecfr.gov/cgi-bin/text-idx?SID=a3db503068f5f3b0ec5abcbcf360940f&mc=true&tpl=/ecfrbrowse/Title21/21cfr58_main_02.tpl (accessed June 27, 2017).

[3] 21 C.F.R. §312.21(b).

[4] 21 C.F.R. §312.21(c).

[5] Note that "manufacturer" refers to an entity engaged in manufacturing, preparing, propagating, compounding, processing, packaging, or labeling of a product (e.g., a drug), while "sponsor" is defined in the regulations for Investigational New Drug applications as the pharmaceutical company, government agency, academic institution, private organization, or other entity that takes responsibility for and initiates a clinical investigation (21 CFR 312.3). Although a drug's manufacturer may not be its sponsor, for simplicity, and because in the context of unapproved investigational opioids the committee expects that the sponsor will frequently be the manufacturer, the committee uses the term "manufacturer" throughout this chapter.

effectiveness. To meet the substantial evidence standard, the FDA traditionally interpreted its statute as requiring two adequate and well-controlled studies, each convincing on its own, because results from any single trial "may be subject to unanticipated, undetected systematic biases" (FDA, 1998). However, the Food and Drug Administration Modernization Act of 1997[6] amended the FDCA to allow efficacy to be demonstrated by one adequate and well-controlled trial under certain circumstances, and about one-third of all drugs are currently approved on the basis of a single pivotal trial (Downing et al., 2014).

The FDA is now synthesizing the efficacy and safety data that make up the NDA into a structured qualitative benefit-risk assessment (discussed in detail later in this section), leading to a determination as to whether the benefits of approval outweigh the risks for the particular clinical indication sought by the manufacturer. During the review process, the FDA may engage advisory committees of outside experts to obtain additional input and to provide a public forum for discussion of the drug. These committees also include at least one consumer representative and one nonvoting industry representative. One study examining more than 200 advisory committees between 2008 and 2012 found that approval was recommended 74 percent of the time, and approval subsequently was granted by the FDA in 79 percent of those cases (Ciociola et al., 2014).

The FDA also reviews the manufacturer's proposed labeling describing use related to the indications sought, and this labeling is finalized a the time of approval. This labeling contains, among other things, the drug's approved indications, directions for use, dosing frequency and duration, and route of administration and preparation, as well as clinically significant adverse reactions, safety hazards, or other limitations on its use. The labeling must be revised to include warnings of new, clinically significant hazards as soon as reasonable evidence of a causal association with the drug exists.[7]

Drug Reformulations

Many drugs approved by the FDA are reformulations of previously approved products. Reformulated drugs, which include nearly every opioid product approved in the past few decades, can be approved via an abbreviated pathway described in section 505(b)(2) of the FDCA through which the application relies on published literature or on an FDA finding of safety and/or effectiveness for an approved drug product. In these cases, the manufacturer provides data to bridge to the FDA's prior findings for the approved product, as well as data necessary to support any differences between the two formulations (FDA, 1999).[8] The FDA can require studies to establish efficacy and safety, as well as additional safety studies should unforeseen safety signals arise (FDA, 2014b).

Application to Opioid Approval

The requirement that prescription drugs be subject to prospective clinical trials that provide data on their safety and efficacy is an essential component of the regulatory apparatus that protects patients, allows for collection of rigorous data that can guide clinical practice, and promotes a well-functioning prescription drug marketplace by preventing the widespread use of

[6]Public Law 105-115.
[7]See FDCA 502(f)(2) for specific statutory language and 21 C.F.R. 201.57(c)(6) for relevant regulations.
[8]21 C.F.R. 201.57.

ineffective products. The FDA's standards for new drug approval, therefore, serve a key public health function. However, the investigational drug evaluation process also has important limitations, particularly with respect to the approval of opioids.

For example, showing that a drug has substantial evidence of efficacy does not necessarily mean that the drug is more effective than currently available therapies, or that the efficacy demonstrated is clinically meaningful. In the case of hydrocodone ER (see Box 6-1), the drug was tested against a placebo. Also, while the hydrocodone ER case showed a statistically significant improvement in pain outcomes, it is not clear whether the slight numeric difference in the pain scale is clinically meaningful for patients with pain, particularly since pain worsened overall over the course of the trial among both the subjects receiving hydrocodone ER and those receiving placebo (FDA, 2017b).

In addition, clinical trials sufficient to meet the FDA's efficacy standard can be conducted in a brief, highly protocolized setting and often exclude many patients who would be expected to get the drug following its approval. In the case of hydrocodone ER, the entire pivotal study was conducted among patients with lower back pain, and did not include patients with cancer, arthritis, or other conditions who may receive opioid medications for pain (FDA, 2017b). Clinical trials could be designed with more robust follow-up periods or be prospectively powered to ensure that well-known side effects are adequately measured. However, the FDA bases its approval decision on the data provided by the manufacturer at the time of the NDA and does not require that trials of investigational drugs be conducted with particular characteristics.

Post-Approval FDA Authorities

The FDA's regulatory authority continues following the initial marketing approval of a drug. Pre-approval prospective clinical trials cannot comprehensively assess the risks of drugs. Therefore, it is not unusual for specific questions to arise that do not preclude marketing but nevertheless warrant further investigation after approval. Additionally, risks observed in the clinical trials may require ongoing evaluation and mitigation, and post-approval monitoring may necessitate timely communication with health care providers and the public. These activities take place against a backdrop of industry activities promoting use of the drug to providers and patients.

Spontaneous Adverse Event Reporting and Active Surveillance

Traditionally, the FDA has relied on passive collection of spontaneous adverse event reports submitted by health care facilities, providers, drug manufacturers, patients, and others as its primary source of information about post-approval drug safety. Manufacturers are required to submit to the FDA within 15 days any reports of adverse events that are both serious and unexpected. Other reports manufacturers receive are to be submitted to the FDA quarterly for the first 3 years post-approval and annually thereafter. The FDA's Adverse Event Reporting System (FAERS) database stores all such reports. Physicians and patients may also submit reports to FAERS, but do so voluntarily (and rarely). FAERS data are available to the public, but often contain less information than may be needed to fully assess the relationship between the drug and the event in question (Findlay, 2015). Nevertheless, past examples of FAERS data being used to identify safety signals provide evidence that this type of passive post-approval surveillance does have some value (FDA, 2014d).

In addition to receiving and processing adverse event reports, nearly all brand-name manufacturers conduct active post-market surveillance of their products, which may include observational studies or other safety-related research. They report results of these pharmacovigilance activities to the FDA, along with their adverse event reports, in Periodic Adverse Drug Experience Reports, Periodic Safety Update Reports, or Periodic Benefit-Risk Evaluation Reports. The FDA now also has the capacity to actively monitor safety outcomes related to drugs in the post-approval setting. Based on a pilot program launched in 2008, the Sentinel System allows the agency, through an independent contractor that has established a secure distributed data network, to assess an emerging drug risk using data from a broad array of electronic health care data. While Sentinel has not yet facilitated rapid drug safety assessment and improved regulation, it holds promise for regulatory decisions to be based on big-data tools that help in organizing and evaluating evidence (FDA, 2015a).

Post-Market Commitments and Requirements

At the time a product is granted marketing approval, the FDA can impose various post-market requirements, or the agency and the manufacturer can agree on post-market commitments, intended to help address questions that arise during the review of the pre-approval data, to help assess a known serious risk or a signal of a serious risk, or to identify an unexpected serious risk when data suggest the potential for such a risk. These requirements and commitments can include clinical trials, observational studies, or the creation of patient registries, which can be used to help adjust the labeled indication or safety warnings, and even can lead to withdrawal of the approved indication (OIG, 2016). Yet despite additional authorities granted to the FDA in 2007,[9] post-market requirements and commitments often are delayed or not completed (Fain et al., 2013).

Risk Evaluation and Mitigation Strategies

One particularly important type of post-market requirement is a Risk Evaluation and Mitigation Strategy (REMS). The FDA can require that a manufacturer develop a REMS to provide safeguards for the use of high-risk medications when the FDA determines that such safeguards are necessary to ensure that benefits of a drug outweigh its risks (Sarpatwari et al., 2014). A REMS may simply involve disseminating means of educating prescribers and patients about the drug, but it may also require manufacturers to implement "elements to assure safe use," such as mandatory training or certification for prescribers and pharmacies, restrictions on dispensing, and targeted patient follow-up and testing that can rely on the establishment of registries (Sarpatwari et al., 2014). Although elements to assure safe use often target prescribing and dispensing practices, it is drug manufacturers, not health care providers, that are responsible for ensuring that REMS requirements are met (Zettler, 2015). Brand-name manufacturers also are required to periodically monitor and assess the success of their REMS.[10]

Evidence about whether REMS can substantially affect prescribing and dispensing practices is conflicting. In a 2013 report, the U.S. Department of Health and Human Services (HHS) Office of the Inspector General raised concerns about the effectiveness of REMS in improving safe use of drugs (HHS OIG, 2013). An evaluation of post-FDA approval use of

[9]Public Law 110-85.
[10]21 U.S.C. 355-1(d).

bosentan (Tracleer), a treatment for pulmonary hypertension, uncovered a high level of nonadherence to liver function tests required among the elements to assure safe use in the REMS for the drug (Blanchette et al., 2015). On the other hand, some REMS with elements to assure safe use may be effective in reducing non-evidence-based off-label drug prescribing. One rigorous study found that the REMS for the thrombopoietin agonist eltrombopag (Promacta), which before the FDA eliminated the REMS required such elements to assure safe use as a signed acknowledgment of drug risks and semiannual patient monitoring, decreased off-label use of the drug (for an indication later approved by the FDA) (Sarpatwari et al., 2015). As mentioned previously in this report, the FDA has required a REMS with elements to assure safe use for ER/long-acting (LA) opioids, which currently requires manufacturers of these drugs to provide education to prescribers based on an FDA prescriber education "blueprint" (FDA, 2017e).

Individual professional schools have produced their own online REMS teaching modules based on an FDA REMS blueprint for ER/LA opioids. Boston University's SCOPE (Safe and Competent Opioid Prescribing Education) of Pain program was funded by an independent education grant awarded by the manufacturers of ER/LA opioid analgesics, known collectively as the REMS Program Companies or RPC.[11] Boston University School of Medicine partnered with the Federation of State Medical Boards and the Council of Medical Specialty Societies in the development, execution, and promotion of the SCOPE of Pain program (Alford et al., 2015). The committee notes that education through REMS represents one source of education on safe opioid prescribing, but is not a substitute for fundamental knowledge of multidisciplinary pain care that utilizes nonopioid and nonpharmacologic strategies for managing acute pain and especially chronic painful conditions.

Communicating Drug Safety Information

The combination of data from passive adverse event reporting, the Sentinel System, and other surveillance activities conducted by the FDA and manufacturers, together with post-market commitments and requirements, can point to the need to update a drug's labeling. While the FDA can, under certain conditions, require the manufacturer to update the label with new safety information, primary responsibility for keeping labeling up to date for brand-name drugs lies with the manufacturer.[12]

A boxed warning (also called a black-box warning)—the most prominent safety warning on a drug's label—is appropriate when an identified hazard poses a risk of death or serious injury.[13] A boxed warning can be required at the time of drug approval or after a drug is already on the market and, in tandem with the media coverage it inevitably generates, can reduce prescribing (Dorsey et al., 2010). However, some boxed warnings fail to change practice as substantially as expected, and physicians commonly prescribe drugs without regard to information in these warnings (Lasser et al., 2006).

When a label change is made after a drug's approval, it is often accompanied by a Drug Safety Communication. Between 2010 and 2016, 233 Drug Safety Communications were issued (39 in 2010, 66 in 2011, 29 in 2012, 32 in 2013, 16 in 2014, 30 in 2015, and 21 in 2016) (FDA, 2017c). One review found little impact of FDA drug risk communications on prescribing behaviors (Dusetzina et al., 2012).

[11]For more information, see http://www.er-la-opioidrems.com/IwgUI/rems/home.action (accessed June 27, 2017).
[12]21 C.F.R. §201.57(c)(6).
[13]21 C.F.R. 201.57(c)(1).

Regulating Industry Promotion

After a drug has been approved, its manufacturer promotes it to physicians and patients. Promotion to prescribers includes detailing (face-to-face interactions between a sales representative and a prescriber); educational programing; provision of drug samples; and direct financial incentives, such as meals, travel expenses, grants, and consulting fees (Pew Charitable Trusts, 2013). Research shows that pharmaceutical marketing to physicians has a strong, consistent, and specific effect on driving prescribing practices toward the product being promoted, particularly when it is not necessarily the first-line or most cost-effective therapeutic option available (Avorn et al., 1982; Manchanda and Honka, 2005). Similarly, direct-to-consumer (DTC) promotion affects prescribing by changing how patients interact with their health care providers—for example, by prompting patients to ask for a particular drug and increasing the likelihood that patients will be prescribed both appropriate and inappropriate medications (Kravitz et al., 2005; Skeldon et al., 2015; Spence et al., 2005). In the opioid context, McKinlay and colleagues (2014) conducted a study that involved showing primary care physicians two different video-based scenarios in which actors played patients with sciatica-like symptoms. In one of the scenarios, the "patients" requested oxycodone; in the other, they requested no specific pain medication. After viewing each scenario, physicians were interviewed about how they would manage the case: after viewing the scenario in which the "patients" specifically requested oxycodone, 19.8 percent of physicians prescribed that drug, compared with 1 percent following viewing of the scenario in which no specific pain medication was requested (McKinlay et al., 2014).

The FDCA prohibits false or misleading prescription drug labeling and advertising,[14] and the FDA regulates the promotion of prescription medications and certain medical devices to both prescribers and patients by encouraging companies to portray products in a way that is truthful, balanced, and accurate (FDA, 2010b). Advertisements must provide fair and balanced information with respect to the risks and benefits of a drug, reveal material facts related to the representations in the advertisement, give comparable prominence to risk and benefit information, and not overstate efficacy or safety.[15] If the FDA becomes aware of promotional material that it believes violates the law (e.g., states or implies that a drug can treat a condition when the FDA has not approved it for such use, overstates a drug's benefits, omits or downplays information about a drug's risks), it sends the company a letter asking that the promotional material be removed and/or corrected (FDA, 2015b). Improper prescription drug marketing also can violate other laws, including the federal antikickback statute; state consumer fraud statutes; and federal and state false claims acts, which permit the government to recover payments made for prescriptions (such as through Medicare or Medicaid) as a result of fraudulent advertising.

After a drug has been approved, physicians ordinarily may use it in ways that the FDA has not approved (known as "off-label" use), a practice that is common in the field of pain medicine (Radley et al., 2006). When an off-label use is particularly risky and non-evidence-based, the FDA can factor this consideration into its post-approval regulatory decisions. For example, when data emerged showing that antipsychotics used off-label in elderly patients with dementia increased the risk of mortality, the FDA added a boxed warning that helped reduce such dangerous prescribing. Off-label use for opioids contributes to misuse and opioid use

[14] 21 U.S.C. §§ 321(n), 352.
[15] 21 C.F.R. § 202.1.

disorder (OUD), and the inevitability of such off-label use of opioids is another justification for the development of an opioid-specific FDA review framework (discussed later in this chapter).

While off-label use is common, industry promotion of off-label uses violates the FDCA by causing the drug to be misbranded or to be an unapproved new drug (Cortez, 2016). In recent years, constitutional questions have been raised about the FDA's ability to limit manufacturers' off-label marketing.[16] In test cases, the drug industry and libertarian advocacy organizations have had some success in persuading courts that the FDA violates industry's First Amendment rights when enforcing its policies against off-label promotion.[17] The agency is "currently engaged in a comprehensive review" of its regulatory framework for medical product promotion.[18]

Drug Quality and Supply Chain Security

Another key area of oversight for the FDA is drug quality and security. The primary means through which the FDA regulates drug quality is its Current Good Manufacturing Practice (CGMP) requirements. The agency's CGMP regulations cover the methods, facilities, and controls used for the manufacture, processing, packing, holding, or preparation of a drug.[19] These requirements include standards for the qualifications of the personnel involved in drug manufacturing, for the design of facilities and equipment, and for sanitation and cleaning. The purpose of these regulations is to help ensure that a drug is safe and has the identity, strength, quality, and purity that it is represented as possessing. Before approving a drug, the FDA reviews compliance with CGMP requirements,[20] and it continues to monitor compliance after approval.[21]

The FDA also oversees the security of the drug supply chain. The 2013 Drug Quality and Security Act amended the FDCA to create an electronic, interoperable system to "track and trace" many prescription drugs throughout the supply chain.[22] Once fully in effect in 2023, the system will include product identifiers for certain prescription drug packages; information on who handles a drug each time it is sold in the United States; requirements that industry stakeholders investigate products suspected to be counterfeit, substandard, or otherwise illegitimate; and processes for notifying the FDA and others when illegitimate drugs are found.[23] Various requirements will apply to drug manufacturers, wholesale drug distributors, repackagers, third-party logistics providers (entities that help coordinate distribution of a drug but never take ownership of it), and dispensers. The intent of this expansive system is to enable the FDA and industry to verify the legitimacy of drug products; enhance detection of counterfeit, substandard, or otherwise illegitimate products; and more easily conduct drug recalls.[24] Although the track and trace system is designed to prevent illegal drugs from entering the pharmaceutical supply

[16] *Virginia State Board of Pharmacy v. Virginia Consumer Council*, 425 U.S. 748, 748 (1976); *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Sorrell v. IMS Health Inc*., 131 S. Ct. 2653, 2670 (2011).
[17] United States v. Caronia, 703 F.3d 149 (2d Cir. 2012); Washington Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000); Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015).
[18] See https://www.federalregister.gov/documents/2017/01/19/2017-01013/manufacturer-communications-regarding-unapproved-uses-of-approved-or-cleared-medical-products (accessed June 27, 2017).
[19] 21 C.F.R. § 210.1-211.1.
[20] 21 U.S.C. § 355(d), 355(j)(4)(A).
[21] 21 U.S.C. § 351(a)(2)(B).
[22] Public Law 113-54 127 Stat. 587 (2013).
[23] Public Law 113-54 127 Stat. 587 (2013).
[24] Federal Register, Vol 81, No. 181, September 19, 2016: 64175-64177, available from https://www.gpo.gov/fdsys/pkg/FR-2016-09-19/pdf/2016-22441.pdf (accessed June 27, 2017).

chain, it may help identify some instances of opioid diversion by providing more information about drug distribution.

Application to Safety Monitoring of Opioids

Opioids have been the subject of numerous post-approval strategies to address the serious safety concerns associated with these products, although thus far these approaches have had little effect in terms of stemming harms. For example, as reports of misuse and diversion of oxycodone controlled-release mounted, Purdue Pharma and the FDA fashioned a risk management plan in 2001 encouraging improved surveillance and the education of prescribers about the risks of the drug. In addition, the label was updated to include a boxed warning calling attention to the potential for misuse and diversion. But neither of these interventions appeared to have much effect on diminishing the rate of opioid overdose, which crested over the next decade.

Recent actions by the FDA have included requiring manufacturers of immediate-release (IR) opioid analgesic products to update the safety information in their product labeling (FDA, 2016b) and requiring additional warnings about interactions between opioids and benzodiazepines (FDA, 2016c). In 2012, the FDA imposed a REMS for all ER/LA opioid analgesics. As discussed in Chapter 5, the REMS requires manufacturers to provide unrestricted education grants to accredited continuing education providers to develop and provide voluntary prescriber education programs. To date there has been little evidence that the REMS has had much effect on prescribing practice or on curbing opioid-related harms. The current opioid REMS also has been criticized for providing inadequate checks on unsafe opioid prescribing practices (FDA, 2016d). Propelled by the unrelenting increase in opioid-related deaths in the United States, one element of the FDA's Opioid Action Plan, launched in 2016, is to expand the REMS for opioids to incorporate pain management, include a broader range of health care professionals involved in the management of patients with pain, include IR opioid analgesic manufacturers, and evaluate approaches for implementing mandatory pain management education for prescribers (FDA, 2017e).

Similarly, passive adverse event surveillance and active use of such systems as Sentinel have proven insufficient with respect to opioids or medications to treat substance use disorder (SUD), because of delay in reporting and detecting problems. The International Classification of Diseases (ICD) has multiple ICD codes for chronic pain, and there are known challenges with diagnosis and documentation in medical records and billing for stigmatized conditions. The most recent post-marketing requirements for ER/LA opioids include studies to validate better mechanisms for extracting these data from medical records (FDA, 2014e).

Recent efforts to augment the post-market surveillance of opioid medications include, but are not limited to, the development of the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) system for active, real-time surveillance, with the aim of using this information to guide risk reduction interventions. Developed by Purdue Pharma after the FDA provided suggestions and comments, it collects this information through regular surveys of individuals entering or being assessed for SUD treatment, experts in SUD, and law enforcement agencies, as well as analysis of exposure calls to poison control centers pertaining to misuse and diversion of licit and illicit drugs, including prescription opioid analgesics (Cicero et al., 2007). Around the same time, the National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO) was developed to provide post-marketing surveillance, signal detection, signal verification, and prevention and intervention programs for scheduled therapeutics. The

surveillance component of NAVIPPRO integrates multiple data streams to monitor drug use both temporally and spatially at a product-specific level, in part by collecting data from a national network of SUD treatment centers on substances used by adult individuals entering treatment (Butler et al., 2008).

Another recent step taken by the FDA was to update the shared list of post-marketing requirements for all ER/LA opioid analgesics in 2014 (see Annex Table 6-1 at the end of the chapter), such that the holders of the NDAs for the entire class would be responsible for performing 10 observational studies to assess the known serious risks of misuse, OUD, overdose, and death associated with these products, as well as one clinical trial to assess the risk of hyperalgesia associated with long-term, high-dose opioid therapy (FDA, 2014e). These required observational studies focus on the development and validation of algorithms or measures to identify patients exhibiting signs of SUD, including through electronic health records and other data, and the use of these algorithms to support studies of patients prescribed these products long-term to determine the risk and risk factors for the known serious adverse events. Beyond these class-wide studies, manufacturers of individual opioid analgesics can be subject to additional requirements related to safety signals and other issues that arose during NDA review or have arisen in the post-market context.

Finally, the FDA's rules concerning marketing and promotion did not stop manufacturers from engaging in illegal off-label marketing, as well as dissemination of advertisements that overstated the benefits of opioids and downplayed the risks of addiction.[25] As discussed in Chapter 1, one well-publicized example involved Purdue Pharma's marketing of oxycodone ER for chronic noncancer pain during the years after its approval. During that marketing campaign, Purdue Pharma promoted oxycodone ER to prescribers and also engaged in DTC promotion through brochures, videotapes, and a "Partners Against Pain" website (VanZee, 2009). That marketing effort drove oxycodone ER sales from $48 million to more than $1 billion as the drug became the most prescribed brand name opioid for moderate to severe pain. These promotional practices therefore were a strong contributor to the subsequent and ongoing increase in oxycodone misuse and oxycodone-related deaths (Dhalla et al., 2011; GAO, 2003). State and federal prosecutors have sued opioid manufacturers for allegedly fraudulent marketing in violation of the law.[26] However, the penalties imposed in these cases invariably fall well short of the billions of dollars in revenues earned by opioid manufacturers as a result of these marketing campaigns.

Scheduling of Opioids Under the Controlled Substances Act

As discussed in Chapter 5, the five schedules for drugs covered by the Controlled Substances Act (CSA) (see Table 6-1) were designed to provide a structure for balancing the nuanced requirements of perceived safety, medical utility, and "abuse potential" (Spillane, 2004). Scheduling status affects prescribing authority (e.g., manner of prescribing and limits on refills), triggers requirements for supply chain record keeping, and determines the degree of

[25]United States House of Representatives Committee on Governmental Reform—Minority Staff Special Investigations Division, *FDA Enforcement Actions Against False and Misleading Prescription Drug Advertisements Declined in 2003* (Washington DC: Government Printing Office, January 2004).
[26]Kentucky Settlement, http://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf (accessed June 27, 2017); http://www.latimes.com/local/california/la-me-pharma-20150828-story.html (accessed June 27, 2017).

criminal punishment for illicit trafficking. The most restrictive controls on use cover Schedule I and II substances.

TABLE 6-1 Schedules Under the Controlled Substances Act

Schedule	Definition	Prescribing Restrictions[a]	Examples
Schedule I	Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.	Not applicable.	Heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine (ecstasy)
Schedule II/IIN	Substances in this schedule have a high potential for abuse that may lead to severe psychological or physical dependence.	Prescriptions must be written and signed by the prescriber. Telephone prescriptions are permitted only in emergencies,[b] and only when followed by a written version within 7 days. No prescription refills permitted.	II: hydromorphone, methadone, meperidine, oxycodone, fentanyl, morphine, opium, codeine, and hydrocodone; IIN: amphetamine, methamphetamine
Schedule III/IIIN	Substances in this schedule have a potential for abuse less than that of substances in Schedules I or II; abuse may lead to moderate or low physical dependence or high psychological dependence.	Prescriptions may be written, oral, or transmitted by fax. Five refills are allowed every 6 months.	III: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®) and buprenorphine; IIIN: benzphetamine, phendimetrazine, ketamine, and anabolic steroids
Schedule IV	Substances in this schedule have a low potential for abuse relative to substances in Schedule III.	Prescriptions may be written, oral, or transmitted by fax. Five refills are allowed every 6 months.	Alprazolam, carisoprodol, clonazepam, clorazepate, diazepam, lorazepam, midazolam, temazepam, and triazolam
Schedule V	Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.	Prescriptions may be written, oral, or transmitted by fax. Refills are allowed as authorized by the prescriber.	Cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams, and ezogabine

[a]All Schedule II–V substances can be prescribed electronically through systems that meet Drug Enforcement Administration requirements, and are also subject to any additional state-level regulations.
[b]An exception also exists for hospice care programs, where Schedule II controlled substances may be prescribed via telephone or fax.
SOURCES: DEA, 2017a,b.

Decision Making About Scheduling

The CSA allows DEA to place a drug temporarily in Schedule I when it believes the drug may pose "imminent hazards to public safety." The substance may be retained in Schedule I for up to 3 years, after which it must be removed or permanently scheduled.[27] The DEA has used this temporary scheduling authority for more than 35 synthetic drugs since 2002. Most recently, the DEA has used it to place several synthetic opioids temporarily in Schedule I.[28]

The CSA's somewhat ambiguous designation of authority to make permanent scheduling decisions is the result of a compromise that was reached at the time of its passage. The American Medical Association (AMA) resisted providing broad regulatory authority to the regulatory agencies, preferring that particularized decisions be made for each drug, similar to the approach of drug-by-drug approval used under the FDCA. Physicians distrusted the ability of federal regulatory agencies to accurately assess the therapeutic and research value of any given drug (Spillane, 2004), and pharmaceutical manufacturers feared that strict controls could have a serious impact on profitability. The FDA was uncomfortable with wielding enforcement power and ceded that power to the U.S. Department of Justice (DOJ). DOJ wanted to have the authority to control a drug quickly to address incipient issues of abuse. The resulting shared authority reflects an attempt to address all of those concerns.

Under the CSA, "If, at the time a NDA is submitted to the Secretary for any drug having stimulant, depressant or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall by forwarded by the Secretary to the Attorney General."[29] That determination by the FDA triggers a coordinated response by the FDA and the DEA designed to limit the potential for such abuse by assigning the drug to an appropriate "schedule."[30] The CSA requires HHS and the attorney general (usually acting through the FDA and the DEA) to consider eight factors in determining whether and at what level to schedule a drug: "(1) the drug's actual or potential for abuse, (2) scientific evidence of the drug's pharmacologic effect, (3) the state of current scientific knowledge regarding the drug, (4) the drug's history and current pattern of abuse, (5) the scope, duration and significance of abuse, (6) risk to public health, (7) the drug's psychic or physiologic dependence liability and (8) whether the substance is an immediate precursor of a substance already controlled under the CSA."[31]

The FDA begins the process by making a recommendation as to whether the drug should be "controlled or removed as a controlled substance" and if so, "the appropriate schedule, if any

[27]21 U.S.C. 811 (h) CSA and amendments Synthetic Drug Abuse Prevention Act of 2012, Subtitle D of Title XI FDASIA (P.L. 112-144).

[28]An example is synthetic opioid 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (also known as U-47700), placed in Schedule I in 2016. The DEA announced and then later withdrew temporarily the placement of kratom in Schedule I through this authority.

[29]21 U.S.C. 811(f). Since 1973, the attorney general has subdelegated her authority for drug scheduling to the administrator of the DEA. See Exec. Order No. 11,727, 38 Fed. Reg. 18,357 (July 10, 1973); 28 C.F.R. § 0.100 (2003). Under the CSA, a scheduling proceeding "may be initiated by the Attorney General (1) on her own motion, (2) at the request of the Secretary [of Health and Human Services (HHS)], or (3) on the petition of any interested party." 21 U.S.C. 811(a).

[30]As noted previously, there are five scheduled classifications under the CSA based on potential for abuse. Schedule I drugs are those that have high abuse potential and are not approved in the United States. Schedule II–V drugs are allowed to be marketed under restrictions depending on their potential (high to limited) for physical or psychological dependence (see Table 6-1 for further information).

[31]21 U.S.C. 811(c).

under which such drug…should be listed."[32] In so doing, the FDA is directed to consider factors (2), (3), (6), (7), and (8) above, as well as any other relevant scientific or medical considerations.[33] The FDA may require the drug's manufacturer to provide relevant data pertaining to its abuse potential as part of the NDA requirements.[34] The FDA's recommendation is binding on the DEA, although any specific scheduling recommendation is not.[35] If the FDA has recommended that the drug be controlled as a scheduled drug, the baton passes to the DEA administrator for consideration of the above eight factors in the context of appropriate scheduling.[36]

The FDA and the DEA thus play different roles in their evaluation pursuant to the CSA. The FDA's role is to perform a risk assessment of the drug's abuse potential. If the FDA determines that such a potential exists, it may require appropriate labeling for both physicians and patients. As discussed above, under the REMS authority, the FDA may also require various measures intended to ensure safe use of the drug, including the provision of patient medication guides, prescriber and/or patient agreements, and prospective registries. It can recommend extensive education for prescribers and counseling for patients as well. The DEA may also have input into the drug's labeling, and is responsible for licensing manufacturers of scheduled drugs and prescribers and for setting quotas for Schedule I and II drug production. The DEA has enforcement authority for violations under the CSA.

Once a drug has been placed in a schedule, that placement is unlikely to be changed (Henningfield and Schuster, 2009). "Down-scheduling," or moving a drug to a tier with fewer controls, is very rare; however, "up-scheduling" has occurred in recent years in the context of increased prescribing and misuse of opioids. Schedule changes may be initiated by the FDA, the DEA, Congress, or any other interested party.[37] In such cases, as in the original scheduling, the DEA seeks scientific and medical advice from the FDA and then acts through formal rulemaking. In the case of hydrocodone combination products, for example, a physician specializing in treatment of SUD petitioned the DEA to reschedule those products from Schedule III to Schedule II in 1999 (DEA, 2014). Five years later, following its review of the abuse potential of the drug, the DEA forwarded relevant data on the petition to the FDA for a scientific and medical evaluation. When the FDA undertook a review based on the eight factors listed earlier in 2008, it paid special attention to how rescheduling might affect prescribing practices. It found, for example, that rescheduling might result in the need for additional physician visits, that prescribers might then opt for oxycodone rather than hydrocodone combination products since they were in the same schedule, and that patients might receive inadequate pain relief (FDA, 2012). The FDA then recommended that hydrocodone combination products be maintained as Schedule III drugs. In 2009, after receiving another petition for rescheduling, the DEA sent additional data to the FDA providing further information about misuse in 2009, and the FDA undertook another review. In 2013, after an advisory committee voted 19-10 to recommend a scheduling change, the FDA forwarded a letter to the DEA

[32] 21 U.S.C. 811(b). The FDA has a manual that outlines these procedures: MAPP 4200.3, *Consulting the Controlled Substance Staff on Abuse Liability, Drug Dependence, Risk Management and Drug Scheduling*.
[33] 21 U.S.C. 811(c).
[34] 21 C.F.R. §314.50(d)(5)(vii) This includes a proposal for scheduling under the CSA.
[35] 21 U.S.C. 811(c).
[36] 21 U.S.C. 811(c).
[37] 21 U.S.C. 811(a). Congress can and does insert itself into this process. In 2000, Congress legislatively required emergency scheduling of GHB (liquid ecstasy), and the 2012 Synthetic Drug Abuse Prevention Act required permanent scheduling of a number of synthetic stimulants and opiates.

recommending the rescheduling of hydrocodone combination products to Schedule II. The DEA issued a final rule to that effect in 2014.

Effects of Scheduling on Medical Practice

The design of the CSA reflects the inherent tension between optimizing the medical benefits of the controlled drugs and minimizing the dangers associated with their misuse. This tension is reflected in the CSA's tiered classification scheme, which anticipates that the responsible agencies will balance these considerations in making scheduling decisions. The tension is also evident at the level of the individual prescriber, given that placing a drug in the higher schedules can have a chilling effect on medically appropriate prescribing. As discussed in Chapters 2 and 5, prudent clinical judgment is required in deciding whether, when, and how to taper or terminate prescribing of opioids for patients reporting chronic pain. Well-meaning providers may be concerned about whether continued prescribing over the long term might be regarded by law enforcement or licensing agencies as being without "legitimate medical purpose" on the part of a practitioner "acting in the usual course of his professional practice," and therefore in violation of the federal or state CSA.

Despite a DEA guidance document that attempts to clarify those terms,[38] they may create enough concern that physicians may choose not to prescribe controlled substances at all. For physicians who do prescribe controlled substances, the CSA's tiered scheduling has had a more nuanced effect. Schedule tiers impose different prescribing requirements; CSA scheduling also affects how state law may impose additional requirements on prescribing of drugs assigned to the various tiers. Schedules III–V do not impose stringent prescribing limitations, but for Schedule II substances, prescriptions may not be refilled, the amount of drug or duration of use that may be prescribed on a single prescription is limited, and the prescription is required to be in written form. Many states require triplicate forms for Schedule II drugs and limit prescriptions to a short duration.

Schedule II requirements may increase providers' reluctance to prescribe substances that are so classified. Scheduling requirements do not provide incentives for providers to find other avenues for treatment, and they are not coupled with education. Making prescribing difficult for all providers, regardless of patient population, may result in denying access to individuals who need these drugs (Noah, 2003). The reclassification of hydrocodone combination products in 2014 has provided a natural experiment with which to study the effect of moving a drug to Schedule II. As noted in Chapter 5, early evidence shows that the reclassification substantially reduced the prescribing of these drugs (Chumpitazi et al., 2016; Jones et al., 2016), but whether health outcomes have improved as a result remains to be seen. Indeed, concern has been raised that rescheduling opioids to Schedule II is an unduly blunt instrument with which to limit overprescribing, and that it may have serious offsetting effects for individuals who need adequate pain treatment (Dineen, 2016). If rescheduling were simply to deter prescribing, the objection raised by the AMA when the CSA was adopted would be validated. More research is needed to study the effect of scheduling to Schedule II on pain treatment.

Three points emerge from the committee's review of CSA scheduling. First, the CSA requires explicit trade-offs between the effects of regulatory decisions on legitimate medical use and the harms associated with misuse and OUD. Second, the rescheduling of hydrocodone

[38]DEA Docket No. DEA-286P, Dispensing Controlled Substances for the Treatment of Pain (2006).

combination products reveals the diverging perspectives of the FDA and the DEA in exercising regulatory judgment on these issues and the inefficiency thus produced. Finally, because the FDA has many tools available under the FDCA for balancing these interests, the experience with hydrocodone combination products highlights the virtues of harmonizing the regulatory analysis undertaken under the two statutes, especially in relation to opioids.

Current FDA Benefit-Risk Framework

Currently, after the FDA reviews an NDA, it lays out the key details to help guide its decision making. The benefit-risk table shown in Figure 6-1 had its origins in an FDA initiative of 2009 "to develop a structured approach for drug benefit-risk assessments that could serve as a template for product reviews, as well as a vehicle for explaining the basis for the FDA's regulatory decisions in drug approvals" (FDA, 2013, p. 1). In 2012, section 905 of the FDA Safety and Innovation Act formalized this commitment by requiring the agency to implement a structured benefit-risk framework in its new drug approval process.[39] The FDA states that while "quantitative assessments certainly underpin" any regulatory decisions, this approach is "designed to support the identification and communication of the key considerations in FDA's benefit-risk assessment and how that information led to the regulatory decision" (FDA, 2013, p. 4).

The framework displayed in Figure 6-1 has been applied explicitly in a number of cases since 2012, although not yet for an opioid product. For one product, pimavanserin (Nuplazid), a treatment for the hallucinations and delusions of Parkinson's disease, the framework revealed that the FDA considered the unmet clinical need for a treatment in the "Analysis of Condition" row, the on- and off-label use of other available drugs for this purpose (and their outcomes) in the "Current Treatment Options" row, summaries of the pivotal efficacy trial ("Benefit" row) and serious adverse event profile ("Risk" row), and any key post-market surveillance activities in the "Risk Management" row (FDA, 2017a).

Decision Factor	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition		
Current Treatment Options		
Benefit		
Risk		
Risk Management		

FIGURE 6-1 Current FDA benefit-risk framework.
SOURCE: FDA, 2013.

[39]Public Law 112-144.

The committee believes that this framework was developed thoughtfully and that it achieves its patient-centered goals by clearly organizing the components of the benefit-risk decision leading to a drug's approval. The committee also believes that this framework can be adapted to specifically integrate public health considerations, and can be incorporated into a much more comprehensive approach to gathering and reviewing the available information and making decisions accordingly to guide the FDA's regulation of opioids. As described below, the FDA routinely considers broader public health goals in its assessment of drugs, and the committee believes there is a growing public health mandate to apply this flexibility in certain ways to the approval and oversight of opioids.

PUBLIC HEALTH DIMENSIONS OF FDA DRUG REGULATION

To approve a drug, the FDA must determine that the drug is safe and efficacious "under the conditions prescribed, recommended, or suggested in the proposed labeling."[40] The FDA has long interpreted this approval standard as meaning that a drug's benefits must outweigh its risks. Since at least the early 1990s, the agency also has acknowledged that it has "flexibility" in applying the approval standard, and in "determin[ing] the kind and quantity of data and information an applicant is required to provide" to demonstrate that a drug meets the standard.[41]

One of the ways in which the FDA exercises this flexibility is by integrating public health considerations into its benefit-risk determinations. Public health considerations may include how the availability or use of the product will affect an unintended population or the broad public health impact resulting from the aggregated effects on patients taking the drug. For drugs with the potential for misuse, for example, NDAs must include "studies or information related to abuse of the drug,"[42] which, of course, is not information about the use of the drug as directed in the proposed labeling. The FDA's authority to consider the broad impact of its pre- and post-approval decisions on the health and well-being of American patients and consumers is an extension of the FDA's primary role as a public health agency.[43]

Indeed, various provisions of the FDCA and FDA regulations make clear that the FDA has considerable discretion in determining what information is relevant to its regulatory decisions. Consistent with this flexibility, the FDA considers the public health consequences of its approval decisions in many aspects of its oversight of prescription drugs. For example, it may require a REMS, safety labeling changes, or post-market studies or trials to address risks of misuse, SUD, and overdose associated with a drug.[44] When requiring a REMS, the agency also must consider the broad context within which the drug will be used, including the burden on patient access and the health care delivery system.[45]As another example, as noted earlier, the FDCA requires holders of approved NDAs to report to the agency any adverse drug experiences, regardless of whether the drug was used as directed.[46] Likewise, the FDA's Sentinel initiative is

[40]21 U.S.C. § 355(d).
[41]21 C.F.R. § 314.105(c).
[42]21 C.F.R. § 314.50(c)(5)(vii).
[43]21 U.S.C. § 393 (1997).
[44]Sections 505(o)(3) and (4); 505-1(2)(b).
[45]Section 505-1(f)(2).
[46]21 C.F.R. § 314.80.

intended to identify and analyze a broad range of drug risks, not limited to those associated with the intended patient population using the drug as directed.[47]

The following examples of FDA decision making with respect to testosterone products, transmucosal IR fentanyl (TIRF) products, antibiotics, and prescription acetaminophen products further illustrate that the FDA is able to integrate, and has integrated, public health considerations into its drug approval and withdrawal decisions pursuant to its existing authority under the FDCA. This integration of public health considerations into regulatory decisions has encompassed decisions approving drugs and withdrawing approval of drugs, the content that must be in drug labeling, and REMS requirements. The following examples are not exhaustive. The FDA has incorporated public health considerations into numerous other decisions not described in depth in this report, including its approval of vaccines, requirements for misuse warnings on all opioid labeling, and certain requirements for labeling of over-the-counter (OTC) drug products, among others. Since the agency already incorporates these issues into its decision making in various contexts, integrating public health considerations into its regulation of opioids—including its approval decisions on new opioids—would be consistent with both its past practice and a generally accepted understanding of its statutory authority.

Examples of the FDA's Taking a Public Health Approach to Regulation

Example 1: Testosterone Products

In 2009, the FDA received a series of adverse event reports of children who had not been prescribed testosterone gel suffering serious side effects after inadvertent exposure to the products. After reviewing these cases, the FDA determined that the labeling for the products failed to adequately protect children from unintended side effects because some patients for whom they were being prescribed did not follow instructions, and as a result, children were coming into direct contact with the patients' treated skin (FDA, 2009b). In response, the FDA required manufacturers of certain formulations to include a boxed warning on the products' labels and implement a REMS that included a medication guide providing more thorough instructions for the user. At the time, this regulatory action drew some attention because it was the first instance of the FDA's requiring a REMS designed exclusively to protect a third party rather than the patient. (The manufacturers did not contest the label changes.)

Example 2: Transmucosal Immediate-Release Fentanyl Products

TIRF products are intended to manage breakthrough pain in adults with cancer who are already taking, and are tolerant to, other opioids for their consistent pain. TIRF products, however, pose significant public health risks, including diversion, misuse, and overdose.[48] These risks are particularly acute for off-label use among non-opioid-tolerant patients and for accidental exposure and toxicity in children, because TIRF products come in a variety of easy-to-

[47]Section 505(k)(3).
[48]Actiq Medical Reviews, http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20747_Actiq.cfm.(accessed June 27, 2017).

ingest forms, including sublingual and buccal tablets, lozenges, nasal sprays, and buccal soluble films.[49]

Because of these risks, FDA regulation of TIRF products provides an example of how the agency has dealt with concerns about the use of a drug in unintended populations. The FDA reviews published at the time of the TIRF product approvals address the risks of use in non-opioid-tolerant populations and accidental exposure and overdose in children, suggesting that the agency considered those risks as part of its approval decisions.[50] That the agency considered these risks in its approval decisions is further apparent from the TIRF products' approved labeling. All TIRF product labeling contains a contraindication for non-opioid-tolerant patients and a warning explaining that TIRF products contain fentanyl in a dose that can be fatal to a child, and advising that patients ensure the products' proper storage and disposal.[51]

Beyond these measures, the TIRF REMS is designed to mitigate the risk of exposure to non-opioid-tolerant patients and children. Express goals of the TIRF REMS include "prescribing and dispensing TIRF medicines only to…opioid-tolerant patients" and "preventing accidental exposure to children and others for whom [the TIRF product] was not prescribed" (FDA, 2015c). To accomplish the first of these goals, the REMS requires prescribers, dispensers, and patients to confirm that they are aware of the risk of TIRF products for non-opioid-tolerant patients and the contraindication for that population. To accomplish the second goal, the REMS requires a prescriber–patient agreement form in which the prescriber documents that she or he has counseled the patient on the risk that TIRF products pose to children and on proper storage, and in which the patient documents that she or he understands this information. In sum, the FDA has considered the risks of the use of TIRF products by unintended patient populations in its approval and labeling decisions, as well as in the design of the REMS, for these products.

Example 3: Antibiotics and Resistance

Antibiotic resistance has been recognized as a problem since the late 1960s (Swann et al., 1969), and the FDA has struggled with how best to regulate antibiotic use in humans and animals in light of this problem, which poses risks not only for the patient or animal being treated but also for the population broadly. Use of antibiotics in animals has been widespread, not only for treatment or prevention of illness but also because such drugs promote weight gain and feed efficiency. The FDA has been legitimately concerned that such use of antibiotics in animals leads to greater antibiotic resistance in humans.

The FDA first announced its intent to withdraw approval for penicillin and tetracycline for livestock production uses in 1977, but for decades, the agency struggled to provide conclusive evidence that such use posed risks to humans. Finally, in 2003 the FDA determined that while it did not have full proof of the resistance risks posed by livestock production use of antibiotics, it could not conclude that such use was safe. Accordingly, it issued a guidance document describing a risk-based assessment process for new antimicrobial animal drug applications (FDA, 2003). This document explained that the FDA expected new animal

[49]Actiq Medical Reviews, http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20747_Actiq.cfm (accessed June 27, 2017).
[50]Abstral, Actiq, Fentora, Lazanda, Onsolis and Subsys reviews, http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=60 (accessed June 27, 2017).
[51]See, e.g., Abstral Labeling at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022510s000lbl.pdf (accessed June 27, 2017).

antimicrobial drug applications to demonstrate not only safety and efficacy for the intended animal use but also "reasonable certainty of no harm to human health" from that use. The document was followed by additional guidance further explaining the agency's thinking on mitigating the risks of resistance associated with use of antibiotics in animals.

With respect to human use, in 2003 the FDA published a final rule[52] requiring specific language on labels for human antibiotics encouraging doctors to limit prescription of the drugs. This language advises providers to prescribe antibiotics only when bacterial infection is strongly suspected and warns against the potential for antibiotic resistance. These admonitions appear at least four times on each label: at the beginning of the label, in the section on indications and usage, and twice in the precautions section. The precautions section also provides specific guidance for physicians in counseling their patients about the proper use of antibiotics. Additionally, the 21st Century Cures Act, enacted in 2016, amended the FDCA to create an approval pathway for antibiotic drugs intended for patients with unmet medical needs that would require the drugs' labeling to caution prescribers that the drug is intended only for a limited population"[53]

Example 4: Prescription Acetaminophen Products

Acetaminophen is an active ingredient in many prescription combination drug products for pain, such as hydrocodone/acetaminophen (Vicodin), as well as in OTC pain relievers, such as Tylenol. It has been a persistent cause of liver injury, and acetaminophen overdoses—both intentional and unintentional—are a leading cause of acute liver failure in the United States. The FDA has taken numerous steps to address the problem, including working with the National Association of State Boards of Pharmacy to label prescription medications containing acetaminophen more clearly, organizing a 2002 advisory committee meeting regarding OTC acetaminophen products, launching a patient education campaign in 2004, initiating an internal agency working group on acetaminophen in 2007, requiring changes to OTC drug labeling in 2009, and holding another advisory committee meeting in 2009 focused on both OTC and prescription products (FDA, 2009a).

In January 2011, the FDA published a *Federal Register* notice announcing that it was taking two additional steps[54]: requiring a warning about hepatoxicity on the labeling of prescription drugs containing acetaminophen[55] and asking prescription drug manufacturers to limit the maximum amount of acetaminophen per dosage unit to 325 mg (previously, some products had dosage units with as much as 750 mg). The agency explained that if manufacturers did not comply voluntarily within 3 years, it would use its authority under section 505(e) of the FDCA to withdraw approval of any prescription acetaminophen products that exceeded the new maximum dosage unit strength. The agency ultimately was successful in removing all high-dose acetaminophen products from the market by March 2014 (FDA, 2014a).

These actions all involved consideration of the broader public health implications of acetaminophen use. In particular, in explaining its rationale for planning to withdraw approval of prescription acetaminophen products that did not comply with the new maximum dosage unit

[52]21 C.F.R. 201.24.
[53]Sec 3042 of the 21st Century Cures Act.
[54]76 Fed. Reg. 2691 (Jan. 14, 2011).
[55]Section 505(o)(4) of the FDCA (added by the Food and Drug Administration Amendments Act of 2007 [FDAAA]).

strength, the agency pointed to some conventional individual health considerations, including the lack of evidence suggesting that the benefits of the higher-strength products outweigh their risks and the need to establish a larger margin of safety because of uncertainty about the precise toxicity threshold for different patient populations. But the agency also discussed various public health considerations. One basis for its decision was the high risk of unintentional overdose—in other words, the risks associated with the drugs when patients do not use them as directed. The FDA also discussed some of the societal impacts of acetaminophen-associated overdoses, including the estimated 56,000 emergency room visits, 26,000 hospitalizations, and 456 deaths per year caused by such overdoses (numbers far lower than those for opioid overdoses) (Nourjah et al., 2006). Additionally, the agency pointed to the contribution of prescription acetaminophen products to the high incidence of acetaminophen-related liver injury as another reason for withdrawing approval of the higher-dose products.

Public Health Considerations Relevant to Opioid Regulation

Some reasons why opioid analgesics warrant a unique regulatory approach are summarized in Table 6-2. As discussed n previous chapters, in addition to pain relief, opioids can produce feelings of pleasure, relaxation, and contentment (NIDA, 2017). Misuse and diversion associated with seeking these effects, facilitated to some degree by variability in prescribing practices and suboptimal management of pain, have fueled the development of black markets for opioids and counterfeiters.

Accordingly, a public health orientation assumes particular importance in the case of opioids and opioid derivatives, which are associated with nonmedical use and OUD and often are diverted from the lawful system of medical distribution. Related problems arise for opioid agonists and partial agonists (e.g., medication-assisted treatment for OUD), which share many of the same chemical properties and, like opioids, are diverted from lawful medical distribution or used by others beyond the patients for whom they are prescribed. Even opioid antagonists (e.g., the overdose reversal drug naloxone) are used legally and regularly to great benefit beyond the individuals to whom they are prescribed, and sometimes must be administered to the individuals to whom they were prescribed by other persons.

As discussed in Chapter 4, an approach to opioid regulation that actively takes public health considerations into account also requires the recognition that actions taken with respect to one opioid will affect the use and misuse of other opioids, opioid derivatives, and forms of pain management and consideration of the social system shaping use of those drugs.

TABLE 6-2 Special Biological and Social Characteristics of Opioids and Opioid Derivatives

Characteristic	Opioids	Opioid Agonists/ Partial Agonists	Opioid Antagonists
Genetic predisposition to misuse	X	X	
Repeated exposure alters neurobiology of brain	X	X	
Licit/illicit product replacement capacity	X	X	
Reinforcing effects due to chemical properties	X	X	
Clinical need is great	X	X	X
Unintentional/intentional harm or benefit from exposure is great	X	X	X
Exposure or availability can cause risks or benefits to others besides the patient	X	X	X

The interrelations among regulatory decisions concerning different drugs are a prominent feature of the opioid marketplace. The FDA recognizes that continued decisions about drug A require updating the information about the benefits and risks of drug A and its alternatives. For example, in the wake of placebo-controlled randomized trials linking the nonsteroidal anti-inflammatory drugs (NSAIDs) rofecoxib (Vioxx) and celecoxib (Celebrex) to increased cardiovascular risk, the FDA required that new boxed warnings about cardiovascular risk also be added to the labels for older, nonspecific NSAIDs, even though the strength of the evidence implicating those drugs was based on observational data. In the case of opioids, the various drugs in the class interact in the legal and illegal markets and often substitute for one another, so regulatory decisions about opioid A should not be based solely on predicted outcomes among users of opioid A. As an extreme example, it might be excellent policy to approve a new opioid formulation that was expected to cause 500 overdose deaths per year if that new opioid reduced overdose deaths from all other opioids by 5,000 per year. Likewise, randomized clinical trials might show that an ADF of opioid B was safer than an ADF of opioid C, but for various reasons, opioid B would achieve little market penetration and would be used primarily by people who would not develop OUD in any case, while opioid C was positioned to displace use of the current dangerous non-ADF more successfully. Opioid B might win a head-to-head competition in a traditional clinical trial, but a more circumspect decision to instead approve opioid C would save more lives.

Finally, the social system surrounding opioids is a key driver of the committee's recommendations in this report. Integrating public health considerations into regulatory decision making helps in considering distributional effects of those decisions over time. Important state-to-state and regional differences in opioid prescribing and problems have been observed since oxycodone ER was introduced in 1995 (Cicero, 2005). Thus an optimal regulatory process will consider not only what is best for the country as a whole but also the possibility that what is best for the country as a whole might create unacceptable problems in certain states or regions that are more vulnerable because of established opioid trafficking routes, migration patterns, poverty and unemployment, and other social determinants of opioid misuse and OUD. Similar logic applies to key subpopulations, such as pregnant women (see the discussion in Chapter 4) and persons with mental health conditions that historically have been heavily impacted by SUD (Edlund, et al., 2010). Considering the effects of a policy action on the health and welfare of these subpopulations could also serve as a "warning signal" for the population at large.

KEY ELEMENTS OF AN INTEGRATED DECISION-MAKING FRAMEWORK FOR OPIOID REGULATION

A public health perspective is necessary but not sufficient for rational opioid regulation. Rather, as reflected in the committee's recommendations in this chapter, public health considerations need to be embedded in a regulatory framework that is flexible enough to capture and weigh an array of diverse outcomes occurring at multiple levels, from individual to societal. This integrated framework needs to facilitate informed regulatory decisions throughout a drug's life cycle, and include built-in periodic monitoring of each decision's consequences instead of decisions being treated primarily as self-contained events. If correctly formulated, this integrated framework will minimize mistakes and allow the community to recover expeditiously from any that are made. This is the ideal scenario for decision making in the face of uncertainty, which is

the hallmark of regulating new drugs. This approach may also be applicable to other drug classes with similar concerns related to risk of misuse, SUD, diversion, and illicit market–based substitutes, likely with some alterations for the specific issues those drug classes present, although in the context of this report the discussion is focused on opioids.

The starting point for the development of an integrated decision-making framework for the FDA's regulation of opioids is recognition that attempting to introduce considerations beyond the clinical trial and other scientific data presented in the NDA will substantially increase the complexity of the agency's decision-making process. To promote rational, data-driven, and transparent decision making under such conditions, the FDA would need to (1) identify all relevant outcomes; (2) quantify those outcomes to the extent feasible; and (3) integrate those outcomes into an evaluative framework, including a common metric that would facilitate comparison and balancing.

Step 1: Identifying All Relevant Outcomes

An integrated framework for opioid regulation would include all relevant outcomes with an impact on public health. For most drugs, these outcomes are adequately summarized by the potential benefits and risks for individuals for whom the drug is indicated in the labeling. For example, a regulatory analysis of a cholesterol-lowering statin drug would need to consider its impact on users' cardiovascular risk reduction (the potential benefits) and on the development of diabetes and muscle and liver injury (the potential risks), as well as any other outcomes that are anticipated to affect the health of the drug's users. Another important consideration in the regulation of many drugs is the quantification of "risk compensation." For example, if statins make users feel less concerned about their diets, they may revert to less healthy eating habits, therefore partially offsetting the hoped-for benefits of the drug.

As discussed in more depth in the next section, application of this step to an opioid would involve consideration of its impact on such outcomes as users' short- and long-term pain relief and functional improvements (the potential benefits); hyperalgesia, misuse, OUD, overdose, and death (the potential risks); and the possibility of risk compensation. It could also include outcomes that are not directly experienced by the drug's users but affect families, communities, and society as a whole.

Other outcomes that might need to be considered include illegal markets for diverted prescription opioids, illegal opioids such as heroin and illicitly manufactured fentanyl, and counterfeit pills that look like prescription opioids. Approval or withdrawal of a prescription opioid on the legal market can affect levels of use of black market opioids such that the total net effect on mortality may be very different from the apparent effect if one considers only outcomes directly related to the approved or withdrawn opioid. Indeed, one survey found that roughly three-quarters of people who used heroin in the past year misused prescription opioids first, and seven of ten people who used heroin in the past year also misused prescription opioids over the same period (Jones, 2013). The challenge of monitoring indirect effects also is illustrated by the introduction of ADFs, which may prevent misuse through specific modes of administration (e.g., injection or insufflation) but may have unintended impacts (see discussions in Chapters 4 and 5).

Step 2: Quantifying the Outcomes

Traditionally, the FDA appropriately relies on randomized trials, observational studies, and other patient experiences to quantify drugs' benefit-risk profiles. However, because supplying opioids for long-term use outside of medical facilities creates additional risks from misuse and diversion, many of the relevant outcomes cannot be identified or quantified using the FDA's usual research tools. In these situations, regulation would need to be informed by data on behaviors of intended users or others designed to evade or neutralize desired outcomes (including intentional efforts to defeat the system, such as by physician shopping or operating "pill mills" in the case of opioids). To accomplish this important task, the FDA might need to monitor nontraditional data sources (e.g., prescription drug monitoring programs, relevant online message forums, and special populations such as people in treatment for OUD) to quantify the extent of these behaviors in support of its regulatory decisions.

Evaluation of this full spectrum of outcomes is an inherently interdisciplinary task that requires alternative data sources and inputs from experts in epidemiology, economics, and other social and behavioral sciences. Although improvements in measurement and surveillance are under way, the precision and completeness of the tools available to measure the many relevant outcomes are not ideal (Secora et al., 2014), and may never be given the illicit nature of most opioid misuse. However, sound regulatory decisions need not overlook important benefits and risks just because they are difficult to quantify. In addition, incorporation of the full range of considerations need not be postponed until all pertinent data sources have been developed, but may proceed tactically and strategically, incorporating available outcomes and data sources as they are developed and improved.

The outcomes would ideally be measurable in at least one extant surveillance system. Risks could generally reflect mortality (e.g., risk of fatal overdose) or substantial morbidity (e.g., measures of OUD among women of childbearing age). A denominator reflecting the drug's availability or its potential for misuse or diversion at the local level could be applied to aid in comparing across the components (Butler et al., 2008; Secora et al., 2014). Because geographic trends could be especially useful in risk-benefit considerations, preservation of the lowest possible geographic unit for numerator and denominator might be optimal. Another important choice would be what to consider as the denominator. For example, morphine milligram equivalent (MME) availability could be used because data on dispensed medications are readily available at high levels of specificity (zip code, county), and because availability of illicit drugs can be captured at this geographic unit level and equated with prescription opioid–generated MME to provide a more accurate measure of the relevant health outcomes. Diversion and corruption of the drug's access mechanisms could be anticipated based on information on comparable products captured by government and private datasets. These "secondary" outcomes of the opioid under consideration could be estimated at the patient, provider, manufacturer, and distribution levels.

One of the FDA's major challenges would be to evaluate the currently available data sources addressing these outcomes and to work with the sponsoring agencies or institutions to improve these sources, such as by identifying gaps in the data and collaborating with partners to close those gaps or generate new datasets. Appendix C of this report provides a tabular summary of current data sources, as well as their strengths and limitations.

Step 3: Integrating Outcomes into an Evaluative Framework

Beyond creating a comprehensive list of outcomes and quantifying those outcomes, a key conceptual challenge is determining how to integrate many outcomes into a single framework that permits a transparent comparison of policies with differential effects on each outcome.

For most drugs, the procedure for weighing benefits and risks typically involves a mix of quantitative estimates (e.g., findings from clinical studies) and qualitative judgments (e.g., opinions of advisory committees). A 2012 Institute of Medicine report proposes a framework for assessing a drug's benefit-risk profile (IOM, 2012). For opioids, however, the weighing of benefits and risks is more complex than is the case for other drugs because the relevant consequences affect intended and unintended users as well as third parties, operate at multiple levels (individual, household, community), and encompass a wide array of fatal and nonfatal outcomes. Weighing benefits and risks in this context requires a decision-analysis framework that can adequately capture the dynamic interrelations among the many variables involved. One possibility, discussed briefly in Chapter 5, is building a mathematical model of the opioid system that simulates the expected outcomes. However, developing and testing such a model is likely to take several years, and the committee believes the need to expand the FDA's regulatory framework, including by incorporating unquantified elements and "best estimates," warrants action to meet that need in the meantime.

Another challenge is to weigh the risks avoided by tighter regulation of an opioid against the pain, functional limitations, and other adverse effects experienced by patients who would benefit from that drug if its access were not restricted. The FDA's current approach informally weighs the available measures of pain utilized in clinical trials against estimated increases in misuse and OUD and the derivative risks. Although this approach will remain necessary for the immediate future, the committee also encourages and expects the FDA to explore use of a common yardstick (e.g., quality-adjusted life years) to incorporate all the outcomes of interest within a single metric.

The committee recognizes that no single quantitative exercise, even an integrated one using a common metric, can replace the agency's regulatory judgment for every decision. However, the FDA could quantify the outcomes as fully as possible given the available data and integrate these outcomes into a transparent framework that utilizes a common metric for measurement to the extent feasible. In the next section, the committee provides its recommendations for how this transparent framework might look and how it might be implemented.

IMPLEMENTATION OF AN INTEGRATED FRAMEWORK FOR OPIOID REGULATION

In the committee's judgment, the FDA should take steps toward the implementation of an integrated, transparent framework for opioid regulation at three different stages of its decision-making process: clinical development, drug approval, and post-approval monitoring. Box 6-2 contains the committee's overarching recommendation framing this discussion.

BOX 6-2
Overarching Recommendation for Development of an Integrated Framework for Regulation of Opioids

Recommendation 6-1. Incorporate public health considerations into opioid-related regulatory decisions. The U.S. Food and Drug Administration (FDA) should utilize a comprehensive, systems approach for incorporating public health considerations into its current framework for making regulatory decisions regarding opioids. The agency should use this approach, in conjunction with advisory committee input, to evaluate every aspect of its oversight of prescription opioid products in order to ensure that opioids are safely prescribed to patients with legitimate pain needs and that, as actually used, the drugs provide benefits that clearly outweigh their harms. When recommending plans for opioids under investigation; making approval decisions on applications for new opioids, new opioid formulations, or new indications for approved opioids; and monitoring opioids on the U.S. market, the FDA should explicitly consider

- benefits and risks to individual patients, including pain relief, functional improvement, the impact of off-label use, incident opioid use disorder (OUD), respiratory depression, and death;
- benefits and risks to members of a patient's household, as well as community health and welfare, such as effects on family well-being, crime, and unemployment;
- effects on the overall market for legal opioids and, to the extent possible, impacts on illicit opioid markets;
- risks associated with existing and potential levels of diversion of all prescription opioids;
- risks associated with the transition to illicit opioids (e.g., heroin), including unsafe routes of administration, injection-related harms (e.g., HIV and hepatitis C virus), and OUD; and
- specific subpopulations or geographic areas that may present distinct benefit-risk profiles.

Subpopulations and geographic areas that may present distinct benefit-risk profiles include, but are not limited to, pregnant women, individuals with a history of SUD/OUD or other mental health conditions, and geographic areas with high rates of unemployment or SUD/OUD.

Stage 1: The Clinical Development Stage

The FDA can first intervene to implement a new approach to opioid regulation after the submission of the IND application. During the investigational clinical trial period that follows submission of an IND application, crucial data currently are collected on the drug's pharmacodynamics, safety, and efficacy for intended users, but data also could be collected on its potential public health consequences. To date, evidence generation for opioids, as for many drugs, often has involved short-term trials involving narrowly defined patient populations (e.g., patients with back pain). A more comprehensive approach to organizing pre-approval trials could encompass

- testing the drug in subpopulations at high risk of harmful outcomes, including those in locations of the country with high rates of misuse, OUD, or diversion;

- including patients with mental health disorders and OUD and other populations in which opioid drugs are known to be widely used to ensure a representative sample of patients in the pivotal clinical trials;
- measuring outcomes reported by household members or other third parties expected to be affected by the product (to partially overcome underreporting of misuse and OUD);
- conducting continued testing of ADFs to understand the mechanisms of manipulation that might be used to defeat them; and
- understanding interactions with other drugs (both prescription and illicit) commonly used with opioids or by people who use opioids illicitly, including how the drug interacts with antiretrovirals or anti–hepatitis C virus (HCV) medications.

While the committee understands that not all of these outcomes could be collected for every opioid being tested, this also may not be a comprehensive list—the particular public health outcomes would need to be specific to the opioid and its predicted effects. To that end, the FDA could issue a guidance document delineating the specific public health data that are likely to be most relevant to different types of opioids and that would need to be collected during pre-market clinical trials. This guidance document would explain the agency's current thinking on the overall development program and clinical trial design for opioids intended to treat acute and chronic pain. In addition to commenting on public health outcomes, the guidance could address the current state of the evidence on the essential features of trials for new opioids or opioid formulations, such as the duration necessary to collect appropriate outcomes. Such a document could also specifically address how the agency will handle new applications through the 505(b)(2) pathway frequently used for opioid reformulations or dosing changes. While reformulations may undergo less drug efficacy and safety testing, they may entail important public health considerations based on ongoing experience with the formulations that are currently being marketed. Similarly, studies have documented a positive opioid dose–harm relationship (with respect to OUD and death in particular). FDA approval of opioids through the 505(b)(2) process would need to involve the same rigorous data evaluation process as that used for approvals made under the traditional pathway.

Communication of the types of public health outcomes sought by the FDA for a particular opioid could be communicated during the meetings that manufacturers are permitted to have with the FDA after each stage of testing, and at other times with sufficient notice. At these meetings, manufacturers may discuss plans for the design and outcomes of their trials, as well as the early evidence on the drug that has emerged. The FDA can impart useful advice during these meetings on optimal trial designs that can meet the considerations outlined in this chapter; indeed, according to one review, manufacturers that had an end-of-phase-2 meeting were far more likely to have their drugs approved than those that did not (Booz Allen Hamilton, 2006). Some manufacturers are diligent about having these meetings, while others are not. These meetings could serve as a useful mechanism for encouraging a new paradigm for opioid testing. The FDA guidance could suggest that manufacturers developing new opioids or new opioid formulations request a certain number of pre-approval meetings before submitting an NDA. These meetings could also help build a paper trail to inform FDA post-approval surveillance and help regulators understand why any recommendations about measurement of public health outcomes are not being implemented.

While the committee did not wish to make specific recommendations on what the FDA should do if manufacturers' development plans were to diverge substantially from the above guidance or if signals of potential problematic public health outcomes were to arise (such as evidence of diversion or misuse even in the highly structured environment of a clinical trial), issuance of a clinical hold is a strategy the FDA can use to delay additional proposed clinical studies or suspend an ongoing study. Reasons why a clinical hold may be issued under the current regulations include an unreasonable risk for subjects participating in the clinical research or a protocol for a phase 2 or phase 3 trial that is clearly deficient in design to meet its stated goals.[56] Twenty-nine clinical holds were issued between 2008 and 2014 (Boudes, 2015), a remarkably low number given the number of investigational drugs being tested during those years. A clinical hold, if needed, could be issued as soon as possible after the IND was submitted or after the FDA received new information about ongoing opioid development trials, thereby reducing disruption for manufacturers and clinical trial enrollees. For example, if a manufacturer sought to bring a new LA formulation of an opioid to market without a tamper-resistant formulation, the FDA could decide to act at this point to hold the clinical trial until the company's rationale could be assessed. In this case, the proposed formulation would present an unreasonable risk of contributing to harmful outcomes among the subjects of the trial, and the trial would clearly be deficient in design, assuming that one of its stated goals would be to obtain FDA approval of the product.

As another example, if the FDA observed that a proposed pivotal trial for a new opioid or opioid formulation had not been designed to be of sufficient duration to enable collection of the necessary public health outcomes, this could be the basis for issuing a clinical hold until the trial had been redesigned. In this case, the agency might conclude that the trial was clearly deficient in design, assuming that one goal of the trial was to support FDA approval. The FDA could create an internal system to prioritize review of opioid INDs to facilitate the issuance of clinical holds, when warranted, and develop a similar system for integrating new information it received about opioids later in the development process to help in deciding whether clinical holds would be needed at any point.

The FDA could also specially consider the public health implications of opioid approval when making use of the multiple pathways leading to approval of investigational drugs. In addition to the 6-month priority review option, drugs can receive four other special designations to expedite their development or approval (see Table 6-3). While the expedited access provided by these pathways can be highly useful in cases of transformative new products or drugs intended to serve an unmet medical need, shortened development and review times have also been associated with negative public health outcomes. Drugs approved shortly before their regulatory deadlines have been found to be more likely to have post-marketing safety problems—including safety-related withdrawals and the need for added boxed warnings—relative to drugs approved at any other time (Carpenter et al., 2008, 2012). Drugs receiving faster reviews also have more spontaneous reports of drug-related adverse events (Lexchin, 2012; Olson, 2008; Reaves, 2009).

[56] 21 C.F.R. 312.42.

TABLE 6-3 The U.S. Food and Drug Administration's Expedited Drug Development and Approval Pathways

Special Designation (Year Initiated)	Criteria and Notable Pathway Features
Orphan Drug (1983)	Applies to drugs intended to treat diseases affecting <200,000 people per year. Such drugs often are approved based on smaller trials with few rigorous features (controlled, randomized, testing a real clinical outcome versus a surrogate measure).
Fast Track (1988)	One phase 2 trial is sufficient to demonstrate safety and efficacy.
Accelerated Approval (1992)	Approval is based on a surrogate or intermediate endpoint "reasonably likely to predict clinical benefit."
Priority Review (1992)	The new drug should "significantly improve" safety or effectiveness; FDA review is shorter (6 months versus the 10-month standard).
Breakthrough Therapy (2012)	Based on preliminary clinical evidence with clinically significant endpoint(s), the drug offers "substantial improvement" over existing therapy; intensive guidance is intended to expedite development.

SOURCE: Darrow et al., 2014.

In the case of opioids, it would be inadvisable to truncate the development time in the absence of extraordinary circumstances. Instead, opioids and their secondary effects need to be fully investigated and the normal amount of time allotted to reanalyze the results of that investigation (currently 10 months for standard-review drugs). Because it is highly unlikely that a new opioid would satisfy the criteria for an expedited review or development pathway (e.g., fills an unmet medical need or offers a substantial improvement over available treatments for a serious condition), guidance might be issued defining how these pathways apply to opioids and other drugs with addiction potential. Recently, the 21st Century Cures Act of 2016 permitted supplemental approvals—for newly approved indications for drugs already on the market—to be granted on the basis of summaries of the data, rather than full FDA review of the underlying data. Again, the committee believes this truncated pathway is inappropriate for opioids, and instead review of the underlying data for supplemental NDAs for these drugs is necessary in all cases. Box 6-3 contains the committee's recommendations to the FDA for the clinical development stage.

BOX 6-3
Recommendations for the Clinical Development Stage

Recommendation 6-2. Require additional studies and the collection and analysis of data needed for a thorough assessment of broad public health considerations. To utilize a systems approach that adequately assesses the public health benefits and risks described in Recommendation 6-1, the U.S. Food and Drug Administration (FDA) should continue to require safety and efficacy evidence from well-designed clinical trials while also seeking data from less traditional data sources, including nonhealth data, that pertain to real-world impacts of the availability and use of the approved drug on all relevant outcomes. The FDA should develop guidelines for the collection of these less traditional data sources and their integration in a systems approach.

Recommendation 6-3. Ensure that public health considerations are adequately incorporated into clinical development. The U.S. Food and Drug Administration (FDA) should create an internal system to scrutinize all Investigational New Drug (IND) applications for opioids. This review should examine whether public health considerations are adequately incorporated into clinical development (e.g., satisfactory trial design; see Recommendation 6-2). In implementing this recommendation, the FDA should rarely, if ever, use expedited development or review pathways or designations for opioid drugs and should review each application in its entirety.

Stage 2: Drug Approval

The next major intervention point for the FDA in its regulation of opioids is the time of market authorization, when it is considering an NDA for a new opioid molecule or formulation. As indicated above, a decision usually is made at this stage based on the efficacy and safety data related to the specific drug for the intended clinical use. In making this decision, the FDA conducts a formal, qualitative benefit-risk assessment and ultimately arrives at a decision as to whether a drug's benefits to patients for whom it is prescribed outweigh its risks. The committee believes, given the evidence presented thus far in the report, that formal incorporation of public health considerations into the existing assessment process is warranted since the risks of opioids are so profound, and their diversion is so prevalent. To this end, using its existing legal authority to take into account the public health considerations outlined in Recommendation 6-1, the FDA would consider use by the individual patient (including, for example, the possibility that the drug would not be used as intended) or by unintended persons (such as household members), as well as the broader societal consequences of likely use, such as the scale of diversion and the overall impact of addiction on the health and well-being of patients who develop OUD. One would expect a thorough regulatory analysis of a new opioid within this framework to consider the drug's broad impact on untreated pain, the risk of diversion/OUD, the risk of overdose/death, and an assessment of the expected number of persons who would experience each of these outcomes. Relevant considerations for each of these factors could include the following:

- Impact on untreated pain
  - expected prevalence of patients who would be served by the drug in question (versus with other opioids or with nonopioid treatment regimens);

  - pain relief observed in clinical trials (number of people benefiting and average improvement on pain and/or functioning scales);
  - differences between short-term effectiveness in highly protocolized clinical trials with selected patients and long-term effectiveness in health care settings (i.e., avoiding assuming that real-world impact on pain relief will correspond directly with outcomes of randomized controlled trials); and
  - prevalence of untreated pain if the drug were not approved and prescribed for the desired indication.
- Impact on diversion//OUD
  - expected prevalence and frequency of nonmedical use, which could be extrapolated from data on people currently using a related compound nonmedically;
  - expected diversion and impact on existing black markets, again extrapolated from data on people diverting (giving, selling, exchanging, buying, or otherwise receiving from someone other than one doctor/one pharmacy) related drugs that have already been approved; and
  - expected prevalence and frequency of SUD involving the drug in question if approved and involving use of substitute opioids (e.g., other prescription opioids or illicit opioids).
- Impact on overdose/death—estimated rates of fatal and nonfatal overdoses associated with or involving (1) the drug in question, (2) the compound in question, (3) other prescription opioids not of the same compound, and (4) illicit opioids.
- Other public health outcomes—if the drug is injectable, the risk of transmission of infectious diseases (e.g., HIV and HCV) caused by such use.

Potential effects of the drug on individuals for whom it is indicated and prescribed—as well as those whose use of the drug is unintended and not as prescribed—can be anticipated during the pre-approval stage and, if the drug is approved, can then be monitored post-approval. The factors outlined above could fit into an opioid-specific expansion of the FDA's current benefit-risk framework presented earlier in Figure 6-1 (see example Table 6-4), used when making approval decisions on applications for new opioids, new opioid formulations, or new indications for approved opioids.

The proposed expanded framework includes measurable, opioid-specific considerations relevant to public health, including patient and public safety. Should the information thus amassed suggest to the FDA that an opioid product should not be granted marketing approval, the committee believes the current FDA practice of providing a response letter complete with the rationale for the decision and suggestions for positioning the application for subsequent approval would remain appropriate. Complete response letters traditionally are not made public, but recent research has shown that manufacturers' press releases often misstate the reasons for disapproval. Because of the significant public health concerns associated with opioids and the need to be able to evaluate the FDA's new regulatory processes accurately, the FDA may want to reexamine its policies relating to publication of complete response letters and consider what steps it needs to take to ensure that all complete response letters related to opioids are publicly released at the time of issuance. Notably, an FDA Transparency Task Force in 2010 proposed that releasing certain relevant documents currently kept confidential, including the agency's letters to drug,

biologic, and device manufacturers when their products are not approved, would be consistent with existing agency rules related to safeguarding commercial information (FDA, 2010a).

The final rows in the opioid-specific framework in Table 6-4 relate to post-approval mitigation strategies and are discussed in below. Box 6-4 contains the committee's formal recommendation to the FDA for the drug approval stage.

Stage 3: Post-Approval Monitoring

When the FDA makes an approval decision or after a drug is on the market, the agency can establish post-approval commitments and requirements, including whether the opioid requires a REMS. As detailed in prior chapters, prescribing of opioids for long-term use for chronic pain has led to numerous safety concerns that cannot be adequately addressed or anticipated in limited, prospective pre-approval trials. For this reason, the committee believes that rigorous, active post-approval monitoring of the ongoing safety and effectiveness of opioids is essential.

TABLE 6-4 Example of an Adapted Benefit-Risk Framework for Approval of Opioid Products

Decision Factor	Evidence and Uncertainties	Conclusions and Reasons
Characteristics of Opioid		
How Opioid Fits among Currently Available Pain Treatment Options		
Benefits Observed in Clinical Trials, Overall • Benefits to patients • Public health benefits		
Risks Observed in Clinical Trials • Risks to patients • Public health risks		
Predicted Benefits/Risks to Families of Patients		
Predicted Benefits/Risks to Society, Overall • Special communities • Subpopulations		
Diversion Potential		
Predicted Effects on Use of Other Opioids or Illicit Drugs		
Risk Management, Overall • Potential for off-label use • Advertising/promotion		

BOX 6-4
Recommendation for the Approval Stage

Recommendation 6-4. Increase the transparency of regulatory decisions for opioids in light of the committee's proposed systems approach (Recommendation 6-1). The U.S. Food and Drug Administration should commit to increasing the transparency of its regulatory decisions for opioids to better inform manufacturers and the public about optimal incorporation of public health considerations into the clinical development and use of opioid products.

Steps that the FDA might take to implement this recommendation include

- *Issuing a guidance document that outlines opioid-specific clinical development considerations, including how the new guidance differs from existing analgesic development guidance and relates to public health.*
- *Releasing summary versions of complete response letters for opioid products to inform the public about the public health considerations that FDA has determined would preclude marketing approval.*

The key question is through what mechanisms optimal monitoring can occur such that the benefits of opioids are maximized and their risks minimized. As the FDA considers how to optimize its current post-approval monitoring authority for opioids, a useful way to integrate the review of the collected pre-approval data with the prospect of post-approval monitoring can be found in a three-step decision-making process previously proposed by an Institute of Medicine committee (IOM, 2012). In that process, each step corresponds to one of the three fundamental requirements for rational decision analysis under uncertainty reviewed in the previous section:

- In the first step of the analysis, the FDA would define the public health question that prompted the need for a regulatory decision under the applicable statute. This step would include identifying the specific characteristics of the drug and the health problem at issue, available information about the drug, alternative treatments that are available, and plausible regulatory actions and their potential consequences. This stage would be aimed at identifying the information needed for a regulatory decision.
- In the second step of the analysis, the FDA would evaluate the quality of evidence on both the benefits and the risks associated with the drug, including any new information that has triggered the need to consider regulatory action. The output of this step would include estimates of the likelihood and magnitude of a drug's benefits and risks and a characterization of the scientific evidence on which the estimates are based.
- The third step of the analysis would involve synthesizing and integrating the estimates of benefits and risks and the quality of the evidence on which these estimates are based (Step 2) with the public health question (as specified in Step 1); deciding on the appropriate regulatory actions, including whether further study should be required; communicating the decision; implementing the regulatory actions; evaluating the effects of the regulatory actions; and, particularly in the case of complex or difficult decisions, evaluating the decision-making process and the impact of the actions taken on the public's health. Note that this step would involve deciding

whether immediate regulatory action is warranted, or holding a decision in abeyance in anticipation of better information from additional study would justify the costs and consequences of further delay.

With this model in mind, the committee suggests a number of specific actions (reflected in Recommendation 6-5 in Box 6-5 at the end of this section) relating to the FDA's use of post-approval monitoring for opioids. The first set of actions relates to the use of currently available authorities, such as REMS, safety labeling changes, and risk communications. Currently, ER/LA opioids must be incorporated in a shared REMS, and the FDA has said that it intends to update the opioid REMS requirements to include IR opioids as well (FDA, 2017e) (the committee supports such a step). The current REMS for opioids is intended to reduce the serious risks associated with these formulations while maintaining access to the drugs for patients in need by educating providers about the limitations, benefits, and continued abuse potential of these formulations. However, the REMS may instead provide a false promise of risk mitigation (Nelson and Perrone, 2012). As discussed previously in this report, evidence is conflicting as to whether REMS can substantially affect prescribing and dispensing practices and is lacking on the effectiveness of the REMS for opioids. As part of efforts to improve its post-approval oversight of opioids, the FDA could make better use of REMS components that have been shown to improve prescribing practices (see Recommendation 6-5).

Meanwhile, the FDA could evaluate the data on the performance of the existing REMS, collecting additional data if needed, and change the features of the REMS so it would more optimally ensure the evidence-based use of opioids while reducing unsafe prescribing. For example, the FDA could consider additional supplemental education strategies when strengthening the opioid REMS, similar to the SCOPE of Pain program discussed in the first section of this chapter. Related considerations include how heightened prescribing restrictions might affect the supply of prescribers willing or able to prescribe opioids to patients with legitimate pain needs. Thus, it would be important to actively solicit the perspectives of prescribers and patients who are independent from the pharmaceutical industry in developing an optimal REMS. Development of an optimal opioid REMS also could be facilitated through collaborations between the FDA and other relevant government agency stakeholders, such as the Substance Abuse and Mental Health Services Administration, National Institute on Drug Abuse, Centers for Disease Control and Prevention, Health Resources and Services Administration, and U.S. Department of Veterans Affairs, among others.

Similarly, the boxed warning on opioids was strengthened in August 2016 to indicate that opioids carry "serious risks, including misuse and abuse." It may be instructive for the FDA to study whether this change and the publicity surrounding it helped more prescribers and patients better balance the benefits and risks of opioid prescribing. For example, FDA efforts to communicate risk and safety information to providers and the public through advisories and warning labels appear to have variable impact (Dusetzina et al., 2012). If no clear effects are observed, the FDA could further modify opioid labels to include more specific statements about particular clinical situations, such as the management of chronic noncancer pain, in which there is clear evidence that the risks of opioids outweigh their benefits. These enhanced warnings could be included in the boxed warning, or disseminated through Drug Safety Communications and other media intended for a broad audience of prescribers and patients.

When new opioids are approved, requirements for boxed warnings or post-approval monitoring strategies such as REMS could be used as a way of justifying approval of a drug with an important safety risk, recognizing that the heightened post-approval surveillance or data from

additional tests could inform changes to the label or even the marketing status of the product that might prove necessary. Before the FDA relied on such a strategy, however, the committee believes it would be best to study such post-approval actions as applied to opioids rigorously to ensure that they offer the real prospect of safety protections or timely acquisition of necessary data.

Another component of the committee's recommendation concerning post-approval monitoring pertains to the gathering of emerging information about the use of prescription opioids and how they are being used in both safe and unsafe ways. The collection of such information is part of the FDA's oversight of the safety and effectiveness of drugs in widespread use. Following approval of a new opioid or opioid formulation, initial estimates of the drug's risks and benefits would be informed and updated by data on the cumulative impacts of the drug as used in the community. As indicated above, the FDA might seek to impose post-marketing commitments or requirements to conduct ongoing studies. As the committee proposes in Recommendation 6-5, the FDA should engage in active surveillance of data on the use and misuse of approved opioids. This surveillance might include monitoring of new data that emerge from post-market commitments or requirements or the REMS program, which could be acted upon efficiently and integrated with spontaneous adverse event reports and other observational data conducted through the Sentinel System. Other mechanisms for monitoring and generating new data might include periodic literature searches for independent reports of potential concern and the organization of prospective studies to respond to safety or other signals that might arise. Given the unique considerations related to opioids outlined in this report, the FDA might consider establishing a special center for opioid oversight to coordinate these activities in the Office of Surveillance and Epidemiology and work with the secretary of HHS to ensure adequate funding for its work. Newly emerging information might require changes to an opioid's labeling, although decisions to change the label wording or add safety warnings would ideally be guided by knowledge of whether past changes to opioid labeling have positively affected prescribing practices. Should such changes be deemed necessary, clear information dissemination plans that go beyond the Drug Safety Communication mechanism currently in place, for which there is insufficient evidence of effectiveness, would be essential.

Recommendation 6-5 includes establishing a new post-approval monitoring structure for opioids to promote adequate post-approval oversight that would include periodic follow-up. During these formal re-reviews, the totality of the pre- and post-approval data available at the time could be collected and an advisory committee convened to help the FDA review the drug's real-world use and outcomes. The FDA could develop guidance on the types of data that would lead to withdrawal of the drug, the requirements to revise the label, initiation of other REMS or monitoring pathways, or other outcomes of this review process. The progress of such post-market commitments or requirements could be reviewed, giving the FDA an opportunity to examine preliminary data. Conversely, if warranted, the FDA could take an enforcement action, including imposing civil monetary penalties authorized under the FDA Amendments Act, if a manufacturer failed to comply with post-market requirements (including by failing to comply with the timetable for a study or trial).

In extreme cases, after the formal re-review, the FDA might conclude that withdrawal of an opioid was necessary because its benefits no longer outweighed its risks. Notably, the FDA cannot require a mandatory recall of an approved prescription drug. If an approved prescription opioid were later found to be unsafe because it was contributing excessively to misuse and OUD, a recall would have to be initiated voluntarily by the manufacturer in response to an FDA

request. The FDA could request a voluntary recall in such extreme circumstances, or other federal or state enforcement authorities could evaluate their potential enforcement roles.

A third component of the committee's recommendation on post-approval oversight of opioids is more effective regulation of industry promotional activities. The committee bases this part of the recommendation on the fact that, as discussed earlier in this chapter, decades of research have shown that industry promotion of prescription drugs to physicians and consumers influences prescribing practices (Robertson et al., 2012). The FDA could issue new guidance outlining what it views as responsible advertising and promotion of opioids to prescribers. Just as the FDA should move to incorporate public health considerations in its approval-related decisions for opioid drugs, it should incorporate such considerations into its review of industry promotional strategies for these products. Requiring that advertising of a drug explicitly mention these public health considerations might be necessary for the advertising of approved opioids to be considered accurate, truthful, and not misleading. For example, the FDA might require that advertising mention the risk that someone in the patient's household might misuse or sell the drug if it is not safely stored, or that it include specific statements about the risks of developing tolerance and OUD after unduly prolonged use for alleviating pain. More significantly, the FDA could find that there is no way to incorporate such broader considerations fairly into broadcast media advertising, ending the practice of DTC advertising of opioids via these media. The committee urges the FDA to issue guidance on responsible practices of DTC advertising and promotion as expeditiously as possible. Violations of promotional rules related to opioids should be pursued to the fullest extent of the government's current powers; in particular, off-label marketing of opioids should be carefully scrutinized.

Box 6-5 contains the committee's formal recommendation for post-approval monitoring.

BOX 6-5
Recommendation for the Post-Approval Monitoring Stage

Recommendation 6-5. Strengthen the post-approval oversight of opioids. The U.S. Food and Drug Administration should take steps to improve post-approval monitoring of opioids and ensure the drugs' favorable benefit-risk ratio on an ongoing basis. Steps to this end should include use of Risk Evaluation and Mitigation Strategies that have been demonstrated to improve prescribing practices, close active surveillance of the use and misuse of approved opioids, periodic formal reevaluation of opioid approval decisions, and aggressive regulation of advertising and promotion to curtail their harmful public health effects.

More specific actions under this recommendation might include the following

- *Maximizing the use of REMS with elements to assure safe use, boxed warnings, and other available risk communication methods in an evidence-based way to help influence safe and appropriate prescribing and dispensing practices. These tools could be implemented with input from prescribers and patients.*
- *Actively seeking emerging data on actual use and misuse of opioids through the Sentinel system and other methods to identify safety issues, and then act on them with all deliberate speed.*
- *Formal reevaluation of opioid approval decisions on a periodic basis based on the totality of the evidence, including evidence of public health outcomes, at that point.*
- *Restricting advertising and promotion of opioids to the fullest extent possible under existing rules, including prohibiting off-label marketing, to curtail practices inimical to the public health.*

Implications for Other Regulatory Decisions

The framework outlined in this section was designed for new opioid products and formulations, but can be applied with equal force to opioids already on the market. Thus in Recommendation 6-6 (presented in Box 6-6 at the end of this section), the committee recommends that the FDA conduct a full review of currently marketed/approved opioids. Such a review could be carried out by an expert panel that would systematically examine the current range of approved brand-name and generic opioids to determine which of these drugs remained effective and safe; which might need revised labels, formulations, or post-market requirements; and which should be withdrawn from the market entirely. Such a model could be modeled on the Drug Efficacy Study Implementation (DESI) of the 1960s and 1970s, in which the FDA worked in concert with the National Academy of Sciences/National Research Council to classify the risk-benefit ratios of the purported indications for drugs approved between 1938 and 1962, ultimately finding that more than 300 products were ineffective for all indications and had to be withdrawn from the market, and more than 2,400 products had labels for indications for which they were ineffective. Although modeled on DESI, the Opioid Study Implementation (OSI) process envisioned by the committee could be carried out in a much shorter time frame and with far fewer resources than DESI because it would be limited to a single drug class for which the medical literature already provides substantial evidence to help answer the questions about opioids that the expert panel might want to address.

Although the OSI process would not be prohibitively expensive—and should be overall cost-saving to the U.S. health care system given its potential to reduce the substantial costs due to opioid-related harms—it would require sufficient funding sustained until the full range of available opioid products could be reviewed. In addition, several of the ideas offered for how the FDA might implement the committee's recommendations (e.g., the creation of a special center for opioid oversight within the Office of Surveillance and Epidemiology, routine post-approval reviews of new opioid approvals) would require additional regulatory resources. The cost of such interventions could be accounted for without additional legislation as part of the FDA's discretionary budget until the next reauthorization of the Prescription Drug User Fee Act, at which time the user fees applied to NDAs could be adjusted to account for the additional costs of adequate oversight of the prescription opioid market. Funding for this work might also be donated voluntarily by opioid manufacturers interested in helping to ensure a safer opioid marketplace. Another approach, which would require congressional action, would be to add a very small surcharge to each opioid prescription, in the same way that the National Childhood Vaccine Injury Act established a trust fund to compensate those suffering vaccine-related injuries through a $0.75 excise tax on each vaccine dose. All of these approaches warrant study to ensure that the FDA has the funding it needs to modernize its approach to exercising its vital role in oversight of the opioid market.

The committee recognizes that the OSI process might lead to the removal of some of the opioid formulations or doses currently on the market because it is highly unlikely that all of these products would be judged safe and effective under the new drug approval framework proposed in this chapter should they just now be entering the market. However, the committee does not believe that this process would unduly restrict the availability of opioids for appropriate use in treating pain syndromes overall, since one of the advantages of the proposed OSI process would be its public health scope and the ability to take into account the advantages and disadvantages of

removing a product in the context of the current marketplace of pain treatment modalities. Additionally, the FDA could establish reasonable time periods within which manufacturers would have to come into compliance with decisions resulting from the OSI process to minimize any disruption to treatment resulting from changes to marketed opioids (and reduce burdens on industry). Patients also would not need to be concerned that the OSI process would affect the cost of opioids as long as sufficient numbers of generic manufacturers were producing the opioid formulations remaining on the market at the conclusion of the OSI review.

The committee also believes that its recommendations may be relevant to some of the next-generation pain medications outlined in Chapter 3. Many of these products are designed to be nonaddictive, in which case they could be reviewed under the FDA's normal paradigm. But the agency might have lingering doubts about how some products will perform in long-term or widespread use, in which case it might want to apply relevant recommendations detailed in this chapter. When considering the various guidance documents suggested in this report, the FDA could indicate which recommendations it believed would also apply to novel nonopioid pain medications that nonetheless posed a potential risk for misuse, OUD, or illicit use.

Similarly, it is possible that some of the recommendations offered in this chapter could be applied to other controlled substances, such as benzodiazepines, neurostimulants, or other performance-enhancing drugs. This possibility warrants additional study, and the committee expresses no opinion on whether other drug categories should be added to the special focus it proposes for opioids.

The FDA has approved several ADFs of opioids that have physical or chemical properties to prevent misuse, as noted earlier in this chapter. A component of the FDA's Opioid Action Plan is to expand access to ADFs to discourage misuse (FDA, 2016a). While ADFs may have a role in preventing escalation of opioid misuse, as discussed in Chapters 4 and 5, multiple factors will determine the impact of a given ADF on public health. These include such factors as whether shifts in use behaviors that occur as a result of attempting to defeat the abuse-deterring properties introduce risks and whether substitutions are made for comparably harmful prescription or illicit opioids. Indeed, in June 2017 the FDA requested that the manufacturer of the ADF Opana ER remove the drug from the market because of concern that the drug's ADF properties had led to increased injection of the drug and outbreaks of HIV and HCV, as well as cases of thrombotic microangiopathy (a serious blood disorder) (FDA, 2017d). The evidence on the specific role of ADFs in efforts to curb opioid-related harms is still developing. In light of continuing uncertainty about the benefits and risks of various types of ADFs, the FDA's cautious case-by-case approach appears warranted.

While the committee's recommendations for revised regulatory treatment pertain to brand-name and generic opioid products, many other products relevant to the opioid crisis, particularly opioid reversal agents (such as naloxone) and treatments for OUD, have been discussed in this report. To the extent that these products are intended to alleviate the opioid crisis and themselves present no risk of addiction, the committee favors rigorously testing them for efficacy and safety and making them widely available to patients as expeditiously as possible. In the case of these agents, REMS and other restrictive post-approval prescribing systems might do more harm than good by making them less available to patients and providers. The public health considerations relevant to approval of these drugs are therefore quite different from those outlined in this chapter and would not fit well under the proposed approach for opioid regulation. Thus, a different set of considerations may need to be enumerated in FDA guidance for products intended primarily to treat OUD or manage the opioid crisis rather than to treat pain.

The committee believes further that the process for initial DEA scheduling—and subsequent rescheduling—of drugs also could benefit from implementation of the approach discussed in this chapter. The FDA and the DEA are already required to take "risk to public health" into account in making scheduling decisions, but the considerations included under this heading have not been enumerated in detail. For example, there may be differences in the value placed by the FDA and the DEA on different public health risks, how heavily the two agencies weight these risks, and how they balance these risks against the potential health benefits of opioids. Thus, the committee favors taking the same public health considerations incorporated in the opioid benefit-risk framework into account when the FDA and DEA evaluate the "risk to public health" criterion in making scheduling—and rescheduling—recommendations and decisions.

Finally, predictions about the various risks of initial scheduling and re-scheduling decisions to various public health parameters need to be made based on solid data, and gathering such data will require development of proper methods and data sources. While recognizing that decisions about scheduling of opioids will have to continue based on the best available data while more data are generated, the committee supports a sustained commitment among funders and policy makers in the field to better understanding the outcomes of scheduling decisions.

BOX 6-6
Recommendations for Other Regulatory Decisions

Recommendation 6-6. Conduct a full review of currently marketed/approved opioids. To consistently carry out its public health mission with respect to opioid approval and monitoring, the U.S. Food and Drug Administration should develop a process for reviewing, and complete a review of, the safety and effectiveness of all approved opioids, utilizing the systems approach described in Recommendation 6 1.

Recommendation 6-7. Apply public health considerations to opioid scheduling decisions. To ensure appropriate management of approved opioids, the U.S. Food and Drug Administration and the Drug Enforcement Administration should apply the same public health considerations outlined in Recommendation 6-1 for approval decisions to scheduling and rescheduling decisions, and study empirically the outcomes of scheduling determinations at the patient and population health levels.

SUMMARY AND RECOMMENDATIONS

Traditionally, the FDA takes a product-specific approach to drug approval decisions by focusing on the data generated and submitted by the manufacturer on the drug at hand, and balancing the benefits of the drug revealed by those data against the risks known (and unknown) at the time of the review. While this process works well in most cases, the committee believes that the regulatory oversight of opioids needs to be viewed differently. The recommendations offered to the FDA in this chapter are intended to balance manufacturers' ability to introduce new opioid products that hold promise for pain management with the agency's obligation to manage the risks posed by opioids, which extend beyond risks to individual patients. In line with the FDA's public health authorities, mission, and practice, these recommendations focus on incorporating public health considerations into the entire life cycle of drug development to create a safer prescription opioid marketplace. If implemented, these recommendations will enable both the drug companies and the FDA to evaluate the full range of benefits and risks that need to be reviewed and considered before pre-market approval as well as during post-approval surveillance.

Given the well-described individual-, household-, and society-level outcomes that have emerged from decades of experience with opioids, special considerations are necessary in the opioid development, approval, and post-approval stages that incorporate some of the principles discussed in this report.

Recommendation 6-1. Incorporate public health considerations into opioid-related regulatory decisions. The U.S. Food and Drug Administration (FDA) should utilize a comprehensive, systems approach for incorporating public health considerations into its current framework for making regulatory decisions regarding opioids. The agency should use this approach, in conjunction with advisory committee input, to evaluate every aspect of its oversight of prescription opioid products in order to ensure that opioids are safely prescribed to patients with legitimate pain needs and that, as actually used, the drugs provide benefits that clearly outweigh their harms. When recommending plans for opioids under investigation; making approval decisions on applications for new opioids, new opioid formulations, or new indications for approved opioids; and monitoring opioids on the U.S. market, the FDA should explicitly consider

- benefits and risks to individual patients, including pain relief, functional improvement, the impact of off-label use, incident opioid use disorder (OUD), respiratory depression, and death;
- benefits and risks to members of a patient's household, as well as community health and welfare, such as effects on family well-being, crime, and unemployment;
- effects on the overall market for legal opioids and, to the extent possible, impacts on illicit opioid markets;
- risks associated with existing and potential levels of diversion of all prescription opioids;
- risks associated with the transition to illicit opioids (e.g., heroin), including unsafe routes of administration, injection-related harms (e.g., HIV and hepatitis C virus), and OUD; and

- specific subpopulations or geographic areas that may present distinct benefit-risk profiles.

The committee acknowledges that the quality of data for some of these considerations (e.g., data from nontraditional sources, such as rates of transition from prescription to illicit opioids) is currently suboptimal, but nevertheless stresses the need to include these considerations in a comprehensive public health framework to inform regulatory decision making for opioids.

Implementing this approach successfully will require significant changes in collection and analysis of data. One important implication is that the evidence necessary to demonstrate safety and efficacy for opioid products will necessarily broaden, and this will affect the traditional FDA review and approval process at multiple points. Specific considerations to meet these needs may extend beyond the protocolized setting of traditional clinical trials to encompass use of data from less traditional sources, such as online forums. The agency should include reports from family members or other third parties affected by the drug, as well as data on outcomes in subpopulations at high risk of OUD or with metal health comorbidities common in patients with pain. Outcomes of interest include impact on function and long-term efficacy for pain reduction.

Other data that could inform the agency's decisions include the drug's estimated impact on the demand for and availability of all other prescription and illicit opioids, as well as interactions with other drugs (both prescription and illicit) commonly used with opioids or by people who use opioids illicitly (e.g., considering how the drug interacts with antiretrovirals or anti-HCV medications). Nontraditional data sources will be needed to inform regulatory decisions for opioids. The FDA should also apply these nontraditional study design considerations in the setting of post-marketing requirements imposed as conditions of approval.

As discussed in Chapter 5, another important implication of the need to take a systems approach is that the agency, perhaps in collaboration with the CDC or other agencies, will eventually need to develop and implement a quantitative model of the opioid ecosystem and establish the data infrastructure needed to support and apply that model. An explicit model can better integrate information from different sources, articulate assumptions, incorporate dynamic processes, and assess the public health consequences of different decisions and value judgments. However, the committee recognizes that developing such a model will be a challenging task given the complexity of the opioid markets and consumption patterns and the weaknesses of the data currently available to measure several of the outcomes outlined in Recommendation 6-1. To begin the process, the agency could periodically convene experts in policy modeling to review available data and needs pertaining to opioid distribution, use, and consequences—with the eventual objective of formulating a conceptual map and a formal quantitative model of the opioid ecosystem. Doing so would enable the agency to better predict the effects of changes in policy or other changes in the opioid ecosystem.

Recommendation 6-2. Require additional studies and the collection and analysis of data needed for a thorough assessment of broad public health considerations. To utilize a systems approach that adequately assesses the public health benefits and risks described in Recommendation 6-1, the U.S. Food and Drug Administration (FDA) should continue to require safety and efficacy evidence from well-designed clinical trials while also seeking data from less traditional data sources, including nonhealth data, that pertain to real-world impacts of the availability and use of the approved drug on all relevant outcomes. The FDA should develop guidelines for the collection of these less traditional data sources and their integration in a systems approach.

Recommendation 6-3. Ensure that public health considerations are adequately incorporated into clinical development. The U.S. Food and Drug Administration (FDA) should create an internal system to scrutinize all Investigational New Drug (IND) applications for opioids. This review should examine whether public health considerations are adequately incorporated into clinical development (e.g., satisfactory trial design; see Recommendation 6-2). In implementing this recommendation, the FDA should rarely, if ever, use expedited development or review pathways or designations for opioid drugs and should review each application in its entirety.

The committee believes a commitment to transparency is critical to maintain balance between preserving access to opioids when needed by patients experiencing pain and mitigating opioid-related harms. Implementation of a related recommendation would optimize the clinical development and use of opioids considering the proposed comprehensive systems approach.

Recommendation 6-4. Increase the transparency of regulatory decisions for opioids in light of the committee's proposed systems approach (Recommendation 6-1). The U.S. Food and Drug Administration should commit to increasing the transparency of its regulatory decisions for opioids to better inform manufacturers and the public about optimal incorporation of public health considerations into the clinical development and use of opioid products.

Steps the FDA could take to implement Recommendation 6-4 might include issuing a guidance document that outlines opioid-specific clinical development considerations, or releasing summary versions of complete response letters for opioid products to inform the public about the public health considerations that the FDA has determined would preclude marketing approval.

The committee believes that use of REMS that have been demonstrated to improve prescribing practice, surveillance activities, formal reevaluation of opioid approval decisions, and regulation of advertising and promotion are critical to supporting the safe use of opioids.

> **Recommendation 6-5. Strengthen the post-approval oversight of opioids.** The U.S. Food and Drug Administration should take steps to improve post-approval monitoring of opioids and ensure the drugs' favorable benefit-risk ratio on an ongoing basis. Steps to this end should include use of Risk Evaluation and Mitigation Strategies that have been demonstrated to improve prescribing practices, close active surveillance of the use and misuse of approved opioids, periodic formal reevaluation of opioid approval decisions, and aggressive regulation of advertising and promotion to curtail their harmful public health effects.

Evidence on the effectiveness of the current REMS for opioids is conflicting and ineffective, and the REMS may provide a false sense of risk mitigation. To improve the data on the existing opioid REMS, the FDA could continue to evaluate the data on its performance, collecting additional data if needed and changing the features of the REMS so it more optimally ensures the evidence-based use of opioids while reducing unsafe prescribing. Maximizing the use of REMS and other post-approval oversight mechanisms for opioids may be facilitated through collaborations among the FDA and other relevant government agency stakeholders, such as the Substance Abuse and Mental Health Services Administration, National Institute on Drug Abuse, Health Resources and Services Administration, and U.S. Department of Veterans Affairs, among others.

The consistent regulatory oversight of opioid products under the committee's proposed systems framework will necessarily raise concerns about the safety and efficacy of products currently approved for market. The committee believes the FDA possesses the authority and responsibility to reexamine the opioid class of drugs, consistent with previous agency actions motivated by public health concerns with a drug class, to ensure that they remain safe and effective. Options for such a large-scale review include a process similar to that used for DESI or a process for reviewing individual applications that would give manufacturers a time frame within which to submit supplemental data necessary for the FDA's review.

> **Recommendation 6-6. Conduct a full review of currently marketed/approved opioids.** To consistently carry out its public health mission with respect to opioid approval and monitoring, the U.S. Food and Drug Administration should develop a process for reviewing, and complete a review of, the safety and effectiveness of all approved opioids, utilizing the systems approach described in Recommendation 6-1.

Finally, the process for initial DEA scheduling of drugs could benefit from the explicit incorporation of the public health considerations discussed in this report. The FDA and the DEA are already required to take "risk to public health" into account in making drug scheduling decisions, but the considerations included under this heading have not been enumerated in detail, and the two agencies may differ in prioritizing certain benefits or risks. Moreover, the ultimate impact on health outcomes related to these decisions remains largely unknown.

Recommendation 6-7. Apply public health considerations to opioid scheduling decisions. To ensure appropriate management of approved opioids, the U.S. Food and Drug Administration and the Drug Enforcement Administration should apply the same public health considerations outlined in Recommendation 6-1 for approval decisions to scheduling and rescheduling decisions, and study empirically the outcomes of scheduling determinations at the patient and population health levels.

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ANNEX TABLE 6-1 Extended-Release (ER)/Long-Acting (LA) Opioid Post-Marketing Study Requirements

Main Study Objective	Research Schedule
Quantify the serious risks of misuse, abuse, and addiction associated with long-term use of opioid analgesics for management of chronic pain.	Final Protocol Submission: 11/2015 (completed) Study Completion: 10/2019 Final Report Submission: 03/2020
Measure the incidence and predictors of opioid overdose and death (OOD), as well as opioid abuse/addiction, using patient health records.	Final Protocol Submission: 11/2014 (completed) Study Completion: 04/2019 Final Report Submission: 09/2019
Assess the content validity and patient interpretation of the Prescription Opioid Misuse and Abuse Questionnaire (POMAQ).	Final Protocol Submission: 04/2015 (completed) Study Completion: 10/2015 (completed) Final Report Submission: 01/2016 (completed)
Evaluate the validity and reproducibility of the Prescription Opioid Misuse and Abuse Questionnaire (POMAQ).	Final Protocol Submission: 04/2015 (completed) Study Completion: 10/2016 Final Report Submission: 02/2017
Validate measures of prescription opioid substance use disorder and addiction in patients who have received or are receiving opioid analgesics for chronic pain.	Final Protocol Submission: 04/2015 (completed) Study Completion: 12/2016 Final Report Submission: 05/2017
Develop and validate an algorithm using coded medical terminologies and other electronic health care data to identify opioid-related overdose and death.	Final Protocol Submission: 11/2014 (completed) Study Completion: 09/2016 Final Report Submission: 12/2016
Develop and validate an algorithm using coded medical terminologies to identify patients experiencing prescription opioid abuse or addiction, among patients receiving an ER/LA opioid analgesic.	Final Protocol Submission: 11/2014 (completed) Study Completion: 10/2016 Final Report Submission: 01/2017
Define and validate doctor and/or pharmacy shopping outcomes by examining their association with abuse and/or addiction, using coded medical terminologies and other electronic health care data.	Final Protocol Submission: 03/2015 (completed) Study Completion: 10/2017 Final Report Submission: 01/2018

Main Study Objective	Research Schedule
Evaluate the association between doctor/pharmacy shopping outcomes and self-reported misuse and abuse using a validated patient survey.	Final Protocol Submission: 03/2015 (completed) Study Completion: 09/2018 Final Report Submission: 12/2018
Evaluate the association between doctor/pharmacy shopping outcomes and patient behaviors suggestive of misuse, abuse, and/or addiction using medical record review.	Final Protocol Submission: 03/2015 (completed) Study Completion: 03/2017 Final Report Submission: 06/2017
Conduct a clinical trial to estimate the serious risk for the development of hyperalgesia following the long-term use of high-dose ER/LA opioid analgesics for at least 1 year to treat chronic pain. Include an assessment of risk relative to efficacy.	Final Protocol Submission: 11/2014 (completed) Trial Completion: 02/2019 Final Report Submission: 08/2019

SOURCE: FDA, 2014e.

Appendix A

Data Sources and Methods

DESCRIPTION OF THE STUDY COMMITTEE

The study committee comprised 18 members with expertise in pain management, basic pain research, epidemiology, medical anthropology, substance use disorder, nursing, law, drug development, public health, health policy and policy modeling, and decision science. Two consultants with expertise in health care and food and drug law were appointed to contribute to the regulatory components of the report. See Appendix B for biographical sketches of the committee members. The committee convened for six 2-day meetings in July 2016, September 2016, November 2016, December 2016, January 2017, and March 2017.

LITERATURE REVIEW

Several strategies were used to identify literature relevant to the committee's charge. First, a search of bibliographic databases, including MEDLINE, Scopus, and Web of Science, was conducted to obtain articles from peer-reviewed journals. In addition, the Cochrane Database of Systematic Reviews was queried, as were relevant federal, state, and local agencies and organizations for guidelines or other grey literature. The LexisNexis database was also reviewed for relevant legal and policy literature. The searches focused on pain management, education, and research, as well as opioids, epidemiology, law, and policy. The keywords used included *best practices, pain management, evidence-based treatment, epidemiology, insurance/reimbursement (health coverage, health insurance, Medicaid, Medicare, payer reimbursement), non-pharmaceutical pain management (acupuncture, cognitive behavioral therapy, self-care, non-pharmacologic pain management, self-management, psychological pain management), pharmacologic pain management (pain relievers, pain medicine, pharmacological treatment, medical pain management), pain conditions (acute pain, analgesia, arthritis, back pain, burn pain, cancer, chronic pain, chronic diseases, end of life, fibromyalgia, hyperalgesia, joint pain, knee pain, mental health disorders, neck pain, neuropathic pain, osteoarthritis, palliative care, post-traumatic stress, shoulder pain), age (young adult, adult, geriatric, nursing home residents, pregnant women, neonatal, neonatal abstinence syndrome, neonatal opioid withdrawal syndrome, nursing mothers), law enforcement (policing, drug enforcement, prescription drug monitoring), public health, vulnerable populations, opioids, heroin, fentanyl, abuse/misuse, abuse-deterrent, addiction/dependence, illicit drugs, medication assisted treatment, naloxone, opioid diversion, overdose/death, prescribing practices, routes of administration, safe use/storage/disposal, synthetic opioids).* In addition, committee members, meeting participants, and others from the public submitted articles and reports on these topics.

PUBLIC WORKSHOPS

The committee hosted a brief public session at its first meeting as well as two public workshops to obtain information on specific aspects of the study charge. These were held in conjunction with the committee's July, September, and November meetings. The committee determined the topics and speakers for the public workshops. The committee also held open forums at each public workshop at which members of the public were encouraged to provide testimony on any topics related to the study charge. The committee found these workshops to be highly informative for its deliberations. Agendas for the three meetings are presented in Boxes A-1 through A-3.

The brief public session at the committee's first meeting in July (see Box A-1) was attended by representatives from the U.S. Food and Drug Administration (FDA), the study sponsor, to review and discuss the charge to the committee. The first workshop, held in September, focused on the portion of the committee's task related to updating the state of the science of pain medicine and related education and research (see Box A-2). The workshop presentations and discussions are summarized in a Proceedings of a Workshop—in Brief titled *Pain Management and Prescription Opioid-Related Harms: Exploring the State of the Evidence*, which was released to the public on November 4, 2016.

The second workshop, held in November, focused on regulatory strategies that can be implemented by the FDA, as well as actions that can be taken by others, to address the opioid epidemic while taking into account the needs of pain patients (see Box A-3).

BOX A-1
MEETING 1 OPEN SESSION AGENDA

July 6, 2016

Room 106
Keck Center
500 Fifth Street, NW
Washington, DC 20001

1:00 pm	**Welcome and Introductions** *Richard Bonnie, L.L.B.,* Committee Chair
1:15 pm	**Background on the Opioid Epidemic** *Christopher Jones, Pharm.D., M.P.H.*, Director, Division of Science Policy Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services
1:45 pm	**Public Comment (as needed)**
2:00 pm	**FDA Charge to the Committee: FDA Opioid Action Plan and Incorporating the Broader Public Health Impact into the Formal Risk-Benefit Assessment for Opioids** *Robert M. Califf, M.D.* Commissioner of Food and Drugs
2:20 pm	**Discussion of Committee Statement of Task**
	FDA Representatives:
	Robert M. Califf, M.D. Commissioner of Food and Drugs
	Doug Throckmorton, M.D., Deputy Center Director for Regulatory Programs Center for Drug Evaluation and Research, FDA
	Sharon Hertz, M.D., Director, Division of Anesthesia, Analgesia, and Addiction Products
	Joshua Lloyd, M.D., Clinical Team Leader, Division of Anesthesia, Analgesia, and Addiction Products
3:10 pm	**Closing Remarks** *Richard Bonnie, L.L.B.,* Committee Chair
3:15 pm	**Adjourn Open Session**

BOX A-2
PAIN MANAGEMENT AND PRESCRIPTION OPIOID-RELATED HARMS: EXPLORING THE STATE OF THE EVIDENCE

A Workshop Hosted by the Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse

September 22, 2016

Auditorium
National Academy of Sciences Building
2101 Constitution Avenue, NW
Washington, DC 20418

Agenda

The Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse is hosting two workshops as part of its information gathering. This first workshop will feature presentations on and discussion of topics relevant to the first four elements of the committee's statement of task:

- the state of the science of pain research, care, and education, including the evolving role of opioids in pain management;
- best practices regarding safe and effective pain management;
- the epidemiology of the prescription opioid epidemic and strategies to address it; and
- areas for future research to inform efforts by the U.S. Food and Drug Administration (FDA) to further develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the public health consequences of opioids.

The second workshop, scheduled for November 4, 2016, in Washington, DC, will focus on the fifth element of the committee's statement of task: actions that the FDA and others can take now to address the opioid epidemic, including the FDA actions to be taken as part of development, review, and approval of pain medicines.

8:30 am **Welcome and Opening Remarks**
Richard Bonnie, L.L.B., Committee Chair

8:45 am **Session 1 – Perspectives on Progress and Future Directions in Clinical Pain Management and Provider Education**
Moderator: David Clark, M.D., Ph.D., Palo Alto Veterans Affairs Pain Clinic and Stanford University (Committee Member)

Pharmacological Pain Management, the Evolving Role of Opioids, and Improving Education of Health Care Providers
James P. Rathmell, M.D., Brigham and Women's Health Care and Harvard University (15 min)

	Non-Pharmacological Pain Management *David Shurtleff, Ph.D., National Center for Complementary and Integrative Health, National Institutes of Health (15 min)* Research on Pain Management and Education at the National Institutes of Health: Response to the 2011 IOM Report Relieving Pain in America *David A. Thomas, Ph.D., Division of Epidemiology, Services and Prevention Research, National Institute on Drug Abuse; National Institutes of Health Pain Consortium (15 min)* **DISCUSSION (20 min)**
9:55 am	**BREAK**
10:10 am	**Session 2 – Perspectives on Progress and Future Directions in Basic Pain Research and the Development of New Analgesics** *Moderator: Jose Moron-Concepcion, Ph.D., Washington University (Committee Member)* Identification of Targets for New Analgesics *Clifford Woolf, M.D., Ph.D., Harvard University (15 min)* Barriers to and Facilitators of Discovery and Development of New Analgesics *William Schmidt, Ph.D., NorthStar Consulting, LLC (15 min)* Opioid Analgesia and Reward: Can They Be Separated? *Howard Fields, M.D., Ph.D., University of California, San Francisco (15 min)* **DISCUSSION (20 min)**
11:20 am	**Public Comment/Continued Discussion of Morning Sessions** *Moderator: Richard Bonnie, L.L.B., University of Virginia (Committee Chair)*
11:45 am	**LUNCH**
12:30 pm	**Session 3 – Trends in Harms and Consequences of Prescription Opioids** *Moderator: Lee Hoffer, Ph.D., Case Western Reserve University (Committee Member)* Intertwined Epidemics: Opioid- and Heroin-Related Overdoses *Daniel Ciccarone, M.D., M.P.H., University of California, San Francisco (15 min)* Prescription Drug Abuse in Rural Appalachia: Ushering in the Next Decade of the Epidemic

	Jennifer Havens, Ph.D., M.P.H., University of Kentucky (15 min)
	Harms and Consequences of Prescription Opioid Use Among Subpopulations *Linda B. Cottler, Ph.D., M.P.H., F.A.C.E., University of Florida (15 min)*
	DISCUSSION (20 min)
1:40 pm	**Session 4 – Interventions to Reduce Opioid-Related Harms: Misuse, Abuse, Addiction, and Overdose** *Moderator: Traci Green, Ph.D., M.Sc., Boston University (Committee Member)*
	Prescription Drug Monitoring Programs and Other State-Level Strategies *Tamara M. Haegerich, Ph.D., Division of Unintentional Injury Prevention, Centers for Disease Control and Prevention (15 min)*
	Naloxone for Opioid Safety *Phillip Coffin, M.D., M.I.A., San Francisco Department of Public Health (15 min)*
	Opioid Analgesics with Abuse-Deterrent Properties: Current Data and Future Opportunities *Richard C. Dart, M.D., Ph.D., Rocky Mountain Poison and Drug Center (15 min)*
	Agonist Therapies for Treatment of Opioid Addiction *Yngvild Olsen, M.D., M.P.H., Institute for Behavioral Resources, Inc. (15 min)*
	DISCUSSION (20 min)
3:05 pm	**BREAK**
3:20 pm	**Session 5 – Reflections on the Day: Promising Ideas and Interventions and Remaining Critical Issues** *Moderator: Richard Bonnie, L.L.B., University of Virginia (Committee Chair)*
	Daniel Raymond, Policy Director, Harm Reduction Coalition (10 min)
	Penney Cowan, Founder and CEO, American Chronic Pain Association (10 min)
	Jonathan Goyer, Outreach Coordinator, Anchor Recovery Community Center (10 min)
	Christin Veasley, Co-Founder and Director, Chronic Pain Research Alliance (10 min)

	DISCUSSION (20 min)
4:25 pm	**Closing Remarks** *Richard Bonnie, L.L.B.*, Committee Chair
4:30 pm	**Adjourn**

BOX A-3
REGULATORY STRATEGIES TO ADDRESS PRESCRIPTION OPIOID-RELATED HARMS

A Workshop Hosted by the Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse

November 4, 2016

Room 125
National Academy of Sciences Building
2101 Constitution Avenue, NW
Washington, DC 20418

Agenda

This second workshop hosted by the Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse will include presentations on and discussion of topics relevant to the fifth element of the committee's statement of task: actions that based on available data the U.S. Food and Drug Administration (FDA) and others can take to address the opioid epidemic while taking into account the needs of pain patients, including FDA actions to be taken as part of development, review, and approval of pain medicines.

8:15 am **Welcome and Introductions**
Richard Bonnie, L.L.B., Committee Chair

8:25 am **Directions for Future Research to Support Regulatory Decision Making**
Nora D. Volkow, M.D., National Institute on Drug Abuse (30 min)

DISCUSSION (15 min)

9:10 am **FDA Perspectives on Balancing the Risks and Benefits of Opioid Analgesics**
Joshua Lloyd, M.D., Center for Drug Evaluation and Research, U.S. Food and Drug Administration (20 min)

Peter Lurie, M.D., M.P.H., Office of the Commissioner, U.S. Food and Drug Administration (20 min)

DISCUSSION (20 min)

10:10 am **BREAK**

10:25 am **Perspectives on How to Incorporate Public Health Considerations into an FDA Regulatory Evaluation Framework**
Moderator: Aaron Kesselheim, M.D., J.D., M.P.H., Harvard Medical School (Committee Member)

	Bruce Psaty, M.D., Ph.D., M.P.H., University of Washington (15 min)
	Wendy E. Parmet, J.D., Northeastern University (15 min)
	G. Caleb Alexander, M.D., M.S., Johns Hopkins University (15 min)
	Diana Zuckerman, Ph.D., National Center for Health Research (15 min)
	DISCUSSION (20 min)
11:50 am	**LUNCH**
12:30 pm	**Accelerating the Development of Better Treatments for Pain: Notes from the Drug Development Battlefield**
	Nathanial Katz, M.D., M.S., Analgesic Solutions (15 min)
	DISCUSSION (10 min)
12:55 pm	**Perspectives on Regulatory Opportunities for Improving the Communication of Drug Safety Information** *Moderator: Valerie Reyna, Ph.D., Cornell University (Committee Member)*
	Provider Education and Opioid Risk Evaluation and Mitigation Strategies *Daniel P. Alford, M.D., M.P.H., Boston University (15 min)*
	Safety Communications and Product Labeling *Lisa Schwartz, M.D., M.S., and Steven Woloshin, M.D., M.S., Dartmouth (20 min)*
	Product Labeling to Communicate Benefits and Risks of Treatment for Opioid Use Disorder in Pregnant Women *Hendrée Jones, Ph.D., University of North Carolina at Chapel Hill (15 min)*
	DISCUSSION (20 min)
2:10 pm	**BREAK**
2:25 pm	**Post-marketing Surveillance: Lessons Learned and Recommendations for the Future**
	Theodore J. Cicero, Ph.D., Washington University (15 min)
	DISCUSSION (10 min)
2:50 pm	**Prevalence, Correlates and Regulatory Strategies Related to Pain, Opioid Misuse and Overdose: The Experience in Vancouver, Canada**

	Pauline Voon, R.N., Ph.D. (c), University of British Columbia (15 min)
	DISCUSSION (10 min)
3:15 pm	**Public Comment/Continued Discussion of Day's Presentations** *Richard Bonnie, L.L.B.,* Committee Chair
3:55 pm	**Closing Remarks** *Richard Bonnie, L.L.B*., Committee Chair
4:00 pm	**Adjourn**

Appendix B

Biographical Sketches of Committee Members and Consultants

COMMITTEE MEMBERS

Richard J. Bonnie, LL.B. (*Chair*), is the Harrison Foundation professor of medicine and law, professor of psychiatry and neurobehavioral sciences, professor of public policy, and director, Institute of Law, Psychiatry and Public Policy at the University of Virginia. He was elected to the National Academy of Medicine (NAM) in 1991. He teaches and writes about criminal justice, bioethics, and public policies relating to mental health, substance abuse, and public health. He was associate director of the National Commission on Marijuana and Drug Abuse (1971–1973), secretary of the first National Advisory Council on Drug Abuse (1975–1985), and chair of a Commission on Mental Health Law Reform (2006–2011) at the request of the chief justice of Virginia. He has also served on the MacArthur Foundation's research networks on Mental Health and the Law, Mandated Community Treatment, and Law and Neuroscience. Mr. Bonnie has chaired numerous consensus committees for the National Academies of Sciences, Engineering, and Medicine, including multiple studies on tobacco policy, underage drinking, elder mistreatment, injury prevention, juvenile justice, and the health and well-being of young adults. He received the Yarmolinsky Medal in 2002 for his contributions to the NAM and the National Academies. In 2007, Mr. Bonnie received the University of Virginia's highest honor, the Thomas Jefferson Award. He holds a B.A. from Johns Hopkins University and an LL.B. from the University of Virginia School of Law.

Hortensia de los Angeles Amaro, Ph.D., is associate vice provost for community research initiatives and dean's professor of social work and preventive medicine at the University of Southern California. Previously, she served as associate dean and distinguished professor of health sciences and of counseling psychology in the Bouve College of Health Sciences, and director of the Institute on Urban Health Research at Northeastern University. Prior to that, she served as professor in the Boston University School of Public Health and School of Medicine. Her research interests include alcohol and drug use and addiction among adolescents and adults, substance abuse and mental health treatment for Latinos and African Americans, and alcohol and drug use among college populations. She is a member of the National Academy of Medicine and has received numerous awards from professional, government, and community organizations and honorary degrees from Simmons College and the Massachusetts School of Professional Psychology. Additionally, she has served on review and advisory committees for the National Institutes of Health, including the National Institute on Drug Abuse, and for the U.S. Department of Health and Human Services, the Substance Abuse and Mental Health Services Administration, and the Centers for Disease Control and Prevention. Dr. Amaro founded five substance abuse

treatment programs for women in Boston and served on the board of the Boston Public Health Commission for 14 years. She received her Ph.D. in psychology from the University of California, Los Angeles.

Linda Burnes Bolton, Dr.P.H., R.N., FAAN, is system chief nursing executive and vice president for nursing, Cedars-Sinai in Los Angeles. Her research, teaching, and clinical expertise include nursing and patient care outcomes, improving organization performance, quality care, and cultural diversity within the health professions. She is co-investigator of the regional Collaborative Alliance for Nursing Outcomes research team and has made significant contributions to the advancement of nurses and other clinical team members in decreasing patient harm. Dr. Burnes Bolton is a past president of the American Academy of Nursing, American Organization of Nurse Executives, and National Black Nurses Association. She has provided leadership for several state and national programs, including service as chair of the Robert Wood Johnson Foundation advisory committee on Transforming Care at the Bedside and the Veteran Affairs Commission on Nursing, and vice chair of the Robert Wood Johnson Foundation Initiative on the Future of Nursing at the Institute of Medicine. She is a trustee at Case Western Reserve University and a board member of the Robert Wood Johnson Foundation. She received the James R. Klinenberg, MD and Lynne Klinenberg-Linkin Endowed Chair in 2016. Dr. Burnes Bolton earned her B.S. degree in nursing from Arizona State University. She received her M.S. degree in nursing as well as her M.P.H. and Dr.P.H. from the University of California, Los Angeles. She was elected to the National Academy of Medicine in 2015.

Jonathan Caulkins, Ph.D., is university professor of operations research and public policy in the Heinz College of Carnegie Mellon University. His research interests include modeling the effectiveness of interventions related to drugs, crime, violence, delinquency, and prevention. He has been on the Heinz College faculty since 1990, with leaves of absence to be co-director of RAND's Drug Policy Research Center in Santa Monica (1994–1996), to found RAND's Pittsburgh Office (1999–2001), and to teach at Carnegie Mellon's campus in Doha, Qatar (2005–2011). He has published on such topics as epidemiological models for examining marijuana use over the life course and evidence of the effectiveness of drug policy interventions. Dr. Caulkins serves or has served on the editorial board of *Management Science*, *Operations Research*, *Mathematical and Computer Modelling*, the *Journal of Drug Issues*, *Socio-Economic Planning Sciences*, and *I/S: A Journal of Law and Policy for the Information Society*, and has refereed for more than 85 different journals. He completed his undergraduate work in engineering and computer science at Washington University in St. Louis. He holds master's degrees in systems science and mathematics (Washington University, 1987) and electrical engineering and computer science (Massachusetts Institute of Technology, 1989) and a Ph.D. in operations research (MIT, 1990).

David Clark, M.D., Ph.D., is professor of anesthesia, perioperative medicine and pain at Stanford University and director of the Palo Alto Veterans Affairs Pain Clinic, and as such comes into contact with pain and its consequences in many settings. Commonly encountered pain consultations include patients with very difficult-to-manage postoperative pain, patients with chronic pain after surgical procedures, and patients with chronic pain syndromes related to war injuries. Referral to his pain management clinic due to difficulties with opioid management is extremely common. His laboratory has been dedicated for more than a decade to identifying

mechanisms supporting chronic pain as well as maladaptations to opioids. Much of this work has focused on genetic mechanisms and approaches, including the use of laboratory animals and humans. Some of his laboratory's findings have resulted in translational studies and clinical trials. Current projects include efforts to understand immunological contributions to chronic pain after limb injury, pain mechanisms after traumatic brain injury, and maladaptations to the long-term use of opioids. Dr. Clark received both his Ph.D. in pharmacology and his M.D. from Vanderbilt University.

Eli Eliav, D.M.D., Ph.D., is a professor and the director of the Eastman Institute for Oral Health at the University of Rochester and the vice dean for oral health within the School of Medicine and Dentistry at the University of Rochester Medical Center. Dr. Eliav joined the University of Rochester Medical Center in 2013. Previously, he served as the chair of the Department of Diagnostic Sciences, the director of the Center for Temporomandibular Disorders and Orofacial Pain, and Carmel Endowed Chair in Algesiology at Rutgers School of Dental Medicine, part of Rutgers University. He earned his D.M.D. and Ph.D. from the Hebrew University in Jerusalem, specialized in oral medicine in Hadassah Medical Center in Jerusalem, and trained in the National Institute for Dental and Craniofacial Research. He is a member of several professional organizations, including the American Pain Society and International Association for the Study of Pain. Dr. Eliav's current research projects involve orofacial pain, quantitative sensory testing, neuropathic pain, pain modulation, and the role of inflammation in neuropathic pain.

Garret FitzGerald, M.D., F.R.S., professor of medicine and pharmacology, is the McNeil professor in translational medicine and therapeutics at the Perelman School of Medicine at the University of Pennsylvania, where he chairs the Department of Systems Pharmacology and Translational Therapeutics and directs the Institute for Translational Medicine and Therapeutics. Dr. FitzGerald's research has been characterized by an integrative approach to elucidating the mechanisms of drug action, drawing on work in cells, model organisms, and humans. His work contributed fundamentally to the development of low-dose aspirin for cardioprotection. Dr. FitzGerald's group was the first to predict and then mechanistically explain the cardiovascular hazard from nonsteroidal anti-inflammatory drugs (NSAIDs). He has also discovered many products of lipid peroxidation and established their utility as indices of oxidant stress in vivo. Dr. FitzGerald's laboratory was the first to discover a molecular clock in the cardiovascular system and has studied the importance of peripheral clocks in the regulation of cardiovascular and metabolic function. Dr. FitzGerald has received the Boyle, Coakley, Harvey, and St. Patrick's Day medals; the Lucian, Scheele, and Hunter Awards; and the Cameron, Taylor, Herz, Lefoulon-Delalande, and Schottstein Prizes. He is a member of the National Academy of Medicine, a fellow of the American Academy of the Arts and Sciences and of The Royal Society, and an honorary member of the Royal Irish Academy.

Traci Green, Ph.D., M.Sc., is an epidemiologist whose research focuses on opioid use, addiction, and injury. Specifically, the areas in which she is most interested and to which she has contributed include the intersecting worlds of HIV infection and drug abuse, nonmedical use of prescription drugs, corrections health, drug policy, and opioid overdose prevention and intervention. By consequence, this work addresses issues of health disparities, gender, and place effects on health. She earned a master of science degree in epidemiology and biostatistics from McGill University and a Ph.D. in epidemiology from Yale University. Dr. Green helped design

the ASI-MV®, a real-time illicit and prescription drug abuse surveillance system developed by Inflexxion, Inc. Currently, she is deputy director of the Boston Medical Center Injury Prevention Center and associate professor of emergency medicine and epidemiology at the Warren Alpert School of Medicine at Brown University. Dr. Green chairs the Drug Overdose Prevention and Rescue Coalition for the Rhode Island Department of Health and advises the Rhode Island governor on addiction and overdose. She is a past recipient of salary support (<$3,000) from Purdue Pharmaceuticals for development of an educational brochure on overdose prevention for drug users injecting illicit pharmaceutical opioids. She is a member of the Board of Scientific Counselors for the National Center for Injury Prevention and Control and served on a workgroup to critically review the 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain. Her research is supported by the CDC, the National Institute on Drug Abuse, the Agency for Healthcare Research and Quality, the Patient-Centered Outcomes Research Institute, and the U.S. Department of Justice.

Miguel Hernán, M.D., Dr.P.H., studies causal inference methods and implements them to evaluate strategies for the treatment and prevention of disease. Together with collaborators in several countries, he designs analyses of health care databases, epidemiologic studies, and randomized trials. Dr. Hernán teaches clinical data science at the Harvard Medical School, clinical epidemiology at the Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology, and causal inference methodology at the Harvard T.H. Chan School of Public Health, where he is the Kolokotrones professor of biostatistics and epidemiology and where he has mentored dozens of doctoral students and postdoctoral fellows. His book *Causal Inference*, co-authored with James Robins and freely available online, is used in graduate programs throughout the world. Dr. Hernán is a fellow of the American Association for the Advancement of Science, past chair of the American Statistical Association Section on Statistics in Epidemiology, past associate editor of the *Journal of the American Statistical Association* and of *Biometrics*, associate editor of the *American Journal of Epidemiology*, and an editor of *Epidemiology*. He has served on several committees of the U.S. National Academies.

Lee D. Hoffer, Ph.D., is an associate professor of anthropology at Case Western Reserve University. His research focuses on understanding the political, social, economic, and cultural contexts related to illicit drug use. His ongoing research involves synthesizing computational modeling techniques and ethnographic research to develop new tools for policy makers and researchers. Borrowing from theories of complexity systems, these projects seek to connect the rich descriptive detail offered by anthropology with the epidemiology of drug abuse.
Dr. Hoffer's research has informed a range of topics, including HIV risk behaviors, diagnostic nosology for substance use disorders, and understanding trends in drug use, as well as drug policy and intervention studies. More recently, his research examines how illicit drug markets and the acquisition of drugs influence behaviors and negative health outcomes. His fieldwork focuses on customer transactions, the interactions between addiction and drug acquisition, and the social and economic exchange relationships between users and their dealers. His book *Junkie Business: The Evolution and Operation of a Heroin Dealing Networ*k (2006), details much of this work. His research is supported by grants from the National Institutes of Health, National Institute on Drug Abuse (NIDA), as well as the National Science Foundation (Cultural Anthropology & Methods, Measurement, and Statistics program). From 1997 to 1999 he was Colorado's representative to the NIDA Community Epidemiology Workgroup. He was also

active in the Colorado Department of Public Health and Environment and the Centers for Disease Control and Prevention HIV community planning efforts. From 2002 to 2005 he trained as a (T32) NIDA postdoctoral fellow in psychiatric epidemiology at Washington University School of Medicine, Epidemiology and Prevention Research Group. From 2013 to 2014 he served on the National Research Council Committee on the Context of Military Environments: Social and Organizational Factors. He holds an M.A. in anthropology and a Ph.D. in health and behavioral sciences from the University of Colorado in Denver and an M.P.E (master of psychiatric epidemiology) from Washington University School of Medicine in St. Louis.

Paul E. Jarris, M.D., M.B.A., is senior vice president, Maternal and Child Health Program Impact, and deputy medical officer at the March of Dimes. He leads March of Dimes' Maternal and Child Health Program Impact department, with overall responsibility for the March of Dimes Prematurity Campaign, which seeks to reduce the rate of preterm birth, the number one cause of death among babies in the United States. Dr. Jarris, a nationally known expert in national health care policy, clinical quality initiatives, and disease prevention and wellness, among other areas, previously served as executive director of the Association of State and Territorial Health Officials (ASTHO). One of his many achievements at ASTHO was partnering with the March of Dimes to challenge all 50 states, the District of Columbia, and Puerto Rico to lower their preterm birth rates. Dr. Jarris has had a distinguished career spanning 20 years leading policy and care initiatives to improve public health at the local, state, and national levels. Prior to his role at ASTHO, he served as commissioner of health for the State of Vermont, where he led health care policy matters and championed new public health initiatives, addressing access to care, prevention, and the factors that impact population health. In addition, he has held a number of health insurance executive-level positions, including president and CEO of Vermont Permanente Medical Group. Throughout his career, Dr. Jarris has received numerous prestigious awards and honors, and has served as a member of many health-related boards and committees. He received his B.A. from the University of Vermont, his M.D. at the University of Pennsylvania School of Medicine, and an M.B.A. from the University of Washington.

Karol Kaltenbach, Ph.D., is emeritus professor of pediatrics at the Sidney Kimmel Medical College of Thomas Jefferson University and professor of psychiatry and human behavior (retired). She is the former director of Maternal Addiction Treatment, Education and Research (MATER), a division of the Department of Pediatrics, Sidney Kimmel Medical College of Thomas Jefferson University. MATER includes Family Center, a comprehensive intensive outpatient treatment program for pregnant and parenting opioid-dependent women; My Sister's Place, a long-term residential treatment program for women and children; and a research component. Family Center has provided the prototype both nationally and internationally for the management of opioid use disorders during pregnancy and the treatment of neonatal abstinence. Dr. Kaltenbach is a member of the College on Problems of Drug Dependence and has been the principal investigator of grants from the National Institute on Drug Abuse (NIDA) and the Center for Substance Abuse Treatment. She was the principal investigator at the Jefferson site for the NIDA MOTHER clinical trial comparing the use of buprenorphine and methadone in the treatment of opioid dependence during pregnancy and was the lead principal investigator of the MOTHER developmental follow-up study. She is a co-investigator of a NIDA-funded clinical trial investigating the use of buprenorphine in the treatment of neonatal abstinence syndrome (NAS) and co-investigator of a U.S. Department of Health and Human Services Children's

Bureau–funded intervention project investigating whether the use of a mindfulness-based parenting intervention for mothers with opioid use disorders can improve parenting outcomes. Dr. Kaltenbach is an internationally recognized expert in the field of maternal addiction and has published extensively on the management of opioid use disorders during pregnancy and NAS, trauma-informed treatment for pregnant and parenting women with substance use disorders, and the effect of prenatal drug exposure on the perinatal and developmental outcomes of children. She has lectured throughout the world and has participated in the development of national guidelines for the management of opioid-dependent pregnant women and their neonates in Australia and Norway.

Aaron S. Kesselheim, M.D., J.D., M.P.H., is an associate professor of medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. Within the Division, Dr. Kesselheim leads the Program On Regulation, Therapeutics, And Law (PORTAL), an interdisciplinary research center addressing intersections among prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law. Current areas of focus include the research and development process; U.S. Food and Drug Administration (FDA) approval; and the costs, availability, and evidence-based use of these products. In 2013, Dr. Kesselheim was named a Greenwall faculty scholar in bioethics by the Greenwall Foundation, which supports innovative empirical research in bioethics. Dr. Kesselheim's work is also currently funded by the FDA, the Robert Wood Johnson Foundation Public Health Law Research Program, and the Laura and John Arnold Foundation. He has testified before Congress on pharmaceutical policy, medical device regulation, generic drugs, and modernizing clinical trials, and served as a consultant for the National Institutes of Health, FDA, United States Patent and Trademark Office, and numerous state government offices. Dr. Kesselheim also serves as a supervisor for the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; a core faculty member of the Harvard Medical School Center for Bioethics; and a visiting associate professor of law at Yale Law School, where he teaches Food and Drug Administration law. He graduated from Harvard College and received his postgraduate training at the University of Pennsylvania School of Medicine and Law School, and most recently at the Harvard School of Public Health. He is board certified in internal medicine and serves as a primary care physician.

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Jose Moron-Concepcion, Ph.D., is an associate professor in the Departments of Anesthesiology and Neuroscience at Washington University in St Louis. Dr. Moron-Concepcion is a world leader in the study of the nervous system's adaptive responses to chronic opioid exposure. Research in his laboratory is focused on understanding the mechanisms underlying opioid addiction and the intersection with pain. In addition, his lab is interested in elucidating mechanisms underlying pain in the central nervous system and in the periphery. After completing his Ph.D. in biochemistry at the University of Barcelona (Spain), Dr. Moron-Concepcion was awarded a fellowship to join the intramural program at the National Institute on Drug Abuse to work in the laboratory of Dr. Toni Shippenberg, a pioneer in the field of opioid pharmacology. Then, he continued his postdoctoral training in the laboratory of Dr. Lakshmi Devi at Mount Sinai, where he continued his studies on the mechanisms of opioid dependence. After completing his training, he was recruited as a faculty member in the Department of Pharmacology at The University of Texas Medical Branch. He then moved to Columbia University in New York, where he was on the faculty of the Department of Anesthesiology for 6 years. Dr. Moron-Concepcion joined the faculty of Washington University on October 1, 2015.

A. David Paltiel, Ph.D., M.B.A., is professor of health policy and management at both the Yale School of Public Health and the Yale School of Management. He employs the methods of operations research to address issues of resource allocation and decision making in health and medicine. He has conducted numerous model-based cost-effectiveness analyses of prevention, screening, and treatment interventions, including several widely cited studies of expanded HIV screening in the United States and abroad. He has served on guideline review and advisory committees for the National Institutes of Health, the Centers for Disease Control and Prevention (CDC), the U.S. Preventive Services Task Force, the Institut de Veille Sanitaire (French national equivalent of the CDC), and the French National Agency for AIDS Research (ANRS). He has served on five previous project committees for the National Academies of Sciences, Engineering, and Medicine, including panels that produced the 2004 report on the Ryan White CARE Act, the 2007 Evaluation of the President's Emergency Plan for AIDS Relief, and the 2009 Review of Priorities in the National Vaccine Plan. Dr. Paltiel holds a B.A. from McGill University and received both an M.B.A. and a Ph.D. in operations research from Yale.

Valerie Reyna, Ph.D., is the Lois and Melvin Tukman professor of human development, director of the Human Neuroscience Institute, director of the Cornell University Magnetic Resonance Imaging Facility, and co-director of the Center for Behavioral Economics and Decision Research. Her research integrates brain and behavioral approaches to understand and improve judgment, decision making, and memory across the life span. Her recent work has focused on the neuroscience of risky decision making and its implications for health and well-being, especially in adolescents; applications of cognitive models and artificial intelligence to improving understanding of genetics (e.g., in breast cancer); and medical and legal decision making (e.g., about jury awards, medication decisions, and adolescent culpability). She currently has an unrestricted research grant from the Xerox Corporation and has studied treatment adherence in diabetes patients among other topics. She is a developer of fuzzy-trace theory, a model of the relation between mental representations and decision making that has been widely applied in law, medicine, and public health. Dr. Reyna has been elected to the National Academy of Medicine and is a fellow of the Society of Experimental Psychologists, the oldest and most prestigious honorary society in experimental psychology. She is also a fellow of the American

Association for the Advancement of Science; the Divisions of Experimental Psychology, Developmental Psychology, Educational Psychology, and Health Psychology of the American Psychological Association; and the Association for Psychological Science. Dr. Reyna has been a visiting professor at the Mayo Clinic; a permanent member of study sections of the National Institutes of Health; and a member of advisory panels for the National Science Foundation, the MacArthur Foundation, and the National Academy of Sciences. For example, she is on the Advisory Committee of the National Academies' Behavioral and Social Sciences and Education, which oversees 10 boards and standing committees, and serves as the chief scientific liaison and representative to the Federation of Associations in Behavioral and Brain Sciences of the Psychonomic Society. Dr. Reyna is the editor of *Psychological Science in the Public Interest* and sits on the editorial board of such journals as *Decision* and *Journal of Experimental Psychology: Learning, Memory, and Cognition*, leading journals in psychology. She has received many years of research support from private foundations and U.S. government agencies, and currently serves as principal investigator of several grants and awards (e.g., from the National Science Foundation and the National Institutes of Health).

Mark Schumacher, Ph.D., M.D., is a professor of anesthesiology at the University of California, San Francisco (UCSF), with a clinical, research, and educational focus on pain management. He is currently division chief of pain medicine in the Department of Anesthesia and Perioperative Care. Dr. Schumacher was the principal investigator for National Institutes of Health/National Institute on Drug Abuse awards in 2012 and 2015 to establish a Center of Excellence in Pain Education at UCSF. He has expertise in opioid and nonopioid strategies in pain control and has worked successfully to introduce multidisciplinary pain care and nonopioid analgesic strategies at UCSF Medical Center. His scientific achievements include being part of the team that isolated the Capsaicin Receptor–TRPV1, a major target in the development of nonopioid analgesic therapies. He is a member of several professional societies, including the International Anesthesia Research Society, the International Association for the Study of Pain, the American Pain Society, and the Association of University Anesthesiologists. Dr. Schumacher received his Ph.D. in physiology and pharmacology as well as his M.D. from the University of California, San Diego.

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Patricia J. Zettler, J.D., is an associate professor of law and a faculty member of the Center for Law, Health & Society at the Georgia State University College of Law. She writes and teaches about food and drug law, health law and policy, and torts. Before joining Georgia State in 2015, she was a fellow at the Center for Law and the Biosciences at Stanford Law School. Prior to her fellowship, she served as an associate chief counsel in the U.S. Food and Drug Administration's (FDA's) Office of the Chief Counsel, where she advised the FDA and the U.S. Department of Health and Human Services on various issues including drug safety, human subjects protection, expanded access to investigational drugs, over-the-counter drugs, dietary supplements, prescription drug advertising and promotion, incentives for developing antibiotics, and advisory committees. In addition to her legal background, Ms. Zettler has bioethics experience through work at the Program in Medical Ethics at the University of California, San Francisco, and at the Department of Bioethics at the National Institutes of Health. Ms. Zettler received her undergraduate and law degrees from Stanford University, both with distinction.

Appendix C

Existing Data Sources on Opioid Use, Misuse, Overdose, and Other Harms

Data	Source	Numerators	Description	Timing	Strengths	Limitations
National Forensic Laboratory Information System (NFLIS)	Drug Enforcement Administration (DEA)	Drug cases investigated by Drug Enforcement Administration at compound level (diversion)	Chemistry on drugs seized by law enforcement is analyzed by state, county, and volunteer forensic labs. Available for states, participating localities, and nationally	Monthly	Uniform data collection across sites and over time. Detects new/emerging drugs.	Captures only mentions, not quantity seized. Not an appropriate surrogate for misuse. Decisions regarding enforcement and prosecution may influence which drugs are seized/tested. Significant lag in identifying new synthetic drugs because reference standards may not exist.
Poison control calls	State poison control centers, National Poison Data System (NPDS)	Poison control calls related to "intentional exposures" (includes abuse, misuse, and suspected suicidal) or "intentional abuse exposures"	Number of exposure calls by drug/substance at state and national levels	Monthly	Ability to detect new/emerging drugs in real time. Product- and drug-specific information.	NPDS analyses must be requested and purchased; available 12 months after year ends; specific poison center data may be available in real time (depends on center). Possible misclassification of drug involved and reason for exposure. May underrepresent most severe cases of misuse.

Data	Source	Numerators	Description	Timing	Strengths	Limitations
Drug treatment admissions (e.g., Treatment Episode Data Set [TEDS])	State and local drug treatment agencies	Lifetime nonmedical opioid, heroin users; past-year and past-month heroin use, any nonmedical opioid use (not product-specific)	Admissions to publicly funded treatment programs and opioid substitution programs by primary, secondary, and tertiary drug, route of administration, demographics. Available at local, state, and national levels.	Annual, semiannual, or monthly depending upon source	Data collection is relatively uniform across states.	May be influenced by funding streams and referral sources (e.g., criminal justice diversion or emphasis on certain drugs). Publicly available TEDS data lag 1–2 years. Limited differentiation of opioid products. Not nationally representative.
Arrestee Drug Abuse Monitoring (ADAM) Program	Office of National Drug Control Policy	Survey/urine screen of recently arrested individuals (diversion)	Urinalysis results (marijuana, cocaine, opiates, methamphetamine) and self-reported drug use.	Annual	Uniform data collection across sites; sample includes individuals generally not captured in other datasets (e.g., drug treatment).	Male arrestees only, limited to five sites in 2012. No longer fully operational. Not an appropriate surrogate for misuse.
System to Retrieve Information from Drug Evidence (STRIDE)	DEA	Street drug price by geographic area; street drug purity by geographic area	Drug exhibits sent to the DEA laboratories. Provides national data on purity and weight of each sample by month seized. Totals annual seizure weights by drug.	Annual	Only source of data on illicit drug purity and price. Complete datasets can be obtained via Freedom of Information Act (FOIA) request and analyzed.	Strongly influenced by enforcement activities; not representative.

Data	Source	Numerators	Description	Timing	Strengths	Limitations
Uniform Crime Report (UCR)	Federal Bureau of Investigation	Arrests due to possession or trafficking of heroin and other opiates	UCR Part II contains annual summary of drug-related arrests (possession, sale). Reported by each law enforcement unit at the local level.	Annual	System has been in operation more than 30 years; is being updated to allow online analysis.	Strongly influenced by enforcement priorities. Only four categories of drugs. No ability to do any data analysis other than summaries.
National Survey on Drug Use and Health (NSDUH)	Substance Abuse and Mental Health Services Administration (SAMHSA)	Lifetime nonmedical opioid, heroin users; first-time nonmedical opioid use, heroin initiates; past-year and past-month heroin use, nonmedical opioid use by therapeutic drug class; *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition diagnosed abuse or dependence	Self-reported drug use and abuse/dependence among respondents aged ≥12. Results available at national level and for some metropolitan statistical areas (MSAs) and substate areas.	Annual	Longitudinal data collection supports analysis of changes over time. Data can be analyzed online.	Household survey excludes institutionalized and unhoused individuals.

Data	Source	Numerators	Description	Timing	Strengths	Limitations
Youth Risk Behavior Surveillance System (YRBSS)	Centers for Disease Control and Prevention (CDC)	Youth rates of nonmedical use of prescription opioids	National school-based survey of self-reported drug use. Includes results at state (n = 47) and local (n = 22) levels.	Every 2 years	Representative/weighted sample for United States and some states/localities. Longitudinal data collection supports analysis of changes over time.	Limited to youth attending school.
Monitoring the Future (MTF)	University of Michigan	Misuse rates among middle school, high school, college students and young adults	Nationally representative survey of self-reported drug use among 8th, 10th, 12th graders.	Annual	Longitudinal data collection supports analysis of changes over time.	Limited to youth attending school. Not site-specific. Asks about only two prescription opioid products; the rest are considered "narcotics other than heroin."
Automation of Reports and Consolidated Orders System (ARCOS)	DEA	Amount of manufactured controlled substance circulating through legal means, by compound	Measure of prescription drug supply based on mandatory reporting for Schedule I and II controlled substances and selected Schedule III and IV substances from manufacture to sale. Data for each substance reported by quantity (e.g., mg, dosage unit) and 3-digit zip code.	Annual	Comprehensive inventory of all legal drug sources. Can be analyzed longitudinally down to zip code level by individual substance, formula (e.g., extended-release).	Cannot discern between licit and illicit drug use. Data must be procured through FOIA request.

Data	Source	Numerators	Description	Timing	Strengths	Limitations
Drug mortality	Local medical examiners/coroners, state vital records, National Center for Health Statistics nationwide data; SAMHSA's Drug Abuse Warning Network (DAWN-ME) (ended 2011)	Counts of drug-related mortality by compound, some by International Classification of Diseases (ICD) code; for DAWN-ME: mortality data (only for 13 states)	Cause of death and toxicology, drug poisoning deaths, and drug-induced deaths. DAWN-ME captured agent-level data.	Annual, although preliminary reports are available at local level sooner	Data can be analyzed online through CDC WONDER. Data available by state.	Local medical examiner data may not include deaths where private physician was in attendance. Drug use may or may not be based on autopsy reports—depends on state law. State data have 1–2 year time lag; National NCHS is complete in 2–3 years. Cause of death determined by ICD category.
Emergency department (ED) visits and/or hospital discharges for drug-related causes	CDC (SAMHSA's Drug Abuse Warning Network [DAWN-ED] ended 2011; also the Nationwide Emergency Department Sample (NEDS), which conducted a 20 percent sample of EDs, was discontinued)	Unclear, but documentation suggests these will be ICD code–defined ED visits (e.g., unintentional poisoning); for DAWN-ED: misuse/abuse-related ED visits	National Hospital Care Survey is a new survey that will provide data on health care delivery in inpatient, outpatient, and emergency departments, as well as other ambulatory settings. Will include data on drug-related care episodes. Previously, DAWN-ED collected data using retrospective records review at EDs selected	New system is not functional	One of few measures of drug-related morbidity. Unclear at what level of geographic specificity these data will be reported.	New system is not yet operational. Longitudinal data from DAWN will not be compatible with new system. Unclear if agent-level data will be available, as this is a function of hospital toxicological testing procedures.

Data	Source	Numerators	Description	Timing	Strengths	Limitations
			through longitudinal probability sampling. DAWN-ED captured agent-level data on exposures and clinical drug-involved consequences.			
HIV/hepatitis C virus (HCV) data	State and local health departments	New cases of HIV related to injection drug use (IDU); new cases of HCV related to IDU	New infections attributed to IDU, IDU by men who have sex with men (MSM), and heterosexual modes of transmission.	HIV reports usually annual, sometime semiannual or monthly; HCV reports less frequent	Comprehensive record of individuals who test positive for HIV and risk factors. Reported at county, state, and national levels.	Risk group (e.g., IDU, MSM-IDU, heterosexual) is self-reported. Levels of HIV—and especially HCV—testing vary across sites.
Trends in Trafficking Reports	DEA Field Divisions	Street price of drugs; availability and sources of drug	Each Field Division reports price data, availability, sources, and trafficking by drug.	Semiannual	Extensive data on supply side. Unclear geographic specificity. Unclear whether product- and/or compound-specific.	DEA redacts sensitive data prior to release. Possible sampling biases, possible selection biases.
Proprietary surveillance system	Researched Abuse, Diversion and Addiction-Related Surveillance System (RADARS)	Lifetime nonmedical opioid, heroin use; first-time nonmedical opioid use, heroin initiates; past-year and past-month heroin use, nonmedical	Drug diversion, poison center, opioid treatment, impaired health care worker, Survey of Key Informants, college survey, StreetRx (streetrx.com for street drug price) programs	Near real time	Product and substance with composition- and formulation-specific differentiation. Exposure among certain high-risk groups can be identified (e.g., impaired health care workers). Multifaceted data collection effort. Geographically	Must be requested and purchased. Possible sampling biases, possible information biases. Not nationally representative.

Data	Source	Numerators	Description	Timing	Strengths	Limitations
		opioid use by product; measures of diversion; street price of opioid products			identified data.	
Proprietary surveillance system	National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO)	Lifetime nonmedical opioid, heroin use; first-time nonmedical opioid use, heroin initiates; past-year and past-month heroin use; nonmedical opioid use by product; route of administration; lifetime and past-year nonfatal opioid overdose; source of opioids	Addiction Severity Index-Multimedia Version (ASI-MV) Connect includes assessments of adults on drug use and for treatment need (intake, criminal justice, drug courts, Temporary Assistance for Needy Families) at 3-digit zip code level. Web Informed Services (WIS) quantifies endorsement of drugs among drug-use forums and discussion boards. Comprehensive Health Assessment for Teens assesses teenagers and young adults on drug use and for treatment need at 3-digit zip code level.	Near real time	Product and substance with composition- and formulation-specific differentiation. Multifaceted data collection effort. Geographically identified data. Exposure among important high-risk groups can be identified (e.g., pregnant women, sexual minorities). Geographically identified data.	Must be requested and purchased. Sampling bias possible; not a probability sample. Recall bias possible. Not nationally representative.

Meeting Our Patients Where They Are

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Change is not only hard but also sometimes it is just plain ugly. When emergency medical services (EMS) first started to grow and provide services to patients outside the hospital setting, many physicians decried it as unsafe and pushed to have a physician aboard every ambulance. After we got tired of this bad idea, the next step was often to require that medics always call into the receiving facility's emergency physician to receive medical direction. After we got tired of that waste of our time, we developed hospital "base stations," where an emergency physician would oversee multiple cases, all while trying to care for patients in the emergency department (ED). Eventually, the medical community supported a model in which medical direction is provided through offline protocols, with occasional online communications. The current model of EMS continues to grow, mature, and provide value to our patients and is essential to the health care system.

Now, as centralized, hospital-based care continues to be moved into a more distributed health care system, freestanding EDs are beginning to sprout up "in the field." This has already happened with other specialties such as surgery, radiology, and orthopedics but is fairly new for emergency medicine. The descriptive article by Schuur et al[1] provides a glimpse of where that new model is growing and offers some insights into our future. Although there are variations both in ownership and structure from state to state, freestanding EDs are sprouting in areas of higher growth. The article notes that these choices reflect both the economic realities of reimbursement and the decision to match resources with areas of higher population growth as a predictor of increased demand. This generally follows the approach used by hospitals, health care facilities, and physician practices.

The messages in the media and even within the medical profession could not have been more different, using the article as proof that freestanding EDs were sprouting up to steal patients from hospitals and were actually dangerous because they weren't in hospitals. An often-spouted theme was that freestanding EDs should be locating in areas of low income and disadvantaged populations, and that placing them in growing or higher-income areas was a travesty of justice. But few businesses can survive in those environments. Drive through such areas and keep count of the businesses such as Starbucks, Marriott, or even food stores such as Kroger, that choose to locate there. To survive, you must thrive.

When risk perception is examined, things that are new inspire fear and uncertainty, and we become comfortable with things that are old and known, even if they present much higher risk. That is simply how we think, so facts help us better understand the realities of risk. So what are the facts?

We all know that the current system of ED care is broken. In fact, we've known that for quite a long time. In 2006, the Institute of Medicine released its seminal report *Hospital-Based Emergency Care: At the Breaking Point*.[2] The report described a national epidemic of crowded EDs, underscored the fragmentation of emergency care, and raised issues of access, patient safety, and quality associated with a burdened system. It called for major change.

This is not new. In 1990, the American College of Emergency Physicians Overcrowding Task Force published their results stating that Americans faced a crisis in health care and that crowding limited access to, and the quality of, emergency care. The task force suggested measures to address this critical issue.[3]

In times of crowding, demand outweighs accessible resources. The effects of crowding are well recognized to affect patient care quality, experience, and outcomes. Crowding also affects other quality metrics such as timeliness, efficiency, and safety.[4] Increasingly, we also understand that it affects the caregivers, too, with emergency physicians having one of the highest burnout rates of medical professionals.

Two major changes exacerbate this trend. First, the US population is both aging and more likely to have chronic diseases, requiring more complex evaluations and greater use of resources in the ED.[5] Second, alterations in health care policy put greater focus on the ED. The Patient Protection and Affordable Care Act concentrated on better

management of patients with chronic disease and on providing health insurance for the uninsured. It did not address acute disease or time-sensitive conditions. Patients increasingly have turned or are sent to the ED for treatment of their acute conditions. Even if primary care medical homes were open from 7 AM to 7 PM Monday through Friday, those access points would provide availability only 36% of the time during patient demand.

How do we fix this? For decades, emergency physicians have built bigger and bigger EDs with more staff and larger waiting rooms and pleaded for others to provide services and resources that help our profession care for our patients, all while taking patients at any time of the day or night. In 2012, Kocher and Asplin[6] noted that ED crowding was becoming a chronic disease itself and asked, "What is the crowding endgame?"

We can start by putting our patients first and leading from there. After years of asking others to help solve our problems in the ED, emergency physicians are now leading the change from centralized hospital-based EDs to a more distributed access model of emergency care that incorporates freestanding EDs. It is a model of moving emergency care to "where the patients are."

As freestanding EDs proliferate, more information will be required. Important questions remain that, like medicine itself, can best be answered over time and after continuous adjustments. Freestanding ED, EMS, and health system data can bring better insight into the types of patients and acuity treated; system's and facilities' quality care performance; best approaches to time-sensitive conditions; effects of patient distribution on crowding, quality care, and safety; optimal integration with EMS and the spectrum of health care facilities; incorporation with public health and disaster preparedness; overall cost-effectiveness and total cost of care; and optimal value in care continuum. All of this is required to best integrate emergency care within a region into a meaningful whole that improves emergency care for our patients.

Emergency medicine will lead this change. The transition in emergency care is not an "us versus them" phenomenon but one in which we as emergency physicians work together to build our own future—for our patients, our communities, and our profession.

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COMMENTARIES

Academic Emergency Medicine and the "Tragedy of the Commons"

THE "TRAGEDY OF THE COMMONS" DEFINED

Occasionally, one comes across an idea which, although old, can lead to greater insight into current problems. The concept of the "Tragedy of the Commons" is such an idea. To define the Tragedy of the Commons, one can begin by examining each word. The term "tragedy," according to the second definition in *Webster's 7th New Collegiate Dictionary*, is "a serious drama typically describing a conflict between the protagonist and a superior force (as destiny) and having a sorrowful or disastrous conclusion...." The word "tragedy," when used to describe a story or legend, is not meant to imply only a sequence of unfortunate or painful events but, furthermore, to imply a certain natural progression or inevitability of those events.

Also according to *Webster's*, the fifth definition of a "common" is "a piece of land subject to common use: as **a:** un-divided land used especially for pasture (or) **b:** a public open area in a municipality...." In old England, the term "commons" referred to an area of land that was used for grazing livestock. It was a shared common resource used for the benefit of all. In contrast, however, each shepherd owned his own livestock, and benefited only from the livestock within his own herd. In modern times, the term "commons" also applies to any area of public use that is open to all.

The Tragedy of the Commons was first described by William Forester Lloyd in 1833, but placed into modern context by population biologist Garrett Hardin, in an essay published in 1968 in the journal *Science*[1] and updated in 1998.[2] The Tragedy of the Commons is a principle that applies in numerous health care, academic, and other settings. It is one of those rare concepts that, once understood, is found to be relevant in more and more areas of our daily lives.[3–6]

In its original context, the Tragedy of the Commons refers to the fate of shared pasture land. The old English system of sharing pasture space seems inherently fair, and our intuition might be that this system would maximize the benefit of the common space for all. There is appealing equality and simplicity in the commons. Each shepherd finds himself in the same position—no one owns the land or has more or less claim to it.

Every year, each herdsman seeks to improve his wealth by deciding whether to graze additional, fewer, or the same number of animals. Of course the commons has a fixed carrying capacity and, as the number of animals grazed on it increases and approaches this limit, the average weight gain of each animal decreases. From the point of view of each herdsman, the decision to add one more animal to his herd yields almost the benefit of one of his current animals. It is true that each animal may be slightly leaner because of the additional competition, but virtually all of the benefit of one animal will be realized. The benefit of adding an animal is neither shared with others nor diluted. In contrast, the negative effect on the commons is distributed among all herds and all herders, and is thus relatively small from the point of view of each individual herder. Thus, any rational herder will conclude that it is in his best interest to add additional animals to his herd each year.

The tragedy occurs because each herder finds himself in exactly the same situation, and thus each herder adds more and more animals to his herd. Eventually the commons is overgrazed, and all of the animals become weak, underweight, and susceptible to disease. This leads to the collapse of the herds and the downfall of the herders. A fundamental asymmetry—complete interest in the size of one's own herd, but only an indirect and partial interest in the well-being of the commons itself—leads to this tragedy. This sequence of events, which results in the destruction of not only the commons, but also the herds and the herders, is an inevitable result of the system that governs the use of the commons—hence the tragedy.

What are the key elements of the tragedy of the commons? First is the existence of a shared but limited resource, vitally important to the lives of those who share it. Second is the desire of each participant to have more of the resource than currently allocated to him or her. Finally, there is equal and unfettered access—a lack of external control. For example, there is no governing agency that sets limits on the number of sheep each herder may graze on the commons. The outcome of this combination of factors is sometimes summarized as "freedom in a commons brings ruin to all." Importantly, these elements occur frequently in many settings, sometimes even intentionally,

Based on the 2003 President's Address delivered by Dr. Lewis at the Society for Academic Emergency Medicine (SAEM) Annual Meeting, May 2003, Boston, MA.

recreating the tragedy. The three elements of the tragedy, when in place, lead rational people to make decisions that ultimately destroy their common resource.

Have we learned the lessons taught by the tragedy of the commons? Consider the fact that cattle herders in the United States still constantly pressure authorities to allow larger herds to graze on federal land. Or the fact that many fishers still believe in the ''freedom of the seas'' and the ''inexhaustible resources of the oceans.'' While we might criticize these groups for failing to heed lessons of the past, we also must consider the current state of emergency health care and the current state of academic emergency medicine. In the rest of this commentary, I would like to point out some situations that partially or completely replicate the tragedy of the commons, but from within the world of emergency medicine.

EMERGENCY MEDICAL CARE AS A COMMONS

The emergency medical services (EMS) system is a resource that, by law, is available to all without restriction. It is also a limited resource, as both equipment and personnel are limited by budgetary constraints and competing priorities of local, county, and state governments. Furthermore, there is generally no negative incentive in place to limit use of the EMS system for non-emergency care. Since each of the key elements of the Tragedy of the Commons are recreated in our EMS system, it is not surprising that we see an EMS system that is often stretched to capacity, being used as an expensive taxi service, or that there is a subset of people who utilize the system far more than others.

Just as with the overgrazing of pasture lands, this dynamic leads to a degradation in the quality of the common resource. This degradation manifests as reduced availability of EMS units, long response times, provider ''burnout,'' and the institution of compensatory changes (e.g., tiered response). Each of these factors reduces the overall quality of the resource—a deterioration of the commons.

The emergency care provided in emergency departments (EDs) across the country is also an example of a commons. It is a resource that is valuable to all, especially in times of unexpected need, and under the Emergency Medical Treatment and Labor Act/Consolidated Omnibus Reconciliation Act (EMTALA/COBRA) legislation, it is available to all without restriction or consideration of ability to pay.[7] For many members of our society, the ED is their only access to needed medical care, and they often need more care than they currently receive. In addition, there are little or no incentives to limit use. The resulting behavior, on the part of a subset of users, is to use the ED as their primary source of care, to use the ED for non-emergency care, and to fail to identify and access other sources of primary care that may be available to them. It is important to note that these behaviors are the logical and inevitable consequence of creating a commons—*they are not the result of any lack of moral character or judgment on the part of individuals*. In fact, these individuals are appropriately reacting to the health care system we have created, in which there is only one source of medical care that is open to all without restriction or limit. The irony here, of course, is that primary care in our country is a closely managed resource, whereas emergency care is purposely unmanaged.

As is well known to all emergency physicians, our EDs are being ''overgrazed.'' This is manifested by overcrowded waiting rooms and EDs, frustration on the part of both physician and nurse providers, physician ''burnout,'' and decreased quality and timeliness of care. It is fundamentally irrational for academic emergency physicians to bear witness to the continual degradation of the commons that is emergency health care while, simultaneously, arguing vehemently that this precious resource remain unmanaged. Unfortunately, that is exactly the position of many organizations and leaders within the field of emergency medicine.

Now consider the moral and equity arguments in support of universal health insurance in our country. The total public funds to be spent on health care are essentially limited by external economic and political factors, creating a sort of economic commons. Under our current system, of course, many members of our society have essentially no access to health insurance. This constitutes *de facto* management of the common resource. Ironically, arguments in favor of universal health insurance, to the extent that they fail to increase the size of the commons by creating new sources of funding, are arguments in favor of creating the key elements of the tragedy. Given the limited resources, this tragedy would consist of universal health coverage that, over time, is slowly degraded in its scope and value, and in its ability to ensure quality health care for all. The initial stages in this process have already been seen in some settings, in which a large segment of the population is ''covered'' using public funds, but the level of reimbursement is so low that skilled providers will not voluntarily provide care. With this approach, we may create an *illusion* of universal health care, but that may be all.

RESEARCH DEVELOPMENT AND TRAINING IN ACADEMIC EMERGENCY MEDICINE

I will now switch my focus from emergency health care to the processes required to establish a productive research program in an academic ED. I will begin by

Figure 1. Departmental research development.

discussing a cycle of research productivity, and then identify relevant commons and consider how we manage those resources.

In Figure 1, different stages in the development of a research program, and their relationships, are shown. A fundamental first step is the research training of one or more (hopefully more) core investigators. Without such research training, it is unlikely that an investigator can initiate, obtain funding for, and complete research projects of the quality and scope necessary to garner recognition for the department as a whole. Solid research training leads to both an improved quality and an increased quantity of research in a department, which in turn lead to local recognition for the department, usually from inside the medical school or university. Such internal recognition leads to improved opportunities for local funding and for academic recognition. With the additional resources available from local funding and improved opportunities for collaboration associated with recognition locally, investigators in the department are able to initiate and complete projects of a quality and scope that yield recognition nationally. National recognition leads to opportunities for extramural funding, as well as for substantive collaboration outside of one's own institution. These opportunities, in turn, ultimately yield other research resources and infrastructure through extramural grants and/or national collaborations.

The last link in the cycle, and perhaps the most important, is the relationship between a nationally-recognized research program and the opportunity to provide research training. This link occurs both because of the relative ease with which appropriate candidates can be recruited if one has a national reputation and because of the increased chance of obtaining extramural funding for career development and training grants when the local mentors have demonstrated productivity. Thus, there can be a complete, self-perpetuating cycle of research productivity and development, but it must begin with a core group of well-trained investigators.

TABLE 1. Key Elements of Research Training

Access to formal coursework
Mentor
Protected time
Facilities, equipment, and supplies
Supportive environment (mentor, chair, colleagues)

Table 1 shows key elements required by a trainee to acquire essential research skills—the first step in development of a research program. In the following I will focus on two of these key elements: 1) the availability of a qualified and effective mentor; and 2) sufficient protected time to develop a set of research skills.

Although specific data are difficult to obtain, it is widely believed that a good mentor is one of the most important predictors of long-term research success on the part of the trainee. This is especially true for trainees with little formal research training, as is typical of young investigators in emergency medicine whose primary post-college training is focused on medicine (e.g., an MD degree and residency) rather than on research activities. Accordingly, the qualifications of the mentor, the mentor's track record in research training, and the quality of the mentor–trainee relationship are all important factors considered during the evaluation of fellowship and research training grant applications.

From the point of view of a young researcher, the mentor is a type of commons. A good mentor is extremely valuable to all trainees wishing to enhance their research skills and productivity. The mentor is valuable unless, of course, he or she must be shared with too many other trainees or has too many other research, clinical, or administrative responsibilities. If the mentor is spread too "thin," regardless of his or her qualifications and intent, the mentor will be of little use to his or her trainees. One way this issue can be addressed, however, is to increase the size of the "mentor commons," by recognizing that good mentors can often be found outside of emergency medicine. At institutions in which insufficient mentoring capacity is available within emergency medicine, one must be willing to identify and cultivate relationships with outside mentors.

Given that mentors are a valuable and limited resource, it is ironic that we sometimes create a tragedy by insisting that all emergency medicine residents perform research. This practice often leads to the mentor's time being spread so thin that the mentor is of little use to the few residents who truly wish to pursue a research career, or to the junior faculty within the department who desperately need the mentor's assistance. In essence, we recreate the Tragedy of the Commons, and this is manifested by

a degradation in the quality of mentoring for all who need it.

In virtually all departments of emergency medicine, non-clinical, non-administrative time is also a type of commons. Such protected time is critically important to the young investigator wishing to develop research skills and to establish a track record of productivity. In fact, such protected time is critical for even the most experienced investigators who wish to remain productive. If the non-clinical, non-administrative time is spread evenly among all faculty, however, in most settings the absolute quantity of such time will be so limited that it will be insufficient to support the career-development phase of a young investigator. In other words, even with the current size of our ''herds'' of faculty members (which are necessary to fulfill our clinical and clinical teaching responsibilities), the commons of protected time is insufficient to support the development of a research career if distributed equally.

As a field, how good are we at research training and research career development? In 1999, Blanda et al. published a study based on a survey of self-identified research directors in emergency medicine.[8] That survey showed that 53% of research directors were junior faculty (at the instructor or assistant professor level), and that the median length of time spent in the position was three years. Furthermore, approximately one-third of research directors reported no publications in the prior three years. Only 27% of research directors had a research degree and 21% had completed a research fellowship, although the duration of these research fellowships was unclear.[8] Assuming that the research director is usually the research mentor in each department, it would appear that, as a specialty, we have been largely unsuccessful in creating an adequate group of mentors (the commons) for our young trainees.

It is instructive to contrast the research training and productivity of *research directors* in emergency medicine with the minimum training requirements for *trainees* suggested in the guidelines for institutional fellowship grants supported by the National Research Service Awards (NRSA) program. In the latter case it is stated that ''...postdoctoral trainees should agree to engage in at least 2 years of research, research training, or comparable activities beginning at the time of appointment since the duration of training has been shown to be strongly correlated with post-training research activity.''[9] *In other words, the national standard, based on actual data regarding subsequent research success, implies a higher level of training for fellows than we are able to document for the majority of research directors in emergency medicine.* Thus, for most departments to be able to initiate the cycle of research training and development shown in Figure 1, a substantial and sustained investment in our research trainees, in the form of protected time and resources, must be made.

AVOIDING THE TRAGEDY OF THE COMMONS

How do we avoid the tragedy of the commons and maximize the benefit of a common resource for all? Most approaches attempt to alter one of the key elements of the tragedy so that the underlying dynamic is never realized. Approaches include converting common resources to private property, eliminating the commons altogether, or regulation of the use or active allocation of common resources—restricting personal freedom. Such approaches can be summarized as ''mutual coercion, mutually agreed upon.'' In addition, a number of authors have identified other social mechanisms that, in specific cases, appear to prevent the tragedy.

While mutually agreed upon limitations may prevent destruction of the commons, in some cases the resources will be so dilute as to be of little use (e.g., protected time). Thus, the maximum benefit for the whole group, or an entire academic department, may be achieved only with unequal allocation of a scarce resource. This is unsettling to many who implicitly assume that an equal allocation of resources is optimal.

There are a number of common barriers to any solution to the Tragedy of the Commons. These barriers include devotion to individual freedoms, namely, a belief that all should have equal and unfettered access to any valuable resource. In many settings, we seem to believe that equality requires freedom—that external controls are inherently unfair. In many settings there is also a distrust of external regulation. Furthermore, many believe in simplistic defenses of the right to equal access to commons. By simplistic, I mean without regard to an analysis of the effect of this free and unfettered access on the commons itself. Lastly, many believe in the fundamental value of equality, independent of the consequences of such equality. A defense of right to access, however, without explicit consideration of the consequences, is shortsighted and often misleading.

What solutions have been found to the tragedy? Solutions include limits on fishing in international waters, the use of parking meters, and international limits on air pollution. Examples in the health care setting are more difficult to find, although systems for the equitable distribution of solid organs for transplantation are one example.

Focusing back on the field of emergency medicine, what are possible solutions to the tragedies that we have created? One approach to avoiding the tragedy of the commons would be to institute negative social or financial incentives to reduce inappropriate use of EMS or ED resources. Such an approach raises difficult ethical issues regarding the rights of individuals to

access medical care freely versus the rights of the population as a whole to have high-quality emergency care available when needed. A number of related and very difficult research questions would need to be addressed regarding the definition and detection of inappropriate use and the reliability and validity of any measures used to define inappropriate utilization.

Examples of this approach include the use of small financial copayments that can be refunded when a patient requires admission to the hospital from the ED. Interestingly, emergency physicians often react emotionally to such solutions, and often believe that this reaction is in the best interest of their patients. In truth, however, some approach to manage the commons that is emergency care will be required if we are to preserve the quality of emergency care for all patients. In other words, we must take an active role in managing the commons if we are to preserve it, rather than reacting negatively and emotionally toward any attempt to manage it.

Focusing on the development of research capability within a department, active management of each limited resource is again the key. This may include active management of a mentor's time, active management of protected time, and active management of other resources (e.g., funds for tuition, equipment, and support personnel). Such an approach requires "mutually agreed upon" sacrifice by others in the department, and in the institution, so that adequate resources can be identified to allow an intensive and sustained investment in the initial research career of young investigators. Without such an investment, however, we will be consistently setting up our young investigators to fail, and then finding external excuses to explain their failure.

In summary, in a setting of limited resources, a blind devotion to equal allocation of resources severely limits the research potential of a department. Since an adequate investment in a promising young investigator must occur early in his or her career, must be sustained, and must be intensive, this can only occur with a mutually agreed upon sacrifice by others in the department. Thus, support of colleagues is critical and, in many departments, such support will not occur without a fundamental change in the culture of the department.

CLOSING THOUGHTS

While I take personal pride in the tradition of equal and unfettered access to medical care that characterizes emergency medicine, we must learn the lessons taught by the Tragedy of the Commons if we are to preserve the *quality* of this care for those who need it. This will require active management of limited resources, rather than a single-minded devotion to equality and unfettered access. Likewise, if we are to realistically and meaningfully support the development of research capability within emergency medicine, we must be willing to disproportionately shift resources, whether they are a mentor's time or protected academic time, to our promising young investigators. This will require a sacrifice by many so that a few may push the limits of our academic specialty.—**Roger J. Lewis, MD, PhD** (roger@emedharbor.edu), *Department of Emergency Medicine, Harbor-UCLA Medical Center, Torrance, CA*
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Editor's note: The biologist who wrote the landmark 1968 article on the Tragedy of the Commons recently passed away.[10]

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