Medication Safety Committee Meeting

April 4, 2018

California Hospital Association - Boardroom

1215 K Street, Ste 800

Sacramento, CA, 95814

Conference Call Option: 800-882-3610 passcode: 4206832

Meeting Book - Medication Safety Committee Meeting

AGENDA

10:00	CALL TO ORDER/INTRODUCTIONS Fong		
	Committee Roster/Member Map/Member Breakdown		Page 4
	Committee Guidelines		Page 10
	Membership Updates		Page 14
10:15	MINUTES Fong	Recommend: Approval	
	January 10, 2018 Meeting Minutes		Page 17
10:20	OLD BUSINESS		
	340B Update Amber Ott		Page 21
	CHPAC William Emmerson		Page 28
	Medication Safety Toolkit Bartleson/Roth		Page 33
	Sterile Compounding Fong/Herold		
	Board of Pharmacy Letter on Definition of Hazardous		Page 36
	Other Issues/Changes		
	Board of Pharmacy/CAU-CDPH/OSHPD Construction Waiver Process Debby Rogers		Page 40
	AHA Leadership Summit - Update on Submission Bartleson		Page 45
12:00	LUNCH		
12:30	LEGISLATION Bartleson		
	Legislation		Page 46
1:00	NEW BUSINESS		

IV Opioid Drug Shortages — Page 106
Bartleson

Incidents of Smart Pump Malfunctioning — Page 140
Bartleson

CURES
Bartleson

11:40 STANDING REPORTS

Board of Pharmacy
Herald

CDPH
Lee/Woo

CSHP
DeMartini

CALNOC
Foley

ACNL
Tomasi

CHPSO — Page 141
Jaffe

CAHF
Hall

1:50 OTHER BUSINESS
All

HQI - Statewide Opioid Summary — Page 150

NEXT MEETING

Wednesday, July 11, 2018

2:00 ADJOURNMENT
Hanni

MEDICATION SAFETY COMMITTEE
2018

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Medication Safety Committee
Hospital Representation

BY COUNTY

As of March 22, 2018

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

Medication Safety Committee
Member Geographics - January, 2018

HOSPITAL MEMBERS

Member Name	Organization Name	County
Amy Gutierrez	Kaiser Permanente National Pharmacy Programs and Services	Los Angeles
Candace Fong	Dignity Health	Sacramento
Carolyn Brown	Santa Clara Valley Medical Center	Santa Clara
Chris Patty	Kaweah Delta Health Care District	Tulare
Christine Low	Scripps System	San Diego
Dan B. Dong	Kaiser Permanente	Alameda
Diana Schultz	Palomar Medical Center	San Diego
Doug O'Brien	Kaiser Foundation Hospitals	Sacramento
Eddie Avedikian	Providence Health & Services	Santa Barbara
Jeannette Hanni	Sutter Health - West and South Bay Region	Santa Clara
Kathy Ghomeshi	UCSF Medical Center	San Francisco
Katie Choy	Washington Hospital Health Care System	Alameda
Kevin Dorsey-Tyler	Enloe Medical Center	Butte
Lori Nolan	Providence Little Company of Mary Medical Center	Los Angeles
Mary Foley	UCSF, School of Nursing	San Francisco
Nasim Karmali	Kaiser Foundation Hospital	Alameda
Richard Rabens	The Permanente Medical Group, Inc.	Alameda
Rita Shane	Cedars-Sinai Medical Center	Los Angeles
Sarah Stephens	Kaweah Delta Health Care District	Tulare
Susan Herman	San Joaquin Community Hospital/Adventist	Kern

NON-HOSPITAL COMMITTEE MEMBER

Kim Tomasi	Association of California Nurse Leaders	Sacramento
Art Woo	California Department of Public Health	Contra Costa
Cari Lee	California Department of Public Health	San Mateo
Dan Ross	California Society of Health System Pharmacists	Sacramento
John Christensen	California Department of Public Health - Redwood Coast and Santa Rosa	Sonoma
Lisa Brundage O'Connell	Hospital Council of Northern and Central	Contra Costa
Lisa Hall	California Association of Health Facilities	Sacramento
Loriann DeMartini	California Society of Health System Pharmacists	Sacramento
Randy Kajioka	California Correctional Health Care	Sacramento
Rory Jaffe	California Hospital & Patient Safety Organization	Sacramento
Virginia Herold	California Board of Pharmacy	Sacramento

GUIDELINES FOR THE
CALIFORNIA HOSPITAL ASSOCIATION
MEDICATION SAFETY COMMITTEE

I. NAME

The name of this committee shall be the Medication Safety Committee.

II. MISSION

The mission of the Medication Safety Committee is to provide leadership within the health care community to promote the highest standards related to the safe and effective use of medications.

III. PURPOSE

The purpose of the Medication Safety Committee is to provide a forum for diverse multi-disciplinary health care organizations, which includes health care delivery organizations, patient safety organizations, discipline specific professional associations/organizations and regulatory agencies, to promote safe medication practices in the state of California. The Committee will focus on acting as a source of medication safety expertise, providing a venue for the coordination of medication safety activities and making recommendations related to medication safety legislation and regulations.

IV. COMMITTEE

The Committee (the "Committee") shall consist of a minimum of 16 representatives and not more than 35 representatives from hospital members and the following related organizations:

California Department of Public Health California
Society of Health System Pharmacists California
Board of Pharmacy
Centers for Medi-Care and Medi-Caid Services
Collaborative Alliance for Nursing Outcomes
Association of California Nurse Leaders California
Medical Association
California HQI and CHPSO
Risk Management Association
Representatives from the following CHA committees/centers:
Center for Behavioral Health
- Rural Health Center
- Quality Committee
- Joint Committee on Accreditation and Licensing Center
- for Hospital Medical Executives EMS/Trauma
- Committee
- Hospital Based Clinics Committee
- Center for Post Acute Care
- Governance

A. MEMBERSHIP

1. Membership on the Committee shall be based upon membership in CHA, or organizations that have a direct relationship to the purpose and mission of the Committee. CHA members will be hospital members. Non-hospital members are ex-officio members and can only be appointed to the Committee at the discretion of the CHA staff liaison.
2. The CHA Committee members shall consist of various representatives from large hospital systems, public institutions, private facilities, free-standing facilities, small and rural facilities, university/teaching facilities and specialty facilities. A member may fulfill more than one required membership position.
3. Hospital members are appointed by CHA Staff per recommendation of hospital Committee members and per hospital and non-hospital membership requirements listed above.
4. Guidelines for membership – these guidelines should be used when selecting potential new members for the Committee:
   a) Demonstrated experience in medication safety and understanding of regulatory environment based on current or recent job responsibilities
   b) Contributions to medication safety at the organizational and/or professional level
   c) Practice experience related to medication safety and regulatory compliance: at least 3 years (preferred).
5. Term:
   a) Terms of office shall be based on member participation and desire to remain active on the Committee. The CHA staff liaison will perform an annual review of member attendance, participation and desire to remain active on the committee.
   b) Chairs and Co-Chair positions will be filled by hospital members only and selected by the CHA staff liaison per recommendation of the present chair, co-chairs and by other members of the Committee. They will be selected based on their leadership and desire to fill the position.

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee and CHA Board of Trustees.
2. Identify issues and develop possible solutions and best practices to improve the safety of the medication use process.
3. Work cooperatively with key stakeholders to develop creative solutions.
4. Provide communication to member hospitals regarding medication safety issues.
5. Maintain/increased awareness of the legislative and regulatory environment with regard to medication safety issues.

C. COMMITTEE MEETINGS

1. Meetings of the Committee shall be held quarterly in person.
2. To maintain continuity, substitution of members should be discussed with the staff liaison and co-chairs on an individual basis.
3. Three consecutive unexcused absences by a Committee member will initiate a review by the co-chairs and CHA staff liaison for determination of the Committee member's continued service on the Committee.
4. Special meetings may be scheduled by the co-chair, majority vote, or CHA staff liaison.

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 present at a duly called meeting or telephone conference call.

E. QUORUM

Except as set forth herein, a quorum shall consist of a majority of members present or not less than eight.

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.

V. OFFICERS

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

A. SUB-COMMITTEES

1. Task forces of the Committee may be formed at the discretion of the Committee chairs and members and CHA staff liaison for the purpose of conducting activities specific to a special topic or goal.

VI. GENERAL PROVISIONS

Goals, and objectives, shall be developed annually by the Committee with approval by the CHA staff liaison. 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 Hospital Council, the Hospital Association of Southern California, and the Hospital Association of San Diego and Imperial Counties. The primary office and public policy development and advocacy staff of the Committee shall be located within the CHA office.

The Committee staff liaison 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 and with approval by CHA.

VIII. LEGAL LIMITATIONS

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

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Review New Committee Membership

SUMMARY

Kim Tomasi is the new CEO for ACNL, replacing Pat McFarland after her retirement earlier this year. Kim will be joining the Medication Safety Committee representing ACNL. Her bio is attached for review.

Also attached is a resume for Deepak Sisodiya – Pharm. D., MHA, and Administrative Director of Pharmacy Services at Stanford Health Care. He is interested in CHA's Medication Safety Committee.

ACTION REQUESTED

- Please review and discuss Deepak Sisodiya's qualifications for recommendation to the committee.

Attachments: Kim Tomasai bio
Deepak Sisodiya resume

BJB:br

Kimberly Tomasi, MSN, RN
Chief Executive Officer
Association of California Nurse Leaders

Kim Tomasi, MSN, RN, is Chief Executive Officer of the Association of California Nurse Leaders, a nonprofit professional organization representing nurse leaders in hospitals, health systems, academia, research and business.

As part of her role as ACNL's CEO, Kim also serves as the Executive Officer for the California Nursing Students Association (CNSA) and the California Association of Colleges Nursing (CACN), representing colleges and universities providing baccalaureate and higher nursing degree programs.

An experienced nurse executive, Kim has extensive expertise in nursing practice, healthcare administration and management/leadership development. Prior to joining ACNL, Kim was Deputy Director of Nursing at San Joaquin General Hospital in French Camp, California. Her areas of responsibly include administrative oversight of the Intensive Care Unit, Telemetry Unit, Medical/Surgical Units, Emergency Department, Dialysis, Nursing Education, Continuum of Care Department, Emergency Preparedness Planning, and the Sexual Assault Forensics Examiner (SAFE) program. During her tenure at San Joaquin General, Kim has overseen the development of new programs and compression of programs to meet changing health care needs and priorities. She also led strategic planning, training and change initiatives to improve outcomes. Kim has collaborated extensively with leaders from healthcare, education and business on performance and community improvements through program design, partnerships, policy development, business and marketing plans, coaching and team development.

Kim holds graduate and baccalaureate degrees in Nursing Science from the University of Phoenix. She has been very involved in community activities in the Stockton area, including serving on multi-disciplinary teams aiding homeless veterans and victims of child and adult abuse, sexual assault and human trafficking. For several years she has been an active member of ACNL's North Central Chapter, serving as president and secretary. She is also a member of the American Organization of Nurse Executives (AONE). Kim can be contacted at: kim@acnl.org.

Deepak R. Sisodiya – Pharm.D., MHA

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Engaging, innovative, and financially astute leader with proven ability to function as an organizational change agent and return considerable and consistent results

Executive Summary

Deepak Sisodiya is the Administrative Director of Pharmacy Services at Stanford Health Care in Stanford, California. He oversees a growing pharmacy enterprise consisting of a 450 bed hospital, multiple outpatient infusion centers, and a wide array of Ambulatory clinic practices across the Bay Area.

Deepak received his Bachelor of Science degree in Pharmaceutical Sciences from the University of Alberta and went on to earn his Doctorate in Pharmacy from the University of Michigan. After completing a pharmacy practice residency at Stanford, he spent some time practicing as a clinical pharmacist before transitioning into leadership. In 2013, he completed his Masters in HealthCare Administration which positioned him well for his role today as a health system pharmacy leader within an academic medical center.

Deepak has a wealth of experience in pharmacy operations and leadership. Where he currently serves as the administrative director of pharmacy services at Stanford Health Care. He leads a large team of 200+ FTEs. Reporting directly to the VP of Diagnostic and Treatment Services and Executive Director of Imaging, Lab, and Pharmacy. In his role, he Oversee all aspects of health system pharmacy. Including 340B drug pricing program, pharmacy platform management, financial and analytical metrics and KPIs, medication management processes and services, cost-effectiveness Inventory control, policies and procedures and represents pharmacy at various hospital and medical staff committees

Significant Experience

Deepak spearheaded recent efforts to start-up Stanford Health Care's first outpatient specialty pharmacy business from the ground up. Including developing operating/economic models, IT platform implementation, facilities and construction.

Deepak launched and oversees SHC's 340B drug program.

He has developed and implemented cost savings initiatives targeted to save $27M million over a period of 15 months.

He led the Ambulatory Care growth initiatives that have positioned pharmacists to directly manage medication management needs in primary and specialized practices.

Successfully activated numerous satellite infusion centers (Ambulatory Surgery, Oncology, Neuro).

He has been published in numerous publications including the American Health System Pharmacists and Clinical Microbiology.

Education

- Master's Health Administration | 2013 | (Accelerated)
  Simmons College, Boston, MA
- Doctorate of Pharmacy | 2002 | University of Michigan
  Graduated with Highest Distinction
- Bachelor of Science, Pharm Sciences | 1998 | University of Alberta
  Graduated with Distinction

Knowledge & Skills

- Pharmacy operations and process improvement
- Cost optimization initiatives and value based selection
- Clinical program development
- Specialty pharmacy
- 340B program
- AM Care growth
- EPIC, Omnicell, Inventory management solutions

Leadership & Professional Activities

- ASHP Faculty Member
- UCSF Assistant Clinical Professor
- University of Pacific Adjunct Professor
- Preceptor, Hospital Practice & Practice Management
- Stanford Hospital and Clinics Leadership Academy
- ASHP Capstone Leadership Program
- PGY2 Drug Information Specialty Residency Coordinator
- Preceptor, Internal Medicine & Infectious Diseases

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
January 10, 2018 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: Eddie Avedikian, Loriann DeMartini, Jeannette Hanni, Kathy Ghomeshi, Susan Herman, Virginia Herold, Rory Jaffe, Christine Low, Dan Ross, Diana Schultz, Rita Shane, Terri Vidals

Members on Call: John Christensen, Kevin Dorsey-Tyler, Lisa Hall, Nasim Karmali, Doug O'Brien, Sarah Stephens

Members Absent: Carolyn Brown, Katie Choy, Edna DeLeon, Dan Dong, Mary Foley, Amy Gutierrez, Randy Kajioka, Cari Lee, Lori Nolan, Christopher Patty, Richard Rabens, Art Woo

Guest: Randi Agata, Vicky Ferrarsi

CHA Staff: BJ Bartleson, Staci Grabill, Lori Richardson, Debby Rogers

I. CALL TO ORDER/INTRODUCTIONS – Hanni/Fong

The committee meeting was called to order by co-chairs at 10:00 a.m. Ms. Hanni briefly reviewed operational items.

II. REVIEW OF PREVIOUS MEETING MINUTES – Hanni/Fong

The minutes of the October 11, 2017, Medication Safety Committee meeting were reviewed.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: Minutes approved as presented*

III. OLD BUSINESS

A. Sterile Compounding Changes - Herold

Referring to the documents provided in the meeting book, Ms. Hanni discussed proposed changes to the regulations. Ms. Bartleson referred members to the December Board of Pharmacy (BoP) meeting report provided in the meeting book. Ms. Herold discussed compliance with USP 800 and stated those that received sterile compounding construction waivers received a questionnaire to complete. The BoP is pushing for hospitals to become compliant.

Ms. Hanni then moved on to the draft comments created by CHA asking Ms. Herold if this is the best way to provide the BoP feedback, or should the comments be voiced directly to the Board in the February Board Meeting. Ms. Herold stated the written comments are good. This allows CHA and this group to provide detailed comments during the comment period. Members discussed missing pieces and concerns with the changes of the board regulations, as

well as their process in labeling and handling hazardous drug such as Pitocin and other reproductive and chemotherapy drugs.

Per Ms. Hanni, the comment letter should include the crosswalk to labeling, and suggested wording.

- *ACTION: Sterile Compounding subgroup to make changes to the hazardous medication proposed definition and circulate to the committee for additional input prior to finalizing and forwarding to the BoP. Per Ms. Shane, USP 800 FAQs would be a good information resource.*

B. Board of Pharmacy Construction Waivers/Process/CAU – Hanni/Fong

Waivers – Ms. Herold addressed backlog. In many cases BoP is waiting for a response from hospitals on BoP's request for additional items. Ms. Herold advised members to give BoP 30-days to complete their process.

CAU – Mr. Christensen stated he does not have the power to speed up the process, but is taking note of member concerns and will discuss with his team. Ms. Bartleson referred members to the roundtable process memo and the CDPH checklist for review and discussion.

Ms. Rogers discussed CAU as related to sterile compounding. She advised members that are ready for inspection and seem to be on hold, to work through Ms. Rogers to ensure the delay gets addressed.

- *ACTION: Mr. Rogers and Ms. Hanni to work with Mr. Christensen to raise CAU issues to Ms. Lee from CDPH.*

C. Medication Safety Toolkit Update - Bartleson

Ms. Bartleson reminded members the tools have been posted to the CHA website. She requested members to forward outstanding items to her and she will ensure they get posted.

- *ACTION: Toolkit webpage comes back with an error message. CHA staff to work on fixing the link.*

D. Education Next Steps – Bartleson

Referencing the memo included in the meeting book, Ms. Bartleson discussed the topic of education with regard to sterile compounding. General consensus is that formal education should wait until the hazardous language has been finalized.

- *ACTION: Information only.*

E. Medication Reconciliation Next Steps - Shane

Ms. Bartleson introduced this discussion then turned the conversation over to Ms. Shane who provided detailed information on the *Cost of Harm Due to Incorrect Medication Lists* document provided in the meeting as well as her work on providing bill language to Senator Stone.

- *ACTION: Ms. Shane to confirm with Senator Stone she can share the bill language with committee members, and if so, forward the language directly to committee members.*

F. IV Minibag Shortage – Hanni/Fong

Ms. Bartleson advised the group that she will be participating in a call with AHA and Baxter to discuss further. Mr. Avedikian provided an example of a hospital issue that Ms. Herold weighed in on.

- *ACTION: The Board of Pharmacy is unable to extend BU dates for shortages*

G. Hospice Facility and Use of ADD – Bartleson

Ms. Bartleson discussed the information and provided a brief update referencing the information provided in the meeting book.

- *ACTION: CHA will continue to monitor the legislation proposed.*

H. 340B Update – Bartleson

Ms. Bartleson briefly discussed the Medicare document and memo provided in the meeting book.

- *ACTION: Information only.*

IV. LEGISLATION AND REGULATORY

A. Antibiotic Stewardship Program – Rogers

Ms. Rogers discussed the information included in the meeting book, as well as, answered questions presented by members.

- *ACTION: Information only.*

V. NEW BUSINESS

A. Advanced Pharm Tech Role - Herold

Ms. Herold reached out to Ms. Bartleson to see if the committee could provide feedback. Ms. Bartleson outlined the information provided by members. The goal is to create more of a career path for pharmacy technicians. Ms. Herold fielded questions presented by committee members.

Ms. DeMartini provided an update on California Society of Health System Pharmacists activities regarding pharmacy technician programs

- *ACTION: Ms. Ghomeshi to forward Ms. Bartleson additional information she has come across regarding this issue.*

B. **AHA Leadership Summit - Bartleson**

Ms. Bartleson took a moment to thank Ms. Stephens, Ms. Ghomeshi, and Ms. Shane for their work in providing abstracts to the American Hospital Association for possible inclusion in a future program.

- *ACTION: Information only.*

C. **Emergency Regulations - Bartleson**

- *ACTION: Discussed in Old Business section.*

V. STANDING REPORTS

A. Board of Pharmacy (BoP) – Herold

Ms. Herold outlined current BoP activities which includes:

- Will be sponsoring several legislative bills
- Proposing changes to the CURES system
- Billboards for opioid abuse
- CE video for the requirement of 2 unites of BoP CE for license renewal
- CE event on drug abuse scheduled for January 27, 2018

B. CDPH – Lee, Woo, Christensen

Mr. Christensen briefly reviewed his tasks from this meeting as discussed earlier.

C. CSHP – DeMartini/Dong

Ms. DeMartini provided a brief update on recent CSHP activities

D. CALNOC – Foley

No update provided

E. ACNL – Foley

No update provided

F. CHPSO – Jaffe

Dr. Jaffe discussed the

- small-bore connector issue
- engaged in a 3-year program to work on an outpatient simulator. They will be using CHPSO data to feed into it.

G. CAHF – Hall

No update provided

VI. OTHER BUSINESS

VII. NEXT MEETING

Wednesday, April 4, 2018

VIII. ADJOURNMENT

Having no further business, the committee adjourned at 1:40 PM

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: 340B Update

SUMMARY

The 2018-19 proposed state budget includes changes to the 340B Drug Discount Program. In California, 175 hospitals across more than 1,800 sites participate in the 340B Drug Discount Program, which provides safety-net hospitals with discounted drug pricing. These hospitals rely on 340B savings to provide pharmaceuticals to uninsured and low-income patients, and to maintain health services in their communities. The state budget proposes to prohibit hospitals from purchasing discounted drugs for Medi-Cal patients through the 340B program.

Amber will update the committee on budget activity to date and outstanding issues surrounding the 340B drug program.

ACTION REQESTED

- How would a change in the 340B drug program affect you?

Attachments: DHCS Releases 340B Budget Trailer Bill Language Proposal

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

DHCS Releases 340B Budget Trailer Bill Language

FEBRUARY 6, 2018 | AMBER OTT

Last week, the Department of Finance released the Administration's budget trailer bill proposals, including the Department of Health Care Services (DHCS) proposal to restrict the federal 340B Drug Pricing Program within Medi-Cal. Specifically, the proposal would require the department to seek federal authorization to prohibit a covered entity from dispensing a drug purchased through the 340B program to a Medi-Cal beneficiary or other individual participating in another program that is eligible for federal drug rebates. CHA opposes the state budget proposal, which would cost safety-net hospitals across the state hundreds of millions of dollars each year. CHA will meet with DHCS and members of the Legislature to share its concerns and mitigate the proposal's impact on hospitals that participate in the 340B program.

An act to amend and repeal Section 14105.46 of, and to add Section 14105.465 to, the Welfare and Institutions Code, relating to Medi-Cal.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 14105.46 of the Welfare and Institutions Code is amended to read:

14105.46. (a) For purposes of this section:

(1) "Covered entity" means a provider defined as a covered entity in Section 256b of Title 42 of the United States Code.

(2) "340B" means the discount drug purchasing program described in Section 256b of Title 42 of the United States Code.

(b) A covered entity shall dispense only 340B drugs to Medi-Cal beneficiaries.

(c) If a covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary. If a covered entity dispenses a drug purchased at regular drug wholesale rates pursuant to this subdivision, the covered entity is required to maintain documentation of their inability to obtain the 340B drug.

(d) A covered entity shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01.

(e) A covered entity shall identify a 340B drug on the claim submitted to the Medi-Cal program for reimbursement.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

(g) This section shall become inoperative upon the effective date specified in a written notification by the director to the applicable fiscal and policy committees of the Legislature that all applicable federal approvals have been obtained to implement Section 14105.465. The department shall post the director's notification on its Internet Web site. This section shall be repealed 90 days following the effective date specified in the notification provided pursuant to this subdivision.

SEC. 2. Section 14105.465 is added to the Welfare and Institutions Code, to read:

14105.465. (a) (1) "Covered entity" means a provider defined as a covered entity in Section 256b of Title 42 of the United States Code.

(2) "340B Program" means the discount drug purchasing program described in Section 256b of Title 42 of the United States Code.

(b) Notwithstanding any other law and in accordance with subdivision (h), the department shall seek federal approval to prohibit any covered entity from dispensing or administering any drug to any Medi-Cal beneficiary or other individual in any other program eligible for federal drug rebates pursuant to Section 1396r-8 of Title 42 of the United States Code that the covered entity purchased through the 340B Program.

(c) If the department determines that federal approval is not available under subdivision (b), the department shall instead seek federal approval for either or both of the following, notwithstanding any other law and in accordance with subdivision (h):

(1) To prohibit or otherwise limit the use of contract pharmacies by a covered entity participating in the Medi-Cal program, including, but not limited to, the fee-for-service and Medi-Cal managed care delivery systems.

(2) To prohibit or otherwise limit certain types of covered entities, as determined by the department, from dispensing or administering any specified covered drug to a Medi-Cal beneficiary that the applicable covered entity purchased through the 340B Program. Subject to any necessary federal approvals, the department may apply that prohibition or limitation to the entirety of the Medi-Cal program or to a segment thereof, including, but not limited to, the fee-for-service and Medi-Cal managed care delivery systems, and any other program eligible for federal drug rebates pursuant to Section 1396r-8 of Title 42 of the United States Code.

(d) A covered entity, limited pursuant to subdivision (b) or (c) as applicable, shall bill Medi-Cal its usual and customary charge.

(e) For covered entities that the department requires or allows to dispense or administer a drug purchased through the 340B Program, as applicable, the covered entity shall bill the following:

(1) Medi-Cal an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional dispensing fee, or other associated fees authorized in federal or state law and published in all-county letters, provider bulletins, or similar instructions.

(2) A managed care plan an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional dispensing fee, or other associated fees pursuant to a contract entered into between the covered entity and the Medi-Cal managed care plan.

(f) If a covered entity required to use 340B drugs pursuant to subdivision (e) is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary. If a covered entity dispenses a drug purchased at regular drug wholesale rates pursuant to this subdivision, the covered entity is required to maintain documentation of its inability to obtain the 340B drug, in the form and manner specified by the department.

(g) A covered entity shall identify a 340B drug on the claim submitted to the Medi-Cal program or to a managed care plan for reimbursement, in the form and manner specified by the department.

(h) (1) The department shall seek any necessary federal approvals, as applicable, to implement this section.

(2) This section shall not be implemented until the applicable necessary federal approvals are obtained. If, and only to the extent, federal approval is obtained to implement either subdivision (b) or (c), as applicable, the department shall implement either subdivision on a prospective basis according to the effective date identified in the applicable federal approval obtained. The department shall seek an effective date for dates of service commencing at least 90 days from the date the applicable federal approval is obtained, but no sooner than January 1, 2019.

(3) This section shall be implemented only to the extent that any necessary federal approvals are obtained and federal financial participation is available and is not otherwise jeopardized.

(i) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2023, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

- 0 -

LEGISLATIVE COUNSEL'S DIGEST

Bill No.
as introduced, _____.
General Subject: Discount drug purchasing program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing federal law, known as the 340B discount drug purchasing program, generally requires pharmaceutical manufacturers participating in Medicaid to give discounts on pharmaceutical drugs to covered entities serving the Medicaid population.

The Medi-Cal program requires a covered entity to dispense a drug purchased through the 340B program only to a Medi-Cal beneficiary. If a covered entity is unable to purchase a drug for a Medi-Cal beneficiary through the 340B program, the covered entity may dispense a drug purchased at a regular drug wholesale rate, but existing law limits the amount the covered entity may charge the Medi-Cal program for reimbursement of the purchase of the drug. Existing federal law prohibits a covered entity from requesting payment pursuant to the 340B program with respect to a drug that is subject to payment of a rebate from a pharmaceutical manufacturer to the state.

This bill would require the department to seek federal authorization to prohibit a covered entity from dispensing a drug purchased through the 340B program to a Medi-Cal beneficiary or other individual participating in another program that is eligible for federal drug rebates. If the department determines that this federal approval is not available, the bill would require the department to instead seek federal approval to limit the use of contract pharmacies by covered entities, as specified, or to authorize the department to limit the types of drugs purchased through the 340B program that covered entities may dispense to Medi-Cal beneficiaries, or both. Upon receiving a type of federal approval, the bill would require a covered entity to seek reimbursement from the Medi-Cal program in a modified process, as specified.

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


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CHPAC
CALIFORNIA HOSPITAL ASSOCIATION
Political Action Committee
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What is CHPAC?

California Hospital Political Action Committee (CHPAC) is the political arm of the California Hospital Association. The purpose of CHPAC is to elect candidates who understand the vital role hospitals play in our state as a part of the health care system, and the positive impact hospitals have on the economy.

CHPAC receives contributions from individuals and corporate members and uses those funds to support officeholders and candidates for state and local offices.

The CHPAC Board of Directors governs the activities and funds of CHPAC. The board includes health care leaders from across the state as well as corporate partners.

Why give to CHPAC?

As it becomes increasingly difficult for companies to do business in California, it is imperative that we help to elect candidates who understand and support hospitals. It is vital for hospitals to provide quality care while also maintaining the financial stability necessary to employ a workforce of more than a half-million individuals. Additionally, California hospitals purchase vast amounts of goods and services, further fueling the economy by supporting both small and large businesses.

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- Recognition throughout the year at CHPAC events and in publications
- A specially-designed CHPAC lapel pin

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- Recognition throughout the year at CHPAC events and in publications
- A specially-designed CHPAC lapel pin

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Membership in the CHPAC Corporate Presidents' Club is for corporations that have a vested interest in the vitality of hospitals and are committed to working with CHPAC to help elect policy makers who understand the important role hospitals play in their communities. Vendors and businesses that supply goods and services to the state's hospitals and health systems may demonstrate their support and commitment to their clients by joining the CHPAC Corporate Presidents' Club.

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- Recognition in publications throughout the year that reach an audience of over 400 heath care administrators and CEOs
- Members can request a personal meeting with hospital executives by submitting a form.
- Corporate profile on the CHA website, with a link to your company website

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California Hospital Association, Sacramento

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Fax: (916) 552-7692
Email: chpac@calhospital.org

www.calhospital.org/chpac

CALIFORNIA HOSPITAL ASSOCIATION
Political Action Committee

2018 State Contribution Form

Yes, I wish to support the state activities and causes of the California Hospital Association Political Action Committee (CHPAC) by making a contribution of:

Amount

☐ Presidents' Club Platinum Level ($5,000)
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Recurrence

Pledges must be paid in full by December 31.
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Contribution levels are suggestions — you may contribute more or less. You have the right to refuse to contribute to CHPAC without reprisal. The decision to participate will in no way affect your employment or job status.

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➢ Name of hospital(s) or regional association to receive credit:

_____

➢ Name of CHA Center, Committee or Workgroup to receive credit:

_____

➢ Please give recognition to my professional organization:

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Medication Safety Toolkit

SUMMARY

At the 1/10/2018 meeting it was noted that there were several issues with the CHA online Medication Toolkit. Below is a summary of updates regarding the toolkit:

1. Med Safety Toolkit –

    a. It is visible to everyone (not just members)
    b. Anticoagulant – done
    c. Drug Product Shortages – information provided (guidelines)
    d. ED Management – not done
    e. High Alert Medication tools – ISMP Assessment provided
    f. Improving Safe Opioid Use – done
    g. Insulin safe practice – done
    h. Medication Reconciliation – infographic done
    i. Nursing Sterile Compounding – info from 9/17 ISMP webinar provided
    j. Reducing Adverse Drug Events – not done
    k. Reducing Controlled Substance Diversion – done
    l. SB 1039 Implementation – needs to be updated since AFL has been distributed discontinuing the need for a waiver, (see attached)
    m. Sterile compounding – Article by Patricia Kienle provided
    n. Track and Trace Law FAQs – not done

ACTION

- Continue to review toolkit and update as needed.

Attachment: AFL 18-13

BJB:br

KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health

EDMUND G. BROWN JR.
Governor

February 28, 2018

AFL 18-13

TO: General Acute Care Hospitals (GACHs)
Acute Psychiatric Hospitals (APHs)

SUBJECT: Program Flexibility – Pharmacy Technicians and Intern Pharmacists – Senate Bill (SB) 1039

AUTHORITY: Business and Professions Code (BPC) sections 4115, 4119.6, 4119.7

All Facilities Letter (AFL) Summary

- This AFL updates AFL 14-34 that notified facilities of the enactment of SB 1039, Statutes of 2014.
- This AFL clarifies that hospitals will not need to apply for program flexibility for pharmacy technicians and intern pharmacists, to act within their scope of practice as described in BPC 4115, 4119.6 and 4119.7.

This AFL updates and clarifies the requirements enacted by SB 1039 (Chapter 319, Statutes of 2014), effective January 1, 2015, that expanded the scope of practice for pharmacy technicians and intern pharmacists.

Facilities do not need to request program flexibility to allow pharmacy technicians and intern pharmacists to operate within their scope of practice, as outlined in BPC 4115, 4119.6 and 4119.7.

A pharmacy technician, working under the direct supervision and control of a pharmacist in a GACH, is authorized to perform any of the following duties:

- package emergency supplies for use in the GACH and the hospital's emergency medical system, or as authorized by BPC section 4119 regarding the furnishing of dangerous drugs/devices for emergency pharmaceutical supply containers,
- seal emergency containers for use in the GACH, and
- perform monthly checks of the drug supplies stored throughout the GACH, with irregularities being reported within 24 hours to the pharmacist in charge and the director or the chief executive officer of the facility in accordance with the facility's policies and procedures (P&Ps).

An intern pharmacist, working under the direct supervision and control of a pharmacist in a GACH, is authorized perform any of the following duties:

- stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a GACH, and
- inspect the drugs maintained in the GACH at least once per month, with the facility being required to establish specific written P&Ps for such inspections.

The remaining content in AFL 14-34 is still valid. If you have any questions, please contact LNC-PHARM-Consult@cdph.ca.gov.

Sincerely,

Original signed by Jean Iacino

Jean Iacino
Deputy Director

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA 95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)

Page Last Updated : February 28, 2018

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Sterile Compounding Hazardous Definition and Sterile Compounding Update

SUMMARY

Attached is the February 2, 2018 letter sent to the Board of Pharmacy regarding a request to change the board's definition of hazardous drugs.

The Board of Pharmacy and committee members will update the members on board compounding activities, particularly next steps with USP 797.

ACTION REQUESTED

- Please review and update the committee on "hazardous definition" update
- Determine next steps relative to member issues on compounding regulations.

Attachment: Letter to Board of Pharmacy

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

February 2, 2018

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Boulevard
Sacramento, CA 95834

Dear Ms. Herold:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA), appreciates the opportunity to comment on proposed changes to the California Board of Pharmacy sterile compounding regulations, specifically the definition of "hazardous drug" as applied in California Code of Regulations (CCR), Title 16, Section, 1735.1(r). CHA and its Medication Safety Committee have reviewed the language proposed at the board's December 11, 2017, meeting and respectfully offer the following recommendations related to the definition of hazardous.

CCR Section 1735 et seq., and CCR section 1751 et seq., establish requirements for compounding drug preparation. Business and Professions Code section 4127.1 requires the board to adopt regulations to establish policies, guidelines and procedures to implement Article 7.5, Sterile Drug Products; it further requires the board to review any formal revisions to General Chapter 797 of the United States Pharmacopeia and the National Formulary (USP-NF) related to the compounding of sterile preparations no later than 90 days after the revision becomes official.

Since adoption of the board's current compounding regulations, public comments addressing the regulations' impact on patient care have been submitted to both the board itself and its enforcement and compounding committee. CHA respectfully requests that the board delay adopting the proposed change until its impact on hospital and health system pharmacy practice can be meticulously reviewed.

The Board of Pharmacy Enforcement and Compounding Committee previously considered a request to change the board's definition of "hazardous drug" to mirror the definition provided in USP 800. In late September 2017, USP announced the postponement of the official date of Chapter 800 until December 1, 2019, to coincide with the anticipated update to Chapter 797. Consistency between the board USP 800 definitions would be beneficial to hospitals and health systems.

The language proposed by the Enforcement and Compounding Committee is:

> (r) Until December 1, 2019, "hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds or materials identified as hazardous by the

1215 K Street, Suite 800, Sacramento, CA 95814 · *Telephone:* 916.443.7401 · *Facsimile:* 916.552.7596 · www.calhospital.org
Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

pharmacist-in-charge. Effective December 1, 2019, "hazardous" means any drug identified by NIOSH and that exhibit as at least one of the following six criteria:

(1) Carcinogenicity
(2) Teratogencity of developmental toxicity
(3) Reproductive toxicity in low doses in human or animals
(4) Organ toxicity in low doses in human or animals
(5) Genotoxicity
(6) New drugs that mimic existing hazardous drugs in structures or toxicity

CHA and its member hospitals have reviewed the proposed language, and do not believe it offers the flexibility hospital and health system pharmacies need to safely meet patient needs and protect employees, particularly with respect to non-chemotherapeutic drugs listed in the National Institute of Occupational Safety and Health (NIOSH) tables 2 and 3. Flexibility, as allowed under USP 800, to use a risk mitigation strategy to distinguish the differing handling requirements of those drugs is key.

For example, oxytocin — a drug used to induce labor — is included in NIOSH Table 3 as a "non-antineoplastic drug that primarily has adverse reproductive effects" and is hazardous only for women in the third trimester of pregnancy. Using the current language in the Board of Pharmacy Sterile Compounding Regulations, dated January 1, 2017, pharmacies would be required to label that product as "Hazardous – Dispose of Properly," likely causing undue alarm and confusion to a woman in the final stages of childbirth. Likewise, this situation should not require compounding in a negative pressure room with a negative pressure hood. Rather, normal compounding could occur in a laminar flow positive pressure room, thereby decreasing employee exposure to cleanrooms where chemotherapy is made and removing potential product exposure to areas where chemotherapy is made.

We respectfully request that the USP 800 language related to risk mitigation strategy be included in any updated regulations, in the interest of providing safe and effective patient pharmaceutical practice and safeguarding patients from undue alarm when the word "hazardous" appears on their medication label. To further avoid labeling issues, CHA recommends using appropriate wording that matches our proposed definition, detailed below, of hazardous drugs. Section 1735.4(e), as presently written, would mandate that all drugs listed in NIOSH tables 1, 2 and 3 be labeled as hazardous. Using our proposed mitigation strategy and redefinition, we would propose to replace the term "hazardous" with a coded option reflecting appropriate policies and procedure staff should perform — for example, "Special Handling – Level 1" or "Special Handling – Level 2," which would alert a health care worker to special handling requirements but avoid alarming the patient.

In considering changes to the definition of "hazardous," CHA agrees that the term applies to drugs listed in NIOSH table 1, eliminating the need for the further refinement by category risk (e.g. reproductive, teratogenic); risk mitigation strategies could be applied to certain drugs in tables 2 and 3. Further, we agree that any definition should reflect the pharmacist in charge's agreement and identification of hazardous materials. Therefore, CHA proposes that the definition be redefined with the following considerations in mind:

- Hazardous drugs are defined as those listed in NIOSH Table 1 drugs.

- The facility's pharmacist in charge can perform an "assessment of risk," as described in USP 800, for specific dosage forms of hazardous drugs that may not pose a significant risk of direct occupational exposure — for example, tablets that are administered whole, without crushing.
- Drug labeling strategy should be determined based on a coded option reflecting appropriate policies and procedures staff should perform, versus using the term "hazardous" for drugs risk-adjusted in tables 2 and 3.
- The risk assessment approach allows alternative containment strategies or work practices to be employed, rather than a full containment strategy.

If the language change to the definition of "hazardous" drugs is adopted as we have proposed, its impact would span entire sterile compounding regulations document — not only in section 1735.1 (r), but also where the term hazardous is used to describe a sterile compounding procedure (see attachment 1, Board of Pharmacy – Sterile Compounding Regulations – 1735 Hazardous Term Usage). Therefore, any changes should be postponed to allow the board, as well as hospital and health system pharmacist experts, time to review the implications.

We strongly urge the board to delay adoption of its proposed change to the definition of "hazardous" to allow time to carefully consider the potential impact on sterile compounding practice. We appreciate the board's flexibility in this matter. As always, CHA and its member hospitals look forward to continuing to work collaboratively to devise a solution that provides quality patient care as well as optimum patient and employee safety.

Sincerely,

BJ Bartleson
Vice President, Nursing and Clinical Services

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

April 4, 2018

TO: CHA Medication Safety Committee

FROM: Debby Rogers, RN, MS, FAEN, Vice President, Clinical Performance and Transformation

SUBJECT: CDPH Applications Update, Sterile Compounding and Antibiotic Stewardship

CDPH Applications Update

The California Department of Public Health (CDPH) Licensing and Certification Centralized Applications Unit's (CAU) continues to have long wait times to complete/approve applications. The CAU processes applications for many types of changes including: Initial application for licensure, Change of ownership (CHOW), Change of location, Change of name, Change of services, Reports of changes (of governing board, administrator, director of patient care services, beds, geographical service area, indirect ownership change, stock transfers).

CDPH-CAU has undertaken several improvement activities to increase the efficiency of the CAU, including: hiring additional permanent staff and several temporary staff and automation of some applications (starting with skilled nursing facilities). Despite many improvement activities initiated by CDPH-CAU it is taking approximately 8-10 months for an application to be assigned to an analyst. It takes an additional 4.5 months after the applications complete to receive approval for the new services, expanded service.

CDPH provided an opportunity for hospital CEOs to hear more about the applications process and the improvement activities. CDPH was candid about its current performance and optimistic that the automation, increased staffing and other improvements would make a big difference in the CAU timeframe for hospitals.

CHA is sponsoring AB 2798 (Maienschein) which would establish specific time frames for CDPH to complete hospital applications. If the time frames are not met, the service would subsequently be deemed approved. AB 2798 would also require CDPH to develop an assistance unit for hospitals to contact with questions about the application process, to fully automate the application process and to publish performance metrics. Hospitals are encouraged to talk with their local Legislators about the delays they have experienced and the impact on patient care.

Proposed Increase in Hospital Fees

The California Department of Public Health (CDPH) released its 2018 Fee Report, which proposes to increase hospital fees by 5 percent (from $515.04 to $540.79 per licensed bed) and add a supplemental facility fee of $50.53 per bed for hospitals in Los Angeles County.

Historically, the department has contracted with Los Angeles County to use county employees, rather than state workers, to perform facility licensing and certification duties for facilities in that area. The

budget proposal asserts that the cost of doing business is higher there than other parts of the state, and that licensing fees are commensurate with Los Angeles County's costs to complete the workload. This increase coincides with a proposal to extend the current Los Angeles County contract for one year, and then negotiate a three-year contract beginning in July 2019; this proposal includes a "pay-for-performance" program.

This delay occurs as CDPH proposes to raise hospital licensing fees for the fourth consecutive year. CHA and its member hospitals believe an increase in both hospital fees and CDPH staff should contribute to improved performance, and look forward to more work being done in this area.

CHA is hosting a Sterile Compounding Requirement Webinar
Over 100 hospitals have received a waiver from the Board of Pharmacy (BoP) to delay the implementation of the sterile compounding requirements placed into law a few years ago. After the construction upgrades are completed, hospitals must receive approval from the BoP and OHSPD before the application can be approved by the CDPH - CAU. CHA is hosting a webinar on April 17th were BoP, OSHPD and CDPH will detail the process for each oversight entity. See attached flyer.

CHA, HQI and CDPH to Host Antibiotic Use Webinar
CHA, the Hospital Quality Institute and the California Department of Public Health will host a webinar April 5 from 9-10 a.m. (PT) to explain the National Healthcare Safety Network's (NHSN) tool for helping hospitals track their antibiotic use. California law requires hospitals to implement an antimicrobial stewardship policy that meets guidelines established by the federal government and professional organizations. The Centers for Disease Control and Prevention recommends tracking antibiotic use to identify ways to improve and assess the impact of antimicrobial stewardship efforts.
To help in those efforts, NHSN has developed an antibiotic use module that hospitals can use to track and analyze their antibiotic use data, and compare it to other U.S. hospitals. Benchmarking to national risk-adjusted data has been helpful in reducing health care-associated infections and may play an important role in antimicrobial stewardship.
The webinar will:

- Introduce the NHSN antibiotic use module
- Discuss the benefits of using the module to track and benchmark antimicrobial use
- Explain how to implement antibiotic use reporting
- Review antibiotic use reporting resources

In addition, staff from the California Department of Public Health will discuss assistance for hospitals, including:

- Technical assessment of hospitals' IT infrastructure and antibiotic use reporting readiness
- Step-by-step antibiotic use implementation plans
- An antibiotic use verification and validation toolkit
- A statewide collaborative forum to discuss progress and barriers to implementation with other participating hospitals

Registration is available online. For more information, contact Debby Rogers, vice president clinical performance and transformation, at drogers@calhospital.org or Barbara Roth at broth@calhospital.org.

Attachments: Sterile Compounding Requirement Webinar information
Antibiotic Use Webinar information

DR:br

CHA **Webinars**

Sterile Compounding Pharmacies: Guidance for Implementing Regulatory Changes Webinar

Tuesday, April 17, 2018
10:00 – 11:30 a.m., Pacific Time

In January 2017, the California Board of Pharmacy set new regulatory requirements for hospitals performing sterile compounding. Last year's sterile compounding webinar addressed both the "what" and "why" of this new regulation, including application for a waiver. This webinar will go beyond the waiver and provide information on "how" to navigate the processes of each regulatory agency in order to meet the regulatory requirements.

Experts from California's Board of Pharmacy, Office of Statewide Health Planning and Development (OSHPD) Facilities Development Division and the Department of Public Health (CDPH) Licensing and Survey Program will discuss steps to achieve approvals at the various agencies, and share common pitfalls that hinder compliance with the new requirements.

Recommended for

Chief operating officers, chief compliance officers, chief pharmacists, plant managers, construction directors and managers, architects and engineers, inspectors of record.

Agenda

Office of Statewide Health Planning and Development — Guide to Compliance

- Highlights from the Advisory Guide Series
- Timelines, processes, and key benchmarks to ensure a successful sign-off
- Common errors and how to avoid them

Board of Pharmacy — Setting Expectations

- Background on the waiver application process
- Strategies for temporary permit, relocating pharmacy, mobile units
- Sequence of events for obtaining licensure

CDPH Centralized Applications Unit — Licensing Application Process

- Documentation requirements and submission deadlines
- Establishing your licensure timelines and expectations

CDPH Pharmacy Consultant Review — Preparing for Final Reviews

- How to prepare for a survey and site visit
- Documentation needed prior to pharmacy consultant review

Faculty

Tina Paschke, Branch Chief, Center for Health Care Quality, Licensing & Certification Program, California Department of Public Health

Diana Scaturro, Supervisor, Rapid Review Unit, Facilities Development Division, Office of Statewide Health Planning and Development

Christine Acosta, PharmD, Supervising Inspector, California State Board of Pharmacy

Cari Lee, Pharm.D, Pharmaceutical Consultant, California Department of Public Health

CHA **Webinars**

Registration Form

Webinar: Sterile Compounding Pharmacies: Guidance for Implementing Regulatory Changes

Tuesday, April 17, 2018
10:00 – 11:30 a.m., Pacific Time

Tuition

Members* — $135 (per connection)
Nonmembers —** $185 (per connection)
Multiple staff can participate from one location for one tuition fee.
*Members are CHA member hospitals, CHA associate members and government agencies. **Nonmembers are limited to non-hospital health care providers, clinics, post-acute facilities, and consultants, insurance companies, law firms and other entities that serve hospitals. Education programs and publications are a membership benefit and are not available to eligible nonmember California hospitals.

Continuing Education

CEs are complimentary and available for the registrant only. Full participation in the webinar is required to receive professional continuing education (CE) credit. Registrant must complete an online survey, attest to participation and, when required, provide a professional license number.

Compliance — This education activity has been submitted to the Compliance Certification Board (CCB)® and is currently pending their review for approval of CCB CEUs.

Healthcare Executives — CHA is authorized to award 1.5 hours of pre-approved ACHE Qualified Education credit for this program toward advancement, or recertification, in the American College of Healthcare Executives. Participants in this program who wish to have the continuing education hours applied toward ACHE Qualified Education credit must self-report their participation. To self-report, participants must log into their MyACHE account and select ACHE Qualified Education Credit.

How a Webinar Works

You only need a telephone and a computer with a web browser to participate. Audio for the seminar is accessed through a toll-free number (U.S. calls only). If multiple people will be listening to the program at your office, you can listen via speakerphone. The slide presentation is accessed on your computer via the web.

Confirmation and Instructions

Upon registration, you will receive a confirmation email that includes a link to a web page containing complete instructions for accessing the program and presentation materials.

Three Ways to Register

Online:
www.calhospital.org/sterile-compounding-web

Mail:
Complete this registration form.
CHA Education
1215 K Street, Suite 800
Sacramento, CA 95814
Make check payable to CAHHS/CHA

Fax:
Complete this registration form.
Fax credit card order to (916) 552-7506

☐ Member ($135) ☐ Nonmember ($185)

Name:

Title:

Organization:

Address:

City: State: Zip:

Telephone:

Email (required):

Cc Email (optional):

Payment:
☐ Check enclosed. Make check payable to CAHHS/CHA and include registrant's name.
☐ Credit Card (check one): ☐ VISA ☐ MC ☐ AMEX

Card Number:

Cardholder:

Expiration Date: Security Code:

Billing Address:

City: State: Zip:

Authorizing Signature:

Cancellation Policy

A $50 nonrefundable processing fee will be retained for each cancellation. Cancellations must be made in writing seven days prior and emailed to education@calhospital.org. No refunds will be made after this date. In the unlikely event the program is cancelled, paid registrants will receive a full refund within 30 days.

CALIFORNIA HOSPITAL ASSOCIATION

For more information, call (916) 552-7637

Upcoming Webinar to Focus on Strengthening Antibiotic Stewardship Programs

April 5, 9-10 a.m.
Register online: www.surveymonkey.com/r/AntiboticUseWebForum

The California Hospital Association, the Hospital Quality Institute and the California Department of Public Health invite you to an upcoming webinar that will explain the National Healthcare Safety Network's (NHSN) tool for helping hospitals track their antibiotic use.

California law requires hospitals to implement an antimicrobial stewardship policy that meets guidelines established by the federal government and professional organizations. The Centers for Disease Control and Prevention recommends tracking antibiotic use to identify ways to improve and assess the impact of antimicrobial stewardship efforts. To help in those efforts, NHSN has developed an antibiotic use module that hospitals can use to track and analyze their antibiotic use data, and compare it to other U.S. hospitals. Benchmarking to national risk-adjusted data has been helpful in reducing health care-associated infections and may play an important role in antimicrobial stewardship.

The webinar will:

- Introduce the NHSN antibiotic use module
- Discuss the benefits of using the module to track and benchmark antimicrobial use
- Explain how to implement antibiotic use reporting
- Review antibiotic use reporting resources

In addition, staff from the California Department of Public Health will discuss assistance for hospitals, including:

- Technical assessment of hospitals' IT infrastructure and antibiotic use reporting readiness
- Step-by-step antibiotic use implementation plans
- An antibiotic use verification and validation toolkit
- A statewide collaborative forum to discuss progress and barriers to implementation with other participating hospitals

Questions? Contact Debby Rogers, CHA vice president clinical performance and transformation, at drogers@calhospital.org or Barbara Roth at broth@calhospital.org.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: AHA Leadership Summit – Abstract Submission

SUMMARY

Kathy Ghomeshi, Pharm.D., MBA, BCPS, Sarah Stephens, Pharm. D. BCPS, and Rita Shane, Pharm.D., FASHP, FCSHP are to be congratulated for their extra efforts in submitting abstracts to the July, 2018 AHA Leadership Summit meeting. Their submissions were three of over 400 submittals.

ACTION

- Special thanks to Kathy, Sarah and Rita for their last minute efforts for submission.

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Legislation

SUMMARY

There are a number of pharmacy bills being monitored by CHA. Many of the bills cross multiple topics. Below highlights bills that CHA is following.

A. CURES
   1. AB 1752 (Low) – Adds Schedule IV drugs to the system
   2. AB 2086 (Gallagher) – Provider patient request from system
   3. SB 1240 (Stone) – Prescription plus ICD-9

B. Opioid
   1. AB 2741 (Burke) – Opioid Rx to a minor for no more than 5 days except in specific incidents
   2. AB 2760 (Wood) – Requires a prescriber to prescribe NARCAN for patients when certain conditions met along with education
   3. AB 1998 (Rodriguez) – prohibits provider from more than 3 day supply of opioid unless specified, requires reporting and other additional activity for chronic pain RX.
   4. AB 1229 (Stone) – Opioid education before RX – (retail?)

C. Pharmacy
   1. AB 2037(Bonta) – ADD in remote site to authorize remote site to provide pharmacy services to covered entities that are eligible for 340B discount programs
   2. **SB 1373 (Stone)** – Hospitals with less than 100 beds to have a part time employed pharmacist- more than 100 beds to have 1 FT pharm & additional on pro rata basis – (bill attached)
   3. **SB 1254 (Stone)** – Medication profiles for high risk patients (bill attached)
   4. **SB 1286 (Stone)** – Pharm tech 1:4 (retail?) (bill attached)
   5. **SB 1442 (Newman)**- Pharmacist operating alone in pharmacy (retail?) (bill attached)
   6. **SB 1447 (ADD Requirements) –** ADD and ADPD requirements (bill attached)

D. Medi-Cal/Payment
   1. SB 1322 (Stone) – Comprehensive Medication Management (bill attached)
   2. SB 1264 (Stone) – Hypertension Medication Management (bill attached)
   3. SB 1285 (Stone) – Advanced Practice Pharmacist (bill attached)

ACTION

- Please review bills and be prepared to discuss to inform CHA on bill positions.

Attachments: SB 1373
SB 1254
Information pertaining to SB 1254
SB 1286
SB 1442
SB 1447
SB 1322
SB 1264
SB 1285

BJB:br

SENATE BILL No. 1373

Introduced by Senator Stone

February 16, 2018

An act to add Section 1250.10 to the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 1373, as introduced, Stone. General acute care hospitals: minimum levels of pharmaceutical staff.

(1) Existing law requires the State Department of Public Health to license and regulate general acute care hospitals. Existing regulations require a hospital with a capacity of 100 or more beds to have a pharmacy on the premises that is licensed by the California State Board of Pharmacy. Existing regulations require a hospital having fewer than 100 beds to comply with other licensing requirements enforced by the California State Board of Pharmacy. Existing law requires general acute care hospitals to comply with specific statutory provisions for standards of care and regulations promulgated by the department, and a violation of these provisions or regulations is a crime.

This bill would require a general acute care hospital licensed by the department to employ, at a minimum, one full-time pharmacist for every 100 licensed beds, and for additional licensed beds, employ additional pharmacists on a pro rata basis. The bill would require a general acute care hospital that is licensed for less than 100 beds to employ one pharmacist on at least a part-time basis.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. Section 1250.10 is added to the Health and Safety Code, to read:

1250.10. A general acute care hospital licensed pursuant to this chapter shall employ, at a minimum, one full-time pharmacist for every 100 licensed beds, and for additional licensed beds, shall employ additional pharmacists on a pro rata basis. A general acute care hospital that is licensed for less than 100 beds shall employ one pharmacist on at least a part-time basis.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

SENATE BILL No. 1254

Introduced by Senator Stone

February 15, 2018

An act to add Section 4118.5 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1254, as introduced, Stone. Hospital pharmacies: medication profiles for high-risk patients.

Existing law, the Pharmacy Law, a willful violation of which is a misdemeanor, provides for the licensure and regulation of pharmacists, intern pharmacists, pharmacy technicians, and pharmacies by the California State Board of Pharmacy. Existing regulatory law requires a pharmacy to maintain medication profiles on all patients who have prescriptions filled at that pharmacy, except under specified circumstances.

This bill would require a pharmacist at a hospital pharmacy to obtain an accurate medication profile for each high-risk patient upon admission and discharge of the patient. The bill would authorize an intern pharmacist or a pharmacy technician to perform that function if the intern pharmacist or pharmacy technician has successfully completed training and proctoring by a pharmacist and where a quality assurance program is used to monitor competency. The bill would require the board to adopt regulations specifying the training and proctoring required to be completed.

By expanding the scope of a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. Section 4118.5 is added to the Business and Professions Code, to read:

4118.5. (a) At a hospital pharmacy, a pharmacist shall obtain an accurate medication profile for each high-risk patient upon admission and discharge of the patient. A pharmacy technician or a pharmacy intern may perform this function if the pharmacy technician or pharmacy intern has successfully completed training and proctoring by a pharmacist and where a quality assurance program is used to monitor competency.

(b) The board shall adopt regulations specifying the training and proctoring required to be completed pursuant to this section.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Proposed Legislation – Acute Care Hospital Medication Safety

Quick Summary

Up to 70% of patients have errors on their medication lists or histories when they are admitted to hospitals and up to 59% of these have the potential to cause moderate to severe harm. A recent study in high risk patients demonstrated 8 errors per patient's admission medication list which resulted in an average of 3 errors per patient when they were hospitalized. There was an 80% reduction in medication errors when pharmacists and trained technicians obtained medication lists in comparison to standard care and the risk of patient harm was also significantly reduced. Pharmacy staff have the training and advanced skills to focus on the accuracy and appropriateness of medications. Additionally, electronic health records enable continuation of orders from the medication list even if they are incorrect. Medication errors lead to adverse drug events which can increase the length of stay by 3 days. Twenty percent (20%) of hospitalizations are medication-related and in California, a recent report indicates that 21.7% of Medicare patients on drugs known as high risk for harmful events were readmitted. At discharge, up to 80% of patients have at least one medication error and patients with errors had a higher 30-day hospital readmission rate when pharmacists did not correct these discharge errors. Currently, the lack of defined responsibility to ensure medication lists are accurately obtained at hospital admission and discharge places patient at significant risk for harm. Pharmacy staff in acute care hospitals have the expertise to perform this essential function.

Define in statute medication safety services for hospitals that delineate responsibility of the pharmaceutical services for obtaining medication lists for high risk patients upon admission and discharge.

Fiscal Effect:

Cost Reduction by Preventing Harm

The cost of harm for high risk patients in California for medication-related readmissions is at least 9 billion/year (Source: 2015 OSHPD hospital data for patient discharges based on a 20% risk for adverse events and readmissions in Medicare, MediCal and indigent patients and a 5% risk for other third party patients. https://www.oshpd.ca.gov/HID/Hospital-Financial-Trends.html, accessed 12/29/17)

Analysis

- Despite over two decades since the Institute For Healthcare Improvement's report ("To Err is Human") and its follow-up report ""Crossing the Quality Chasm") on medical errors in hospitals, harm due to medications still occurs.
- **Hospital admissions**
    - Up to 20% of admissions are medication-related due to the prevalence of chronic diseases, increasing number of new and complex medications and factors such as age, literacy and access.
    - The most recent statewide data on Medicare beneficiaries on high risk medications indicates a readmission rate of 21.7% representing approximately 58,000

readmissions for the 12 month period ending June 2017 (source: CMS Health Services Advisory Group 2017 Quarter 2 report)
    - Patients on 6 or more discharge medications are at a significantly higher risk of 30-day readmissions (26% higher odds)
- **Errors upon hospital admission**
    - Examples of serious or life-threatening errors include an order for chemotherapy daily instead of weekly, an order for high dose of an opioid in a patient not on opioids before hospitalization and the lack of a blood thinner in a patient with a blood disorder at high risk for a life-threatening blood clots
    - Errors occur in up to 70% of patients. A variety of individuals with varying levels of training obtain medication lists of histories across different settings, i.e., doctor's offices, skilled nursing facilities, hospitals, etc. They enter the medications including dose, route and frequency into electronic health records which then can be continued during the hospitalization or at discharge even if the medication information is incorrect. For example, in doctors' offices, medication information is often entered into the electronic health record by credentialed medical assistants who may have only had 5 hours of training in entering orders that does not include medications.
    - High risk patients (i.e., patients on multiple medications and those with chronic diseases such as hypertension, diabetes, asthma, especially elderly patients and patients on medications such as insulin, blood thinners, transplant or HIV drugs) have an average of 8 errors on their admission medication lists which leads to 3 errors per patient during their hospitalization. In one study, only 5.3% of patients 65 year or older on $\geq$5 medications had an accurate medication list.
    - One third of medication orders in hospital patients have errors and 85% originate from the medication list or history. Up to 59% of these errors can cause harm. If left uncorrected, these errors lead to adverse drug events and readmissions. Adverse drug events increase hospitalization by 3.1 days and cost over $3000.
- **Errors at discharge**
    - At discharge, up to 80% of patients have at least 1 medication error.
    - Patients with discharge medication errors have a higher 30-day hospital readmission rate when pharmacists do not correct these errors.
    - Having pharmacists provide discharge medication management reduced errors by 46.5% and there was a 9.6% reduction in high or extreme (life-threatening) errors.
- Since the establishment of the MediCare Part D drug benefit in 2006, increases in the number of individuals with healthcare coverage under the Affordable Care Act and increases in the MediCal population, more patients have access to and are receiving medications.
- The Centers for Disease Control, the Surgeon General of the US Public Health Service and other health care and public policy experts and organizations have recommended that incorporating more pharmacists with medication-focused practice education and training

in to multi-professional health care teams will improve the public's quality and access to safe and affordable healthcare.

- The Solution – Add a new section to California Business and Professions Code, 1707.1 to establish pharmacist's responsibility in acute care hospitals for obtaining an accurate list of the patient's current medications on admission, or promptly thereafter and upon discharge.
    - Proposed Changes in Statutory Language to California Business and Professions Code, 1707.1 add new section as follows:
    - *1701.1.b In hospitals, the pharmacist is responsible for obtaining an accurate medication profile for high risk patients upon admission and discharge. This function can be completed by technicians and interns who have successfully completed training and proctoring by pharmacists and where a quality assurance program is used to monitor competency.*

Full text of 1707.1. Duty to Maintain Medication Profiles (Patient Medication Records).

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.
(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.
(A) The patient's full name and address, telephone number, date of birth (or age) and gender;
(B) For each prescription dispensed by the pharmacy:
(1). The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;
(2). The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;
(3). The date on which a drug was dispensed or refilled;
(4). The prescription number for each prescription; and
(5). The information required by section 1717.
(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.
(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

Up to 70% of Patients Have Errors on Their Medication Lists

Leveraging pharmacy staff prevents harm and increases clinician time for patient care functions

Problem

- ❑ 20% of admissions are medication-related[1]
- ❑ High risk patients have 8 errors on admission medication lists.[2]
- ❑ Only 5.3% of patients 65 year or older on ≥5 medications have accurate lists[3]
- ❑ One third of inpatient orders have errors and 85% originate from the medication history[4]
- ❑ Up to 59% of errors can cause harm[5]
- ❑ Up to 80% of patients have at least 1 medication error at discharge[6]

Solution

On admission, studies demonstrate increased accuracy of medication lists obtained by pharmacy staff vs usual care

- ❑ Accuracy rates: Nurses, 20%; Hospitalists, 50%; Technicians, 100% [7]
- ❑ Nurses 14% vs pharmacy technicians 94% ($p<0.0001$)[8]

At discharge, pharmacists identified errors in medication lists in 49% of patients and problems in an additional 16% vs usual care[9]

Business Case

Cost of Harm

- ❑ Cost of adverse drug event (ADE): $2,262- $5,790[7,10-13]
- ❑ Increased length of stay due to ADE: 3.1 days[13]
- ❑ Cost/readmission ~ $12,300-13,800[14]

Benefits

- ❑ 75% reduction in ADEs[7]
- ❑ 41 minutes of nursing time saved/patient [1]
- ❑ Cost-effective to utilize technicians for medication histories; $830,000[7]
- ❑ Patients have an accurate medication list upon discharge
- ❑ Reduced readmissions
- ❑ Enables clinicians to practice at the highes level of their license and training

Recommendation: For high risk patients, pharmacy will ensure the accuracy of the medication list at admission and discharge

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Cost of Harm Due to Incorrect Medication Lists

Calibrating cost of harm:

Medication-related readmissions

The cost of harm for high risk patients in California for medication-related readmissions is at least 9 billion/year (Source: 2015 OSHPD hospital data for patient discharges based on a 20% risk for adverse events and readmissions in Medicare, MediCal and indigent patients and a 5% risk for other third party patients. https://www.oshpd.ca.gov/HID/Hospital-Financial-Trends.html, accessed 12/29/17)

Rationale:

- 20% of readmissions are medication-related (multiple sources)
- 21.7% readmissions rate for Medicare patients in California on drugs known as high risk for harmful events were readmitted in the 12 month period ending Quarter 2 2017 (CMS QIO:Health Services Advisory Group)
- Average LOS in California is 5 days
- Average cost/day in California is $3400

Adverse drug events

Cost of harm related to adverse drugs events in California for Medicare patients is over $3 billion annually (based on 2015 OSHPD hospital data above)

Rationale:

- 30% of Medicare inpatients experienced an ADE in 2011 (Dept of Health and Human Services Health Research & Educational Trust (February 2017). Adverse Drug Events Change Package: 2017 Update. Chicago, IL: Health Research & Educational Trust. www.hret-hiin.org, accessed 1/5/18)
- High risk pts have 8 errors/pt on their medication lists upon admission
- 1/3 of errors originate from medication list and up to 59% can cause harm-adjusted to 30% harm
- Adverse drug events increase length of stay by 3.1 days (AHRQ Patient Safety Network, 2012)

SENATE BILL No. 1286

Introduced by Senator Pan
(Principal coauthor: Senator Skinner)
(Coauthor: Senator Stone)

February 16, 2018

An act to amend Section 4115 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1286, as introduced, Pan. Pharmacy technicians.

The Pharmacy Law provides for the licensure and regulation of pharmacists, pharmacy technicians, and pharmacies by the California State Board of Pharmacy in the Department of Consumer Affairs. That law authorizes a pharmacy technician to perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. That law makes a pharmacist responsible for the duties performed under his or her supervision by a technician and allows a pharmacy with only one pharmacist to have only one pharmacy technician performing those tasks.

This bill would allow a pharmacy with only one pharmacist to have no more than 4 pharmacy technicians performing those tasks.

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. Section 4115 of the Business and Professions Code is amended to read:

4115. (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f) (1) A pharmacy with only one pharmacist shall have no more than ~~one~~ *four* pharmacy ~~technician~~ *technicians* performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed ~~2:1,~~ *4:1,* except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio

shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

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SENATE BILL No. 1442

Introduced by Senator Newman

February 16, 2018

An act to add Section 4113.5 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1442, as introduced, Newman. Pharmacies: staffing.

Under the Pharmacy Law, the California State Board of Pharmacy licenses and regulates the practice of pharmacy and the conduct of a pharmacy in this state. A knowing violation of that law is a crime.

This bill would prohibit a pharmacy from requiring a pharmacist to engage in the practice of pharmacy unless the pharmacist is assisted at all times by either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located. By imposing a new requirement on pharmacies, the knowing violation of which would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. The Legislature finds and declares as follows:

(a) Licensed pharmacists are health care professionals whose training and experience play a vital role in protecting public health.

(b) Pharmacists are legally and ethically bound to advise their patients, physicians, and other health practitioners on the selection, dosages, interactions, and side effects of medications, as well as monitor the health and progress of those patients to ensure that they are using their medications safely and effectively.

(c) Pursuant to Section 4001.1 of the Business and Professions Code, the highest priority for the regulation of pharmacists is protection of the public.

(d) The duties of a pharmacist include preventing the abuse of prescription opioids. In August 2013, the California State Board of Pharmacy revoked the licenses of both a pharmacy and its pharmacist because the pharmacist failed to comply with corresponding responsibility requirements in the distribution of opioid drugs. Four patients died as a result of the pharmacist's actions.

(e) The California State Board of Pharmacy's decision and order in that case identifies "red flags" that pharmacists are legally obligated to watch for before filling such a prescription. These "red flags" include:

(1) Irregularities on the face of the prescription itself.

(2) Nervous patient demeanor.

(3) The age or presentation of patient (e.g., youthful patients seeking chronic pain medications).

(4) Multiple patients all with the same address.

(5) Multiple prescriptions for the same patient for duplicate therapy.

(6) Requests for early refills of prescriptions.

(7) Prescriptions written for an unusually large quantity of drugs.

(8) Prescriptions written for duplicative drug therapy.

(9) Initial prescriptions written for strong opiates.

(10) Long distances traveled from the patient's home to the prescriber's office or to the pharmacy.

(11) Irregularities in the prescriber's qualifications in relation to the type of medications prescribed.

(12) Prescriptions that are written outside of the prescriber's medical specialty.

(13) Prescriptions for medications with no logical connection to an illness or condition.

(f) In 2013, the Governor signed legislation that significantly expanded the scope of practice of pharmacists. Pharmacists are now, without a prescription from a physician, permitted to vaccinate their patients, aid them in the administration of self-administered hormonal contraception, and provide nicotine replacement products. The California State Board of Pharmacy has by regulation promulgated extensive protocols governing each of these new duties.

(g) For self-administered hormonal contraception, the California Code of Regulations requires a pharmacist to complete the following steps:

(1) Ask the patient to use and complete the self-screening tool.

(2) Review the self-screening answers and clarify responses if needed.

(3) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.

(4) Before furnishing self-administered hormonal contraception, ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.

(5) When a self-administered hormonal contraceptive is furnished, provide the patient with appropriate counseling and information on the product furnished, including:

(A) Dosage.

(B) Effectiveness.

(C) Potential side effects.

(D) Safety.

(E) The importance of receiving recommended preventative health screenings.

(F) That self-administered hormonal contraception does not protect against sexually transmitted infections.

(h) For nicotine replacement products, the California Code of Regulations requires a pharmacist to complete the following steps:

(a) Review the patient's current tobacco use and past quit attempts.

(b) Ask the patient screening questions related to pregnancy, heart attacks, history of heart ailments, chest pain, or nasal allergies.

(c) Review the instructions for use with every patient using a nicotine replacement product.

(i) For vaccines, Section 1746.4 of Title 16 of the California Code of Regulations requires a pharmacist to notify each patient's primary care provider of any vaccine administered to the patent, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider.

(j) Notwithstanding the number, complexity, and importance of a pharmacist's duties, including those new obligations described above, the Legislature has heard uncontradicted testimony that licensed pharmacists are left alone for indeterminate periods of time in the pharmacy and are, simultaneously, required by such establishments to perform nonpharmacist functions such as staffing cash registers and assisting consumers in purchasing prescriptions, groceries, and other nonpharmacy goods. Survey information of pharmacists working in pharmacies reinforces the testimony.

(k) Staffing inadequacies like these interfere with the professional responsibilities of licensed pharmacists, including those requiring time and professional judgment listed above, and pose a risk to the public health because it leaves licensed pharmacists an insufficient amount of time to perform their licensed functions safely and lawfully, exercise their professional discretion, and comply with their legal and ethical obligations to protect the health and well-being of patients.

SEC. 2. Section 4113.5 is added to the Business and Professions Code, to read:

4113.5. A pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy unless the pharmacist is assisted at all times by either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located. This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

the meaning of Section 6 of Article XIII B of the California Constitution.

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SENATE BILL No. 1447

Introduced by Senator Hernandez

February 16, 2018

An act to amend Sections 4008 and 4400 of, to add Section 4017.3 to, to add Article 25 (commencing with Section 4427) to Chapter 9 of Division 2 of, and to repeal Section 4105.5 of, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1447, as introduced, Hernandez. Pharmacy: automated drug delivery systems: licensing.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy, within the Department of Consumer Affairs, to license and regulate the practice of pharmacy. Existing law makes any violation of the Pharmacy Law punishable as a crime.

Existing law generally requires a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system (ADDS) to register the system, as provided, and authorizes the pharmacy to use the ADDS only if certain conditions are satisfied. Existing law authorizes the board to prohibit a pharmacy from using an ADDS if the board determines that those conditions are not satisfied. Existing law exempts from these requirements an ADDS operated by a licensed hospital pharmacy for doses administered in a facility operated under a consolidated license. Existing law specifies additional conditions for an ADDS located in a licensed clinic or a health facility, as defined. Existing law authorizes a pharmacy or licensed wholesaler that is also an emergency medical services provider agency to restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system that is licensed by the board, as provided. Existing law authorizes an inspector employed by the board

to enter specified locations to inspect those locations for compliance with the Pharmacy Law.

This bill would repeal the general ADDS provisions. The bill instead would prohibit an ADDS unit from being installed or operated in the state unless specified requirements are met, including a license for the ADDS unit issued by the board to the holder of a current, valid, and active pharmacy license, and would require the pharmacy holding the license to complete periodic self-assessments. The bill would limit the placement and operation of an ADDS unit to specified locations, including a licensed pharmacy, a licensed health facility, a licensed clinic, or a specified medical office. The bill would require the pharmacy holding the ADDS license to own the drugs and devices located within the ADDS unit and would prescribe specified stocking and transfer requirements for those drugs and devices. The bill would require additional conditions for automated patient dispensing systems, as defined. The bill would also authorize a pharmacy inspector employed by the board to enter the location, or proposed location, of an ADDS unit to inspect the location pursuant to these provisions. Because a violation of the Pharmacy Law is punishable as a crime, the bill would expand the scope of an existing crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. Section 4008 of the Business and Professions Code is amended to read:

4008. (a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250

of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

(g) A pharmacy inspector employed by the board may enter the location, or proposed location, of an automated drug delivery system to inspect that automated drug delivery system pursuant to Article 25 (commencing with Section 4427).

SEC. 2. Section 4017.3 is added to the Business and Professions Code, to read:

4017.3. (a) "Automated Drug Delivery System" (ADDS) has the same meaning as paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.

(b) An "Automated Unit Dose System" (AUDS) is an ADDS unit from which health care providers with appropriate authority retrieve unit doses of drugs for administration to patients.

(c) An "Automated Patient Dispensing System" (APDS) is an ADDS unit from which drugs and devices may be dispensed to patients pursuant to authorization by a pharmacist.

SEC. 3. Section 4105.5 of the Business and Professions Code is repealed.

~~4105.5. (a) For purposes of this section, an "automated drug delivery system" has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.~~

~~(b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.~~

~~(c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:~~

~~(1) Use of the automated drug delivery system is consistent with legal requirements.~~

~~(2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.~~

~~(3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.~~

~~(4) The pharmacy license is unexpired and not subject to disciplinary conditions.~~

~~(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.~~

~~(e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license under Section 1250.8 of the Health and Safety Code shall be exempt from the requirements of subdivision (b).~~

SEC. 4. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the

Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident

sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) The fee for an automated drug delivery system license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250). The annual renewal of the license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250).

~~(z)~~

(aa) This section shall become operative on July 1, 2017.

SEC. 5. Article 25 (commencing with Section 4427) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 25. Automated Drug Delivery System Units

4427. An ADDS unit shall not be installed or operated in the State of California unless it meets the requirements of this article.

4427.1. (a) An ADDS unit installed or operated in the State of California shall be licensed by the board.

(b) An ADDS license may only be issued to the holder of a current, valid, and active pharmacy license.

(c) A separate application and license shall be required for each ADDS unit.

(d) A pharmacy may only obtain five simultaneous ADDS licenses.

(e) Prior to issuance of the license, the board shall conduct a prelicensure inspection at the proposed location of the ADDS unit.

(f) The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not in good standing. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license may be submitted to the board.

(g) The holder of an ADDS license shall advise the board in writing within 30 days if the use of the ADDS unit is discontinued.

(h) The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license. The ADDS license is nontransferable.

(i) An ADDS unit operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to inpatients while in a facility operated under a license pursuant to Section 1250.8 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section.

4427.2. (a) An ADDS unit shall be placed and operated in an enclosed building at a location approved by the board.

(b) An ADDS unit may be placed and operated in any of the following locations:

(1) A pharmacy licensed by the board.

(2) A health facility as defined in Section 1250 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this Code.

(4) A medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and where drugs and devices are routinely dispensed pursuant to Section 4170.

4427.3. (a) Drugs and devices located within the ADDS unit shall be owned by the pharmacy holding that ADDS unit's license.

(b) The stocking and restocking of an ADDS unit shall be performed by licensed pharmacy staff unless otherwise specified by law.

(c) If drugs or devices are not immediately transferred into an ADDS unit upon arrival at the ADDS unit location, the drugs and devices shall be stored for no longer than 48 hours in a secured room. Upon retrieval of these drugs and devices from secured storage, an inventory shall be taken to detect any losses or overages.

4427.4. When an APDS unit is used to dispense drugs or devices directly to patients, the following conditions shall additionally apply:

(a) A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(b) All drugs and devices dispensed from an APDS unit shall be accompanied by a consultation conducted by a pharmacist licensed by the board and consistent with Duty to Consult regulations promulgated by the board.

(c) The APDS unit shall include a notice, prominently posted on the APDS unit, providing the name of the pharmacy that holds that APDS unit's license. The notice shall comply with Notice to Consumers regulations promulgated by the board.

(d) The labels on all medications dispensed by the APDS unit shall comply with Section 4076 and with Patient-Centered Labels of Prescription Drug Containers Requirement regulations promulgated by the board.

4427.5. (a) The pharmacist-in-charge of a pharmacy holding an ADDS unit license shall complete a self-assessment, annually or upon designation of a new pharmacist-in-charge, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS unit.

(b) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AMENDED IN SENATE MARCH 22, 2018

SENATE BILL No. 1322

Introduced by Senator Stone

February 16, 2018

An act to add Section 14132.08 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

SB 1322, as amended, Stone. Medi-Cal: comprehensive medication management.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Existing law provides for a schedule of benefits under the Medi-Cal program, which includes outpatient prescription drugs, subject to utilization controls and the Medi-Cal list of contract drugs.

This bill would provide that comprehensive medication management (CMM) services, as defined, are a covered benefit under the Medi-Cal program, and would require those services to include, among other things, the development and implementation of a written medication treatment plan that is designed to resolve documented medication therapy problems and to prevent future medication therapy problems. The bill would require the department to evaluate the effectiveness of CMM on quality of care, patient outcomes, and total program costs, as specified.

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. Section 14132.08 is added to the Welfare and Institutions Code, to read:

14132.08. (a) (1) Comprehensive medication management (CMM) services are covered under the Medi-Cal program.

(2) (A) For purposes of this section, "comprehensive medication management" means the process of care that ensures each beneficiary's medications, whether they are prescription drugs and biologics, over-the-counter medication, or nutritional supplements, are individually assessed to determine that each medication is appropriate for the beneficiary, effective for the medical condition, and safe given the comorbidities and other medications being taken, and all medications are able to be taken by the patient as intended.

(B) The goals of CMM are to improve quality outcomes for beneficiaries and to lower overall health care costs by optimizing appropriate medication use linked directly to achievement of the clinical goals of therapy.

(b) *(1)* CMM services shall be offered to a beneficiary who has been identified ~~by a treating prescriber~~ as high risk for ~~medication-related problems~~ *poor health outcomes associated with medications, or as high risk for medication-related problems,* and who has one or more chronic diseases.

(2) The department shall establish the criteria to identify high risk for poor health outcomes associated with medications and the criteria to identify high risk for medication-related problems. The department shall base the criteria on peer-reviewed, evidence-based medical practice.

(c) Utilizing the clinical services of a ~~primary care physician or~~ pharmacist, working in collaboration with other appropriate providers and in direct communication with the beneficiary, CMM services that are provided pursuant to this section shall include the following services:

(1) Assessment of the beneficiary's health status, including discussing the beneficiary's personal medication experience and preferences, and documenting the beneficiary's actual use patterns of all prescription drugs and biologics, over-the-counter medications, and nutritional supplements.

(2) Documentation of the beneficiary's current clinical status and clinical goals of therapy for each identified chronic condition for which a medication therapy is indicated, such as current blood pressure and the prescriber's clinical goals of therapy in a hypertensive patient.

(3) Assessment of each medication for appropriateness, effectiveness, safety, and adherence, with a focus on achievement of the desired clinical and beneficiary goals.

(4) Identification of all medication therapy problems.

(5) Development and implementation, in collaboration with the beneficiary, of a written medication treatment plan that is designed to resolve documented medication therapy problems and to prevent future medication therapy problems, including any additions, deletions, or adjustments to a medication treatment plan by, or in collaboration with, the treating prescriber or primary care physician, that may be needed to achieve optimal therapeutic outcomes.

(6) Verbal education and training, information, support services, and resources designed to enhance the beneficiary's adherence to, and appropriate use of, medication.

(7) Follow-up evaluation and monitoring with the beneficiary to determine the effects of any changes made to a beneficiary's medication treatment plan, reassess actual outcomes, and recommend or implement further therapeutic changes necessary to achieve desired clinical outcomes.

(d) The typical intervention for a beneficiary receiving CMM services shall include an average of ~~three to four~~ *eight* visits per year with a CMM primary care physician or pharmacist, as appropriate, to continually monitor and evaluate medication therapy progress and problems, and to recommend resolutions or to make changes consistent with a collaborative practice agreement.

(e) The department shall evaluate the effectiveness of CMM on quality of care, patient outcomes, and total program costs, and shall include a description of any savings generated under the Medi-Cal program that can be attributed to the coverage of CMM services, including the effect on emergency room, hospital, and other provider visit costs. The department may utilize patient and

prescriber surveys to assess the acceptance of, and perceived value added by, CMM services.

O

AMENDED IN SENATE MARCH 21, 2018

SENATE BILL **No. 1264**

Introduced by Senator Stone

February 15, 2018

An act *to amend Section 4052.6 of the Business and Professions Code, and to amend Section 14132.968 of the Welfare and Institutions Code,* relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

SB 1264, as amended, Stone. Medi-Cal: hypertension medication ~~management:~~ *management services: advanced practice* pharmacists.

Existing law establishes the Medi-Cal program, administered by the State Department of Health Care Services, under which qualified low-income persons receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Existing law provides for a schedule of benefits under the Medi-Cal program, which includes ~~outpatient prescription drugs, subject to utilization controls and the Medi-Cal list of contract drugs.~~ *pharmacist services, subject to approval by the federal Centers for Medicare and Medicaid Services. Under existing law, covered pharmacist services include, but are not limited to, furnishing travel medications, initiating and administering immunizations, and providing tobacco cessation counseling and furnishing nicotine replacement therapy.*

~~The Pharmacy Law provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. The law specifies the functions pharmacists are authorized to perform, including to administer, orally or topically, drugs and biologicals pursuant to a prescriber's order, and to administer immunizations pursuant to a protocol with a prescriber.~~

~~Existing law authorizes a pharmacist to administer drugs and biological products that have been ordered by a prescriber, and to perform other functions, including, among other things, to furnish self-administered hormonal contraceptives, nicotine replacement products, and prescription medications not requiring a diagnosis that are recommended for international travelers, as specified.~~

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law authorizes a pharmacist recognized by the board as an advanced practice pharmacist to perform specified tasks, including initiating, adjusting, or discontinuing drug therapy in a specified manner.

This bill would ~~declare the intent of the Legislature to enact legislation to revise provisions related to the Medi-Cal program and advanced practice pharmacy in order to authorize pharmacists to provide hypertension management services to Medi-Cal beneficiaries.~~ *additionally authorize an advanced practice pharmacist to provide hypertension medication management services, as defined, to Medi-Cal beneficiaries. The bill would authorize a pharmacist providing hypertension medication management services to access the state health information exchange and any relevant continuity of care documents maintained by a health facility, subject to applicable federal and state privacy and confidentiality laws. This bill would include hypertension medication management services as a covered pharmacist service under the Medi-Cal program.*

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 4052.6 of the Business and Professions Code is amended to read:

4052.6. (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:

(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.

(3) Refer patients to other health care providers.

(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

(6) Provide hypertension medication management services. For purposes of this section, "hypertension medication management services" means the furnishing of antihypertensive and related medications to Medi-Cal beneficiaries, as authorized by Section 14132.968 of the Welfare and Institutions Code, pursuant to a hypertension diagnosis by a health care practitioner who has prescribing authority and is qualified to make the diagnosis.

(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(f) A pharmacist who provides hypertension medication management services to Medi-Cal beneficiaries pursuant to paragraph (6) of subdivision (a) shall be authorized to access the state health information exchange and any relevant continuity of care documents maintained by a health facility, as defined in Section 1250 of the Health and Safety Code, subject to applicable federal and state privacy and confidentiality laws.

SEC. 2. Section 14132.968 of the Welfare and Institutions Code is amended to read:

14132.968. (a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel medications as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone hydrochloride as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering immunizations as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement therapy as authorized in Section 4052.9 of the Business and Professions Code.

(F) Providing hypertension medication management services pursuant to Section 4052.6 of the Business and Professions Code.

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section does not restrict or prohibit any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code,

the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

~~SECTION 1. The Legislature finds and declares as follows:~~

~~(a) Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States. Hypertension is one of the major contributors to CVD and the greatest directly attributable risk for death worldwide. Hypertension poses a considerable burden on the health care system at the individual level and in terms of the cost burden of approximately $48.6 billion annually.~~

~~(b) The federal Centers for Disease Control and prevention (CDC) estimate that 32.6 percent of adults in the United States have hypertension, 54 percent of which cases controlled and 45 percent that are uncontrolled. From 1999 to 2014, the prevalence of hypertensive adults remained unchanged. While the percentage of controlled hypertensive adults improved from 31.5 percent in 1999 to 54 percent in 2014, there was no meaningful change in percentage of controlled individuals during that time period, suggesting that a different, innovative approach to blood pressure control is needed.~~

~~(c) With the November 2017 release by the American Heart Association of new guidelines for hypertension, the prevalence of hypertension, according to new definitions, has increased to 46 percent of adults—over 100 million with a blood pressure above 130/80 mmHg.~~

~~(d) The United States Preventive Services Task Force and the American Heart Association have conducted systematic reviews and meta-analyses of team-based care, and have concluded that engaging pharmacists in the management of hypertension is key to achieving goal for uncontrolled patients.~~

~~(e) In addition, pharmacist-driven hypertension management programs have proven to be cost effective. The Collaboration Among Pharmacists and Physicians To Improve Outcomes Now (CAPTION) trial found that pharmacist-driven interventions produced statistically significant decreases in both systolic and diastolic blood pressure, at the low cost of $22.55 to increase hypertension control by one percentage point. The CAPTION trial also found that the intervention group had fewer physician visits, suggesting that a pharmacist-driven hypertension management program may allow primary care providers more time to focus on evaluating and diagnosing other complex health issues.~~

~~(f) The potential benefits of designating pharmacists as managers of hypertension medication therapy for Medi-Cal beneficiaries would include improved hypertension control and health status, and greater satisfaction with care for patients, as well as greater workplace satisfaction and better quality scores for providers. Additional benefits include lower costs and lower utilization of medical subspecialists.~~

~~(g) Current provisions authorizing advanced practice pharmacy do not authorize pharmacists to furnish or prescribe antihypertensive and related medications, or to have access to patient continuity of care documents, subject to applicable Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules.~~

~~(h) It is, therefore, the intent of the Legislature to enact legislation to revise provisions related to the Medi-Cal program and advanced practice pharmacy in order to authorize pharmacists to provide hypertension management services to Medi-Cal beneficiaries.~~

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98

SENATE BILL No. 1285

Introduced by Senator Stone

February 16, 2018

An act to add Section 1367.44 to the Health and Safety Code, to add Section 10123.204 to the Insurance Code, and to add Section 14132.09 to the Welfare and Institutions Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1285, as introduced, Stone. Health care coverage: advanced practice pharmacist.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Under existing law, one of the methods by which Medi-Cal services are provided is pursuant to contracts with various types of managed care plans.

This bill would require coverage for services provided by an advanced practice pharmacist, as defined, performed within the scope of his or her practice, including, but not limited to, comprehensive medication management (CMM) services, as defined, in a health care service plan contract and health insurance policy, and, to the extent that federal financial participation is available, in a Medi-Cal managed care plan. Because a willful violation of that provision by a health care service

plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. Section 1367.44 is added to the Health and Safety Code, to read:

1367.44. (a) Every health care service plan contract that is issued, amended, or renewed on or after January 1, 2019, shall provide coverage for services provided by an advanced practice pharmacist, as defined in Section 4016.5 of the Business and Professions Code, performed within the scope of his or her practice, including, but not limited to, comprehensive medication management (CMM) services.

(b) For purposes of this section, "comprehensive medication management" means the process of care that ensures each beneficiary's medications, whether they are prescription drugs and biologics, over-the-counter medication, or nutritional supplements, are individually assessed to determine that each medication is appropriate for the beneficiary, effective for the medical condition, and safe given the comorbidities and other medications being taken, and that all medications are able to be taken by the patient as intended.

(c) This section does not apply to a contract with a pharmacy benefit management company or a direct contract for only prescription dispensing or related services.

SEC. 2. Section 10123.204 is added to the Insurance Code, to read:

10123.204. (a) Every health insurance policy that is issued, amended, or renewed on or after January 1, 2019, shall provide coverage for services provided by an advanced practice pharmacist, as defined in Section 4016.5 of the Business and Professions Code, performed within the scope of his or her practice, including, but

not limited to, comprehensive medication management (CMM) services.

(b) For purposes of this section, "comprehensive medication management" means the process of care that ensures each beneficiary's medications, whether they are prescription drugs and biologics, over-the-counter medication, or nutritional supplements, are individually assessed to determine that each medication is appropriate for the beneficiary, effective for the medical condition, and safe given the comorbidities and other medications being taken, and that all medications are able to be taken by the patient as intended.

(c) This section does not apply to a contract with a pharmacy benefit management company or a direct contract for only prescription dispensing or related services.

SEC. 3. Section 14132.09 is added to the Welfare and Institutions Code, to read:

14132.09. (a) Services provided by an advanced practice pharmacist, as defined in Section 4016.5 of the Business and Professions Code, performed within the scope of his or her practice, including, but not limited to, comprehensive medication management (CMM) services, shall be a covered benefit in a Medi-Cal managed care plan.

(b) For purposes of this section, "comprehensive medication management" means the process of care that ensures each beneficiary's medications, whether they are prescription drugs and biologics, over-the-counter medication, or nutritional supplements, are individually assessed to determine that each medication is appropriate for the beneficiary, effective for the medical condition, and safe given the comorbidities and other medications being taken, and that all medications are able to be taken by the patient as intended.

(c) This section does not apply to a contract with pharmacy benefit management companies or a direct contract for only prescription dispensing or related services.

(d) This section shall be implemented only to the extent that federal financial participation is available.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or

infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CA AB 315

AUTHOR: Wood [D]
TITLE: Pharmacy Benefit Management
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/06/2017
LAST AMEND: 07/11/2017
DISPOSITION: Pending
FILE: A-39
LOCATION: Senate Inactive File
SUMMARY:

Requires pharmacy benefit managers to be registered with the Department of Managed Health Care. Requires the department to develop applications for the registration, and specifies certain information to be provided in those applications. Requires a pharmacy benefit manager to exercise a duty of good faith and fair dealing in the performance of its contractual duties to a purchaser. Requires a pharmacy benefit manager to notify a pharmacy network provider of certain contract changes.

STATUS:

09/07/2017 In SENATE. From third reading. To Inactive File.
INDEX: 39, 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 587

AUTHOR: Chiu [D]
TITLE: State Government: Pharmaceuticals: Procurement
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/14/2017
LAST AMEND: 07/12/2017
DISPOSITION: Pending
LOCATION: Senate Appropriations Committee
SUMMARY:

Requires the Department of General Services to convene the state Pharmaceutical Collaborative to address the rising cost of pharmaceuticals, coordinate best value clinical treatment protocols, leverage governmental efficiencies to achieve best value procurement, and negotiate with manufacturers for discounts on pharmaceuticals. Requires the participation of various agencies in the collaborative.

STATUS:

08/21/2017 In SENATE Committee on APPROPRIATIONS: Not heard.
INDEX: 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 937

AUTHOR: Eggman [D]
TITLE: Health Care Decisions: Order Of Priority
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/16/2017
LAST AMEND: 05/03/2017

DISPOSITION: Pending
LOCATION: Senate Health Committee
SUMMARY:

Provides that to the extent of a conflict between resuscitative measures and a patient's individual health care instruction, the most recent of the documents is effective. Deems a request regarding resuscitative measure signed by specified persons on behalf of the individual to be signed by the individual. Makes conforming changes.

STATUS:

06/01/2017 To SENATE Committees on HEALTH and JUDICIARY.
INDEX: 89, 9
ISSUES: DG, JG, LR*
LOBBYIST: BG
POSITION: F, X

CA AB 1751

AUTHOR: Low [D]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 01/03/2018
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Authorizes the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for the purposes of participating in interjurisdictional information sharing between prescription drug monitoring programs across state lines. Requires any agreement entered into by the department for those purposes to ensure that all access to data within the Controlled Substance Utilization Review and Evaluation System (CURES) complies with California law.

STATUS:

01/16/2018 To ASSEMBLY Committees on BUSINESS AND PROFESSIONS and PUBLIC SAFETY.
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F, X

CA AB 1752

AUTHOR: Low [D]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 01/03/2018
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Adds Schedule V controlled substances to the Controlled Substances Utilization Review and Evaluation System (CURES) database. Additionally authorizes the California State Board of Pharmacy, through regulation, to add additional medications to be tracked in the CURES database. Requires a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than one working day after a controlled substance is dispensed.

STATUS:

01/16/2018	To ASSEMBLY Committees on BUSINESS AND PROFESSIONS and PUBLIC SAFETY.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F, X

CA AB 1753

AUTHOR:	Low [D]
TITLE:	Controlled Substances: CURES Database
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/03/2018
DISPOSITION:	Pending
LOCATION:	Assembly Business and Professions Committee

SUMMARY:

Requires the Department of Justice to limit the number of security printers approved by the department to 3. Requires the prescription forms for controlled substance prescriptions to have a uniquely serialized number, in a manner prescribed by the department, and requires a printer to submit specified information to the department for all prescription forms delivered.

STATUS:

01/16/2018	To ASSEMBLY Committees on BUSINESS AND PROFESSIONS and PUBLIC SAFETY.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1998

AUTHOR:	Rodriguez [D]
TITLE:	Opioids: Prescription Limitations
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/01/2018
LAST AMEND:	03/12/2018
DISPOSITION:	Pending
COMMITTEE:	Assembly Health Committee
HEARING:	04/03/2018 1:30 pm

SUMMARY:

Prohibits a prescriber from prescribing an opioid in an amount greater than the patient needs for a specified period unless otherwise determined by the prescriber for the treatment of chronic pain. Requires a prescriber of such prescriptions to include in the patient's record why the excess prescription was needed and other relevant information. Requires specified actions by a prescriber prior to prescribing an opioid. Requires reporting of such prescriptions and provides penalties for failure to do so.

STATUS:

03/12/2018	From ASSEMBLY Committee on HEALTH with author's amendments.
03/12/2018	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.
INDEX:	73, 89
ISSUES:	BJ, DP*

	LOBBYIST:	AH, CD*
	POSITION:	F, X

CA AB 2037

AUTHOR:	Bonta [D]
TITLE:	Pharmacy: Automated Drug Delivery Systems
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/06/2018
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Provides an alternative program to authorize a pharmacy to provide pharmacy services to covered entities that are eligible for discount drug programs under federal law through the use of an automated drug delivery system. Provides that, under the alternative program, the responsibility for the operation, maintenance, and security of the drugs in the automated drug delivery system would be the responsibility of the pharmacy.

STATUS:

03/20/2018	From ASSEMBLY Committee on BUSINESS AND PROFESSIONS: Do pass to Committee on APPROPRIATIONS. (13-0)
INDEX:	89
ISSUES:	AO, BJ*, DP
LOBBYIST:	AH*, BG
POSITION:	F, X

CA AB 2086

AUTHOR:	Gallagher [R]
TITLE:	Controlled Substances: CURES Database
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/07/2018
DISPOSITION:	Pending
LOCATION:	Assembly Business and Professions Committee

SUMMARY:

Allows prescribers to request from the Department of Justice a list of patients for whom that prescriber is listed as a prescriber in the Controlled Substance Utilization Review and Evaluation System (CURES) database which monitors specified prescriptions of Schedule II, III and IV controlled substances.

STATUS:

02/22/2018	To ASSEMBLY Committee on BUSINESS AND PROFESSIONS.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	S, X

CA AB 2384

AUTHOR:	Arambula [D]
TITLE:	Medication-Assisted Treatment
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/14/2018
DISPOSITION:	Pending
COMMITTEE:	Assembly Health Committee
HEARING:	04/24/2018 1:30 pm

SUMMARY:

Requires a drug formulary maintained by a health care service plan, including a Medi-Cal managed plan, or health insurer to include, at a minimum, specified prescription drugs for the medication-assisted treatment of substance abuse disorders. Provides that medication-assisted treatment is presumed to be medically necessary, and is not subject to specified requirements of a health care service plan or policy of health insurance, including prior authorization and an annual or lifetime dollar limit.

STATUS:

03/01/2018	To ASSEMBLY Committee on HEALTH.
INDEX:	65, 89
ISSUES:	AM, BJ, DG*, SL
LOBBYIST:	AH*, BG
POSITION:	F

CA AB 2576

AUTHOR:	Aguiar-Curry [D]
TITLE:	Emergencies: Healthcare
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/15/2018
DISPOSITION:	Pending
LOCATION:	Assembly Health Committee

SUMMARY:

Authorizes the Governor, during a state of emergency, to direct all state agencies to utilize, employ, and direct state personnel, equipment, and facilities for the performance of any and all activities that are designed to allow community clinics and health centers to provide and receive reimbursement for services provided during or immediately following the emergency. Authorizes any agency directed by the Governor to perform those activities to expend any of the moneys that have been appropriated to it.

STATUS:

03/08/2018	To ASSEMBLY Committees on HEALTH and BUSINESS AND PROFESSIONS.
INDEX:	31, 89
ISSUES:	AK, BJ, CLH*, DG, RY, SL
LOBBYIST:	AH, KAS*
POSITION:	F

CA AB 2624

AUTHOR:	Brough [R]
TITLE:	Prescriptions
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/15/2018
DISPOSITION:	Pending
LOCATION:	ASSEMBLY

SUMMARY:

Makes a nonsubstantive change to the Pharmacy Law, which authorizes a pharmacist filling a prescription order for a drug product prescribed by its brand or trade name to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form.

STATUS:

02/15/2018	INTRODUCED.
INDEX:	89

ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA AB 2741

AUTHOR: Burke [D]
TITLE: Prescription Drugs: Opioid Medications: Minors
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Requires a prescriber, as defined, to comply with specified conditions when prescribing opioid medication to a minor, including not prescribing more than a 5-day supply of an opioid medication to that minor except in specified instances.
STATUS:

03/08/2018 To ASSEMBLY Committees on BUSINESS AND PROFESSIONS and HEALTH.
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA AB 2760

AUTHOR: Wood [D]
TITLE: Prescription Drugs: Naloxone Hydrochloride
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Requires a prescriber, as defined, to prescribe naloxone hydrochloride for patients when certain conditions are present and to provide specified education to those patients and their household. Makes a violation of the bill's provisions unprofessional conduct and would subject the prescriber to discipline by the California State Board of Pharmacy charged with regulating his or her license.
STATUS:

03/08/2018 To ASSEMBLY Committees on BUSINESS AND PROFESSIONS and HEALTH.
INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F, X

CA AB 2789

AUTHOR: Wood [D]
TITLE: Health Care Practitioners: Prescriptions
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Requires health care practitioners authorized to issue prescriptions to have the

capability to transmit electronic transmission prescriptions. Requires pharmacies to have the capabilities to receive those transmissions. Requires those health care practitioners to issue prescriptions as an electronic transmission prescription unless specified exemptions are met.

STATUS:

03/08/2018	To ASSEMBLY Committee on BUSINESS AND PROFESSIONS.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F, X

CA AB 2863

AUTHOR:	Nazarian [D]
TITLE:	Pharmacy: Prescriptions
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2018
DISPOSITION:	Pending
LOCATION:	ASSEMBLY

SUMMARY:

Makes nonsubstantive changes to provisions of the Pharmacy Law.

STATUS:

02/16/2018	INTRODUCED.
INDEX:	89
ISSUES:	DP
LOBBYIST:	AH
POSITION:	F

CA SB 528

AUTHOR:	Stone [R]
TITLE:	Pharmacy: Automated Drug Delivery Systems
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2017
LAST AMEND:	06/12/2017
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Provides an alternative program to authorize a pharmacy to provide pharmacy services to covered entities that are eligible for discount drug programs under federal law, as specified, through the use of an automated drug delivery system.

STATUS:

09/01/2017	In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F

CA SB 641

AUTHOR:	Lara [D]
TITLE:	Controlled Substance Utilization
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/17/2017

LAST AMEND:	04/20/2017
DISPOSITION:	Pending
LOCATION:	Assembly Public Safety Committee

SUMMARY:

Amends existing law which requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances. Prohibits the release of data obtained from CURES to a law enforcement agency except pursuant to a valid court order.

STATUS:

06/15/2017	To ASSEMBLY Committee on PUBLIC SAFETY.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F

CA SB 716

AUTHOR:	Hernandez [D]
TITLE:	California State Board of Pharmacy: Pharmacy Technician
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/17/2017
LAST AMEND:	04/26/2017
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Increases the number of members of the Board of Pharmacy by adding one pharmacy technician appointed by the Governor.

STATUS:

07/19/2017	In ASSEMBLY Committee on APPROPRIATIONS: Not heard.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	N, X

CA SB 1021

AUTHOR:	Wiener [D]
TITLE:	Prescription Drugs
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/07/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Health Committee
HEARING:	04/25/2018 1:30 pm

SUMMARY:

Prohibits a drug formulary maintained by a health care service plan or health insurer from containing more than 4 tiers, and permits a biologic with a therapeutic equivalent to be placed on a tier other than tier 4, as specified. Requires a prescription drug benefit to provide that an enrollee or an insured is not required to pay more than the retail price for a prescription drug if a pharmacy's retail price is less than the applicable copayment or coinsurance amount.

STATUS:

02/14/2018	To SENATE Committee on HEALTH.

	INDEX:	89
	ISSUES:	BJ*, DG, DP
	LOBBYIST:	AH
	POSITION:	F

CA SB 1229

AUTHOR:	Stone [R]
TITLE:	Pharmacists: Opioid Medications: Consultation
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/15/2018
LAST AMEND:	03/19/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Business, Professions & Economic Development Committee
HEARING:	04/16/2018

SUMMARY:

Requires a pharmacist to provide oral consultation to a patient or the patient's agent before dispensing any opioid medication in accordance with regulations adopted by the State Board of Pharmacy.

STATUS:

03/19/2018	From SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT with author's amendments.
03/19/2018	In SENATE. Read second time and amended. Re-referred to Committee on BUSINESS, PROFESSIONS & ECONOMIC DEVELOPMENT.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F, X

CA SB 1240

AUTHOR:	Stone [R]
TITLE:	Prescription Drugs: Cures Database
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/15/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Business, Professions & Economic Development Committee
HEARING:	04/09/2018

SUMMARY:

Requires a prescription, if in writing or transmitted electronically, to include an International Statistical Classification of Diseases, 10 revision (ICD-10) Code or a legible clear notice of the condition or purpose for which the drug is being prescribed, unless the patient requests this information to be omitted and would require a prescription transmitted orally to include either the code or a description of the condition or purpose for which the drug is being prescribed.

STATUS:

03/01/2018	To SENATE Committees on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT and PUBLIC SAFETY.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F, X

CA SB 1254

AUTHOR: Stone [R]
TITLE: Hospital Pharmacies: Medication Profiles
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
DISPOSITION: Pending
COMMITTEE: Senate Business, Professions & Economic Development Committee
HEARING: 04/16/2018
SUMMARY:

Requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile for each high-risk patient upon admission and discharge of the patient. Authorizes an intern pharmacist or pharmacy technician to perform that function if the intern pharmacist or pharmacy technician has successfully completed training and proctoring by a pharmacist and where a quality assurance program is used to monitor competency.

STATUS:

03/01/2018	To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F, X

CA SB 1264

AUTHOR: Stone [R]
TITLE: Medi-Cal: Hypertension Medication Management: Pharmacy
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
LAST AMEND: 03/21/2018
DISPOSITION: Pending
LOCATION: Senate Rules Committee
SUMMARY:

Declares the intent of Legislature to enact legislation to revise provisions related to the Medi-Cal program and advanced practice pharmacy in order to authorize pharmacists to provide hypertension management services to Medi-Cal beneficiaries.

STATUS:

03/21/2018	From SENATE Committee on RULES with author's amendments.
03/21/2018	In SENATE. Read second time and amended. Re-referred to Committee on RULES.

INDEX: 65, 89
ISSUES: AK*, BJ
LOBBYIST: AH, BG*
POSITION: F

CA SB 1285

AUTHOR: Stone [R]
TITLE: Health Care Coverage: Advanced Practice Pharmacist
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018

DISPOSITION: Pending
COMMITTEE: Senate Health Committee
HEARING: 04/25/2018 1:30 pm
SUMMARY:

Requires coverage for services provided by an advanced practice pharmacist, as defined, performed within the scope of his or her practice, including but not limited to, comprehensive medication management (CMM) services, as defined, in a health care service plan contract and health insurance policy, and, to the extent that federal financial participation is available, in a Medi-Cal managed care plan.

STATUS:

03/01/2018 To SENATE Committee on HEALTH.
INDEX: 39, 89
ISSUES: BJ, DG*, DP
LOBBYIST: AH
POSITION: F

CA SB 1286

AUTHOR: Pan [D]
TITLE: Pharmacy Technicians
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Senate Business, Professions & Economic Development Committee
SUMMARY:

Allows a pharmacy with only one pharmacist to have no more than 4 pharmacy technicians performing packaging, manipulative, repetitive, or other nondiscretionary tasks.

STATUS:

03/01/2018 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX: 57, 89
ISSUES: BJ, GBS*
LOBBYIST: AH*, KAS
POSITION: F, X

CA SB 1404

AUTHOR: Stone [R]
TITLE: Pharmacists: Exemption From Overtime Regulations
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
COMMITTEE: Senate Labor and Industrial Relations Committee
HEARING: 04/11/2018 9:30 am
SUMMARY:

Provides that a person employed in the practice of pharmacy, who is participating in a postgraduate training program, as specified, who is in a field relating to the practice of pharmacy or pharmacy research, or who is performing certain procedures or functions, is not subject to coverage under any provisions of the orders of the Industrial Welfare Commission.

STATUS:

03/08/2018 To SENATE Committee on LABOR AND INDUSTRIAL

RELATIONS.
INDEX: 57, 89
ISSUES: BJ, CM
LOBBYIST: AH*, KAS
POSITION: F, X

CA SB 1426

AUTHOR: Stone [R]
TITLE: Pharmacists: Authority To Prescribe and Dispense
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Senate Rules Committee
SUMMARY:

Expresses the intent of the Legislature to enact legislation that would require the California State Board of Pharmacy to convene a Public Health and Pharmacy Formulary Advisory Committee to advise the board in promulgating regulations to establish a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient and establish a formulary of dangerous drugs and devices that a pharmacy may prescribe and dispense to a patient.
STATUS:

03/08/2018 To SENATE Committee on RULES.
INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: S, X

CA SB 1442

AUTHOR: Newman [D]
TITLE: Pharmacies: Staffing
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Senate Business, Professions & Economic Development Committee
SUMMARY:

Prohibits a pharmacy from requiring a pharmacist to engage in the practice of pharmacy unless the pharmacist is assisted at all times by either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located.
STATUS:

03/08/2018 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX: 57, 89
ISSUES: BJ, GBS*
LOBBYIST: AH*, KAS
POSITION: F, X

CA SB 1447

AUTHOR: Hernandez [D]
TITLE: Pharmacy: Automated Drug Delivery Systems
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no

INTRODUCED:	02/16/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Business, Professions & Economic Development Committee
HEARING:	04/16/2018

SUMMARY:

Repeals the general automated drug delivery system provisions. Prohibits an ADDS unit from being installed or operated in the state unless specified requirements are met, including a license for ADDS unit issued by the board to the hold of current, valid, and active pharmacy license, and would require the pharmacy holding the license to complete periodic self-assessments.

STATUS:

03/08/2018	To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F, X

CA SB 1495

AUTHOR:	Health Cmt
TITLE:	Health
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/28/2018
DISPOSITION:	Pending
LOCATION:	SENATE

SUMMARY:

Excludes from the definition of stem cell therapy those therapies involving HCT/Ps that meet specified criteria pursuant to, or that qualify for an exception under, federal law. Requires only health care practitioners who perform a stem cell therapy that is subject to FDA regulation, and that is not FDA-approved, to provide the notice and writing to their patients. Exempts from these requirements a health care practitioner who has obtained clearance for an investigational new drug.

STATUS:

03/08/2018	To SENATE Committee on HEALTH.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	PR

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: PharMEDium Cease and Desist Order/IV Opioid Drug Shortage

SUMMARY

1. PharMEDium Cease and Desist Order

   Following an investigation that indicated noncompliance with state regulations and federal good manufacturing practices, the California Board of Pharmacy issued a 30-day cease and desist order to PharMEDium Services, LLC's Sugarland, TX non-resident outsourcing facility. The Sugarland plant was inspected by the board, which issued a report with findings on Oct. 11, 2017. Although PharMEDium responded to the findings with an action plan, it has failed to remedy 14 areas of non-compliance. This cease and desist order will prevent sterile and non-sterile drug product shipments into California for 30 days or until the date of a hearing seeking an interim suspension order, whichever is earlier.

   PharMEDium has indicated it will seek a formal hearing with the Board of Pharmacy. In the interim, the board has prioritized the licensing of additional non-sterile and sterile compounding manufacturers to assist hospitals with drug procurement, and is working with CHA's Medication Safety Committee pharmacists to identify alternative manufacturers and alternative strategies in lieu of using PharMEDium pre-packaged pharmaceuticals

2. IV Opioid Shortages

   Recently, CHA was made aware of the distribution issues with West-Ward Pharmaceuticals. Our federal office was notified. AHA submitted the attached letter to the DEA and CHA continues to work with our federal office and AHA on behalf of the vital IV opioid medication necessary for hospital operations.

   CHA will continue to work with AHA to urge the DEA to use its discretionary authority to temporarily reallocate or revise APQ to allow other manufacturers to supply product until the shortages resolve.

ACTION

- What activities are you deploying to adjust to shortages?

- Are there issues CHA and or the Board of Pharmacy can assist with to improve manufacturing delays and or shortages?

Attachments: Cease and Desist – PharMEDium
AHA Letter
NEJM Article – Saline Shortages
NEJM Article – Facing the Shortage of IV Fluids
Article – The Other Opioid Crisis

BJB:br

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ORDER TO CEASE AND DESIST

Date: February 27, 2018

Permit No.: NSF 110

Name as shown on Permit: PHARMEDIUM SERVICES LLC

Address: 12620 W AIRPORT BLVD STE 130 SUGARLAND TX 77478

California Business and Professions Code Section 4129.4 provides that whenever the board has a reasonable belief, based on information obtained during an inspection or investigation, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

California Business and Professions Code Section 4129.2 (b) requires a nonresident outsourcing facility to compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

Pharmedium Services LLC, a non-resident outsourcing facility compounded products to be distributed into California without complying with regulations of the board and with federal current good manufacturing practices (cGMPs) applicable to outsourcing facilities, including but not limited to:

1. 21 CFR 211.42(d); cefazolin (penicillin derivative) produced in same primary engineering control (PEC) as other products and stored with other products.
2. 21 CFR 211.46(d); cefazolin (penicillin derivative) produced in same PEC in room with 24 hoods with same air handling system and stored with other products with the same air handling system.
3. 21 CFR 211.84(b); components and container closures not sampled and tested prior to use.
4. 21 CFR 211.84(d)(2); no testing of components for compounded products prior to compounding process. Out of date vendor qualifications.
5. 21 CFR 211.94(a); no container closure integrity studies available for review.
6. 21 CFR 211.122(a); dosage and administration specified by Section 503B (a)(10)(B)(iii) not evident on all labels. One product repackaged from original container labeled "Not for Direct Intravenous Use "did not include this warning on the label. Products labeled injection without specifying intravenous, intramuscular or subcutaneous.

7. 21 CFR 211.137(a): expiration dates assigned without sound scientific support.
8. 21 CFR 211.160(a): visual product inspection did not occur 100% of the time and a black and white board with a light was not available during inspection.
9. 21 CFR 211.166(a)(3): inadequate data used to determine expiration dating.
10. 21 CFR 211.170(a): no retained samples or standard operating procedure describing retained samples.
11. 21 CFR 211.188(b)(7): no statement of actual yield or percentage of theoretical yield on batch records.
12. 16 CCR 1735.2(i)(2): beyond use dates assigned without sound scientific data
13. 16 CCR 1735.2(i)(3): beyond use dates assigned without method suitability test, container closure integrity test, and stability studies.
14. 16 CCR 1751.8(a): beyond use dates exceeded the allowance of the law.

Pharmedium Services LLC has failed to remedy these areas of non-compliance, despite being given multiple opportunities.

On the basis of the foregoing, the Board, through its Executive Officer, has a reasonable belief that drug preparations by Pharmedium Services LLC pose an immediate threat to the public health and safety in California, and therefore **ORDERS**:

Pharmedium Services LLC shall immediately **CEASE AND DESIST** compounding sterile drug products or nonsterile drug products for shipment into California. This cease and desist order shall remain in effect for 30 days or until the date of a hearing seeking an interim suspension order, whichever is earlier. Pursuant to Business and Professions Code section 4129.4(c), within 15 days of the receipt of this notice Pharmedium Services LLC may request a hearing before the president of the board to contest the cease and desist order.

California State Board of Pharmacy

By: Virginia Herold

Signed: Virginia Herold

Date: 2/27/18

Title: Executive Officer

February 27, 2018

[Submitted via U.S. Mail]
Robert W. Patterson
Acting Administrator
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

[Submitted electronically to ODLP@usdoj.gov]
DEA Diversion Control Division
Attn: Liaison and Policy Section
8701 Morrissette Drive
Springfield, VA 22152

RE: Temporary Changes to Aggregate Production Quotas for IV Opioid Products to Address Shortages

The undersigned groups respectfully request that the Drug Enforcement Administration (DEA) adjust aggregate production quotas (APQ) for certain opioids in order to mitigate ongoing drug shortages. As DEA may be aware, hospitals and other providers are currently facing critical shortages of a number of injectable opioid medications, including morphine, hydromorphone, and fentanyl. Intravenous (IV) opioids are used in a variety of practice settings within hospitals and ambulatory surgical centers for the treatment of acute, acute on chronic, or chronic pain that cannot be managed because the patient has a contraindication for oral opioid medications. Some opioids, such as fentanyl, also are used for sedation. Injectable opioids are critical to treating the pain needs of patients undergoing interventional procedures (e.g., cardiac catheterization or colonoscopy) and surgeries. These medications are also frequently used in intensive care units for surgical, trauma, burn, or oncology patients, when it is not clinically appropriate to use oral opioids. Having diminished supply of these critical drugs, or no supply at all, can cause suboptimal pain control or sedation for patients in addition to creating burdensome workarounds for healthcare staff.

Shortages of these injectable medications are largely attributable to manufacturing delays affecting Pfizer, the primary maker of these products, following its acquisition of Hospira. In a letter to customers, Pfizer indicated that the "anticipated full recovery dates for prioritized prefilled syringes have moved to 1Q19 and deprioritized syringes have moved to 2Q19."[1] On January 31, 2018, Pfizer sent customers a further update informing them that, due to a third-party supplier issue, none of these prefilled syringes of injectable opioids are currently being produced or released.[2]

Because these are vital medications, hospitals have been focused on locating alternative sources. We have been informed, however, that other manufacturers have been unable to step in and produce additional product because the DEA is approving only a small number of requests for the

[1] See Attachment A, Pfizer Customer Letters, dated July 20, 2017, and Nov. 27, 2017.
[2] See Attachment B, Pfizer Customer Letter, dated Jan. 31, 2018.

requisite pharmaceutical compounds due to current APQ limits. At present, supply options are dwindling.

Severe shortages of injectable opioids may threaten patient care in hospitals and surgical centers. We understand and share the DEA's concern that these medications need to be well-managed and used judiciously to help stem the nation's opioid epidemic. We fully support and use advances in pain management, such as multimodal analgesia, that enable patients to undergo procedures with fewer opioids and less reliance on opioids after surgery. Nonetheless, injectable opioids remain a crucial component of patient management during and immediately after many operations. With no appropriate opioids available, operations would have to be postponed or cancelled. In some cases, this could prove life-threatening to the patient.

Shortages also increase the risk of medication errors. Rather than selecting a product that might be most clinically efficacious for patients, during shortages prescribers are forced to order whichever IV opioid is available. Furthermore, dosing equivalency between the IV opioids differs significantly, which can lead to dosing errors. Moreover, using a more potent opioid based on supply alone defeats the national efforts to use hydromorphone and fentanyl only when absolutely necessary.

Given the ongoing shortages for these injectable medications, we urge DEA to use its discretionary authority to temporarily reallocate or revise APQ to allow other manufacturers to supply product until the shortages resolve. Our request is specific to these injectable medications and does not extend to other dosage forms or opioid products.

We thank DEA for its ongoing efforts to combat the opioid crisis, and we stand ready to assist the agency in any way possible. If you have questions, the appropriate contact person for each of the signatories can be found below.

Sincerely,

American Hospital Association
Contact: Ashley Thompson
Senior Vice President, Public Policy Analysis & Development
athompson@aha.org

American Society of Anesthesiologists
Contact: Ashley Walton
Pain Medicine and Federal Affairs Manager
A.Walton@asahq.org

American Society of Clinical Oncology
Contact: Karen Hagerty
Director, Reimbursement Policy
Karen.Hagerty@asco.org

American Society of Health-System Pharmacists
Contact: Jillanne Schulte Wall
Director, Federal Regulatory Affairs
jschulte@ashp.org

Institute for Safe Medication Practices
Contact: Allen Vaida
Executive Vice President
avaida@ismp.org

Attachment A: Pfizer Customer Letters – July 20, 2017 and Nov. 27, 2017

Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045

July 20, 2017

Update to Pfizer Injectables
Opioid and Non-Opioid Prefilled Syringe Portfolio

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply shortages so that appropriate contingency plans can be made to facilitate patient care and safety. As such, this letter is to provide you with updated information on the supply status of opioid and non-opioid prefilled syringe (PFS) products. We anticipate that at the end of July we will not be able to meet market demand on opioid and non-opioid PFS products due to remediation efforts at our McPherson manufacturing facility. Although we will continue to manufacture and deliver select presentations throughout the remediation process, we anticipate product shortages and stock outs to begin as early as this month. We expect recovery of prioritized products by the end of Q1 2018.

Pfizer is prioritizing production to minimize patient impact and is making every effort to restock the market. We have prioritized certain CARPUJECT™ and iSecure™ prefilled syringes (see Table A), including select presentations of Diazepam, Heparin, Hydromorphone, Labetalol, Lorazepam, Morphine, and Naloxone. Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products. Pfizer remains committed to the CARPUJECT™ and iSecure™ product line. We are also increasing the production of vials and ampuls where possible to help offset the PFS shortages. However, there will be times when inventory is not available.

Table B lists the CARPUJECT™ and iSecure™ products that have been deprioritized. Once current supply of each product in Table B is exhausted, which will vary by SKU, there will be no further product deliveries until Q1 2018 due to PFS prioritization. It is recommended you check our availability report on our website at https://www.pfizerinjectables.com/Injectables_Availability_Report to receive the most up-to-date information on product availability. You can also contact our Supply Continuity Team between 7:00am – 6:00pm CT to discuss any product availability questions at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]) or via email at PISupplyContinuity@Pfizer.com.

In addition, we have worked with all trading partners and asked them to allocate opioid products to help ensure as many customers as possible have access to supply until the next anticipated shipments arrive. Please continue to work with your trading partner.

We are working closely with the FDA Drug Shortage Staff on our plans to manage this shortage. Shortage information is also being provided to the American Society of Health-System Pharmacists (ASHP), and to Group Purchasing Organizations.

We understand the challenges that this shortage poses to clinicians and patients and are fully dedicated to restoring supply, while ensuring the highest quality and safety standards. I am available to speak with you to discuss any questions you may have. You can reach out to me and the Pfizer Injectables leadership team at PfizerInjectables@Pfizer.com, or through your Pfizer representative, and we will respond as quickly as possible.

Kind regards,

Shawn Olsson
Sr. Manager, Opioid and Syringe Technology Portfolio
Pfizer Essential Health

Table A: Prioritized Products with Full Recovery Expected Q1 2018*

Description	Unit of Sale NDC	Anticipated Recovery
Diazepam Injection, USP, CIV 10 mg/2 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1273-32**	Q1 2018
Heparin Sodium Injection, USP (Preservative-Free) 5,000 USP Units/0.5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1316-32**	Q1 2018
Hydromorphone Hydrochloride Injection, USP, CII 0.5 mg/0.5 mL iSecure™ Luer Lock Glass Syringe (no needle)	**00409-1283-05**	Q1 2018
Hydromorphone Hydrochloride Injection, USP, CII 1 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1283-31**	Q1 2018
Hydromorphone Hydrochloride Injection, USP, CII 2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1312-30**	Q1 2018
Labetalol Hydrochloride Injection, USP 20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-2339-34**	Q1 2018
Lorazepam Injection, USP, CIV 2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1985-30**	Q1 2018
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1890-01**	Q1 2018
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1891-01**	Q1 2018
Naloxone Hydrochloride Injection, USP 0.4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	**00409-1782-69**	Q1 2018

**Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products.*

Table B: Deprioritized List of Impacted Opioid and Non-Opioid PFS Products*

Product	Unit of Sale NDC	Description
0.9% Sodium Chloride Injection, USP	00409-1918-32	2 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-33	3 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-35	5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Buprenorphine Hydrochloride Injection, CIII	00409-2012-32	0.3 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Demerol™ (meperidine hydrochloride injection, USP) CII	00409-1176-30	25 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1178-30	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1179-30	75 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1180-69	100 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diphenhydramine Hydrochloride Injection, USP	00409-2290-31	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Fentanyl Citrate Injection, USP, CII	00409-1276-32	100 mcg/2 mL (50 mcg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Heparin Sodium Injection, USP	00409-1402-12	5,000 USP Units/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Hydromorphone Hydrochloride Injection, USP, CII	00409-1283-10	1 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1312-10	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1304-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ketorolac Tromethamine Injection, USP	00409-2287-31	30 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2287-23	30 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2287-61	60 mg/2 mL (30 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Lorazepam Injection, USP, CIV	00409-1539-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Metoprolol Tartrate Injection, USP	00409-1778-35	5 mg/5 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Midazolam Injection, USP CIV	00409-2306-62	2 mg/2 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2306-12	2 mg/2 mL (1 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2307-60	5 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-1890-11	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1891-11	4 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1892-01	8 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1892-11	8 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1893-01	10 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1893-11	10 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
Ondansetron Injection, USP	00409-1120-12	4 mg/2 mL (2 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)

**Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products*.

Table C: List of Opioids that Pfizer Produces in Ampuls and Vials**

Product	Unit of Sale NDC	Description
Demerol™ (meperidine hydrochloride injection, USP) CII	00049-1203-01	25 mg/0.5 mL (50 mg/mL) Glass Ampul
	00409-1253-01	50 mg/mL Glass Ampul
	00409-1254-01	75 mg/1.5 mL (50 mg/mL) Glass Ampul
	00409-1256-01	100 mg/mL Glass Ampul
	00409-1255-02	100 mg/2 mL (50 mg/mL) Glass Ampul
	00409-1181-30	1,500 mg/30 mL (50 mg/mL) Multiple Dose Glass Fliptop Vial
	00409-1201-20	2,000 mg/20 mL (100 mg/mL) Multiple Dose Glass Fliptop Vial
Fentanyl Citrate Injection, USP, CII	00409-9093-32	100 mcg/2 mL (50 mcg/mL) Glass Ampul
	00409-9094-22	100 mcg/2 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9093-35	250 mcg/5 mL (50 mcg/mL) Glass Ampul
	00409-9094-25	250 mcg/5 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9094-28	500 mcg/10 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9094-31	1,000 mcg/20 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9093-38	1,000 mcg/20 mL (50 mcg/mL) Glass Ampul
	00409-9094-61	2,500 mcg/50 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
Hydromorphone Hydrochloride Injection, USP, CII	00409-2552-01	1 mg/mL Glass Ampul
	00409-3356-01	2 mg/mL Glass Ampul
	00409-3365-01	2 mg/mL Single Dose Glass Fliptop Vial
	00409-2540-01	4 mg/mL Glass Ampul
	00409-2634-01	(High-Potency Formulation) 10 mg/mL Single Dose Glass Fliptop Vial
	00409-2634-05	(High-Potency Formulation) 50 mg/5 mL (10 mg/mL) Single Dose Glass Fliptop Vial
	00409-2634-50	(High-Potency Formulation) 500 mg/50 mL (10 mg/mL) Single Dose Glass Fliptop Vial
Morphine Sulfate Injection, USP, CII (Preservative-Free and contains an antioxidant)	00409-1134-03	1,000 mg/20 mL (50 mg/mL) Single Dose Glass Fliptop Vial
	00409-1134-05	2,500 mg/50 mL (50 mg/mL) Single Dose Glass Fliptop Vial
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-3814-12	5 mg/10 mL (0.5 mg/mL) Single Dose Glass Fliptop Vial
	00409-3815-12	10 mg/10 mL (1 mg/mL) Single Dose Glass Fliptop Vial
	00409-1135-02	250 mg/10 mL (25 mg/mL) Single Dose Glass Fliptop Vial

***Please check our availability report on our website at https://www.pfizerinjectables.com/Injectables_Availability_Report to receive the most up-to-date information on product availability.*

Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045

November 27, 2017

Update to Pfizer Injectables
Opioid and Non-Opioid Prefilled Syringe Portfolio

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply shortages so that appropriate contingency plans can be made to facilitate patient care. Due to longer than expected timelines for upgrade work required at our McPherson manufacturing facility, the currently anticipated full recovery dates for prioritized prefilled syringes (PFS) have moved to 1Q19 and deprioritized syringes have moved to 2Q19. We will continue to manufacture and deliver select presentations throughout the upgrade work taking place but do anticipate backorders and product shortages.

Pfizer will continue to prioritize production of certain Carpuject™ and iSecure™ prefilled syringes (see Table A). Products have been prioritized based on medical necessity and importance to patient care, as determined by customer feedback and our U.S. Medical Affairs team. It is anticipated that the Naloxone Hydrochloride Injection, USP Carpuject™ will remain in adequate supply throughout the upgrade process. Diazepam Injection, USP, CIV Carpuject™ will likely be on long-term back order. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products (see Table B) once supply recovers on the prioritized products. Pfizer remains committed to the Carpuject™ and iSecure™ product line and we are working hard to expidite full recovery.

We are also increasing the production of vials and ampuls (see Table C) where possible to help offset the PFS shortages. However, there will be times when inventory is not available and specifically, the Hydromorphone Hydrochloride Injection, USP, CII Ampul products will be on long term back order.

Please check our availability report on our website at https://www.pfizerinjectables.com/Injectables_Availability_Report to receive the most up-to-date information on product availability. You can also contact our Supply Continuity Team between 7:00am – 6:00pm CT to discuss any product availability questions at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]) or via email at PISupplyContinuity@Pfizer.com.

In addition, we have worked with all trading partners and asked them to allocate opioid products to help ensure as many customers as possible have access to supply until the next anticipated shipments arrive. Please continue to work with your trading partner.

We understand the challenges that this shortage poses to clinicians and patients and are fully dedicated to restoring supply, while helping to ensure the highest quality and safety standards. I am available to speak with you to discuss any questions you may have. You can reach out to the Pfizer Injectables leadership team and me at PfizerInjectables@Pfizer.com or through your Pfizer representative, and we will respond as quickly as possible.

Kind regards,

Shawn Olsson
Sr. Manager, Opioid and Syringe Technology Portfolio
Pfizer Essential Health

Table A: Prioritized List of Products *

Product	Unit of Sale NDC	Description
Diazepam Injection, USP, CIV	00409-1273-32	10 mg/2 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)[+]
Heparin Sodium Injection, USP	00409-1316-32	5,000 USP Units/0.5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Hydromorphone Hydrochloride Injection, USP, CII	00409-1283-05	0.5 mg/0.5 mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1283-31	1 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1312-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Labetalol Hydrochloride Injection, USP	00409-2339-34	20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Lorazepam Injection, USP, CIV	00409-1985-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-1890-01	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1891-01	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Naloxone Hydrochloride Injection, USP	00409-1782-69	0.4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)

**Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products.*

[+]Product is on long term back order

Table B: Deprioritized List of Impacted Opioid and Non-Opioid PFS Products*

Product	Unit of Sale NDC	Description
0.9% Sodium Chloride Injection, USP	00409-1918-32	2 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-33	3 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-35	5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Buprenorphine Hydrochloride Injection, CIII	00409-2012-32	0.3 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Demerol™ (meperidine hydrochloride injection, USP) CII	00409-1176-30	25 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1178-30	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1179-30	75 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1180-69	100 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diphenhydramine Hydrochloride Injection, USP	00409-2290-31	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Fentanyl Citrate Injection, USP, CII	00409-1276-32	100 mcg/2 mL (50 mcg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Heparin Sodium Injection, USP	00409-1402-12	5,000 USP Units/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Hydromorphone Hydrochloride Injection, USP, CII	00409-1283-10	1 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1312-10	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1304-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ketorolac Tromethamine Injection, USP	00409-2287-31	30 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2287-23	30 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2287-61	60 mg/2 mL (30 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Lorazepam Injection, USP, CIV	00409-1539-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Metoprolol Tartrate Injection, USP	00409-1778-35	5 mg/5 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Midazolam Injection, USP CIV	00409-2306-62	2 mg/2 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2306-12	2 mg/2 mL (1 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2307-60	5 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-1890-11	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1891-11	4 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1892-01	8 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1892-11	8 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1893-01	10 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1893-11	10 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
Ondansetron Injection, USP	00409-1120-12	4 mg/2 mL (2 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)

**Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products*.

Table C: List of Opioids that Pfizer Produces in Ampuls and Vials**

Product	Unit of Sale NDC	Description
Demerol™ (meperidine hydrochloride injection, USP) CII	00049-1203-01	25 mg/0.5 mL (50 mg/mL) Glass Ampul
	00409-1253-01	50 mg/mL Glass Ampul
	00409-1254-01	75 mg/1.5 mL (50 mg/mL) Glass Ampul
	00409-1256-01	100 mg/mL Glass Ampul
	00409-1255-02	100 mg/2 mL (50 mg/mL) Glass Ampul
	00409-1181-30	1,500 mg/30 mL (50 mg/mL) Multiple Dose Glass Fliptop Vial
	00409-1201-20	2,000 mg/20 mL (100 mg/mL) Multiple Dose Glass Fliptop Vial
Fentanyl Citrate Injection, USP, CII	00409-9093-32	100 mcg/2 mL (50 mcg/mL) Glass Ampul
	00409-9094-22	100 mcg/2 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9093-35	250 mcg/5 mL (50 mcg/mL) Glass Ampul
	00409-9094-25	250 mcg/5 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9094-28	500 mcg/10 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9094-31	1,000 mcg/20 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
	00409-9093-38	1,000 mcg/20 mL (50 mcg/mL) Glass Ampul[+]
	00409-9094-61	2,500 mcg/50 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
Hydromorphone Hydrochloride Injection, USP, CII	00409-2552-01	1 mg/mL Glass Ampul[+]
	00409-3356-01	2 mg/mL Glass Ampul[+]
	00409-3365-01	2 mg/mL Single Dose Glass Fliptop Vial
	00409-2540-01	4 mg/mL Glass Ampul[+]
	00409-2634-01	(High-Potency Formulation) 10 mg/mL Single Dose Glass Fliptop Vial
	00409-2634-05	(High-Potency Formulation) 50 mg/5 mL (10 mg/mL) Single Dose Glass Fliptop Vial
	00409-2634-50	(High-Potency Formulation) 500 mg/50 mL (10 mg/mL) Single Dose Glass Fliptop Vial
Morphine Sulfate Injection, USP, CII (Preservative-Free and contains an antioxidant)	00409-1134-03	1,000 mg/20 mL (50 mg/mL) Single Dose Glass Fliptop Vial
	00409-1134-05	2,500 mg/50 mL (50 mg/mL) Single Dose Glass Fliptop Vial
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-3814-12	5 mg/10 mL (0.5 mg/mL) Single Dose Glass Fliptop Vial
	00409-3815-12	10 mg/10 mL (1 mg/mL) Single Dose Glass Fliptop Vial
	00409-1135-02	250 mg/10 mL (25 mg/mL) Single Dose Glass Fliptop Vial

***Please check our availability report on our website at https://www.pfizerinjectables.com/Injectables_Availability_Report to receive the most up-to-date information on product availability.*

[+]Product is on long term back order

Attachment B: Pfizer Customer Letter (Jan. 31, 2018)

Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045

January 31, 2018

Notification of
CARPUJECT™ and iSecure™ Prefilled Syringe Portfolio
Supply Interruption

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply shortages so that appropriate contingency plans can be made to facilitate patient care. Due to an issue with a 3rd party incoming component, all Carpuject and iSecure product releases have been placed on hold. We are currently performing a risk assessment to determine when the Carpuject and iSecure product releases can resume.

A full list of Pfizer Carpuject and iSecure products are provided in the table below.

Please check our availability report on our website at https://www.pfizerinjectables.com/Injectables_Availability_Report to receive the most up-to-date information on product availability. You can also contact our Supply Continuity Team between 7:00am – 6:00pm CT to discuss any product availability questions at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]) or via email at PISupplyContinuity@Pfizer.com.

We understand the challenges that this shortage poses to clinicians and patients and are fully dedicated to restoring supply, while ensuring the highest quality and safety standards. I am available to speak with you to discuss any questions you may have. You can reach out to the Pfizer Injectables leadership team and me at PfizerInjectables@Pfizer.com or through your Pfizer representative, and we will respond as quickly as possible.

Kind regards,

Shawn Olsson
Sr. Manager, Opioid and Syringe Technology Portfolio
Pfizer Essential Health

TABLE – List of Carpuject and iSecure Products

Product	Unit of Sale NDC	Description
0.9% Sodium Chloride Injection, USP	00409-1918-32	2 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-33	3 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-35	5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Buprenorphine Hydrochloride Injection, CIII	00409-2012-32	0.3 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Demerol™ (meperidine hydrochloride injection, USP) CII	00409-1176-30	25 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1178-30	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1179-30	75 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1180-69	100 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diazepam Injection, USP, CIV	00409-1273-32	10 mg/2 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diphenhydramine Hydrochloride Injection, USP	00409-2290-31	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Fentanyl Citrate Injection, USP, CII	00409-1276-32	100 mcg/2 mL (50 mcg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Heparin Sodium Injection, USP	00409-1316-32	5,000 USP Units/0.5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1402-12	5,000 USP Units/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Hydromorphone Hydrochloride Injection, USP, CII	00409-1283-05	0.5 mg/0.5 mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1283-31	1 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1312-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1283-10	1 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1312-10	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1304-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ketorolac Tromethamine Injection, USP	00409-2287-31	30 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2287-23	30 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2287-61	60 mg/2 mL (30 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Labetalol Hydrochloride Injection, USP	00409-2339-34	20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Lorazepam Injection, USP, CIV	00409-1985-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1539-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Metoprolol Tartrate Injection, USP	00409-1778-35	5 mg/5 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Midazolam Injection, USP CIV	00409-2306-62	2 mg/2 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2306-12	2 mg/2 mL (1 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2307-60	5 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-1890-01	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1891-01	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1890-11	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1891-11	4 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1892-01	8 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1892-11	8 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1893-01	10 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1893-11	10 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
Naloxone Hydrochloride Injection, USP	00409-1782-69	0.4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ondansetron Injection, USP	00409-1120-12	4 mg/2 mL (2 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Saline Shortages — Many Causes, No Simple Solution

Maryann Mazer-Amirshahi, Pharm.D., M.D., M.P.H., and Erin R. Fox, Pharm.D.

Severe and long-standing prescription-drug shortages have become a major threat to public health and patient safety.[1] Despite increased awareness and mitigation strategies, the United States has experienced shortages of many lifesaving drugs and other supplies essential to patient care. There was already a shortage of saline solution, for example, when Hurricane Maria devastated Puerto Rico, home to a key saline manufacturer, causing the problem to reach critical levels.[2]

Saline is an inexpensive product — it's simply salt water — but proper manufacturing practices are required to keep it sterile, pyrogen-free, and free from particulate matter. Production demands are challenging, since very large quantities are needed: more than 40 million bags per month. Saline is required for virtually all hospitalized patients, whether as a component of a medication infusion or as a hydration, resuscitation, or irrigation fluid.[2] Unfortunately, shortages of saline have become commonplace in recent years (see table).

Most drug shortages occur with older, generic, injectable medications that are produced by a small number of suppliers — typically three or fewer. The United States gets its saline from just three companies: Baxter International, B. Braun Medical, and ICU Medical. Most shortages are caused by a quality or production problem at the manufacturing facility — causes that apply to the current saline shortage as well.[2,3] In addition, when one supplier experiences a shortage, other suppliers often have insufficient manufacturing capacity to make up the difference. Drug manufacturers are not required to have redundancy in their facilities or even a business contingency plan in case of a disaster, no matter how essential or lifesaving the medication they are producing.[1]

The shortage of small-volume saline bags (250 ml or less) became dire almost immediately after Baxter's Puerto Rico manufacturing plant was hit by Hurricane Maria.[2] Baxter supplies approximately 50% of U.S. hospitals with this product, which is used as a diluent to deliver a variety of parenteral medications. Despite this tremendous need, Baxter has no redundancy in manufacturing capacity for small-volume saline bags. The other two saline suppliers have not been able to increase their production enough to make up for the shortage.[2,3] In fact, saline produced by B. Braun was already in short supply before the hurricane, as the company

History of Saline Shortages in the United States.*

Product	Date Shortage Began	Date Shortage Resolved	Reason for Shortage
0.9% Sodium chloride, small-volume bags	5/24/2007	7/25/2008	Supply unable to meet demand
0.9% Sodium chloride, large-volume bags	1/28/2013	Not yet resolved	Manufacturing delays
0.9% Sodium chloride for irrigation	8/12/2014	9/25/2015	Manufacturing problems
0.9% Sodium chloride for irrigation	11/9/2016	Not yet resolved	Manufacturing delays
0.9% Sodium chloride, small-volume bags	8/25/2017	Not yet resolved	Manufacturing delays due to Hurricane Maria

* The reasons for shortages are as determined by the University of Utah Drug Information Service. Drug-shortage information is available at www.ashp.org/shortages.

worked to correct manufacturing-quality problems.[3]

The saline shortage had actually begun in 2014, affecting large- as well as small-volume products.[4] Large-volume saline products (>500 ml) are typically used as maintenance or resuscitation fluids or for irrigation. Although some shortages of large-volume saline solutions are attributable to problems at manufacturing facilities, increased demand for intravenous fluids due to a severe influenza season has also contributed to the current short supply.[2]

Saline shortages can affect patient care in various ways. Medication errors and adverse drug events can result when medications that are typically administered as short infusions are given by intravenous push or when providers choose less familiar but more readily available products as substitutes. Increased ad hoc compounding of drugs may result in dilution errors or microbial contamination.[3,4]

Fixing the problem is difficult and requires a multifaceted approach entailing both focusing on current shortages and working to prevent future ones. Neither Congress nor the Food and Drug Administration (FDA) can force any manufacturer to produce a medication, no matter how lifesaving the product or how critical the need. Incentives such as accelerated approval for another product or tax relief for funding facility repairs may help reduce shortages, yet these incentives may have the unintended consequence of precipitating more shortages if companies value the incentives more than current profits. Alternatively, moving forward, the Department of Homeland Security could mandate that saline be considered part of the essential infrastructure, which would require the relevant companies to develop business continuity plans, although implementing manufacturing redundancies would be costly and require significant time.

The FDA's Good Manufacturing Practice rules require a minimum level of quality, yet shortages continue to occur because of poor conditions at manufacturing facilities. It is costly and time consuming to bring facilities up to standard, and the process of doing so can interrupt the supply chain. Since drug companies are not required to disclose the identity or location of the manufacturer that produces a drug,[1] a complete list of medications affected by Hurricane Maria is available only to the FDA and not to clinicians who need to plan for patient care. Woodcock and Wosinska have argued that poor quality is due to a lack of transparency regarding which company actually makes a product, because without such transparency clinicians cannot purchase drugs and supplies on the basis of quality.[1]

Changing the transparency requirements and mandating manufacturing redundancies may not change the course of the current saline shortage, but they are important actions for preventing future shortages. In response to the current shortage, the FDA has recently approved saline products from two additional manufacturers; however, there is a lag time between approval and the arrival of these products on the market. The newly approved products may also cost more than the currently available ones, since most organizations purchase their saline in a bundle that also includes tubing, pumps, and other accessories.

Importation of products can help in some cases. In response to the current saline shortage, the FDA has permitted manufacturers to import saline from their facilities in other countries, such as Brazil.[2] Importation is usually a temporary measure, because the FDA generally cannot find a company with sufficient foreign supplies to share with the U.S. market without creating a shortage in the country providing the import. When it comes to saline, logistics make it impractical to

import products for long periods: saline is heavy and bulky, making air transport costly and shipment periods lengthy. The FDA has also permitted extension of product expiration dates when that can be done safely. And Baxter's facility in Puerto Rico is expected to be functioning again in the near future, which will help to ameliorate the current shortage.[2]

In the meantime, the saline shortage has required clinicians to use a number of work-arounds that consume valuable resources and increase health care costs.[3,4] Supplies may need to be reserved for the sickest patients, and providers require an ethical framework for rationing products,[4] while pharmacy staff closely monitor inventory. Some medications now have to be administered as direct injections over several minutes, which increases the time nurses must spend with each patient. Some institutions have switched to syringe pumps or use Buretrol (Baxter) infusion devices (which hold small quantities of fluids) to deliver medications. Hospitals are also using more expensive premixed products and are changing the concentration of some medications so they can be mixed in larger volumes, when small-volume bags are unavailable. Making such changes requires substantial informatics resources, because the ordering platform in the electronic health record must be altered.[4,5] To conserve large-volume saline bags, oral hydration is recommended when possible. For patients who cannot take oral fluids or who require aggressive resuscitation, alternative crystalloid solutions may be considered. During shortages of large-volume saline irrigation solution, sterile water or even tap water may be substituted when appropriate.[4]

The current shortage of saline solutions demonstrates the profound effects that drug shortages can have on patient care. It is anticipated that the situation will improve in the United States in the coming weeks to months, although hospitals will continue to face shortages of other basic products. In the meantime, a multifaceted approach will be needed to ensure that patients safely get the medications they need.

Disclosure forms provided by the authors are available at NEJM.org.

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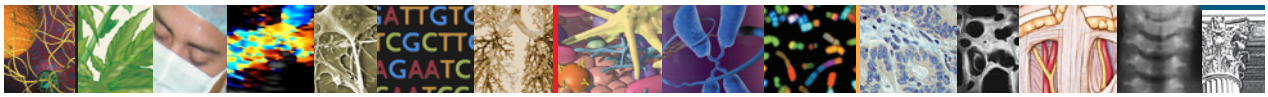

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Facing the Shortage of IV Fluids — A Hospital-Based Oral Rehydration Strategy

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Puerto Rico produces 44% of the intravenous (IV) fluid bags used in the United States.[1] On September 20, 2017, Hurricane Maria struck the island, causing a humanitarian crisis and widespread devastation that escalated a critical shortage of IV fluids throughout the United States. Initially, small-volume bags — 50- and 100-ml bags used to dilute medications — became scarce. Today, the larger 500- and 1000-ml IV-fluid bags are also in short supply. U.S. hospitals are scrambling to develop strategies for rationing IV fluids to ensure availability for the patients who need them most.

Hurricane Maria is only the latest challenge to the U.S. IV-fluid supply. Since 2014, U.S. hospitals have faced varying degrees of IV-fluid shortages, whose causes were multifactorial. IV-fluid production is complex and highly regulated in order to ensure quality and safety, which makes it expensive for hospitals and compounding pharmacies to produce their own. Most of the IV fluid used in the United States is produced by only three manufacturers, so availability is vulnerable to even small fluctuations in supply. In addition, hospitals buy IV fluids through large group-purchasing organizations representing hundreds of hospitals so that they can negotiate with manufacturers for lower prices or better access to scarce resources. Some observers argue that these organizations' market power keeps prices so low that they create a disincentive for manufacturers to increase production or for small producers to enter the market.[2]

Given these supply-side constraints, the U.S. IV-fluid supply will be vulnerable for the foreseeable future. It is therefore critical for U.S. hospitals to develop both short- and long-term alternatives to IV-fluid use.

Emergency departments (EDs) are substantial consumers of IV fluids in the United States. The 59-bed ED at Brigham and Women's Hospital treats more than 62,000 adult patients each year and, in the 5 months from September 2017 through January 2018, used 8519 liters of IV fluids — nearly 30% of the hospital's total consumption. As the current IV-fluid shortage worsened, the team in the Division of International Emergency Medicine and Humanitarian Programs of the Department of Emergency Medicine was asked to develop an oral

Brigham and Women's Hospital Oral Rehydration Protocol

Use for patients with mild dehydration — in general, patients with the following conditions:

- Acute gastroenteritis
- Pregnancy-related hyperemesis
- Mild viral upper respiratory infection or pharyngitis

Exclusion Criteria:

- Moderate or severe dehydration
- Inability to receive oral intake for another reason

Protocol Steps:

1. Order oral rehydration fluids in the electronic health record (EHR); add antiemetic, pain control, or both if needed. Consider benzocaine or menthol lozenges in addition to acetaminophen or ibuprofen for pharyngitis. If there is significant nausea or pain, wait 20 min after medications to begin drinking (can start immediately otherwise).
2. The EHR order will direct the nurse to bring the patient two 500-ml pitchers of desired drink (flavored oral electrolyte solution or dilute sports drink or juice).
   - Provide patient with straw as well as 30-ml medicine cup.
   - Instruct patient to drink two large sips or 30 ml every 3–5 min. Use timers on cell phones or ask family to assist.
   - Explain target hydration goals (see below) and provide a tracking sheet. Draw lines on pitcher for target volumes (e.g., "250 ml left"). Patient or family member should complete the tracking sheet.
   - Return to reencourage oral intake as needed.
3. Troubleshooting:
   - If oral intake is insufficient, determine why and give additional antiemetic, pain control, or both as needed.
   - If taste is a problem and dehydration mild (or not due to gastroenteritis), consider alternative liquid options, such as half-strength sports drink, dilute juice, or ginger ale.
4. For pregnancy-related hyperemesis, oral intake can often help. Encourage patients to try to eat a few crackers if possible.

Target Hydration Goals*:

Target times are given for the amount of liquid remaining at 2 sips or 30 ml every 3 min (or every 5 min)

- 1000 ml remaining: 0 min (0 min)
- 750 ml remaining: 25 min (40 min)
- 500 ml remaining: 50 min (1 hr 20 min)
- 250 ml remaining: 1 hr 15 min (2 hr)
- 0 ml remaining: 1 hr 40 min (2 hr 40 min)

* Patients with vomiting should be encouraged to maintain a slower rate of intake until they tolerate the fluid well. Patients without vomiting can drink faster, as tolerated. After an intake of 250 ml has been successfully completed without vomiting, and if nausea is well controlled, intake can increase to four sips or 60 ml every 3–5 min.

rehydration protocol for ED patients with mild dehydration. The protocol outlined in the box has since been adopted hospital-wide.

Oral rehydration therapy has been studied for nearly 60 years. It has been shown to reduce mortality from diarrheal illnesses by 93%[3] and to reduce the case fatality rate of cholera from 30% to 1%.[4] It is less expensive than IV-fluid therapy, and its use results in fewer admissions and shorter lengths of stay.[5] A 2006 meta-analysis showed that oral rehydration was equivalent to the administration of IV fluid for the management of dehydration due to gastroenteritis in children.[5] Data on use in adults have revealed similar efficacy, although in smaller studies. Oral rehydration therapy has been widely adopted in low- and middle-income countries where IV fluids are expensive and resources limited. Conversely, despite this evidence, oral rehydration has not been widely used in adults in high-income countries, probably owing to the widespread availability and ease of use of IV fluids.

Our protocol is based on research[3-5] and protocols for oral rehydration in low-resource settings and in the United States and on our experience as emergency physicians with more than 50 combined years of work in health care delivery in low- and middle-income countries around the world.

Patients who meet the criteria for deployment of our protocol are adults with mild dehydration from conditions such as pharyngitis, gastroenteritis, pregnancy-related vomiting, and upper respiratory tract infection. Patients with severe dehydration or who are unable to take liquids by mouth for other reasons (e.g., small bowel obstruction) are excluded; these patients constitute the minority of our ED patients who traditionally receive IV fluid. The hospital also created a new order in our electronic medical record and order-entry system, called Oral Rehydration Fluids, that streamlines the process.

Under our protocol, we aim to have patients take 500 to 1000 ml of oral fluids while in the ED, since patients who drink this volume successfully can most likely continue oral rehydration at home. Providers are encouraged to offer analgesics, antipyretics, and antiemetics as needed to improve the tolerance of oral hydration. Patients may start drinking immediately if they are able, or they may wait 20 minutes for symptom improvement after administration of these comfort medications. Patients are offered their choice of drinks, including artifi-

cially flavored oral electrolyte solution, water, dilute juice, or dilute sports drinks. If electrolyte disturbances are suspected on the basis of the clinical presentation, the oral electrolyte solution is preferred. Using powdered formulations of sports drinks reduces the storage space needed. The variety of fluid options reduces reliance on a single brand-name product. As with IV strategies, clinical judgment must be used when choosing oral hydration in patients with coexisting conditions such as renal disease, diabetes, or heart failure.

Each patient is provided a straw, a 30-ml medicine cup, and 1000 ml of the patient's preferred fluid. Patients are instructed to drink 30 ml (two large sips) every 3 to 5 minutes and may ask family members or use a cellphone to time the sips. Providers explain the drinking goals (see box) and draw lines on the pitchers to delineate target volumes (e.g., "250 ml left").

The patient or a family member completes a tracking sheet to monitor total intake. Patient and family participation is key to success. Encouragement is offered regularly. Patients with insufficient oral intake are reevaluated and given additional antiemetics and pain control as needed. If the patient doesn't like the taste of the chosen drink, another drink is tried. The patient may increase the pace after tolerating the first 250 ml. Patients who vomit should wait 20 minutes before starting to drink again.

To ensure implementation of our protocol, providers were sent an email message by hospital leadership detailing the IV-fluid shortage and the oral rehydration protocol. ED nursing leaders trained nurses and ED technicians and posted flyers throughout the ED. We also provided additional training and reminders about the oral rehydration protocol to our faculty and residents.

We are now studying the impact of our protocol on IV-fluid use. According to our preliminary data, IV-fluid use by volume decreased by just over 30% in the first week after the oral hydration protocol was distributed throughout the hospital. In the 3 weeks after protocol implementation, the fraction of ED patients with IV-fluid orders decreased by 15%.

There are potential limitations to our protocol. Oral rehydration can take longer than IV hydration and requires more effort from the patient. However, it also causes less pain because there is no IV catheter insertion, and our protocol's emphasis on structured time goals and drinking small amounts can encourage patients to stay hydrated in a manner that they can continue at home. Although oral rehydration can be effective in moderate to severe dehydration, with the use of a nasogastric tube if needed, currently our protocol targets mild dehydration only. It could be expanded to include more severe cases if the IV-fluid shortage worsened.

We share this protocol as a replicable model for other U.S. hospitals looking for strategies during the IV-fluid shortage. Experience in low-resource settings worldwide has proven the efficacy of oral rehydration therapy, and vulnerabilities of the U.S. IV-fluid supply chain are expected to continue. We believe that widespread use of oral rehydration protocols would therefore be a rational practice change and a mainstream model for use in the United States even after the current IV-fluid shortage crisis ends.

Disclosure forms provided by the authors are available at NEJM.org.

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The Other Opioid Crisis: Hospital Shortages Lead To Patient Pain, Medical Errors

By Pauline Bartolone (https://californiahealthline.org/news/author/pauline-bartolone/)

March 16, 2018

(Hero Images/Getty Images)

[UPDATED at 2:30 p.m. PT on March 16]

Even as opioids flood American communities and fuel widespread addiction, hospitals are facing a dangerous shortage of the powerful painkillers needed by patients in acute pain, according to doctors, pharmacists and a coalition of health groups.

The shortage, though more significant in some places than others, has left many hospitals and surgical centers scrambling to find enough injectable morphine (https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Morphine%20Sulfate%20Injection,%20USP&st=c), Dilaudid and fentanyl (https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Fentanyl%20Citrate%20(Sublimaze)%20Injection&st=c) — drugs given to patients undergoing surgery, fighting cancer or suffering traumatic injuries. The shortfall, which has intensified since last summer, was triggered by manufacturing setbacks and a government effort to reduce addiction by restricting drug production.

As a result, hospital pharmacists are working long hours to find alternatives, forcing nurses to administer second-choice drugs or deliver standard drugs differently. That raises the risk of mistakes — and already has led to at least a few instances in which patients received potentially harmful doses, according to the nonprofit Institute for Safe Medication Practices (http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=1185), which works with health care providers to promote patient safety.

In the institute's survey of hospital pharmacists last year, one provider reported that a patient received five times the appropriate amount of morphine when a smaller-dose vial was out of stock. In another case, a patient was mistakenly given too much sufentanil, which can be up to 10 times more powerful than fentanyl, the ideal medication for that situation.

In response to the shortages, doctors in states as far-flung as California, Illinois and Alabama are improvising the best they can. Some patients are receiving less potent medications like acetaminophen or muscle relaxants as hospitals direct their scant supplies to higher-priority cases. Other patients are languishing in pain because preferred, more powerful medications aren't available, or because they have to wait for substitute oral drugs to kick in.

The American Society of Anesthesiologists confirmed that some elective surgeries, which can include gall bladder removal and hernia repair, have been postponed.

In a Feb. 27 letter (https://www.aha.org/system/files/2018-02/180227-joint-letter-to-dea-re-apq-for-iv-opioids.pdf) to the U.S. Drug Enforcement Administration, a coalition of professional medical groups — including the American Hospital Association, the American Society of Clinical Oncology and the American Society of Health-System Pharmacists — said the shortages "increase the risk of medical errors" and are "potentially life-threatening."

In addition, "having diminished supply of these critical drugs, or no supply at all, can cause suboptimal pain control or sedation for patients," the group wrote.

The shortages involve prefilled syringes of these drugs, as well as small ampules and vials of liquid medication that can be added to bags of intravenous fluids.

Drug shortages are common, especially of certain injectable drugs, because few companies make them. But experts say opioid shortages carry a higher risk than other medications.

Giving the wrong dose of morphine, for example, "can lead to severe harm or fatalities," explained Mike Ganio, a medication safety expert at the American Society of Health-System Pharmacists.

Marchelle Vernell (Courtesy of Marchelle Vernell)

Calculating dosages can be difficult and seemingly small mistakes by pharmacists, doctors or nurses can make a big difference, experts said.

Marchelle Vernell, a nurse at St. Louis University Hospital in Missouri, said it would be easy for medical mistakes to occur during a shortage. For instance, in a fast-paced environment, a nurse could forget to program an electronic pump for the appropriate dose when given a mix of intravenous fluids and medication to which she was unaccustomed.

“The system has been set up safely for the drugs and the care processes that we ordinarily use,” said Dr. Beverly Philip, vice president for scientific affairs at the American Society of Anesthesiologists. “You change those drugs, and you change those care processes, and the safety that we had built in is just not there anymore.”

Dr. Beverly Philip (Courtesy of the American Society of Anesthesiologists)

Chicago-based Marti Smith, a nurse and spokeswoman for the National Nurses United union, offered an example.

“If your drug comes in a prefilled syringe and at 1 milligram, and you need to give 1 milligram, it’s easy,” she said. “But if you have to pull it out of a 25-milligram vial, you know, it’s not that we’re not smart enough to figure it out, it just adds another layer of possible error.”

During the last major opioid shortage in 2010, two patients died from overdoses when a more powerful opioid was mistakenly prescribed, according to the institute. Other patients had to be revived after receiving inaccurate doses.

The shortage of the three medications, which is being tracked by the FDA (https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm), became critical last year as a result of manufacturing problems at Pfizer, which controls at least 60 percent of the market of injectable opioids, said Erin Fox, a drug shortage expert at the University of Utah.

A Pfizer spokesman, Steve Danehy, said its shortage started in June 2017 when the company cut back production while upgrading its plant in McPherson, Kan. The company is not currently distributing prefilled syringes “to ensure patient safety,” it said, because of problems with a third-party supplier it declined to name.

That followed a February 2017 report (https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm542587.htm) by the U.S. Food and Drug Administration that found significant violations at the McPherson plant. The agency cited “visible particulates” floating in the liquid medications and a “significant loss of control in your manufacturing process [that] represents a severe risk of harm to patients.” Pfizer said, however, that the FDA report wasn’t the impetus for the factory upgrades.

Other liquid-opioid manufacturers, including West-Ward Pharmaceuticals (http://www.west-ward.com/) and Fresenius Kabi (https://www.fresenius-kabi.com/index), are deluged with back orders, Fox said. Importing these heavily regulated narcotics from other countries is unprecedented and unlikely, she added, in part because it would require federal approval.

At the same time, in an attempt to reduce the misuse of opioid painkillers, the Drug Enforcement Administration called for a 25 percent reduction of all opioid manufacturing last year, and an additional 20 percent this year.

“DEA must balance the production of what is needed for legitimate use against the production of an excessive amount of these potentially harmful substances,” the agency said in August (https://www.dea.gov/divisions/hq/2017/hq080417.shtml).

When the coalition of health groups penned its letter to the DEA last month, it asked the agency to loosen the restrictions for liquid opioids to ease the strain on hospitals.

The shortages are not being felt evenly across all hospitals. Dr. Melissa Dillmon, medical oncologist at the Harbin Clinic in Rome, Ga., said that by shopping around for other suppliers and using pill forms of the painkillers, her cancer patients are getting the pain relief they need.

Dr. Shalini Shah (Courtesy of University of California-Irvine)

Dr. Shalini Shah (http://www.ucirvinehealth.org/find-a-doctor/s/shalini-shah), the head of pain medicine at the University of California-Irvine health system, pulled together a team of 20 people in January to figure out how to meet patients’ needs. The group meets for an hour twice a week.

The group has established workarounds, such as giving tablet forms of the opioids to patients who can swallow, using local anesthetics like nerve blocks and substituting opiates with acetaminophen, ketamine and muscle relaxants.

“We essentially have to ration to patients that are most vulnerable,” Shah said.

Two other California hospital systems, Kaiser Permanente and Dignity Health in Sacramento, confirmed they’re experiencing shortages, and that staff are being judicious with their supplies and using alternative medications when necessary. (Kaiser Health News, which produces California Healthline, is not affiliated with Kaiser Permanente.)

At Helen Keller Hospital’s emergency department in Sheffield, Ala., earlier this month, a 20-year-old showed up with second-degree burns. Dr. Hamad Husainy said he didn’t have what he needed to keep her out of pain.

Sometime in January, the hospital ran out of Dilaudid, a drug seven times more potent than morphine, and has been low on other injectable opioids, he said.

Because Husainy’s patient was a former opioid user, she had a higher tolerance to the drugs. She needed something strong like Dilaudid to keep her out of pain during a two-hour ride to a burn center, he said.

“It really posed a problem,” said Husainy, who was certain she was in pain even after giving her several doses of the less potent morphine. “We did what we could, the best that we could,” he said.

Vernell, the St. Louis nurse, said some trauma patients have had to wait 30 minutes before getting pain relief because of the shortages.

Dr. Howie Mell (Courtesy of Howie Mell)

“That’s too long,” said Vernell, a former intensive care nurse who now works in radiology.

Dr. Howie Mell, an emergency physician in Chicago, said his large hospital system, which he declined to name, hasn’t had Dilaudid since January. Morphine is being set aside for patients who need surgery, he said, and the facility has about a week’s supply of fentanyl.

Mell, who is also a spokesman for the American College of Emergency Physicians, said some emergency departments are considering using nitrous oxide, or “laughing gas,” to manage patient pain, he said.

When Mell first heard about the shortage six months ago, he thought a nationwide scarcity of the widely used drugs would force policymakers to “come up with a solution” before it became dire.

“But they didn’t,” he said.

[Correction and clarification: This story was updated at 2:30 p.m. PT on March 16 to correct the spelling of nurse Marchelle Vernell’s name. It was also updated to revise Dr. Beverly Philip’s affiliation as vice president for scientific affairs at the American Society of Anesthesiologists.]

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 4, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Incidents of Smart Pump Malfunctioning

SUMMARY

Although free-flow protection is a safety feature in many of the smart pumps, a few hospitals recently shared with us that uncontrolled free-flow of medications have occurred in cases when smart pumps were correctly programmed and there was no evidence of tubing misload or defects of any parts of the pumps/infusion sets. These incidents involved both high-risk medications (morphine, insulin drips, TPN) and high-risk populations (pediatrics), and some of these cases resulted in serious outcomes. In other incidents, the free-flow was noticed by staff timely and harm was averted, however the potential for serious patient harm was apparent. In one incident, a 250ml bag of morphine 1mg/ml was infused over 1.5 hour versus the prescribed dose of 1mg per hour. In all these cases, the pump alarm (visual or audible) was not triggered to alert staff of the free-flow infusion mode. Internal investigations by hospitals were unable to identify the causes of the pump malfunctioning and the free-flow infusion mode could not be replicated during investigations. Upon review of data downloaded from the smart pump in one case, there was an entry indicating "free flow alarmed" in the report during the period of free-flow infusion but staff reported that no visible or audible alarm was activated. The manufacturer indicated that they were aware of some reports of free-flow occurring in their smart pumps without an alarm having been triggered, but declined to further comment.

ACTION REQESTED

- Alert hospital staff of these incidents and report any similar incidents to the manufacturer, ISMP and FDA.

BJB:br

Safe Table Meeting Schedule 2018

01/18/2018	Via Teleconference	Behavioral Health – Inpatient Setting
02/07/2018	Via Teleconference	Telemetry Monitoring Criteria
02/15/2018	Rural Hospitals via teleconference	Mass Transfusion Protocol
03/08/2018	Children's Hospitals/Pediatric Units via teleconference	Alarm Management
03/21/2018	Via Teleconference	Medication Reconciliation
04/11/2018	Via Teleconference	POLST Form Use with End-of-Life Care
04/25/2018	Via Teleconference	EHR Alert Fatigue
05/16/2018	Via Teleconference	Patient Identification
05/24/2018	Via Teleconference	Behavioral Health
06/13/2018	Children's Hospitals/Pediatric Units via teleconference	TBD
06/28/2018	Rural Hospitals via teleconference	TBD
07/05/2018	Via Teleconference	TBD
07/19/2018	Via Teleconference	TBD
08/08/2018	Children's Hospitals/Pediatric Units via teleconference	TBD
08/16/2018	Rural Hospitals via teleconference	TBD
09/12/2018	Via Teleconference	TBD
09/20/2018	Via Teleconference	TBD
10/03/2018	Children's Hospitals/Pediatric Units via teleconference	TBD
10/10/2018	Rural Hospitals via teleconference	TBD
11/14/2018	Via Teleconference	TBD
11/28/2018	Via Teleconference	TBD
12/12/2018	Via Teleconference	TBD

Capabilities for medication safety

CHPSO welcomes collaborations that could improve patient safety. We currently are part of a major grant to develop and disseminate a CPOE "flight simulator" for the ambulatory setting. We also are working with several academic institutions. Additional collaborations are welcomed.

Database currently (March 21) has 450,000 medication events, and an additional 680,000 events that are uncategorized, so there may be some medication events there as well. We have developed a mapping between text in the reports and the RxNorm[1] ingredient concepts. From there it is mapped to the NDFRT[2] pharmacologic class concepts. This allows us to search and aggregate events based on drug ingredients or classes.

Following are two examples of the analyses we can do. Suggestions as to future directions are welcome.

[1] Produced by the National Library of Medicine.

[2] National Drug File – Reference Terminology, produced by the U.S. Department of Veterans Affairs, Veterans Health Administration. For a few drug classes not present in NDFRT, the WHO Anatomical Therapeutic Chemical (ATC) system is used.

Words disproportionately associated with outpatient drug events

The Bayesian confidence propagation neural network (BCPNN) method measures association by the information component (IC) defined as the logarithm of the ratio of the observed rate of a specific word-AE combination to the expected rate of AE under the null hypothesis of no association between the word and the event. Thus, when a word-AE combination is reported more often than expected relative to general reporting of the words and the AEs it results into positive values of IC.

Following is a partial listing comparing outpatient medication events to inpatients events. What words are more likely to be in outpatient events than inpatient, as expressed by the lower 95% credible bound of the IC. Note that drug names have been converted to ingredients prior to analysis. This, for example, combines “acetaminophen” and “Tylenol” into the same word.

paused	4.000524	nivolumab	3.297127
obinutuzumab	3.799433	premeds	3.296083
risks	3.66602	tolerated	3.295087
shortening	3.659723	Hydrocortisone	3.293204
COMPLICATIONS	3.632265	trastuzumab	3.263268
transportation	3.598455	constriction	3.257899
rigors	3.574704	Carboplatin	3.253404
shortened	3.570158	sequelae	3.241812
irb	3.567693	year-old	3.238629
cancer	3.558444	subtype	3.211905
terminate	3.552509	RITUXIMAB	3.207296
ocrelizumab	3.548585	inadequate	3.20054
rechallenged	3.518794	warmth	3.185164
termination	3.502703	palonosetron	3.175044
daratumumab	3.444078	dialyze	3.139172
rechallenge	3.423902	flushing	3.130994
toll	3.400999	regulatory	3.115544
premedicated	3.384493	irinotecan	3.090915
Docetaxel	3.372696	entirely	3.056976
center	3.343621	pembrolizumab	3.054391
oxaliplatin	3.343337	premedications	3.039817
chairside	3.342397	subsided	3.03566
rated	3.341173	cramping	3.0348
Paclitaxel	3.337354	hypersensitivity	3.027078
advanced	3.320142	escalated	3.024001
remainder	3.317661	ambulatory	3.018501
challenged	3.31304	incorporating	3.017908
totally	3.308628	pertuzumab	3.012182

denosumab	3.011846
Antimycobacterial	2.999793
COMPLETION	2.997818
gravity	2.993814
cycle	2.98982
ALEMTUZUMAB	2.989337
bevacizumab	2.98822
clinic	2.975096
challenge	2.972869
resting	2.969282
imperative	2.966135
tightness	2.935968
completing	2.927971
cycles	2.924434
pegfilgrastim	2.906419
Fluorouracil	2.894936
pruritus	2.892916
scratchy	2.889847
Pentamidine	2.881091
afterhours	2.856593
cetuximab	2.8514
reacted	2.847791
excellent	2.847237
custody	2.837886
guideline	2.821494
bendamustine	2.807724
fullness	2.80318
gemcitabine	2.800741
graveyard	2.791761
verbalized	2.77016
restarted	2.762432
throat	2.760797
full-body	2.75948
trial	2.75146
chills	2.748831
doxorubicin liposome	2.747634
slowly	2.746665
persisted	2.745968
Leucovorin	2.7421
Granisetron	2.739611
AMA	2.736868
beacon	2.731323
infliximab	2.728503
Ipilimumab	2.720294
hemodialysis	2.686185
ovarian	2.685861
Famotidine	2.685843
ferumoxytol	2.683395
Pyrazinamide	2.680048
appointments	2.646414
restroom	2.63525
adjuvant	2.633069
sensation	2.632694
Ethambutol	2.630505
bortezomib	2.629111
preventable	2.628355
isoniazid	2.627299
approvals	2.625294
affecting	2.624983
reinforced	2.624748
ambulated	2.623696
congestion	2.619623
rigor	2.61467
diaphoresis	2.612536
cramps	2.59344
Cyclophosphamide	2.588718
tingling	2.587188
feeling	2.585267
vitals	2.581516
tolerate	2.580036
rest	2.579855
seek	2.578042
understanding	2.575385
precautions	2.569814
Ocrelizumab Ocrevus)	2.565642
encountered	2.554866
consequences	2.552763
cll	2.550404
heaviness	2.543481
poliovirus vaccine inactivated, type 2 (MEF-1)	2.537465
ferric carboxymaltose	2.536924
zoledronic acid	2.534444
reactions	2.52536
Texium	2.525171

Streptococcus pneumoniae serotype 19F capsular antigen diphtheria CRM197 protein conjugate vaccine	2.523161
Streptococcus pneumoniae serotype 23F capsular antigen diphtheria CRM197 protein conjugate vaccine	2.52247
Streptococcus pneumoniae serotype 4 capsular antigen diphtheria CRM197 protein conjugate vaccine	2.522447
Streptococcus pneumoniae serotype 6B capsular antigen diphtheria CRM197 protein conjugate vaccine	2.522206
Streptococcus pneumoniae serotype 14 capsular antigen diphtheria CRM197 protein conjugate vaccine	2.521576
Streptococcus pneumoniae serotype 9V capsular antigen diphtheria CRM197 protein conjugate vaccine	2.51961
aprepitant	2.51854
Streptococcus pneumoniae serotype 18C capsular antigen diphtheria CRM197 protein conjugate vaccine	2.518259
sudden	2.517178
Immunoglobulin G	2.516872
erythema	2.516503
COMPLAINED	2.511146
tb	2.498456
subside	2.492184
Cetirizine	2.487237
Dialysis	2.480703
watch	2.477312
premedication	2.47526
EXAM	2.470437
abated	2.464377
premed	2.463769
symptoms	2.461815
terminated	2.459464
summoned	2.45022
urticaria	2.446165
hoarseness	2.441769
causes	2.439311
Trendelenburg	2.437958
dialyzed	2.436716
chair	2.436525
poliovirus vaccine inactivated, type 1 (Mahoney)	2.433754
poliovirus vaccine inactivated, type 3 (Saukett)	2.432227
deemed	2.428212
verbalizes	2.427039
appointment	2.426672
markedly	2.426549
symptom	2.423488
events	2.421674
ACCOMPANIED	2.42167
bumped	2.408254
breast	2.40637
facial	2.401877
sensations	2.380895
blankets	2.371685
oropharynx	2.370468
racing	2.369887
neoadjuvant	2.353193
seated	2.345044
ASYMPTOMATIC	2.344888
Iron-Dextran Complex	2.339912
rhinorrhea	2.331252
providing	2.330768
credentialing	2.330689
mildly	2.329779
ofatumumab	2.327155
Hepatitis B Surface Antigen Vaccine	2.326898
driving	2.320058
aria	2.319595
pegaspargase	2.304113
minutes	2.299305
sob	2.294073
infusion	2.292153
completely	2.287637
cheeks	2.287567
weaned	2.284203
Rifampin	2.2801
coughing	2.273935
bilaterally	2.273041
Doxorubicin	2.252176
supine	2.250505
azacitidine	2.241631

Cisplatin	2.229916
observed	2.228884
perioral	2.227578
pemetrexed	2.223676
Varicella-Zoster Virus Vaccine Live (Oka-Merck) strain	2.215825
slower	2.215678
complication	2.215665
nrbm	2.2084
estimated	2.206913
evaluate	2.206737
scalp	2.201569
fosaprepitant	2.194548
Leuprolide	2.182211
CHEST	2.181474
comparable	2.173837
suggested	2.171006
hot	2.163685
gauze	2.160184
metastatic	2.156271
mediastinal	2.153193
BoxPicker	2.14674
conjugate	2.134743
combinations	2.128007
ACCUMULATIVE	2.120201
Dexamethasone	2.119185
vaccines	2.112721
treating	2.112628
dissipated	2.112411
Pertussis Vaccine	2.110781
elected	2.109476
hands	2.103087
onset	2.102637
radiation	2.102103
category	2.095925
feet	2.086191
discomfort	2.079137
heat	2.07884
relief	2.069973
whole-body	2.065828
investigational	2.059457
brisk	2.058531
reminded	2.057169
adverse	2.056423
offices	2.056176
reclined	2.054696
feels	2.054384
resumed	2.048113
myeloma	2.04358
factors	2.043042
coban	2.031592
half-rate	2.027401
lymphoma	2.025418
radiating	2.02
Meperidine	2.01314
Immune Globulin (Human) (IVIG)	2.01228
latent	2.009901
stomach	2.009623
suddenly	2.007887
Rituxan	2.007232
pausing	2.002689
Dextran	2.001712

Association between drug classes in reports and harm in reported events

Question: For medication event reports, is there an association between the mention in the event of certain drug classes and the level of harm reported? Note this is all about what gets reported, and does not provide information about incidence. These are signals, of possible association between the drug and harm.

Harm Reporting Ratio (HRR)

- Numerator: severe harm and death events
- Denominator: events where harm was assessed plus near misses and unsafe conditions (where no harm exists).

Class	N	Odds Ratio HRR	95% CI	Sig
Coumadin	8,076	3.82	(3.04–4.75)	≤ 0.001
DTI	773	3.66	(1.88–6.37)	≤ 0.001
Opioid:benzo	3,820	3.11	(1.94–5.00)	≤ 0.001
Heparin	13,019	2.18	(1.73–2.72)	≤ 0.001
Antipsychotic	3,087	2.03	(1.28–3.02)	≤ 0.001
Opioid	47,136	1.40	(1.17–1.66)	≤ 0.001
Benzo	17,320	1.05	(0.74–1.44)	NS
Insulin	20,882	0.54	(0.36–0.77)	≤ 0.001

Key:

- benzo: benzodiazepines, non-benzodiazepine hypnotics, and flumazenil.
- coumadin: vit-K antagonists and vit-K, excluding neonates.
- DTI: direct thrombin inhibitors.
- opioid: opioid agonists and antagonists, including naloxone.
- opioid:benzo: effect when both are present in the same report.

Included: All events identified as *Medication or Other Substance*.

Excluded: Events with any of the following words: *'discrepancy', 'discrepant', 'discrepancies', 'count', 'counted', 'counts', 'waste', 'wasted', 'wasting', 'wasted', 'diversion', 'diverted', 'divert', 'diverting'*. Also excluded, events excluded from HRR denominator. After exclusions, N=340,679.

Other drug classes tested as “controls”. Their odds ratio was consistent with no relationship (about 1):

- Penicillins/cephalosporins. N=39,217.
- Vancomycin. N=12,084.

OPIOIDS	BENZODIAZEPINES	HEPARINS	ANTIPSYCHOTICS	INSULIN	DIRECT THROMBIN INHIBITORS
Alfentanil	Alprazolam	Dalteparin	aripiprazole	Insulin	Argatroban
alvimopan	Baclofen	Enoxaparin	Asenapine	insulin degludec	Bivalirudin
Buprenorphine	Benzodiazepine	heparin	brexpiprazole	insulin detemir	Dabigatran
Butorphanol	Bromazepam	Protamines	cariprazine	Insulin Glargine	Dabigatran etexilate
Codeine	Chlordiazepoxide	tinzaparin	Clozapine	Insulin Lispro	Desirudin
dihydrocodeine	clobazam		Fluspirilene	Insulin, Aspart, Human	Lepirudin
eluxadoline	Clonazepam		Haloperidol	Insulin, Glulisine, Human	
Fentanyl	clorazepate		iloperidone	insulin, isophane	
Heroin	Diazepam		Loxapine	Insulin, Protamine Lispro, Human	
Hydrocodone	dichloralphenazone		lurasidone	Insulin, Protamine Zinc, Beef-Pork	
Hydromorphone	Estazolam		Molindone	Regular Insulin, Human	
Levorphanol	Eszopiclone		olanzapine		
Loperamide	Flumazenil		paliperidone		
Meperidine	Flunitrazepam		pimavanserin		
Methadone	Flurazepam		Pimozide		
methylnaltrexone	halazepam		quetiapine		
Morphine	Lorazepam		Risperidone		
Nalbuphine	lormetazepam		Thiothixene		
naldemedine	Medazepam		Typical Antipsychotic		
nalmefene	metaclazepam		ziprasidone		
naloxegol	Midazolam				
Naloxone	Nitrazepam				
Naltrexone	Nordazepam				
Narceine	Oxazepam				
Opioid Agonist	Prazepam				
Opioid Analgesic	quazepam				
Opium	Temazepam				
Oxycodone	tetrazepam				
Oxymorphone	Triazolam				
Pentazocine	zolpidem				
Propoxyphene					
remifentanil					
Sufentanil					
tapentadol					
Tramadol					

What drug classes are most commonly mentioned in drug events?

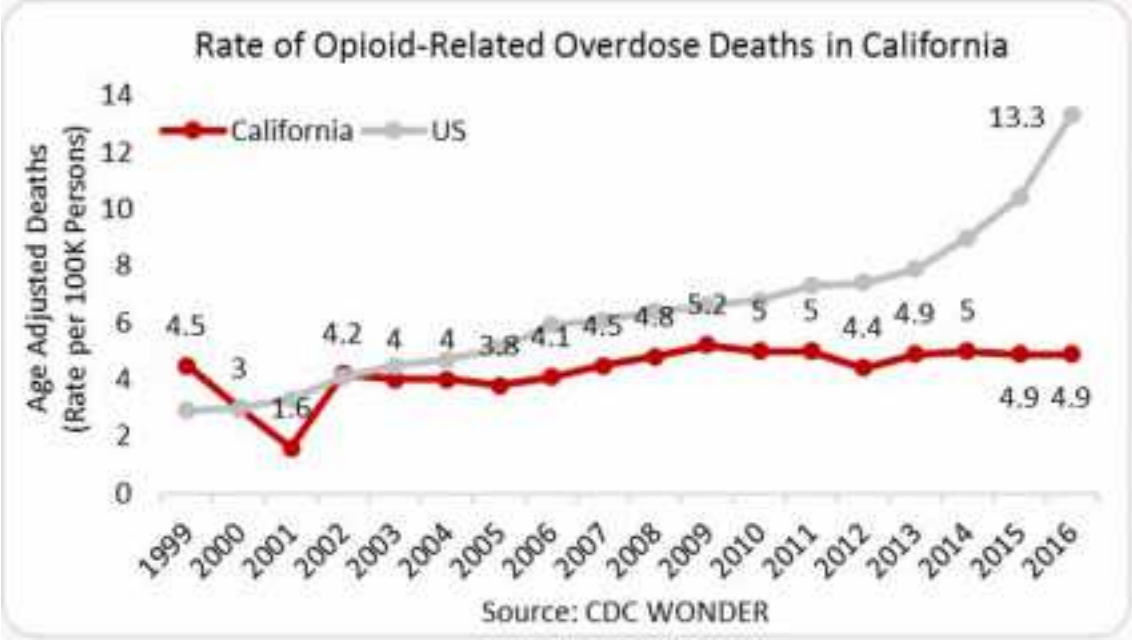
Opioid Agonist	77700
Penicillin-class Antibacterial	34904
Benzodiazepine	24400
Acetaminophen	23499
Insulin	19791
Corticosteroid	14863
Histamine-1 Receptor Antagonist	13679
Glycopeptide Antibacterial	13585
Insulin Analog	11906
Cephalosporin Antibacterial	11641
Anti-coagulant	11361
Glucose	11332
Vitamin K Antagonist	10525
Unfractionated Heparin	10347
Nonsteroidal Anti-inflammatory Drug	9776
Potassium Salt	7741
beta-Adrenergic Blocker	7116
Antiarrhythmic	6989
Radiographic Contrast Agent	6659
Anti-epileptic Agent	6397
Opioid Antagonist	6055
beta Lactamase Inhibitor	5897
Quinolone Antimicrobial	5804
Loop Diuretic	5758
Low Molecular Weight Heparin	5480
Catecholamine	5308
Amide Local Anesthetic	5140
Proton Pump Inhibitor	5067
Serotonin-3 Receptor Antagonist	4987
beta2-Adrenergic Agonist	4869
Angiotensin Converting Enzyme Inhibitor	4342
Platelet Aggregation Inhibitor	4141
Anticholinergic	3652
Sodium	3574
Histamine-2 Receptor Antagonist	3470
beta-Adrenergic Agonist	3363
alpha-Adrenergic Agonist	3205
General Anesthetic	3168
Antidote	3055
Atypical Antipsychotic	2937
Magnesium	2806
Nitroimidazole Antimicrobial	2471
alpha-Adrenergic Blocker	2408
Sulfonylurea	2322
Calcium Channel Blocker	2255
Aminoglycoside Antibacterial	2246
Phenothiazine	2182
Dihydropyridine Calcium Channel Blocker	2175
Macrolide Antimicrobial	2169
Nitrate Vasodilator	2163
Cyclooxygenase Inhibitor	2148
gamma-Aminobutyric Acid-ergic Agonist	2000
Calcium	1964
Phosphate Binder	1956
Biguanide	1886
Thiazide Diuretic	1869
HMG-CoA Reductase Inhibitor	1869
Cholinergic Muscarinic Antagonist	1844
Factor Xa Inhibitor	1820
Typical Antipsychotic	1819
Mood Stabilizer	1778
Serotonin Reuptake Inhibitor	1750
Sulfonamide Antimicrobial	1745
P2Y12 Platelet Inhibitor	1709
Dihydrofolate Reductase Inhibitor Antibacterial	1680
Central alpha-2 Adrenergic Agonist	1616
Lincosamide Antibacterial	1572
Cardiac Glycoside	1560
Dopamine-2 Receptor Antagonist	1526
Benzodiazepine Antagonist	1525
Arteriolar Vasodilator	1516
Penem Antibacterial	1508
Angiotensin 2 Receptor Blocker	1406
Potassium Binder	1393
Leukocyte Growth Factor	1328
Platinum-based Drug	1288
Oxytocic	1231
Human Serum Albumin	1201
Microtubule Inhibitor	1156
Central Nervous System Stimulant	1137
l-Thyroxine	1117
CD20-directed Cytolytic Antibody	1102
Thrombolytic Agent	1094
Azole Antifungal	1079
Antihistamine	1077
Osmotic Laxative	1050
Creatinine	1046
Docusate	1032
Electrolyte	997
Aldosterone Antagonist	988
Stimulant Laxative	974
Barbiturate	964
Direct Thrombin Inhibitor	958
Parenteral Iron Replacement	938
alpha-1 Adrenergic Agonist	930
Nucleoside Metabolic Inhibitor	906
Immunoglobulin G	868
Erythropoiesis-stimulating Agent	848
Muscle Relaxant	818
Alkylating Drug	800
gluconate	777
Methylxanthine	709
Inactivated Clostridium Tetani Vaccine	690
Nondepolarizing Neuromuscular Blocker	666
Ester Local Anesthetic	665

This report provides an overview of current work to address the opioid crisis in California. Hospitals, healthcare providers, Hospital Quality Institute partnered with HSAG HIIN, hospital associations and multiple stakeholder groups are working together to align and optimize effort to save lives and move upstream to de-prescribing and managing access to opioid substances. The sampling of 2018 initiatives can be used for the purpose of HSAG HIIN planning to target ADEs, with a focus on opioids.
Note: HQI point of contact is listed next to the coalition where there is an affiliation

CALIFORNIA ADDRESSES THE OPIOID EPIDEMIC

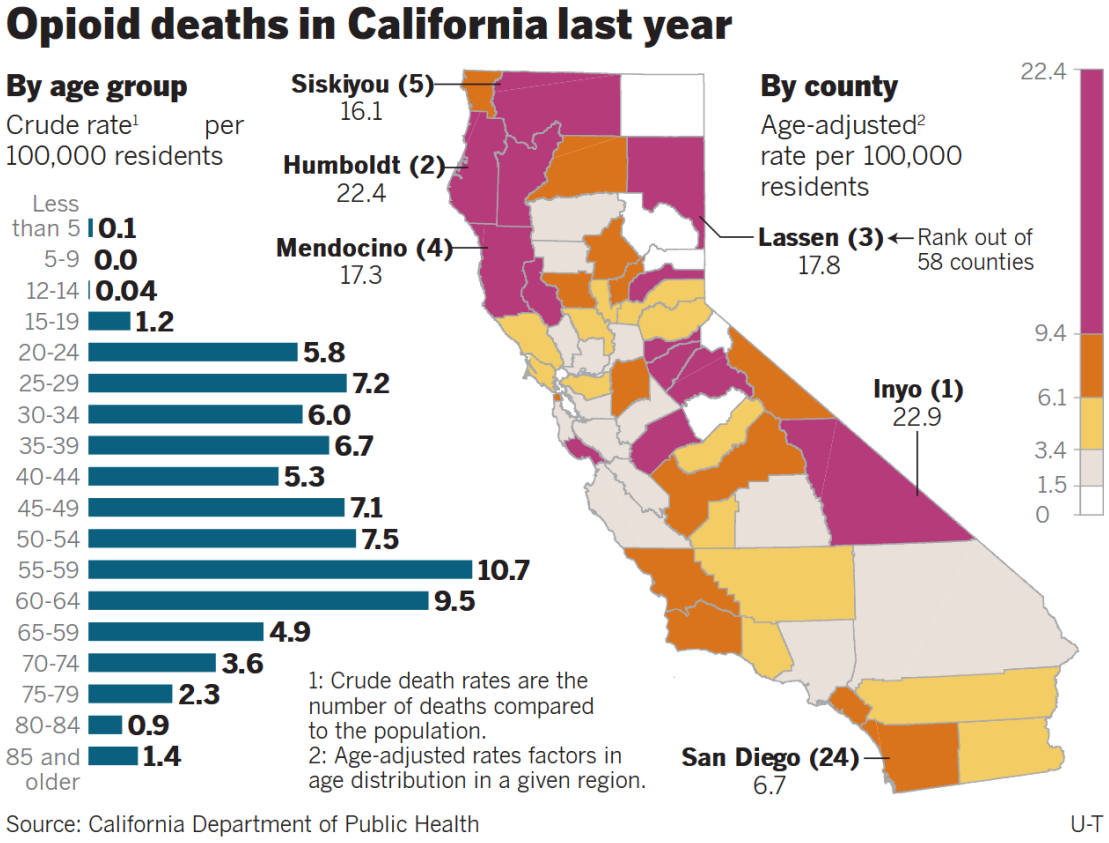
The magnitude of legal and illegal opioid usage and related negative consequences (e.g., addiction) is high in terms of health impact to California residents. However, there is wide variation across the counties within California with some counties having much higher rates than others. CDPH Statewide Dashboard

Opioid-Related Overdose Deaths: California vs. US
In 2016, there were 2,012 opioid-related overdose deaths—in California—a rate of 4.9 deaths per 100,000 persons—compared to the national rate of 13.3 deaths per 100,000 persons. The US rate has risen over the past five years, while the CA rate has remained steady. The overall rate has remained the same since 2012, the number of heroin and synthetic opioid-related deaths has increased from 362 to 587 and from 146 to 355 deaths, respectively.



The opioid crisis has not gripped California in the same way it has other states. Still, nearly 4,100 people were hospitalized for overdoses in the state last year. Nearly 2,000 people died. According to the California Department of Public Health, 70 percent of the deaths involved prescription opioids. And there remain several hot

spots of addiction, mostly in rural California counties. In addition, deaths from street heroin, often a cheaper alternative for those whose addiction begins with costly pills, have risen 57 percent since 2012, an unintended consequence of our efforts to reduce misuse and abuse of opioids.



Besides holding mortality rate from trending upward, there are positive changes in prescribing and treatment access, both key to turning the tide on the ongoing epidemic. Compared with the previous year, the 2016 results were impressive, including:

- A 12% decline in the volume of opioids dispensed in California, as measured by average morphine milligram equivalents (MME) dispensed per resident per year
- A greater than 11% drop in the rate of people on high-dose opioids
- An increase of more than 7% in the number of buprenorphine prescriptions — a measure of access to effective addiction treatment

Source: California Health Care Foundation

State and Local Coalitions Are Making a Difference

In California there are numerous coalitions, collaboratives, and safe prescribing initiatives: The HSAG-HIIN, Hospital Quality Institute, regional associations, hospital and healthcare providers are key partners who have come together to tackle the opioid crisis and address the complex issues involved. The following list of coalitions are a sampling of the state's robust response to the opioid crisis:

California Health Care Foundation's (CHCF) "California Opioid Safety Network" CHCF (Jenna Fischer, Julie Morath, HSAG HIIN and HQI)

The California Opioid Safety Network is a community of local coalitions working across California to share strategies and best practices toward the shared goal of reducing opioid addiction and deaths. It provides a forum for peer-to-peer learning, resources and best practices from the field as well as ongoing communications with news updates, webinar invitations, and other opportunities. Working in partnership with CHCF and an advisory group of leaders and stakeholders, the Network is managed by the Center for Leadership and Practice at the Public Health Institute (PHI).

This statewide network started in 2015 with 16 local coalitions in 23 counties focused on three priority strategies—safe opioid prescribing, use of medication-

California Opioid Safety Network

Local leaders coming together to fight the epidemic, connected across the state

Leaders: medical societies, county leaders, public health, hospitals, and others.

Participants: Bringing together medical providers, pharmacies, law enforcement and corrections, advocates, consumers and families, addiction treatment, health plans, and others.

Priorities:

- Opioid over-prescribing
- Access to addiction treatment
- Naloxone and harm reduction

assisted addiction treatment (MAT), and access to naloxone to reverse drug overdoses. As of April 2017, 36 of California's 58 counties have active coalitions in the statewide network, representing almost 90% of the state population. Public Health Institutes Assessment Report.

A recent CHCF partnership with UCSF called "Support for Hospital Opioid Use Treatment" or Project SHOUT is providing an educational webinar series for our hospitals. Hospitalizations for people with opioid use disorder represent an ideal time to start treatment. Project SHOUT helps hospitals start buprenorphine and methadone services, with coaching from UCSF specialists. *CHCF will partner with HSAG HIIN in getting the word out to our hospitals.*
Project SHOUT (Jenna Fischer, HQI and HSAG-HIIN)

The Network's new 'Accelerator' program will offer customized coaching and PHI was awarded a significant grant to recruit up to 40 AmeriCorps VISTA members to be placed with coalitions. These are full time jobs with benefits. Candidates could be a community member seeking a full time job, a recent college graduate, a current coalition volunteer or a partner organization.

California Department of Public Health's (CDPH) "Prescription Drug Overdose Prevention Initiative" CDPH (Julie Morath, HQI and HSAG HIIN)

In 2015, the California Department of Public Health was awarded a four-year grant from the Centers for Disease Control and Prevention (CDC) to implement a comprehensive program addressing opioid misuse and abuse in California's counties most impacted by the opioid epidemic.
The CDPH awarded twelve local initiatives – "*Local Coalitions to Address Opioid Misuse and Abuse*." These awardees are implementing comprehensive local opioid safety coalition activities through February 2019. Report.

CDPH Awardees

- Health Improvement Partnership of Santa Cruz County
- Mendocino County Health and Human Services
- Siskiyou Community Services Council
- County of San Luis Obispo Behavioral Health Department
- San Diego County Medical Society
- L.A. Care Health Plan
- Sierra Sacramento Valley Medical Society
- Plumas County Public Health Agency
- California Health Collaborative
- Butte County Public Health Department
- Marin County Department of Health and Human Services
- Alameda-Contra Costa Medical Association Community Health Foundation

Integrated Healthcare Association's (IHA) "Smart Care California - Statewide Workgroup on Reducing Overuse" Smart Care (Julia Slininger, Julie Morath, HSAG HIIN and HQI)

Collectively, Smart Care California participants purchase or manage care for more than 16 million Californians—or 40 percent of the state. To date, the intended audience for this project has been the co-chairs (DHCS, CalPERS, and Covered California) and Smart Care California participants, including provider associations, provider systems, health plans, purchasers and consumer representatives.

Smart Care California is focused on decreasing opioid use but with attention to avoiding the unintended consequences like increased heroin usage and inadequate chronic pain management. In addition to healthcare providers, dentists are also identified as a target audience to reduce opioid prescribing, responsible for 17% of prescriptions.

California Department of Justice's "Controlled Substance Utilization Review and Evaluation System" or CURES 2.0

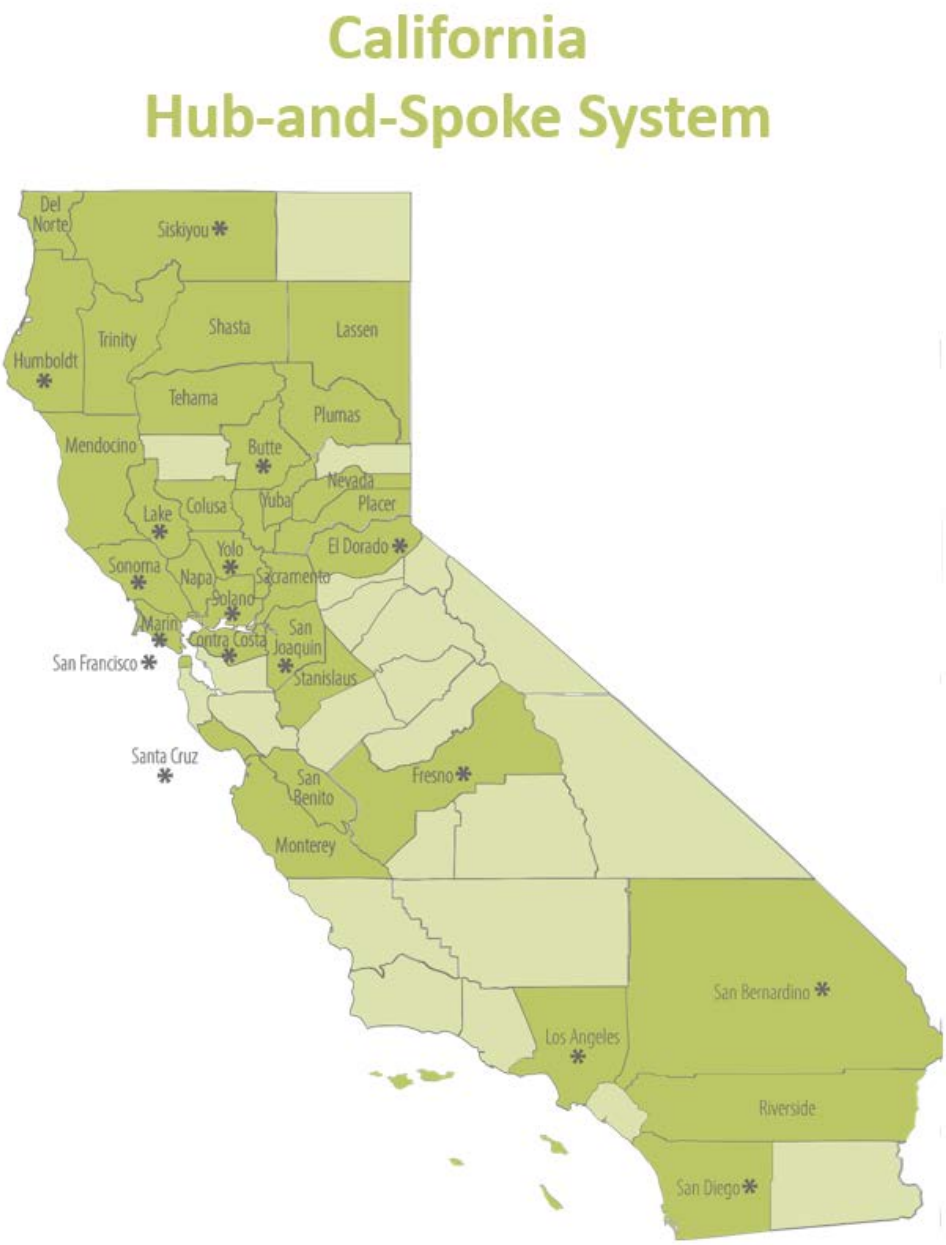
CURES 2.0 is a database created to assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances dispensed in California serving the public health, regulatory oversight agencies, and law enforcement. CURES 2.0 is committed to the reduction of prescription drug abuse and diversion without affecting legitimate medical practice or patient care. CURES 2.0

California Department of Health Care Services (DHCS) $90M Grant; Addiction treatment expansion programs. Announcement

Starting in 2017, under the DHCS grant, California set up at least 15 "hub-and-spoke" systems, modeled after a Vermont program that increased access to MAT and reduced overdose death rates. This model builds on the strengths of Narcotic Treatment Programs -- which are licensed to dispense methadone, and will serve as the "hubs" -- to provide specialized expertise in opioid treatment. The "spokes" are regional physicians working in primary care settings and approved to prescribe buprenorphine.

The Indian Health Services component of the grant will address MAT needs of California's American Indian and Native Alaskan tribal communities. Nationally, the death rate from unintentional drug poisoning is almost twice as high in these demographic groups as in the overall population. These communities face challenges in accessing MAT, such as a lack of physicians to prescribe and oversee treatment.

DHCS estimates that the overall project will serve 21,000 individuals over the two-year grant period and will create a foundation for sustainable treatment programs beyond the end of the grant.



San Diego Safe Prescribing – Pain medicine prescribing in the emergency departments. San Diego Safe Prescribing (Alicia Munoz, HQI)

This task force, one of the first in California, includes pain specialists, internal medicine physicians, emergency physicians, psychiatrists, dentists, pharmacists, hospital administrators, health department administrators, and our local DEA. The task force also includes broad health partners, including Kaiser Permanente, Scripps Health, Sharp HealthCare, UC San Diego Health System, Palomar Health, and the Community Clinics.

Twenty-eight emergency departments across San Diego and Imperial Counties are participating in this coalition.

Santa Clara County Alcohol and Drug Services "Opioid Overdose Prevention Project" OOPP (Jenna Fischer, HSAG HIIN and HQI)

A coalition of community members dedicated to reducing/eliminating All Opioid Overdoses. They hope to achieve this goal through physician education, expanding Buprenorphine providers in our community and Naloxone Distribution.

Community Hospital of the Monterey Peninsula's "Prescribe Safe Monterey County" PSM (Jenna Fischer, HSAG-HIIN and HQI)

The Prescribe Safe initiative was created by Monterey County law enforcement, administration of the four Monterey County hospitals, and local physicians in response to concerns about prescription medication misuse in the county. Prescribe Safe is meant to guide, educate, and provide resources for our local physicians and patients in the safe use of prescription medications and promote safe and effective pain management in Monterey County. This innovative initiative was highlighted at the 2017 HQI Annual Conference. To access the video describing their work, chick here.

Alameda – Contra Costa Medical Association "The East Bay Safe Prescribing Coalition"

EBSPC (Jenna Fischer, HSAG HIIN and HQI)

The East Bay Safe Prescribing Coalition is a collaborative effort by the East Bay medical community, consumers and community leaders to promote safe and appropriate prescribing practices and reduce prescription drug abuse in our community. The Coalition is co-sponsored by local organizations that represent the medical community: the Alameda-Contra Costa Medical Association (ACCMA), the Hospital Council of Northern and Central California, the Alameda County Health Care Services Agency, Contra Costa Health Services and the Alameda Health Consortium. These organizations serve as the steering committee for the Coalition.

Rx Safe Humboldt Coalition – "Safer Care Better Outcomes"
Rx Safe (Jenna Fischer, HSAG HIIN and HQI)

The mission of the Rx Safe Humboldt Coalition is to develop community standards and supporting structures for:

- Diagnosis and treatment for chronic pain while providing patients with the best care possible
- Diagnosis and treatment for acute pain recognizing the risks of prescribing pain medications; and
- Strategies for minimizing misuse and diversion of prescription pain medications.

Los Angeles Prescription Drug Abuse Medical Task Force "Safe Med LA" Prescription Drug Abuse Coalition LA County Safe Med LA (Julia Slininger, HSAG HIIN and HQI)

The coalition is embedded in the Substance Abuse Prevention and Control program within the Los Angeles County Department of Public Health. The program has developed a five-year strategic plan that will be carried out through the Safe Med LA coalition. Thus, the coalition is the mechanism for achieving shared departmental and community goals, and resources are dedicated to its success in the context of a strategic plan. These include well-defined and publicly visible goals and a dedicated evaluation.

The scale of engagement is unique — the adoption of a safe prescribing toolkit includes 78 emergency departments across the county.

Orange County Collaborative "SafeRx OC" SafeRx OC (Julia Slininger, HSAG HIIN and HQI)

SafeRx OC is an initiative launched by the Orange County Collaborative on Prescription Drug Abuse (OCCPDA), a countywide coalition of health and community leaders that are working together to combat an epidemic of prescription overdose deaths.

SafeRx OC brings together health experts, public health agencies, hospitals, prescribers, community clinics, emergency rooms, medical associations and law enforcement, along with key community voices, to save lives and prevent drug abuse.

Examples of California Health Plans Getting Involved

The California Department of Public Health surveyed all health plans in California to determine what they were already doing on the prescription drug overdose prevention front. Thirty out of 38 health plans responded (a 79% participation rate). Most health plans are currently participating in or considering joining opioid safety coalitions in the communities they serve. The California Health Care Foundation has also partnered with health plans to assist with resources and strategies.

Blue Shield of California's "Narcotic Safety Initiative"
Narcotic Safety Initiative (Jenna Fischer/Julia Slininger, HSAG HIIN and HQI)

In the program's first year, there has already been an 11 percent reduction in Blue Shield of California members using the very highest doses of opioids and a 5 percent reduction in those using moderately high doses of opioids. Additionally, Blue Shield has reduced the proportion of new opioid utilizers progressing to chronic use by 25 percent, and has seen an overall reduction in all opioid consumption.

Partnership HealthPlan's (PHC) "Managing Pain Safely Initiative"
PHC (Jenna Fischer, HQI)

Since June 2016, the PHC Managing Pain Safely Initiative is working to improve the health of PHC members by ensuring that prescribed opioids are for appropriate indications, at safe doses, and in conjunction with other treatment modalities.

PHC has observed a 79 percent decrease plan-wide for members on unsafe dose opioids (>120 MED) per 100 members per month since the project induction (January 2014 - December 2016).

A PHC's example of a coalition in one of their 14 counties – "The Safe Rx Mendocino Opioid Safety Coalition." PHC funded Mendocino County Public Health who leads the coalition. The coalition includes one of the most robust clinic-based medication assisted treatment (MAT) programs among rural cohort counties.

Kaiser Permanente's, Southern California "Safe and Appropriate Opioid Prescribing Program" Kaiser Permanente Southern California (Julia Slininger, HSAG HIIN and HQI)

Kaiser Permanente has been focused on this issue for several years and continues to build upon and spread successful practices. The Safe and Appropriate Opioid Prescribing Program aims to reduce overprescribing, overuse and abuse, and to reduce the volume of dangerous drugs being diverted into communities. The program primarily targets members who are receiving chronic opioids, are 18 years and older and do not have cancer.

Aetna

Aetna is working to reverse the rising trend with integrated pharmacy, behavioral health and medical programs. The programs connect health care providers and give members seamless access to the right support – mind and body – to fight addiction, while saving millions of dollars for the health care system. Aetna's programs also attempt to address many different aspects of this complicated issue.

Summary and Opportunities for Future Focus

The list of collaboratives and initiatives in California is too extensive to be listed in its entirety. California has a great story to tell in terms of the compassionate response to the opioid epidemic. The integration efforts in California is impressive – Hospitals and emergency departments, mental health, health plans, pharmacies, homeless services, primary care, jails/prisons, first responders and substance use disorder treatment systems are working together to better coordinate across the communities they serve. California is rich in the tools and resources to guide existing coalitions and assist new ones in getting started.

Still, there is a long journey yet ahead. We need to continue to expand our efforts toward coordinated strategies around access and treatment – ensuring that every door is the right door.

There are several issues to consider when looking at potential focus for future planning (Source: CDPH).

- **Understanding risk-factors**: Data are still limited on the factors that impact risk for misuse, abuse and overdose. Enhanced surveillance and analysis is needed to help proactively identify high-risk populations and target preventive interventions.

- **Upstream intervention:** Positioning policy interventions earlier in the health system to help make safe prescribing the norm. Increasing public awareness about the potential dangers of opioid medications and to create better understanding and expectations around pain treatment, proper prescribing, use, storage and disposal of pain medications

- **Transition for those currently dependent**: The magnitude of the population already impacted by overprescribing is significant; including many individuals who are currently dependent or addicted. Tools are needed (including access to treatment, and provider education) to help this population effectively transition, particularly as tighter prescribing controls and enforcement are implemented. Planning and education are needed to help facilitate effective transition and prevent stigmatization if dependence or abuse is identified.

- **Removing the stigma associated with drug addiction**: Addiction is a disease. Educating the public, healthcare professionals, health plans and health care systems, community organizations, and law enforcement that addiction, including individuals addicted to illicit drugs, need to be treated with a comprehensive team approach will be vital to achieving full success in the fight to eliminate drug abuse and overdose in the state of California

In addition to the CDPH future focus, the HSAG HIIN, HQI, and key stakeholders groups identify the need to understand and predict unintended consequences such as increased heroin usage (cheaper than prescription opioids) and inadequate chronic pain management.

This report is submitted for the purpose of providing an overview of the touch points and influence that HSAG HIIN in partnership with HQI are engaged in to contribute to the learning, tools and methods, and interventions for a safer California and Nation related to the opioid epidemic.