Medication Safety Committee Meeting

July 17, 2019

California Hospital Association

1215 K Street, Suite 800

Sacramento, CA, 95814

Join Zoom Meeting https://calhospital.zoom.us/j/9165527616

Conference Call Option: 720-707-2699 Member ID: 916 552 7616

Meeting Book - Medication Safety Committee Meeting

Medication Safety Committee Meeting Agenda - July 17, 2019

B. Pharmacy Bills
Bartleson

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1:30 PM

VIII. STANDING REPORTS

A. Board of Pharmacy
Sodergren

B. California Department of Public Health (CDPH)
Lee/Woo

C. California Society of Heath-System Pharmacists (CSHP)
DeMartini/Thomson

1:45 PM

IX. ROUNDTABLE
All

X. INFORMATION

A. California for Access to Life-Saving Medicine - Coalition
Informational Packet

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XI. NEXT MEETING

A. Next Meeting - October 17, 2019 (with CSHP Annual Meeting)

2:00 PM

XII. ADJOURNMENT
Hanni

CHA MEDICATION SAFETY COMMITTEE
2019 ROSTER

Officers

Chair
Candace Fong, Pharm.D
System Director, Pharmacy and Medication Safety
Dignity Health
3400 Data Drive
Rancho Cordova, CA 95670
(916) 851-2678
candace.fong@dignityhealth.org

Chair
Jeanette Hanni, R.Ph, MPA, FCSHP
Bay Area Executive Director of Pharmacy Services
Sutter Health
2350 W. El Camino Real
Mountain View, CA 94040
(650) 934-6967
hannij@sutterhealth.org

Members

Eddie W. Avedikian, PharmD
Pharmacy Operations Manager
Providence Holy Cross Medical Center
2727 Alameda Ave.
Burbank, CA 91505
(818) 847-6327
eddie.avedikian@providence.org

Carolyn Brown, RN, MS
Director, Quality/Safety
Santa Clara Valley Medical Center
777 Turner Drive
San Jose, CA 95128
(408) 885-2093
carolyn.brown@hhs.sccgov.org

Kathy Ghomeshi, Pharm.D, MBA, BCPS, CPPS
Medication Safety Specialist
UCSF Medical Center
533 Parnassas Avenue
San Francisco, CA 94143
(415) 851-5284
kathy.ghomeshi@ucsf.edu

Amy Gutierrez, PharmD
Vice President, Chief Pharmacy Officer
Kaiser Permanente
12254 Bellflower Boulevard
Downey, CA 90242
(562) 658-3513
Amarylis.C.Gutierrez@kp.org

Nasim Karmali, RPh
Clinical Director, Quality Services
Kaiser Permanente Redwood City Medical Center
1100 Veterans Boulevard
Redwood City, CA 94063-2087
(650) 299-3713
nasim.karmali@kp.org

Lori Nolan-Mullenhour, MSN, RN, NE-BC, CEN
Director, Women & Children's Service Line
Providence Little Company of Mary Medical Center Torrance
4101 Torrance Boulevard
Torrance, CA 90503-4664
(310) 303-6312
lori.mullenhour@providence.org

Doug O'Brien, Pharm.D
Regional Director for Inpatient Pharmacy Services
Kaiser Foundation Hospitals
3240 Arden Way
Sacramento, CA 95825
(510) 301-3990
doug.c.o'brien@nsmtp.kp.org

Richard B. Rabens, MD, MPH, FAAP
Medical Director
Kaiser Permanente
1800 Harrison Street
Oakland, CA 94612
(510) 625-6881
Richard.Rabens@kp.org

Diana Schultz, RPh, MHSA
Sr Specialist, Safe Medication Practices
Sharp HealthCare
8695 Spectrum Center Boulevard
San Diego, CA 92123-1489
(858) 499-6574
diana.schultz@sharp.com

Rita Shane, Pharm.D, FASHP, FCSHP
Chief Pharmacy Officer
Cedars-Sinai Medical Center
8700 Beverly Boulevard
Los Angeles, CA 90048-1865
(310) 423-5611
rita.shane@cshs.org

Deepak Sisodiya, PharmD, MHA
Administrative Director, Pharmacy Services
Stanford Health Care
300 Pasteur Drive
Palo Alto, CA 94305-2200
DSisodiya@stanfordhealthcare.org

Sarah Stephens, Pharm. D, BCPS, CPPS
Medication Safety Coordinator
Kaweah Delta Health Care District
400 W. Mineral King
Visalia, CA 93291
(559) 624-5652
sastephe@kdhcd.org

Kevin Dorsey Tyler, MD, PhD
Medical Director, Clinical Analytics
Enloe Medical Center - Esplanade Campus
1531 Esplanade
Chico, CA 95926-3386
(530) 322-7994
kevin.dorseytyler@enloe.org

Advisory/Ex-Officio

John Christensen, Pharm.D
Pharmaceutical Consultant II
California Department of Public Health
2170 Northpoint Parkway
Santa Rosa, CA 95407
(707) 576-2418
john.christensen@cdph.ca.gov

Loriann DeMartini, Pharm.D
Chief Executive Officer
California Society of Health System Pharmacists
1314 H Street
Sacramento, CA 95814
(916) 447-1033
ldemartini@cshp.org

Randy Kajioka, Pharm.D
Chief of Pharmacy Services
California Correctional Health Care Systems
PO Box 588500
Elk Grove, CA 95758
(916) 379-1677
randy.kajioka@cdcr.ca.gov

Kimberly Kirchmeyer
Executive Director
Medical Board of California
2005 Evergreen Street
Sacramento, CA 95815
(916) 263-2389
kimberly.kirchmeyer@mbc.ca.gov

Cari Lee, Pharm.D
Pharmaceutical Consultant II
California Department of Public Health
150 North Hill Drive
Brisbane, CA 94005
(415) 330-6779
cari.lee@cdph.ca.gov

Patti Owens
Director of Regulatory Affairs
California Association of Health Facilities
2201 K Street
Sacramento, CA 95816
(916) 432-5201
powens@cahf.org

Anne Sodergren
Assistant Executive Officer
California Board of Pharmacy
1625 N. Market Boulevard
Sacramento, CA 95834
(916) 574-7894
anne.sodergren@dca.ca.gov

Art Woo, Pharm.D
Pharmaceutical Consultant II
California Department of Public Health
850 Marina Bay Parkway
Richmond, CA 94804-6403
(510) 620-3916
art.woo@cdph.ca.gov

Steve Thompson
Director, Pharmacy
California Society of Health System Pharmacists
3330 Lomita Boulevard
Torrance, CA 90505-5073
(310) 517-6997
steven.thompson@tmmc.com

Staff

BJ Bartleson, RN, MS, NEA-BC
Vice President Nursing & Clinical Services
California Hospital Association
1215 K St.
Sacramento, CA 95814
(916) 552-7537
bjbartleson@calhospital.org

Barb Roth
Administrative Assistant
California Hospital Association
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 552-7616
broth@calhospital.org

Medication Safety Committee
Hospital Representation

BY COUNTY

As of July 17, 2019

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

Contact	Position Type	Represented Organization	County (Represented Org
Candace Fong, Pharm.D	Chair	Dignity Health	San Francisco
Jeanette Hanni, R.Ph, MPA, FCSHP	Chair	Sutter Health	Sacramento
Amy Gutierrez, PharmD	Member	Kaiser Permanente	Alameda
Carolyn Brown, RN, MS	Member	Santa Clara Valley Medical Center	Santa Clara
Deepak Sisodiya, PharmD, MHA	Member	Stanford Health Care	Santa Clara
Diana Schultz, RPh, MHSA	Member	Palomar Medical Center Escondido	San Diego
Doug O'Brien, Pharm.D	Member	Kaiser Foundation Hospitals	Sacramento
Eddie W. Avedikian, PharmD	Member	Providence Holy Cross Medical Center	Los Angeles
Kathy Ghomeshi, Pharm.D, MBA, BCPS, CPPS	Member	UCSF Medical Center	San Francisco
Kevin Dorsey Tyler, MD, PhD	Member	Enloe Medical Center - Esplanade Campus	Butte
Lori Nolan-Mullenhour, MSN, RN, NE-BC, CEN	Member	Providence Little Company of Mary Medical Center Torrance	Los Angeles
Nasim Karmali, RPh	Member	Kaiser Permanente Redwood City Medical Center	San Mateo
Richard B. Rabens, MD, MPH, FAAP	Member	Kaiser Permanente	Alameda
Rita Shane, Pharm.D, FASHP, FCSHP	Member	Cedars-Sinai Medical Center	Los Angeles
Sarah Stephens, Pharm. D, BCPS, CPPS	Member	Kaweah Delta Health Care District	Tulare
Anne Sodergren	Ex-officio	California Board of Pharmacy	
Art Woo, Pharm.D	Ex-officio	California Department of Public Health	
Cari Lee, Pharm.D	Ex-officio	California Department of Public Health	
John Christensen, Pharm.D	Ex-officio	California Department of Public Health	
Kimberly Kirchmeyer	Ex-officio	Medical Board of California	
Loriann DeMartini, Pharm.D	Ex-officio	California Society of Health System Pharmacists	
Patti Owens	Ex-officio	California Association of Health Facilities	
Randy Kajioka, Pharm.D	Ex-officio	California Correctional Health Care Systems	
Steve Thompson	Ex-officio	California Society of Health System Pharmacists	

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.

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
April 3, 2019 / 10:00 am – 12:00pm

CHA
ZOOM Teleconference

Members Participating: **Eddie Avedikian, John Christensen, Loriann DeMartini, Candace Fong, Kathy Ghomeshi, Amy Gutierrez, Jeannette Hanni, Kimberly Kirchmeyer, Christine Low, Lori Nolan, Doug O'Brien, Diana Schultz, Sarah Stephens, Steven Thompson, Art Woo**

CHA Staff: **BJ Bartleson, Barb Roth**

I. CALL TO ORDER/INTRODUCTIONS – Hanni/Fong
The committee meeting was called to order by chair Ms. Hanni at 10:02 a.m.

II. OLD BUSINESS

A. Inventory Reconciliation from Automatic Dispensing Units (ADU) (Bartleson/Fong)
BoP advised there is not a uniform definition of a satellite pharmacy. It is still unclear and BoP is working on it. The FAQs provided in the meeting book are old and lack clarity . Ms. Fong explained their ADU reconciliation processes to Ms. Sodergren at BoP. Ms. Fong has had the surveyors in every one of their hospitals and have not received any further citations after that first one.

Confusion under pharmacy vs a satellite vs equipment (ADM).

- *ACTION: CHA and Ms Fong will follow up with BoP regulatory interpretation*

B. Sterile Compounding Update (Bartleson)
CHA is notifying members on the new CDPH sterile compounding approval process.. CDPH plans to issue an All Facilities Letter (AFL) Mr. Woo confirmed that after Jan 1, 2019 the CDPH process changed secondary to AB 2798 that now requires complete versus incomplete applications be submitted to the Central Applications Branch, Pharmacy Consulting Unit.

CHA is working with CDPH to negotiate solutions to ameliorate this potential approval delay for hospitals. OSPHD has shared a list of 237 hospitals with information on their construction progress to meet the upcoming December 1, 2019, deadline.

Mr. Woo offered, that in his opinion ,he does not sense the 100-day approval timeline is the most important issue.. At the moment, CDPH is working closely with hospitals and there are other issues hospitals can address to hasten the approval process. It is important that there is a knowledgeable person at the site in charge of the pharmacy, that is educated and knowledgeable about the updated requirements.. The vast majority of pharmacists on site on not prepared on important issues such as:

- USP 797 Hand hygiene process
- Errors in certification reports that were not identified by the hospitals.
- Electronic pressure monitoring not set up correctly.
- Not following policy and procedure for cleaning and types of cleaning solutions
- Knowledge on USP 797 and the upgraded IV room specifications
- The Pharmacist in Charge (PC) needs to be educated and responsible for the activity that occurs in the pharmacy and under the pharmacy purview. They need to take leadership in understanding and implementing the new USP standards as they relate to the activities, they perform, and the care delivered.

Members suggested a helpful tips-sheet to assist pharmacies through the approval process. Perhaps a subgroup could be formed to come up with educational topics and tools Ms. Bartleson will draft helpful tips and get committee input. Committee consensus is that this would be better than a webinar.

Ms. Bartleson requested member input about a recently reported problem regarding medical office buildings. Hospitals are purchasing infusion centers or Ambulatory Surgical Care Centers, some of which are using pharmacies that are non-compliant with updated USP sterile compounding standards Compliance is highly dependent upon the type of ownership, Some are joint ventures between hospital and physician groups. If a hospital owns 51% of the joint venture, the hospital is responsible for meeting regulatory compliance.

Ordering, dating and cleaning the rooms are challenges.

- *ACTION: Ms. Bartleson will draft a helpful tip sheet for members*

C. SB 1254 Update (Bartleson/Shane/Stephens)

Many questions and feedback were received from the webinar???? Which webinar. There is a 6-week data collection session for pharmacy residents for January through March 2020 which is in the planning process now. Anyone interested in participating can sign up through the steering committee. Ms. DeMartini is interested in working with the group to advance the initiative. Another planning call for the steering committee will take place in May.

- *ACTION: If anyone is interested in participating in the steering committee, please contact Ms. Shane and/or Ms. Stephens.*

D. Biosimilars (Bartleson)

Ms. Shane is working on this issue and writing an article for ISMP. Not sure what this means

- *ACTION: Ms. Shane suggests that everyone make their oncologists aware of this issue, and that they may not be able to order what they want and/or the organization may not be paid.*

IV. LEGISLATION

A. 2019-20 Legislation

AB 387 –Mr. Christensen commented the purpose of identifying the use rationale on the prescription label can help differentiate drugs that have similar names. It provides double check for pharmacists with drugs with similar sounding names. Ms. Hanni and Ms. Gutierrez think this could be a privacy issue.

AB 528 – CURES Bill – Ms. Hanni advised that the expectation is unreasonable until it has an updated interface. There is a need for more assistance from vendors to help comply with the regulations.

AB 690 – Committee is Ok with this bill.
AB 973 – Committee is Ok with this bill.

AB 1468 – Mr. Thompson attended a legislative day during which this bill came up for discussion. Basically, the manufacturers can pass this tax on to pharmacies, who will not be able to pass on to patients.

SB 159 – Committee members posed potential questions about the results of this bill. Will pharmacists be allowed to bill for this? Where will the training and/or validation be sourced from?

CPHA, BoP and CSHP is also looking at this.

SB 491 – Consensus is that this cannot happen. It's a non-starter.

SB 655 – Ms. Hanni inquired as to why there is a cap on the hours.

- *ACTION: Information Only*

VIII. INFORMATION

EPA Hazardous Waste Pharmaceutical Rule (Bartleson)
Ms. Bartleson will be getting more information and will provide to the committee when available.

- *ACTION: Please advise Ms. Bartleson if you have a good risk management person who might have some input on this topic.*
- *ACTION: Ms. Bartleson to provide additional information to the committee when available.*

IX. NEXT MEETING

Wednesday, July 17, 2019 10 am – 2 pm (In Person Meeting – Sacramento)

X. ADJOURNMENT

Having no further business, the committee adjourned at 11:57 am.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

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

SUBJECT: Sterile Compounding Next Steps

SUMMARY

On June 3, 2019, the United States Pharmacopeia (USP) released new and revised standards to help ensure the quality of compounded medications. USP <795> Pharmaceutical Compounding—*Nonsterile Preparations*), compounding sterile medicines (USP <797> *Pharmaceutical Compounding— Sterile Preparations*) and new standards for compounding radiopharmaceutical drugs (USP <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*). The "official date" by which affected users are expected to meet the requirements is December 1, 2019. Ensuring compliance with the requirements of these standards is the responsibility of regulators such as the FDA, CMS, states, and other government authorities.

California is a leader in preparing hospital compounding pharmacies for USP compliance. Hospitals are actively involved in construction for new or remodeled pharmacy clean rooms; however, many hospitals will not be fully compliant by December 1, 2019. The California Hospital Association (CHA), The California Department of Public Health (CDPH), the Board of Pharmacy (BoP), and the California Office of Statewide Health Planning and Development (OSHPD) collaborated to assist hospitals in meeting USP deadlines and worked actively on tools, solutions and education to augment hospital compliance over the past several years. While some hospitals are well positioned to meet the deadline, many hospitals, for a myriad of reasons, may fall short.

CHA, in collaboration with the American Hospital Association (AHA) is working to inform accreditors and CMS of the challenges of the new standards and the challenge of the current timelines. The information we can provide through a statewide gap analysis will inform our advocacy efforts in seeking delays or compliance mitigation measures.

To advocate effectively, both at the state and federal level, CHA along with other stakeholders are working to:

- Identify gaps, barriers and issues preventing successful compliance by December 1, 2019.
- Develop a list of mitigation measures and strategies for hospitals to deploy if unable to meet the deadline.
- Assist all members through education, for example, FAQ's, Fact Sheets, Webinars.

DISCUSSION

1) What recent revisions to USP 797 need to be included in the compliance requirements?
2) What are the biggest barriers hospitals are facing?
3) What actions in addition to the aforementioned items need to be included in this work?

ACTION REQUESTED

- CHA requests assistance from CHA Medication Safety Members for assistance with the preparation of a gap analysis for advocacy and policy efforts.

Attachments: Sterile Compounding Worksheet
Sterile Compounding Medication Safety Tool:

1. Temperature Requirements and Monitoring
2. Compounding Frequency of Documentation and Cleaning
3. Facilities and Engineering Controls: Hazardous Drugs
4. Facilities and Engineering Controls Requirements: Non-Hazardous
5. Required Environmental, Personnel & End-Product Testing
6. Competency and Training
7. Hazardous Garbing
8. Donning, Hand Hygiene & Doffing for Hazardous Sterile Compounding
9. Donning, Hand Hygiene & Doffing for Non-Hazardous Sterile Compounding
10. Perform an Assessment of Risk to Comply with USP 800

BJB:br

CHA Medication Safety Committee Sterile Compounding Next Steps

Meeting Tool Discussion Guide

A. Information we have: Total number of clean room projects and total number of hospitals:

OSHPD – As of 6/19/2019 there are **212** number of pharmacy construction projects in **177 (approx.) hospitals**

Clean Room Pharmacy Construction Projects

Pending/In Review – 80
0-10 % complete – 49
11%-30% - 25
31%-70%- 21
71%- 100% - 37
Total = 212

CDPH – As of 6/10/2019, there were **47 approved clean room projects**

B. Where are they in the construction process and why? What issues have been identified?
   1. Not started or pending:
      a. Why _____, _____, _____ (for example, finances, contractor issues, other.

   2. Just started:
      b. Why and issues/barriers?

   3. Midway (50%):
      c. Why and issues/barriers?

   4. Almost finished (90%)":
      d. Why and issues /barriers?

C. What issues have been described as barriers?
   1. OSHPD Active User Guide Update"

   2. CDPH list of compliance issues:
      a. Viable sampling plan did not meet USP standards
      b. Certification report not evaluated appropriately by pharmacy leadership & failure to take appropriate actions for microbial growth identified in certification report
      c. Not able to demonstrate required cleaning behind equipment
      d. Improper use of cleaning agents
      e. Pharmacy staff competencies not completed/assessed appropriately
      f. Hand hygiene not performed correctly
      g. Donning and or doffing of PPE not performed correctly

h. EVS staff competencies not established/validated
i. HVAC system not performing to meet USP standards
j. Electronic pressure monitoring system not programmed correctly and staff not knowledgeable in proper use /programming of electronic pressure monitoring system

3. What are the Board of Pharmacy licensing issues?

D. What mitigation measures can be identified for hospitals to implement who will not meet deadline?

E. How should the mitigation measures be communicated to members?

F. What present Sterile compounding tools do we have that need to be discontinued or updated*?*

Sterile Compounding Medication Safety Tool:

1. Temperature Requirements and Monitoring
2. Compounding Frequency of Documentation and Cleaning
3. Facilities and Engineering Controls: Hazardous Drugs
4. Facilities and Engineering Controls Requirements: Non-Hazardous
5. Required Environmental, Personnel & End-Product Testing
6. Competency and Training
7. Hazardous Garbing
8. Donning, Hand Hygiene & Doffing for Hazardous Sterile Compounding
9. Donning, Hand Hygiene & Doffing for Non-Hazardous Sterile Compounding
10. Perform an Assessment of Risk to Comply with USP 800

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

TEMPERATURE REQUIREMENTS AND MONITORING

CSHP CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797>(2008) Requirements)

Temperature Description	**Degrees Centigrade**		**Degrees Fahrenheit**		**Comments/Explanations Requires NIST Certified Temperature Monitoring Devices (USP <1118>**	**USP 39 NF 34 (2016)** *(Used as a reference by the FDA for all package inserts)*	**CDC Vaccine Storage (May 2014) USP <797>**	**Board of Pharmacy January 1, 2017**
	Min	Max	Min	Max				
Controlled Freezer Temperature (USP and BOP)	-25º	-10º	-13º	14º	Check individual monographs for specific requirements outside this range	General Notices 10.20.10		No provision for excursions §1735.1 (i)
Freezer (CDC)	-50º	-15º	-58º	5º	Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Controlled Cold Temperature –	2º 2.2°	8º 7.7°	35º	46º	• Transient excursions (0 ºC to 15 ºC) but the calculated MKT must be ≤ 8 ºC (46 ºF) • Transient spikes to 25 ºC (77 ºF), not to exceed 24 hours, if supported by the manufacturer's stability in writing	General Notices 10.30.40	See CDC Vaccine Storage and Handling Toolkit	No provision for excursions §1735.1 (h) Title 22 – 22 CCR § 70263 (q)(6)
Controlled Room Temperature	20º	25º	68º	77º	• Excursions allowed between 15 ºC to 30 ºC (59 ºF to 86 ºF) as long as the MKT is ≤ 25 ºC (77 ºF) • Spikes to 40 ºC (104 ºF) are permitted for less than 24 hours as long as the MKT is ≤ 25 ºC (77 ºF) • Check for specific drugs with narrow ranges	General Notices 10.30.60		No provision for excursions §1735.1 (j)
Clean Room Temperatures		20° or less		68º or less	In order to compensate for the additional layers of protective garb, this is the general recommendation.		USP <797> proposed language	
	20º	25º	68º	77º				Or lower required

WHAT IS MKT? Mean Kinetic Temperature approximates the effects of temperature on drug degradation. Higher temperatures result in faster degradation, lower temperatures result in less degradation. MKT calculations weight the various temperatures by their natural logs. Temperature spikes result in a greater increase in MKT than the average temperature, often by a critical 2-5 degrees. The MKT can be hand calculated, calculated by the temperature monitoring software vendor, or the manufacturer can be contacted and they have software to determine the MKT for every product.

N.B. Anytime a patient has received a vaccine or drug that is determined to have been out of range longer than allowed by the package insert, the manufacturer should be contacted immediately because all manufacturers have significant amounts of unpublished stability data by lot number, and the patient may not have to be re-dosed.

MONITORING REQUIREMENTS

Location	**Comment**	**USP 37 NF33**	**CDC (Vaccines) May 2014**	**BOP**
Freezers	Daily lapse time monitoring or continuous monitoring CDC vaccine toolkit on CDC website for more information. The vaccines for children program prohibits use of dorm refrigerators for vaccines.	Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Refrigerators		Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Rooms	Includes all drug storage location rooms: no specific requirements for monitoring inside ADCs	Daily		

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Rev. 9/17/18

COMPOUNDING FREQUENCY OF DOCUMENTATION AND CLEANING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797> (2008) Requirements

The most stringent requirement will be required. BOP regulations for BOP requirements, and BOP and USP 797 regulation for CDPH requirements		
DAILY	LOW AND MEDIUM RISK	HIGH RISK
Room Temperature	X	X
Refrigerator temperature (Twice a day for vaccines)	X	X
Freezer temperature (Twice a day for vaccines)	X	X
Incubator temperature	X	X
Air pressure differentials or air velocity between adjoining ISO rooms (ambient room air vs. buffer area vs. ante area)	X	X
MiniHelix differentials for CAI, CACIs	X	X
Cleaning with germicidal cleaners and disinfected with suitable agent (sterile IPA) Counters + Cleanable Surfaces + Floors+ Carts	X	X
Cleaning within the ISO 5 environment (before each shift, every 30 minutes and before and after each batch) Facilities with IV robots will be required to petition the BOP for exception with documentation and description of an alternative cleaning schedule	X	X
Hazardous Drug 1) Deactivation with peroxide or bleach and Decontamination with sterile IPA, sterile water, peroxide or bleach 2) Cleaning with a germicidal 3) Disinfection with sterile 70% IPA	x	x
MONTHLY	LOW AND MEDIUM RISK	HIGH RISK
Cleaning with germicidal cleaners and disinfected with suitable agents (sterile IPA) Exterior workbench Walls/Ceiling Shelves/Storage Tables Stools	X	X
Sporicidal agent used for cleaning, all sites	X	X
Hazardous Drug Cleaning undertray of the BSC 1) Deactivation with peroxide or bleach and Decontamination with sterile IPA, sterile water, peroxide or bleach 2) Cleaning with a germicidal 3) Disinfection with sterile IPA	x	x
QUARTERLY	LOW AND MEDIUM RISK	HIGH RISK
Viable surface sampling, ALL CFUs identified to genus per USP <797>; facility-determined limits for BOP	NA	X
BIANNUAL	LOW AND MEDIUM RISK	HIGH RISK
Viable surface sampling, ALL CFUs identified to genus per USP <797>; facility-determined limits for BOP	X	NA
Volumetric air sampling Particle count CFUs, identified to genus. ALL CFUs identified to genus per USP <797>, only facility-determined limits for BOP	X	X
Hood and room certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Media fill/gloved fingertip testing for employees	NA	X
ANNUAL (at least every 12 months)	LOW AND MEDIUM RISK	HIGH RISK
Media fill/gloved fingertip testing for employees	X	NA
Competency testing Observation Written	X	NA
Review of compounding policies and procedures	X	X

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Last Revised September 17, 2018

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Facilities and Engineering Controls: Hazardous Drugs

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP <800> Pending Requirements

CSHP CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

BOARD OF PHARMACY REGULATIONS CCR§1735 **Effective January 1, 2017**				
SECONDARY ENGINEERING CONTROL • **Temp 20-24C (68-75F)** • **Externally vented** • **HEPA filtered air** • **Negative pressure** • **Physically separate room**	**PRIMARY ENGINEERING CONTROL** • **PECs ISO Class 5 Negative Pressure unidirectional flow** • **HEPA filtered airflow** • **Non-turbulent** • **HEPA filtered exhausted air** • **External venting should be dedicated to one BSC or CACI**	**Beyond Use Dates** **LOW RISK** • **Sterile to sterile** • **=< 3 commercial packages** **=< 2 entries into 1 sterile container**	**MEDIUM RISK** • **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**Comments**
• **ISO Class 7 or better** • Sink in ante area • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 30 Air Changes Per Hour (ACPH) • Ante-area ISO 7 or better CCR §1735.6(e)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI shall not be recirculated or turbulent. CACI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Document daily Pressure Differential or air velocity, or use continuous recording device, between adjoining ISO rooms. 1751.1(a)(8) • Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4)
• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft from PEC • Minimum of at least 3 ft line of demarcation around PEC • Emergency eye wash station acceptable • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 12 ACPH 1735.6 (e) (1)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI must not be recirculated or turbulent CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	NA	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least q 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4) • Sink can be within 3 ft of CACI if CACI meets requirements in 1751.4 (f) (1-3)

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. The tool is not a fixed compliance assessment that must be followed and should not be construed as legal advice or used to resolve legal problems.

Last Revised 9/17/2018

Facilities and Engineering Controls: Hazardous Drugs

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP <800> Pending Requirements

Non-Hazardous Drugs Prepared in a Hazardous Drug Primary Engineering Control (Chemo Hood)				
All drugs prepared in a Hazardous Drug Primary Engineering Control (PEC) must be labeled with HD Cautions				
HAZARDOUS DRUGS : USP <800> Pending Requirements				
SECONDARY ENGINEERING CONTROL Externally vented	**PRIMARY ENGINEERING CONTROL C-PECs ISO class 5 Negative Pressure unidirectional flow C-PECs externally vented**	**BEYOND USE DATES (July 1, 2018)**		**Comments**
		Low Risk	**Medium Risk**	
• **HEPA filtered air in Negative Pressure Physically Separate Room** • **ISO Class 7 or better buffer room** • **0.01" to 0.03" w.c. negative pressure** • **Minimum 30 ACPH HEPA filtered air** • **Sink placed at least 1 meter from the entrance of buffer room**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Requires negative pressure ISO 5 C-PEC • C-PEC and C-SEC externally vented • Eyewash readily available • Drug storage MUST be in a negative pressure space. Includes the refrigerator • Receiving of hazardous drugs must be in a negative or neutral pressure space. • May use the negative pressure room for non-sterile hazardous compounding BUT not at the same time. • Fixed walls
• **Containment Segregated Compounding Area (C-SCA)** • **Must be a negative pressure separate room** • **0.01" to 0.03" w.c. negative pressure** • **Unclassified room** • **Minimum 12 ACPH** • **Sink at least 1 meter from C-PEC**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	12 hours	12 hours **(not allowed by BOP)**	

* Controlled Room Temp: 20 to 25 degrees C, 68 to 77 degrees F

**Controlled Cold Temp (Refrigerator): 2 to 8 degrees C, 35.6 to 46.4 degrees F

***Controlled Freezer Temp: (-25) to (-10) degrees C, (-13) to 14 degrees F

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FACILITIES AND ENGINEERING CONTROLS REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP <797> (2008) Requirements

BOARD OF PHARMACY REGULATIONS -- CCR§1735 and CCR §1751 -- NON-HAZARDOUS DRUGS (Low and Medium Risk)				
SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)	**PRIMARY ENGINEERING CONTROL (PEC=Sterile Compounding Hoods)**	**Beyond Use Dates**		**Comments**
		LOW RISK	**MEDIUM RISK**	**APPLIES TO ALL**
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**	• **Sterile to sterile** • **=< 3 commercial packages** • **=< 2 entries into 1 sterile container**	• **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	
>ISO Class 7 clean room (clean area or buffer area) with ISO 8 or better ante-area • No sink in buffer area • Sink in ante-area • Minimum of 30 air changes per hour • 0.02-0.05" w.c. positive pressure differential relative to all adjacent spaces OR • Displacement airflow method: requires air velocity of >40 feet per minute from the clean area across the line of demarcation into the ante area, from floor to ceiling and wall to wall CCR §1735.1(m) & §1250.4 (1-4)	**Any ISO Class 5 PEC:** • Laminar Flow Hood OR • Biological Safety Cabinet with unidirectional flow OR • Compounding automated robots OR • Compounding Aseptic Isolators (CAI) with unidirectional flow. Air within the CAI shall not be recirculated or turbulent. CAI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State *** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Each ISO environment requires certification at least every 6 months CCR §1751(b)(1), 1751.4(f) • Document **daily** pressure differential or air velocity, or use **continuous recording device**, between adjoining ISO rooms and spaces with immediate entry to ISO rooms. 1751.1(a)(8)
Segregated sterile compounding area • Any preparation area that is not ISO classed, exceeds ISO 7 limits, or does not meet pressure or air flow differentials • Sterile to sterile compounding only • PEC within demarcated area (at least 3 ft. perimeter) or separate room • Shall not have unsealed windows/doors that connect to outdoors • Not in high traffic area • Not adjacent to construction sites, warehouses or food preparation • Sink at least 3 ft. from PEC • Emergency eye wash station acceptable CCR §1735.1(af) & §1250.4 (1-4)	• CAI • Manufacturer of CAI must provide documentation for meeting requirements in 1751.4(f)(1-3) AND CAI must be certified as part of the certification process 1751.4(f)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Requires use of sterile gloves over isolator gloves 1751.4 (h) • PEC requires certification at least every 6 months CCR 1751.4(f) • Sink can be within 3 ft of CAI

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FACILITIES AND ENGINEERING CONTROLS REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP <797> (2008) Requirements

SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)	PRIMARY ENGINEERING CONTROL (PEC=Sterile Compounding Hoods)	Beyond Use Dates		Comments
		LOW RISK	MEDIUM RISK	
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**	• **Sterile to sterile** • **=< 3 commercial packages** • **=< 2 entries into 1 sterile container**	• **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**APPLIES TO ALL**
	• Laminar Flow Hood • CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	N/A	• 12 hours BUD for low-risk, non-hazardous preparations only 1751.8(d)(2) • PEC requires certification at least every 6 months CCR 1751.4(f)
Does not meet requirements for ISO Class 7 clean room or unclassified & Segregated Compounding area	• No PEC or outside ISO 5 PEC • Under conditions not meeting all requirements in any subdivision 1751.8 (a-d)	Labeled "Immediate Use" and shall be administered no later than 1 hour after mixing CCR §1751.8 (e)	N/A	Compounded only in limited situations where failure to administer could result in loss of life or intense suffering, and in quantity to meet immediate need

dde

REQUIRED ENVIRONMENTAL, PERSONNEL & END-PRODUCT TESTING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Environmental Testing Under Dynamic Conditions	Applicable Device, Room or Method	Frequency
Certification of PEC's	All BSC's, CAI's, CACI's, LAFW	Every 6 month (CCR) §1751
HEPA filter integrity testing	All BSC's, CAI's, CACI's, LAFW & ISO classified rooms	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts)	All Buffer room/s and ante rooms. (Not required for segregated compounding rooms)	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts)	All BSC's, LAFW	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts) outside of an ISO 7 cleanroom	CAI and CACI's: ▪ Particle counts sampled 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during operations ▪ Not more than 3520 particles per cubic meter during material transfer where particle probe is located as near to the transfer door as possible w/o obstructing the transfer ▪ Recovery time to achieve ISO Class 5 air quality shall be documented	Every 6 months
Viable air sampling by volumetric impaction	▪ The volume sufficient for sampling is 400-1,000 liters ▪ All ISO classified rooms and PECs ▪ Identification of any colony forming unit (CFUs) to the genus level and action plan for CFUs exceeding USP action level thresholds**.	Every 6 months
Viable surface sampling	▪ Samples based on specified site map ▪ Identification of any (CFUs) to the genus level and action plan for CFUs exceeding USP action level thresholds**.	Low & medium risk compounding: Every 6 months High risk compounding: Quarterly
Air changes per hour (ACPH)	All Buffer room, Ante rooms, and segregated compounding rooms	Every 6 months
Video smoke study	▪ All BSC's, CAI's, CACI's, LAFW ▪ Unidirectional, non-turbulent airflow must be documented	Every 6 months

- Sampling locations, frequencies, and timing must be clearly described in the facility's report from the certification vendor
- Some tests may be performed by properly trained hospital staff if the CETA guidelines are followed
- Dynamic Conditions Definition: Routine staff activity during compounding-related processes must be simulated during certification
  Recertification of areas/equipment must occur is there are changes to the area such as redesign, construction, or replacement or relocation of the PEC, or alteration in the configuration of the room that could affect airflow or air quality

****USP Action Level Threshold**

Location	Viable airborne	Viable surface
ISO-5 (PEC)	>1	>3
ISO-7 (Buffer)	>10	>5
ISO-8 (Anteroom)	>100	>100

Highly pathogenic microorganisms [e.g., G(-) rods, coag (+) Staph, molds and yeasts] must be immediately remedied, regardless of CFU count

CSHP and CHA
REQUIRED ENVIRONMENTAL, PERSONNEL & END-PRODUCT TESTING
CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Process validation: The individuals involved in the compounding of sterile drug preparation must successfully demonstrate competency on aseptic technique and aseptic area practices. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be as complicated as the most complex manipulations performed by staff with the same amount or greater amount of volume transferred during the compounding process.

Tests Required for Personnel (BOP and USP)	Risk Level	When Required
Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing, then 1x at least every 12 months thereafter.	Moderate and low risk compounding – initial competency	Prior to the first compound prepared for a patient
	Moderate and low risk compounding – ongoing competency	At least every 12 months as part of the competency testing process
Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing then at least every 6 months thereafter.	High risk compounding – initial competency	Prior to the first compound prepared for a patient
	High risk compounding – ongoing competency	At least every 6 months as part of the competency testing process

Facility policy should describe processes as determined by the PIC to assure accuracy of sterile compounding processes within the facility

End Product Testing: Requirement for Sterility and Potency Testing for Lots of Low/Med Risk CSPs	Comments	USP <797>	BOP
Beyond Use Date (BUD) is the lesser of the USP<797> or the manufacturer package insert/written communication	• Meets all PEC ISO 5 requirements • Low risk: 48 hour RT, 14 days refrigeration • Medium risk: 30 hour RT, 9 days refrigeration	As long as the shorter of the manufacturer insert stability and the USP <797> BUD is met, there is no batch sterility testing requirement.	None
Extended BUD (Greater than USP <797>)	• The USP <797> BUDs are an exemption from the USP <71> sterility testing. • BUD can only be extended if sterility tests according USP <71> are performed.	• No exemption for sterility testing for extended BUD. • Every batch of extended BUD requires sterility testing and sequestering. • In the revised USP <797> there is no extended BUD option.	BUD extension only allowable when supported by the following: Method suitability test, container closure integrity test, and stability studies. The compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality review, and packaging as the finished CSP.
Potency testing is the USP monograph described testing of potency	Products should have one of the following: • A manufacturer-sanctioned process • A published (refereed journal) method followed exactly • Lab data from testing of facility product	No requirements in USP <797>	Will require potency testing, schedule per the facility policy

Last Revised 9/17/18

COMPETENCY AND TRAINING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797> (2008) Requirements

Competency		
Low and Medium Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Type of Competency	**Test**	**Frequency**
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure	Initially, then at least every 12 months
Process Validation	Media Fill testing	Initially, then at least every 12 months, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU
High Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks Sterilization technique	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure Sterilization techniques	Initially, then at least **every 6 months**
Process Validation	Media Fill Testing	Initially, then at least **every 6 months**, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU

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TRAINING REQUIREMENTS	
Training	**Comments**
Hand hygiene and gloving	• Training includes theoretical principles and practical skills • Must complete didactic training, pass written competency and skills assessment (observation audit, GF testing, and media fill) before any compounding personnel begin to prepare/ handle CSPs • Media fill – simulates most challenging/ complicated condition/procedure actually encountered, and contains same amount of volume transferred. Verifies capability of compounding environment, aseptic technique and processes to produce sterile preparations
Procedure for Gloved Fingertip Sampling	
Order of Garbing procedures	
Aseptic work practices/technique (avoid touch contamination)	
Sterilization procedures for high risk compounding (if applicable)	
Pharmaceutical calculations & terminology	
Sterile compounding documentation (Compounding Log, Master Formula Record, Labelling, BUD, etc.)	
Quality assurance procedures	
Process validation using media fill tests	
General conduct in the controlled area	
Container, equipment and closure system selection	
Safe handling and compounding of CSPs (including hazardous drugs if applicable)	
Procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding	
Procedures for evaluating, maintaining, certifying, cleaning, disinfecting the facility/environment	
Achieving/maintaining ISO 5 (disinfect gloves and surfaces)	
Written training program	
Policy & Procedures	
Spill Management (pharmacy, nursing & other personnel)	
Train other support services (e.g. housekeeping) on hand hygiene, garbing, cleaning & disinfecting procedures	
Training documentation retained	

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HAZARDOUS GARBING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Compounding attire	Order	Order of garbing in the anteroom	Information
Double Shoe covers	1		Don the second pair upon entering the buffer area. Remove upon leaving.
Head cover	2		
Facial hair covers (if applicable)	2		
Face mask	3	(followed by washing of hands to the elbows x 30 seconds with soap and water and drying)	For spills/decontamination of the hood: see additional garbing requirements
*Face shields & goggles	3	*Required when working outside a C-PEC	
Non Shedding/Non Hazardous Gown			
Hand Cleansing	4	Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.	Clean under nails using one-time use disposable nail cleaning tool Note: Do not use scrub brushes
Non-shedding gown Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	5	Must be changed every 2-3 hours or per manufacturer guidance. NEVER worn outside the HD handling area.	Must close in the back, long-sleeved, closed cuffs that are knit or elastic. No seams or closures that HDs could pass through.
Sterile Chemo gloves Must wear sterile gloves over any CAI gauntlet gloves	6	Chemo gloves must meet ASTM standard 6978 (or its successor). NO powder.	Tested for compatibility with sterile 70% isopropyl alcohol (SIPA). Change every 30 minutes or when torn, punctured or contaminated.
PROHIBITED ITEMS AND INDIVIDUALS			
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails			
Excluded from ISO 7 and ISO 5 spaces until resolved			
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases			

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NON HAZARDOUS GARBING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Compounding attire	Order	Order of garbing in the anteroom	Information
Shoe covers	1		
Head cover (bouffant)	2		
Facial hair covers (if applicable)	2		
Face mask	3	(followed by washing of hands to the elbows x 30 seconds with soap and water and drying)	
Hand Cleansing	4	Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.	Clean under nails using one-time use disposable nail cleaning tool Note: Do not use scrub brushes
Non-shedding gown	5		
Sterile gloves Must wear sterile gloves over any CAI gauntlet gloves	6		Tested for compatibility with sterile 70% isopropyl alcohol (SIPA)
PROHIBITED ITEMS AND INDIVIDUALS			
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails			• These items should be removed before entering the gowning area • Sanitize eye glasses (with alcohol wipes) before entering the gowning area • Cosmetics include self-removable false eye lashes
Excluded from ISO 7 and ISO 5 spaces until resolved			
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases			

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Donning, Hand Hygiene & Doffing for HAZARDOUS Sterile Compounding

DONNING SEQUENCE

Step 1: Removal of Jewelry and Cosmetics

Outside the ante-room or outside the perimeter line of the Segregated Compounding Area (SCA):

1) **Remove and store in a safe place:**
   a. **Jewelry: wrist, hand and finger (including watches)**
   b. **All other visible jewelry, piercings, headphones, earbuds and personal electronic device(s)**
2) **Remove any nail polish/artificial nails**
3) **Remove all cosmetics**

Before entering the sterile compounding area, let your manager know if you are experiencing: Exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease.

Step 2: Shoe Covers

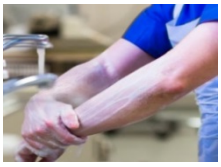
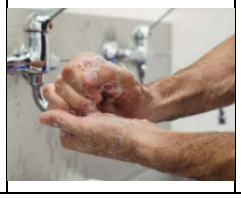
1) **Put on TWO pairs of shoe covers on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD**
2) **Repeat for 2nd foot**

Step 3: Hair Cover & Face Mask

Inside DIRTY side of the Ante Room or outside the perimeter line of the Segregated Compounding Area (SCA)

1) **Put on Hair Cover: Cover entire head and ears**
2) **Put on beard cover (if necessary)**
3) **Put on Face Mask (over nose and pulled all the way beneath the chin. If the mask has ties to secure: put on hair cover first then the face mask)**
4) **Validate sufficient coverage (including coverage of all facial and head hair coverage)**

Step 4: Hand Hygiene Sequence

 **Using warm water, wet hands and arms to the elbow. Apply appropriate cleaning agent. Shut off water in a hands-free manner.**	**Clean under nails using a one-time use disposable nail cleaning tool. Note: Do NOT use scrub brushes** 	 **Using appropriate cleaning agent, vigorously wash hands and arms (up to the elbow) for 30 seconds**	**Use warm water to rinse hands and arms to the elbow** 	 **Use non-shedding wipes to dry hands and arms.**

Step 5: Gowning

1)Don a non-HD long-sleeved gown
2)Don a second long-sleeved HD gown (polypropylene or low-shedding) with sleeves that fit snuggly around the wrist, closes in the back and covers all the way to the neck.

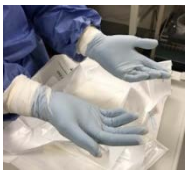
NOTE: HD-gowns must be changed, at a minimum, every 3 hours OR immediately after a spill or splash

Donning, Hand Hygiene & Doffing for HAZARDOUS Sterile Compounding

STEP 6: Hand Hygiene Inside Ante Room or Buffer Area OR within the LOD if the SCA

1) **Disinfect using alcohol based product with persistent activity**
2) **Allow to dry before wearing gloves.**

STEP 7: Sterile Gloves



1) **For HD compounding, put on 2 PAIRS of sterile chemo tested gloves (ASTM 6978-05)**
   - **First pair of gloves: wear underneath the cuffs of the HD gown**
   - **Second pair of gloves: wear over the cuff of the HD gown**
2) **Prior to entry into the PEC, apply sterile isopropyl alcohol to gloves and allow to dry**

Reusing PPEs used for Hazardous Compounding?

The only PPE that can be re-used: **non-HD Gown** if stored for reuse on the CLEAN side of the Ante room, where possible, at least 3 feet from the sink. Reuse restricted to single user, and for the duration of the shift

DOFFING SEQUENCE

DOFFING STEP 1:

Inside the BSC or CACI, remove the outer pair of sterile gloves and discard as hazardous waste

DOFFING STEP 2:

For facilities with HD-buffer room: perform the following steps within the HD-Buffer room doffing area. For facilities with HD-SCA: perform the following steps within the LOD of HD-SCA.
Remove and discard as hazardous waste:

1) **The outer shoe covers**
2) **The outer HD gown AND**
3) **The inner pair of sterile gloves**

DOFFING STEP 3:

Inside CLEAN Side of the Ante Room OR outside the LOD of the SCA:

1) **Remove the non-HD gown. If non-HD gown is not soiled, hang (where possible at least 3 feet from the sink) to reuse gown for the rest of the shift.**

DOFFING STEP 4:

Cross the LOD into the DIRTY Side of the Ante Room and remove and discard into the waste bin:

1) **Non-HD gown – if not reused**
2) **Shoe covers**
3) **Head and face covers**

EXIT THE ANTEROOM

Donning, Hand Hygiene & Doffing for NON-HAZARDOUS Sterile Compounding

DONNING SEQUENCE

Step 1: Removal of Jewelry and Cosmetics

Outside the ante-room or outside the perimeter line of the Segregated Compounding Area (SCA):

1) **Remove and store in a safe place:**
   a. **Jewelry: wrist, hand and finger (including watches)**
   b. **All other visible jewelry, piercings, headphones, earbuds and personal electronic device(s)**
2) **Remove any nail polish/artificial nails**
3) **Remove all cosmetics**

Do NOT enter sterile compounding area if you are experiencing: Exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease.

Step 2: Shoe Covers

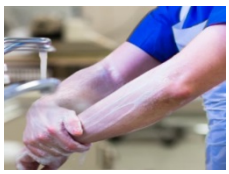
1) **Put on shoe cover on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD.**
2) **Repeat for 2nd foot**

Step 3: Hair Cover & Face Mask

Inside DIRTY Side of the Ante Room or outside the perimeter line of the Segregated Compounding Area (SCA)

1) **Put on Hair Cover: Cover entire head and ears**
2) **Put on beard cover (if necessary)**
3) **Put on Face Mask (over the nose and pulled all the way beneath the chin. If the mask has ties to secure: put on hair cover first then the face mask)**
4) **Validate sufficient coverage (including coverage of all facial and head hair coverage)**

Step 4: Hand Hygiene Sequence

 **Using warm water, wet hands and arms to the elbow. Apply appropriate cleaning agent. Shut off water in a hands-free manner.**	**Clean under nails using a one-time use disposable nail cleaning tool. Note: Do NOT use scrub brushes** 	 **Using appropriate cleaning agent, vigorously wash hands and arms (up to the elbow) for 30 seconds**	**Use warm water to rinse hands and arms to the elbow** 	 **Use non-shedding wipes to dry hands and arms**

Donning, Hand Hygiene & Doffing for NON-HAZARDOUS Sterile Compounding

Step 5: Gowning

1) **Don a non-HD long-sleeved gown with sleeves that fit snuggly around the wrist**

STEP 6: Hand Hygiene Ante Room or Inside Buffer Area OR within the LOD if the SCA

1) **Disinfect using alcohol based product with persistent activity**
2) **Allow to dry before wearing gloves.**

STEP 7: Sterile Gloves

1) **Don sterile gloves - cuff overlapping the gown sleeve**
2) **Prior to entry into the PEC, apply sterile isopropyl alcohol to gloves and allow to dry**

What PPEs may be re-used for Non-Hazardous Sterile Compounding?

A. Booties and Hair Net: **NO.** Discard once you cross the LOD into the dirty side of the Ante Room or outside of the LOD for SCA
B. Face Mask: **NO.** Change at least every 2 hours OR whenever the mask gets wet. Discard once you cross the LOD into the dirty side of the Ante Room or outside the LOD for SCA
C. Gown: **YES,** if stored for reuse on the CLEAN side of the Ante room, where possible, at least 3 feet from the sink. Reuse restricted to single user, and for the duration of a single shift
D. Gloves: **NO**. Discard once you cross the LOD into the dirty side of the Ante Room or outside the LOD for SCA

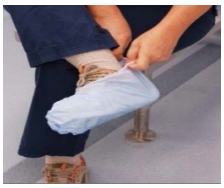
DOFFING SEQUENCE

DOFFING STEP 1:

Inside CLEAN Side of the Ante Room OR outside the LOD of the SCA:

1) **Discard the gloves**
2) **Remove the gown. Hang (where possible at least 3 feet from the sink) to reuse gown for the rest of the shift if gown is not soiled.**

DOFFING STEP 2:



Cross the LOD into the DIRTY Side of the Ante Room and remove and discard into the waste bin:

1) **Gown – if not soiled or not needed for the rest of the shift**
2) **Shoe covers**
3) **Head and face covers**

EXIT THE ANTEROOM

By Patricia Kienle, RPh, MPA, FASHP,
and Kate Douglass MS, RN, CRNI

Perform an Assessment of Risk to Comply with USP <800>

On July 1, 2018, *USP <800> Hazardous Drugs – Handling in Healthcare Settings*[1] will become official, although some states, accreditation organizations, and facility policies may require earlier compliance. In the pursuit of USP <800> compliance, the first step is to identify all of the hazardous drugs (HDs) utilized by the entity, as well as their dosage forms and the specific handling practices for those products.

USP <800> is part of the USP Compounding Compendium, available for purchase at http://www.usp.org/store/products/usp-compounding-compendium.

Handling Options

USP <800> requires compliance with *all* containment strategies and work practices listed in the chapter (see **FIGURE 1**[1]) when entities handle:

- Any antineoplastic drug included in Table 1 of the NIOSH list[2] that requires manipulation
- Any active pharmaceutical ingredients (APIs) for any type of HD included in Tables 1, 2, and 3 of the NIOSH list[2] (See **SIDEBAR 1** for the definition of terms used in the NIOSH list.)

While there is no option for developing alternative handling strategies for these types of HDs, Chapter <800> does allow for some other HDs to be handled differently under specific circumstances. The only HDs that can be considered for alternative handling are antineoplastic drugs listed in Table 1 that will not be manipulated (ie, requiring only counting or packaging), non-antineoplastic drugs listed in Table 2 that are not APIs, and reproductive-only risk drugs listed in Table 3 that are not APIs.[2] These types of HDs may be treated in one of two ways:

1. Handle in the same manner as APIs and antineoplastic drugs that require manipulation, using all of the containment properties and work practices listed in <800>.
2. Perform an Assessment of Risk (AoR) to determine which specific dosage forms of these agents may be handled with alternative containment strategies and/or work practices. The alternative containment strategies and work practices must be sufficient to protect the health care workers from exposure to HDs (see **SIDEBAR 2**).

This article focuses on how to perform an AoR and provides a sample AoR reflecting actual work practice settings (see **FIGURE 2**), as well as an AoR template that may be downloaded and modified for your own use. AoRs are not limited to pharmacy practices only; rather, they are intended to detail organization-wide practice encompassing all areas in the facility that handle HDs. AoRs should include a list of all staff members who may handle HDs, including those who perform HD receiving, inventory storage, compounding, transport, administration, and disposal of items contaminated with HD residues. Designated personnel may include those from materials management, pharmacy, nursing, transport, environmental services, and other departments.

Compliance Steps

In the effort to comply with USP Chapter <800>, all organizations must undertake the following steps:

SIDEBAR 1

Definition of Terms

- **Entity** is the specific location where HDs are handled and is not limited to pharmacies. For example, a hospital is an entity, but the hospital's off-site locations, such as oncology clinics or ambulatory pharmacies, may develop a separate list of HDs, since the drugs used at those locations may differ from those used at the hospital campus.
- **HDs** are drugs that are hazardous to health care personnel, as defined by the National Institute for Occupational Safety and Health (NIOSH). See the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016.[2] The NIOSH list sorts HDs into three tables: antineoplastics (Table 1), non-antineoplastics (Table 2), and reproductive-only hazards (Table 3). These drugs are different from hazardous materials as defined by the Environmental Protection Agency; those agents are hazardous to the environment. Note that there are some drugs that are on both the NIOSH list and the EPA list.
- **Cleanroom Suite** is an ISO 7 positive anteroom and an ISO 7 negative buffer room that meet the requirements of USP <797> and <800>.
- **Containment Segregated Compounding Area (C-SCA)** is a room that meets the requirements of USP <800>.

1. Download the NIOSH 2016 list[2]
2. Identify all of the HDs handled within the entity including each dosage form used. This review must encompass formulary items as well as any non-formulary items utilized. Be sure to consult work groups within the entity that may purchase or obtain drugs from sources other than the hospital pharmacy to ensure the creation of a complete master list
3. Divide the list into two categories:
   a. Drugs that are ineligible for an AoR (APIs and antineoplastics that require manipulation)
   b. Drugs that may be considered for an AoR (antineoplastics that will only be counted or packaged, non-antineoplastic and reproductive-risk-only drugs)
4. Evaluate each of the drugs and dosage forms eligible for an AoR, considering the following:
   a. Dosage form in which it is obtained
   b. Packaging (such as unit dose, unit-of-use, or bulk)
   c. Need for and type of manipulation (eg, crushing, opening capsules, compounding, etc)
5. Determine if practical alternative containment strategies and/or work practices could be developed and implemented to protect employees from ingesting, inhaling, or touching HD particulates or vapors
6. Create a written AoR for each drug dosage form for which alternate strategies will be used

FIGURE 1

Summary of Containment Strategies and Work Practices Required in USP Chapter <800>[1]

Description of Activity	Containment Strategy	Work Practice
Identification of drugs received as hazardous from inspection of the outside of the container	X	X
Protection of HDs received as they are unpacked and transferred to storage	X	X
Store HDs in a space that meets these four **minimum** requirements: ▸ Room with fixed walls and door that is separate from non-hazardous storage ▸ Negative pressure between 0.01" to 0.03" water column (w.c.) to adjacent space ▸ At least 12 air changes per hour (ACPH) ▸ Exhaust vented outside the building	X	
Decontamination of surfaces exposed to HDs or contaminated HD containers		X
Controls that result in protection from HD residue when HDs are transported	X	X
Controls during splitting, crushing, or otherwise manipulating a non-parenteral dosage form of an HD	X	X
Compounding non-sterile HDs in a room that meets these four **minimum** requirements: ▸ Room with fixed walls and door that is separate from non-hazardous storage ▸ Negative pressure between 0.01" to 0.03" w.c. to adjacent space ▸ At least 12 ACPH ▸ Exhaust vented outside the building	X	
Compounding *sterile* HDs in a cleanroom suite that meets these four **minimum** requirements: ▸ Room with fixed walls and door that is separate from non-hazardous storage ▸ Negative pressure between 0.01 to 0.03" w.c. to adjacent space ▸ Room supplied with HEPA-filtered air resulting in ISO Class 7 during dynamic operating conditions (*at least* 30 ACPH) ▸ Exhaust vented outside the building	X	
Compounding *sterile* HDs in a C-SCA that meets these four **minimum** requirements: ▸ Room with fixed walls and door that is separate from non-hazardous storage ▸ Negative pressure between 0.01" to 0.03" w.c. to adjacent space ▸ At least 12 ACPH ▸ Exhaust vented outside the building	X	
Use of PPE ▸ Gloves that meet ASTM standard D6978 ▸ Disposable gowns tested to resist HD permeation, back-closing, cuffed, no seams or sealed seams ▸ Head covers and surgical masks ▸ Double shoe covers ▸ Goggles and face shield if splash potential ▸ Respiratory protection per section 7.5		X
Compounding ▸ Use C-PEC and plastic-backed mat, which is changed daily and after spills ▸ Use of disposable/cleanable equipment such as mortar, pestles, and spatulas dedicated for use with HDs ▸ Consider use of CSTDs	X	X
Controls that result in protection from HD residue when HDs are transported or stored ▸ Labeled as an HD ▸ Labeled to require PPE precautions ▸ Warning message on ADC lidded bin to wear HD PPE ▸ Warning message on ADC lidded bin to wear chemo gloves	X	X
Decontamination of HDs ▸ Decontaminate reusable equipment where HDs are handled ▸ Decontaminate the work surface of the C-PEC at least daily and between different types of HDs ▸ Persons decontaminating are properly garbed ▸ Decontamination agents applied with wet applicator, never sprayed ▸ Decontamination occurs first followed by cleaning and disinfection in areas of sterile compounding ▸ Tray under C-PEC decontaminated at least monthly and consider additional respiratory protection		X
Use CSTDs during administration if the dosage form allows	X	X
Proper disposal of residual HDs and supplies according to local, state, and federal requirements	X	X
Comprehensive spill management and control		X

FIGURE 2

Sample Assessment of Risk

In this sample AoR for oxytocin injection, which is received in unit of use from an outsourced compounding pharmacy, the entity details the risk factor and the corresponding safety measures implemented to protect at-risk staff from exposure. As a result, the entity can utilize these handling procedures in lieu of the more extensive handling requirements detailed in <800>. CriticalPoint has provided an AoR template, which can be modified for your practice; it is available at **pppmag.com/assessmentofrisk.**

Drug Name: Oxytocin **Date Assessment of Risk (AOR) Initially Performed:** January 17, 2017

Date AOR Reviewed: N//A; this is initial

HD Drug Category: ☐ Antineoplastic ☐ Non-antineoplastic ☒ Reproductive Risk Only

Dosage form (select one):
- ☐ Sterile dosage compounded by a vendor and not requiring additional manipulation
- ☐ Dosage form of conventionally manufactured product that require only packaging or counting
- ☐ Dosage form of conventionally manufactured non-antineoplastic or reproductive hazard product that requires only packaging and counting
- ☒ Other (explain): Obtained from FDA Registered 503B Outsourcing Facility

Describe Packaging: Oxytocin 30 units in 500 mL 0.9% sodium chloride injection

Rationale for not requiring all <800> containment strategies	Specific Alternative Administrative, Engineering and Work Practice Control Strategies
Document rationale here: Oxytocin is a human peptide hormone and neuropeptide that is used as a medication to facilitate childbirth. Oxytocin is normally produced in the hypothalamus and released by the pituitary. Oxytocin plays and important role in stimulating cervical dilation as well as stimulating uterine contractions in the 2nd and 3rd stages of labor. Exposure to oxytocin is believed to pose a risk to women in their third trimester of pregnancy relative to the risk of stimulating uterine contractions which may result in early labor.	• The following strategies are documented in administration of oxytocin in the nursing SOP 321.2 • Training in the SOP is scheduled for all nursing staff on January 23, 2017 Document specific alternative strategies below or ☐ N/A (see below) • Receive the compounded units from ABC 503B Outsourcing Facility • Nurses who are in their 3rd trimester and may also be exposed to oxytocin while caring for patients during their normal job duties will sign an Acknowledgement of Risk form after receiving training regarding the risks and proper use of PPE • Nurses and medical staff at risk of exposure to oxytocin during drug administration to patients will wear gloves tested to ASTM 6978 while administering, maintaining or discontinuing IV lines with oxytocin.

Based on Assessment of Risk will proceed as follow: ☒ Follow alternative strategies documented above ☐ Follow all USP <800> requirements

Assessment of Risk written by: Carl Smith, RPh Date: 1/17/2017

Reviewed by Pharmacy Manager: Jane Olsen, PharmD Date: 1/17/2017

F-700.g; Released 12/19/2016

Components of an AoR

USP Chapter <800> allows for certain HDs to be considered for alternative containment strategies or work practices, but only if a systematic AoR is completed and documented for each drug and dosage form. The required elements of an AoR include:

1. Type of HD (antineoplastic per List 1, non-antineoplastic per List 2, or reproductive-only risk per List 3[2])
2. Specific dosage form (for each AoR)
3. Risk of exposure
4. Packaging (ie, description of packaging in which the drug is received)
5. Type of manipulation performed by the organization to render the final dosage form (listed in **SIDEBAR 2**)
6. Specific alternative containment strategies and/or work practices that will be employed to reduce the risk of exposure

To create an AoR, a standard operating procedure (SOP) must first be created that determines how AoRs are performed, who performs them, how they are documented, and what staff training is required. It is important to note that implementing alternative containment strategies and/or work practices may necessitate the development of additional procedure-specific SOPs. Review the AoR annually, and document that this review occurred. As stated previously, any drug dosage forms for which an AoR has *not* been performed must be handled following all of the containment strategies and work practices required in Chapter <800>.

Some drugs present unique challenges due to the location in which they are administered. Review the containment strategies for HDs that are dispensed in vial form to procedural areas, as these are commonly handled improperly. Pay particular attention to drugs such as methotrexate injection (used in the treatment of ectopic pregnancies and rheumatoid arthritis), mitomycin for injection (used for ophthalmic or urology procedures), and Bacillus Calmette-Guerin, which is used during urology procedures. Work with staff in the departments administering these agents to ensure safe practices.

Conclusion

USP <800> is designed to protect patients, personnel, and the environment. The AoR component of the standard provides a systematic way for organizations to ensure safe practices. As the organization's primary drug steward, the sterile compounding pharmacist should lead this compliance effort and work collaboratively with other members of the health care team to assess and develop alterative containment strategies and work practices when possible. ■

Address any questions to Kate Douglass at kdouglass@criticalpointce.com.

References

1. USP Convention, Inc. <800> Hazardous Drugs-Handling in Health care Settings. *USP 40-National Formulary 35*. 1st supp. Rockville, MD: USP Convention, Inc , 2017.
2. Connor TH, MacKenzie BA, DeBord DG, et al. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138). http://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf. Accessed February 17, 2017.

SIDEBAR 2

Alternative Containment Strategies

Alternative containment strategies and work practices might include:

- Use of CSTDs for HDs that are not antineoplastics
- Use of gloves tested to ASTM standard D6978 for HDs that are not antineoplastics
- Purchasing in unit dose or unit-of-use so that no manipulation or compounding is necessary
- Use of personal protective equipment (PPE) as detailed in the NIOSH list (Table 5),[2] which may differ based on the function performed (eg, compounding vs administration)
- Use of a dedicated, enclosed plastic tote that is decontaminated after use when needed to transport HDs from the pharmacy to other areas of the health system
- Labeling lidded automated dispensing cabinet bins so nurses and others who administer medications are reminded of the proper PPE

Patricia C. Kienle, RPh, MPA, FASHP, Director of Accreditation and Medication Safety for Cardinal Health, is a member of the USP Compounding Expert Committee and chair of the Hazardous Drug Subcommittee and Expert Panel, although her comments herein are her own and not official information from USP.

Kate Douglass, MS, RN, CRNI, is the vice president of CriticalPoint, LLC, and serves as the co-director of the annual USP Compliance Survey.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, VP Nursing & Clinical Services
Rita Shane, Pharm.D., FASHP, FCSHP, Chief Pharmacy Officer, Cedars-Sinai Medical Center

SUBJECT: USP 800 Hazardous Drugs – Handling in Healthcare Settings

SUMMARY

USP 800 implications, along with clean room construction progress, is also top of mind, now that USP has been finalized and will be official as of December 1, 2019. USP 800 has workforce planning, wage and non- wage issue inferences.

Workforce and Wage Implications

- Increased number of staff who may refuse to handle hazardous medications and waste- staff involved – nursing, pharmacy, environmental services, safety
- Cross training needs across key areas that are involved in hazardous drug handling and associated expenses; alternative work assignment accommodation
- Approach to training and communication

Non-wage Implications

- Increased cost of disposables and closed system materials for pharmacy and nursing
- Increased waste disposal costs
- Increased staff surveillance /monitoring costs: recommendations for baseline and ongoing monitoring
- Environmental sampling including patient rooms recommended
- Increased need for negative storage space refrigerated and non-refrigerated hazardous drugs
- Non- sterile compounding with crushed tablets (currently performed by nursing) and powder dilution (AHSP)

DISCUSSION

1) Are there standardized actions all hospitals will take or are these issues hospital specific?
2) Does CHA need to form policy and advocate for changes to USP 800 standards?
3) How does Cal OSHA's definitions of "Hazardous Drugs" play into this?
4) Do the committee members think additional education is necessary for the hospital membership?

ACTION REQUESTED

- Information and advice CHA on next steps

Attachment: USP 800 Overview Presentation

BJB:br

USP 800 Hazardous Drugs – Handling in Healthcare Settings
Official December 1, 2019

CEDARS-SINAI
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Agenda

1. Definitions
2. Scope
3. CSMC Multidisciplinary Task Force
4. Key Requirements and Operational Impacts
5. Hazardous Communication Plan and Training
6. Personnel Protective Equipment
7. Medical Surveillance
8. Workforce Considerations
9. FY 20 Budget Impact

2

What is USP 800 Hazardous Drugs

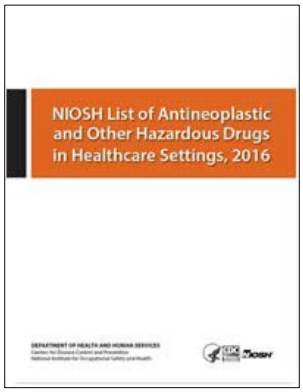
- Based on published reports of adverse effects in healthcare personnel from occupational exposure to HDs
- USP 800 consistent of 18 chapters (see Appendix)
- Any drug defined as hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of six criteria:
  1. Carcinogenicity
  2. Teratogenicity or developmental toxicity
  3. Reproductive toxicity in humans
  4. Organ toxicity at low doses in humans or animals
  5. Genotoxicity
  6. New drugs that mimic existing hazardous drugs in structure or toxicity

National Institute for Occupational Safety and Health (NIOSH)

Categories

1. Antineoplastics (e.g.,chemotherapy)
2. Non-antineoplastics that meet 1 or more criteria and may pose reproductive risk for some populations
3. Reproductive only hazards
4. Investigational drugs-if no information available

HDs are ubiquitously used throughout the medical center and include, infusions, injections, ophthalmic, inhalation, oral and topic drugs

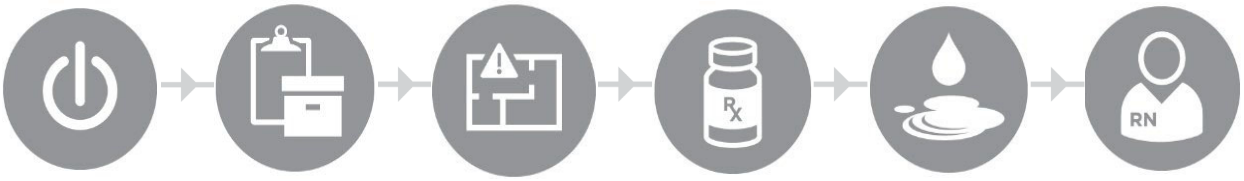


https://www.cdc.gov/niosh/docs/2016-161/images/2016-161.jpg, accessed 9/30/18

USP 800
Hazardous Drugs (HDs)

- Designed to protect employees, patients and the general public who may be accessing facilities where hazardous drugs (HDs) are stored, prepared, transported or administered.
- Includes but not limited to
  - Pharmacists, technicians, nurses, physicians, respiratory therapists, environmental services staff, allied health professionals, other healthcare workers, patients, families
- Applies to entities that handle HDs
  - Pharmacies, hospitals and other healthcare institutions, clinics, physicians' offices or veterinarians' offices
- **Employees <u>must</u> receive HD training and be assessed for an understanding of the training**.

Hazardous Drug Lifecycle



Getting Started – People and Processes

Receiving and Storage

Infrastructure for Compounding

Compounding HD and the Necessary PPE

Spills, Cleaning and Disposal

Administering HDs and the Necessary PPE

6

USP 800 Key Components
(see Appendix for complete list)

- Hazardous Drug (HD) List Risk Assessment
- Hazardous Drug Communication Plan and Training
- Operations
  - Hospital flow of HDs
  - Personnel Protective Equipment
  - Containment of HDs
    - Ex: If non-antineoplastic or reproductive risk HD drugs require crushing tablet(s) or opening capsule(s), containment and work practices defined in the risk assessment must be used (e.g. appropriate personnel protective equipment (PPE), plastic pouch to contain any dust or particles generated).
  - Cleaning of medication rooms, patient rooms
  - Waste management including storage
  - Job descriptions and Job Hazard Analysis-incorporate HD handling
- Monitoring
  - Employees-Medical Surveillance
  - Facilities

7

CSMC USP 800 Hazardous Drug Task Force

- Established multidisciplinary team in 2017
- Goal: Develop policies, standard operating procedures and conduct risk assessment to Hazardous Drugs List to support education, training and management of HDS

1. Nursing
2. Pharmacy
3. ORs
4. Epidemiology
5. Infusion Centers
6. Ambulatory Clinics
7. Human Resources
8. OLAR
9. Respiratory Therapy
10. Purchasing
9. EVS
10. Environmental Safety
11. Physicians
12. Employee Health
13. Transporters
14. Facility Services
15. Supply Chain
16. EIS
17. SOCCI, THO, TACRI and Valley Oncology Group
18. MDR

8

Hazard Communication Program Plan

- A written plan that describes how the standard will be implemented
- All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
- Entities must have an Safety Data Sheet (SDS) for each hazardous chemical they use (29 CFR 1910.1200)
- Entities must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas
- Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
- Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs. Chapter applies to anyone capable of reproduction.

http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf, accessed 13119
http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings, accessed 13119

9

Workforce Considerations: USP 800 Scenario

Organizations should establish a mechanism by which those workers who are actively trying to conceive, are pregnant, or are breast-feeding can request alternative duty or protective reassignment.
https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html, accessed 13119

- Scenario: Healthcare worker notifies Cedars that they want to start a family and are starting IVF and then intends to breastfeed for 12 months. Where will the worker be assigned? For how long? Should others pick up the employee's workload? Should there be a cross-trained workforce to cover shifts?

10

USP <800> Hazard Communication Program at Other Hospitals- 01/16/2019

Hospital	How are you identifying applicable employee types?	How are you identifying applicable employees?	At what point within the employment process are you notifying employees, and what tools are you using?
Penn Medicine	All employees	All employees	1. Outlined in job description, which is signed upon hire. 2. Annual performance evaluation, additional USP 800 document
Nebraska Medicine	All employees	All individuals with applicable job titles/roles	Upon hire Tools: Internal learning/training management software system AND simple paper forms that get filed
Ochsner Health System	All employees **Rationale:** Any employee may walk through a facility and have the potential for exposure to hazardous drug residue on surfaces.	**Training for Jobs with Hazardous Drug Handling duties/Direct Patient Care** Specific online training upon hire and annually • More detailed attestation of awareness of risk • Training and attestation speak to the risk for all people of child bearing years • Understanding of steps to protect themselves and others • Agreement to follow policies and procedures	**All Employees** "USP 800 Awareness " online training module upon hire and annually. Time" five minutes • Reproductive risk is addressed but not in detail • Attestation of awareness of risk, training and understanding of steps to protect themselves and others • Agreement to follow policies and procedures. • Recognition of the HD symbol.
University of Wisconsin Health	Those who might enter a patient care area	All individuals with applicable job titles/roles	1. Upon hire - added to onboarding checklists for RNs, hazardous drug training for RNs 2. Annual education renewal - included in annual safety and infection control Tools: Internal learning/training management software

11

Personnel Protective Equipment Requirements
Will be embedded at the drug level in CS-Link for all HDs identified in risk assessment

CSMC Recommended Minimum Standards for Personal Protective Equipment for Hazardous Drug Administration

HD 1: Antineoplastic

Double chemotherapy gloves
Gown (for injectable medications)
Face shield and goggles if liquid could splash

HD 2: Non-Antineoplastic Hazardous

Formulation/Scenario	Activity	Gloving Requirements	Gowning Requirements	Eye/Face Requirements	Respiratory Requirements
Intact tablet or capsule	Administration from unit-dose package	Single chemo gloves	No gown	None	None
Manipulating tablets or capsules	Crushing tablets or capsules; handling uncoated or cut tablets for administration	Double chemo gloves	No gown	None	Mask
Oral liquid drug or feeding tube	Administration	Double chemo gloves	Gown	Face shield and goggles, if vomit or potential to spit up	None
Topical drug	Administration	Double chemo gloves	No gown	Face shield and goggles, if liquid that could splash	None
Injectable	Preparation (withdrawing from vial/mixing)	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None
	Administration from prepared syringe or IV bag	Double chemo gloves	Gown	None	None
Solution for irrigation	Administration (bladder, HIPEC, limb perfusion, etc.)	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None
Powder/solution for inhalation/serosol treatment	Administration	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	Mask
Any hazardous medication	If patient could vomit or spit up	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None
Any hazardous medication	If liquid could splash	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None

HD 3: Reproductive Risk- PPE ABOVE ONLY REQUIRED FOR AT-RISK PERSONNEL
(Personnel who are pregnant, possibly pregnant or trying to conceive (male or female))

Additional PPE may be added in any situation with a higher risk of exposure
Adapted from NIOSH 2016 Table 5

12

Recommended Medical Surveillance Content for HD Handlers

CSMC Surveillance Plan
To be determined in collaboration with:
Peggy Miles, MD,
Jonathan Grein, MD,
Sarah Kilpatrick, MD,
Risk Management,
HR,
Employee Health

	NIOSH (1)	(2)	ONS (3)	ISOPP (4)	ashp (5)	OSHA (6)	USP (7)
Medical and exposure history	✓	✓	✓	✓	✓	✓	✓
Physical exam	✓	✓	✓	✓	✓	✓	✓
Routine labs	✓	✓	✓	✓	✓	✓	✓
Specialized tests	✓ *		✓ *	✓ **		✓ ***	✓ ***

* Biological monitoring as needed for workers who have shown health changes suggesting toxicity or who have experienced acute exposure (spill)
** Follow up recommended for workers who have shown health changes and/or have been exposed to HDs.
*** Post-exposure evaluation is tailored to the type of exposure; treatment and laboratory studies follow as indicated

1. NIOSH [2013]. Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs. National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2013-103. [http://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf]. NIOSH [2004]. NIOSH alert: preventing occupational exposure to antineoplastic and other hazardous drugs in health care settings. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2004-165.
2. Department of the Army (2014). Technical Bulletin. Occupational and Environmental Health. Occupational Health and Industrial Hygiene Guidance for the Management, use and Disposal of Hazardous Drugs.
3. Polovich, M [2011]. Safe handling of hazardous drugs. 2nd ed. Pittsburgh, PA: Onc Nurs Soc.
4. ISOPP (International Society of Oncology Pharmacy Practitioners) [2007]. Standards of Practice. Safe Handling of Cytotoxics.
5. ASHP (American Society of Health-System Pharmacists) [2006]. Guidelines on handling hazardous drugs. Am J of Health Syst Pharm 63:1172-1193.
6. OSHA [1999]. OSHA technical manual, TED 1-0.15A, Sec VI, Chapt II: Categorization of drugs as hazardous. [www.osha.gov/dts/osta/ otm/otm_vi/otm_vi_2.html#2]. Date accessed:

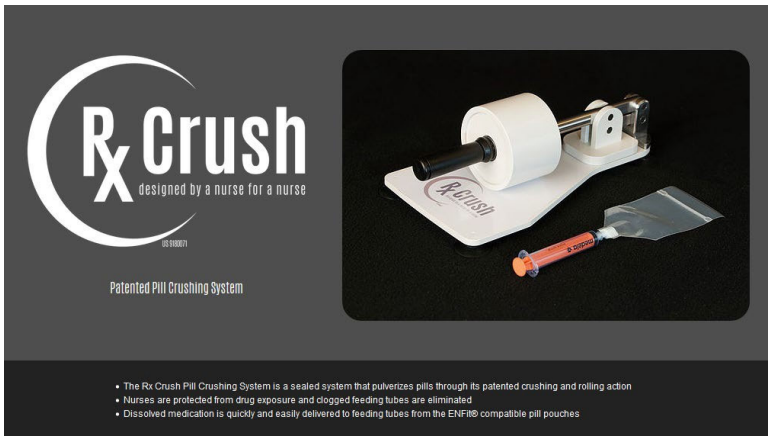
13

USP 800 Hazardous Drugs – Chapter and Status

1. List of HD (90% done)
2. Type of Exposure (done)
3. Responsibilities Personnel Handling HD (70% done)
4. Facilities & Engineering Controls (80% done, contingent on Facility completion)
5. Environmental Quality and Control (not started; Wipe Sampling)
6. Personal Protective Equipment (90% done)
7. HD Communication Program (50% done)
8. Personnel Training (to start 8/19)
9. Receiving (9/17 done)
10. Labeling (1/19 done), Packaging, Transport, Disposal (9/17 done)
11. Dispensing Final Dosage Forms (80% done)
12. Compounding (90% done)
13. Administering (90% done)
14. Deactivating, Decontaminating, Cleaning, Disinfecting (80% done)
15. Spill Control (80% done)
16. Documentation & SOPs (50% done)
17. Medical Surveillance (50% done)

14

Pill Crushing System – Self Contained; Works with ENFit*



*ENfit™ Prevention of enteral feeding misconnection, required in California, effective 7/16. Manufacturer issues delayed implementation

- Self-contained
- Current disposable device: $4.35/dose
- Rx Crush Cost:
  Device: $225-does not come into contact with medication
  Bag: $1.00/dose

15 https://www.bing.com/videos/search?q=rxcrush&pc=MOZI&ru=%2fsearch%3fq%3drxcrush%26pc%3dMOZI%26form%3dMOZLBR&view=detail&mmscn=vwrc&mid=50C65E2E547C23B1499950C65E2E547C23B14999&FORM=WRVORC, accessed 13119

Key Considerations

–Hazard Communication Plan and Workforce Considerations
- Determination of employee job classifications to be training
- Contingency planning for staffing based on reproductive concerns

–Budget impact of Personnel Protective Equipment and disposables across CSHS

–Medical Surveillance scope decision

–Waste management and storage

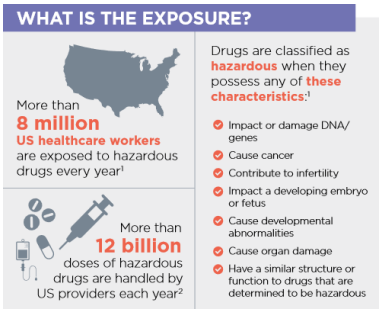
–CSHS unlicensed sites compliance determination

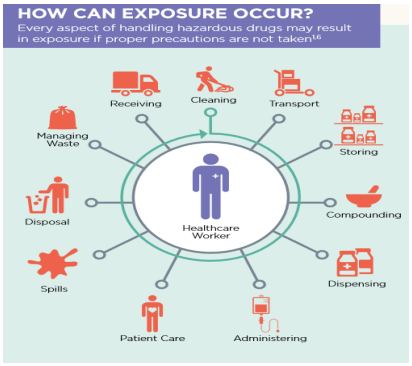
16

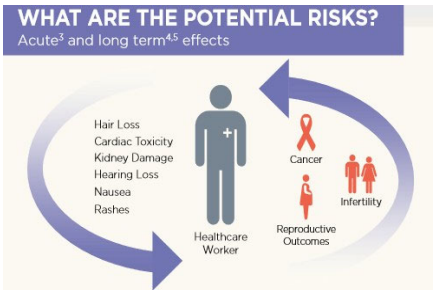
Appendix

17

USP 800 Infographic (excerpt)







http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare, accessed 13119

USP 800 Hazardous Drugs Chapters

1. Introduction Scope
2. List of HD
3. Type of Exposure
4. Responsibilities of Personnel Handling HDs
5. Facilities & Engineering Controls
6. Personnel Training
7. Personal Protective Equipment
8. HD Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, Disposal
12. Dispensing Final Dosage Forms
13. Compounding
14. Administering
15. Deactivating, Decontaminating, Cleaning, Disinfecting
16. Spill Control
17. Documentation & SOPs
18. Medical Surveillance

19

PPE Unit Costs – Pharmacy Sterile Compounding Areas Estimate

PPE Item	Cost Per Unit	Est Pharmacy Cost/Day
Gloves: Sterile chemo	$1.35	x 300 = $405
Mask (isolation)	$0.05	x 200 = $10
Mask surgical duckbill	$0.08	x 50 = $4
Mask N95	$1.14	x 50 = $57
R95 Mask (Odors cleaning soln)	$3.19	
Bouf Surg Cap	$0.03	x 300 = $9
Isolation gown (yellow)	$0.52	N/A
Chemo gown	$0.83	x 75 = $63
Splashguard Visor Mask (Can be Reusable)	$0.46	N/A
Eye shield (Can be Reusable)	$1.21	N/A
Goggles (Can be Reusable)	$0.23	N/A
Chemo Spill Kit	$24.35	Rarely used
PAPR	Reusable – cleaning required-Cartridges costs	
Closed System Transfer Devices	Varied	12 month Expense in Pharmacy $400,000

Need estimated costs for additional areas(non-sterile compounding, pharmacy, nursing, EVS, dietary, etc)

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

FROM: Candace Fong, Pharm.D., System Director, Pharmacy and Medication Safety, Dignity Health
BJ Bartleson, MS, RN, NEA-BC, VP Nursing & Clinical Services

SUBJECT: Inventory Reconciliation from Automatic Dispensing Units

SUMMARY

There continues to be lack of clarity over automated dispensing units (ADUs)reconciliation in hospitals. The Board of Pharmacy was having internal discussions regarding the interpretations and presented this information to the board on July 10, 2019. To follow is information from the California State Board of Pharmacy:

> **QUESTION**: In the emergency room, when the pharmacy is not open, the physician will remove from the ADDS and dispense no more than a 72-hour supply of drugs to a patient pursuant to Business and Professions Code section 4068. Is the hospital pharmacy required to license the ADDS in the emergency room if the ADDS is primarily used for the administration of doses to patients in the emergency room, but occasionally used to dispense a 72-hour supply of drugs to a patient discharged from the emergency room for doses removed from the ADDS by the physician?
> **ANSWER**: Yes, the ADDS will be required to be licensed. The hospital pharmacy is only exempt from licensing the ADDS when the acute care hospital pharmacy **solely uses the ADDS to administer drugs**. When drugs from an ADDS is used to dispense drugs to a patient, the exemption no longer applies. Because the physician is removing the drugs from the ADDS (AUDS) and is not dispensed directly to the patient, the ADDS is not considered an APDS and is not required to follow BPC 4427.6.
>
> **Reference**: BPC 4427.2(i), BPC 4068

DISCUSSION

1) What are the different types and names for narcotic cabinets in a hospital and hospital clinic?
2) What are the requirements for licensure and reconciliation?
3) What are the requirements between ADU used for inpatient care and or those used to dispense, such as some ED ADU's?
4) Do we need a tool to help inform hospitals of the rules for ADU's?

ACTION REQUESTED

- Information and advice to CHA on next steps.

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

FROM: Rita Shane, Pharm.D., FASHP, FCSHP, Chief Pharmacy Officer, Cedars-Sinai Medical Center
Sarah Stephens, Pharm.D., CDPS, CPPS, Medication Safety Coordinator, Kaweah Delta Health District

SUBJECT: SB 1254 Quality Improvement Project

SUMMARY

Last year **SB 1254 Medication Profiles for High Risk Patients** was passed requiring hospitals to establish criteria for defining high-risk patients and complete a medication profile for those patients. The California Hospital Association (CHA) and the California Society of Health-System Pharmacists (CSHP) members are performing a multi-center quality improvement project to demonstrate the impact of SB 1254 on improving patient safety. The project will take place over a 6-week period sometime between Jan-March 2020. Sites will be asked to document and analyze discrepancies and harm avoided, along with economic impact. Sites are required to have an active pharmacy medication history program, ability to track and document medication history errors, a site coordinator to oversee the project, a physician to review errors, and, participation in twice monthly calls beginning in August 2019.

In order to demonstrate the impact of SB 1254 on improving patient safety, hospitals were invited to participate in a multi-center quality improvement project.

Who: Pharmacy staff and/or Pharmacy residents, Class of 2019-20

Methodology:

- Document DRPs and severity (low capacity for harm, serious, life-threatening)
- Physician independent evaluation of severity at each site
- Duration: 6 weeks during Jan-March 2020 timeframe
- Resources: IRB Quality Improvement Template, Project Toolkit
- Planning conference calls

Deliverables:

- Impact of SB 1254 on preventing harm at each site
- Statewide impact on preventing harm and estimated cost savings based on aggregate project results

Study Leads

1. Rita Shane **rita.shane@cshs.org**
2. Sarah Stephens sastephe@kdhcd.org
3. Sara Bajorek **sabajorek@ucdavis.edu**

DISCUSSION

1) How many hospitals are participating in the study?
2) What is the progress to date?
3) How can CHA be of support?

ACTION REQUESTED

- Information

Attachment: SB 1254 Call to Action Flyer
SB 1254 Implementation Plan

BJB:br

CALL FOR PARTICIPATION

SB1254 PATIENT IMPACT QUALITY IMPROVEMENT PROJECT

Site requirements:

- ✓ Active pharmacy medication history program
- ✓ Ability to document medication history errors intercepted
- ✓ Site Coordinator to oversee QI project
- ✓ Physician to review errors intercepted and potential harm prevented
- ✓ Participation in twice monthly calls beginning in August 2019

CONFERENCE CALL WITH POTENITAL SITES

JULY 2019

STUDY GOALS

- ✓ Analyze impact of SB1254 for high risk patients at admission
- ✓ Demonstrate discrepancies and harm avoided due to pharmacy
- ✓ Analyze potential economic impact
- ✓ Align with MERP

BENEFITS

- ✓ Project toolkit
- ✓ IRB template
- ✓ Gantt chart
- ✓ Statewide multicenter support

STUDY LEADS

Cedars-Sinai
Rita Shane
Rita.Shane@cshs.org

Kaweah Delta
Sarah Stephens
sastephe@kdhcd.org

UC Davis
Sarah Bajorek
sabajorek@ucdavis.edu

Please email one of the study leads if you're interested in participating.

% Complete	Topic	Item(s)	Description	Responsible Owner(s)	Due Date	Progress
100%	Initial Project Planning	Preliminary Meeting	Meet to discuss project plans, goals, and timeline	Ryan/Naira/Donna/Rita	3/18/2019	Complete
		Create Implementation Checklist	Create implementation checklist with timeline	Ryan/Naira	6/20/2019	Complete
		Define Objectives/ Design	Objectives: 1. Determine the number of drug-related problems (DRPs) avoided and the associated potential harm as a result of SB 1254 2. Determine the cost savings associated with the DRPs avoided Outcomes: *Primary* : -Average number of DRPs identified per patient -Total number of DRPs identified, types of DRPs identified, and associated severity of harm *Secondary* : -Percent of patients with at least 1 DRP identified -Total cost avoided due to prevented harm Design: 1. *Participating institutions to capture DRPs avoided for 6 weeks (Jan to Mar 2020)* a. Standardized categories of errors intercepted (e.g. wrong dose, wrong frequency, etc.) b. Standardized methodology to rate harm prevented by intercepting errors (utilizing NCC MERP) c. Standardized documentation process of errors intercepted (data collection sheet/form) 2. *Inter-rater methodology* a. Pharmacist #1: identifies the DRP and documents the intervention b. Pharmacist #2: Independently categorizes the DRP and ranks potential severity of harm c. Physician: Reviews the DRP severity congruency (subset of 'Serious' and all 'Life-threatening') Discussion points: standardize therapeutic class breakdown; breakdown of MD type (e.g. academic attending vs resident vs private); DRPs d/t true error (e.g. translated to inpatient order) vs prevented error (e.g. did not translate into inpatient order); site available resources; anticipated limitations	Study Team	7/8/2019	Complete
33%	Recruitment	Compile Background and the Literature Review	Compile background material for initial recruitment Webinar	Study Team	7/15/2019	In Progress
		Flyer	Create recruitment flyer to be shared with CSHP members, etc.	Donna/Rita	7/1/2019	Complete
		Webinar	Outline: 1. Objectives of the Webinar (Rita Shane) 2. Background/Literature (Rita Shane) 3. MARQUIS participation/lessons learned (Sarah Bajorek) 4. Experience in implementing SB1254 (Sarah Stephens) 5. Study objectives, outcomes, design (Ryan Hays) 6. Responsibilities and tools for participating sites (Naira Barsegyan) 7. Study timeline (Naira Barsegyan)	Study Team	8/1/2019	In Progress
		Webex/Call Coordination	1. Coordinate and set up the meetings with participating sites (e.g. office hours) and project team? (primary and secondary) 2. Includes any on-site meetings (e.g. Seminar)	Primary: Sarah Bajorek Secondary: Sarah Stephens	7/8/2019	Complete

% Complete	Topic	Item(s)	Description	Responsible Owner(s)	Due Date	Progress
100%	Define Project Team Major Responsibilities	Minutes	Document minutes from each meeting (to be sent to entire project team)	Residents	7/8/2019	Complete
		Emails	Coordinate email communication to the participating sites (primary and secondary)	Primary: Sarah Stephens Secondary: Sarah Bajorek	7/8/2019	Complete
0%	Study Method/Data Collection Elements	Demographic Survey	Questions to ask participating sites: (ongoing draft) - determine if will use RedCap 1. Do you have reporting capabilities in EHR? What type of EHR? Do you have an error documentation process? 2. Do you currently have a model for completing med hx? What is your model? (e.g. Rx or Tx or both)? Was it implemented prior to SB1254 or after? If before, was it optimized/expanded post SB1254? 3. How do you define high risk? (table with different high risk criteria from each site), Etc. 4. Pending additional questions	Study Team	8/19/2019	In Progress
		Methods	Finalize data collection method (follow up with Dr. Schnipper and Dr. Molla for feedback). CSMC intervention: update error types if needed, train staff to use sub type and prep for data collection, independent rx evaluation, adjudication, duration: 6 weeks during Jan-March 2020	Study Team	9/1/2019	In Progress
		Data Collection Elements	Create excel spreadsheet and word document with data elements	Ryan/Naira	9/1/2019	In Progress
		Redcap	Initial building of RedCap with data collection elements	Ryan/Naira	9/1/2019	In Progress
#DIV/0!	QA/QI Study Approval	P&T approval	QA/QI - one slide with objectives, methods, anticipated results	Ryan/Naira/Donna/Rita	10/1/2019	
		IRB approval	Once approval obtained from P&T, submit for IRB	Ryan	10/1/2019	
#DIV/0!	Toolkit	Toolkit	<u>Elements of the Toolkit</u>: List of primary investigators and contact information Study background, objectives, methods, timeline, etc. Definitions of error types (e.g. wrong dose, wrong frequency) Definitions of severity rankings (NCC MERP) Data collection form for organizations that want to collect data via paper form Data collection Excel spreadsheet for organizations that will collect data manually Therapeutic class reference list Aggregate data elements (minimum required for study participation) IRB quality improvement exemption template Example error documentation process One page training document for staff (ensure staff trained to select TOC pta as subtype)	Residents	10/13/2019	
		Meeting with Participating Sites	<u>CSHP meeting with participating sites</u>: 1. Further discuss project 2. Review Toolkit 3. Examples to rate type and severity 4. FAQs 5. Pending additional agenda items	Study Team	10/13/2019	
		Second Demographic Survey	Additional demographic information if not captured via first survey	Study Team	11/1/2019	
#DIV/0!	Office Hours	Pre-data collection/soft go live			2/1/2020	
		During data collection			2/1/2020	

% Complete	Topic	Item(s)	Description	Responsible Owner(s)	Due Date	Progress
		Post data collection			4/1/2020	
#DIV/0!	Analysis of Aggregate Data				5/1/2020	
					5/1/2020	
					5/1/2020	
#DIV/0!	Manuscript				7/1/2020	
					7/1/2020	
					7/1/2020	

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, VP Nursing & Clinical Services
Rita Shane, Pharm.D., FASHP, FCSHP, Chief Pharmacy Officer, Cedars-Sinai Medical Center

SUBJECT: Biosimilars

SUMMARY

In review, Aetna indicated via a certification letter that they were selecting a specific biosimilar for use, analogous to the payer dictating which generic to use. They have designated Fulphila as the preferred biosimilar to cancer patients who are at risk for neutropenia. This poses many issues for hospitals. It puts the patient at risk and burdens hospitals by having to increase their inventory, EMR build out, ensuring the right drug is ordered based on payer, but most importantly, there is risk of the wrong drug being dispensed due to mix up of products and associated immunogenicity reactions.

At our last meeting we updated the members that CHA had extensive discussions with DMHC and while willing to clarify its certification letter, is unwilling to withdraw its intent. CHA is working with AHA and needs to collect any and all information that will assist with ongoing policy and advocacy efforts.

Attached is the ISMP article written by Rita Shane, a Wall Street Journal Op-Ed by Denny Lanfear, and Rita's response to the Wall Street Journal Op-Ed.

DISCUSSION

1) Will this affect your hospital? If so, what information can you provide us to assist with advocacy efforts?
2) Are you aware of any other payer issues around use of biosimilars?

ACTION REQUESTED

- Information on biosimilar use and its projected issues within your facilities.

Attachment: ISMP Medication Safety Alert
"How Big Pharma Suppresses 'Biosimilars'", Denny Lanfear, WSJ Op-Ed (6-23-19)
Letter to the Editor, WSJ, Response from Rita Shane

BJB:br

May 9, 2019 ▪ Volume 24 Issue 9

ISMP 25 YEARS ADVANCING MEDICATION SAFETY

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

As approval of medical cannabis spreads state by state, product labeling improvements are a must

Problem: Anecdotal support, public opinion, and state laws in the US are outpacing scientific research involving medical marijuana, more professionally known as medical cannabis. Medical cannabis differs from the street product in that the plant must be reliably grown and handled in a manner that resembles good manufacturing practices. This allows growers to assay and establish the products' contents with the intent of passing that information on to dispensaries and patients. However, lack of federal regulation has allowed for heterogeneity of state programs, yielding a wide variety of cannabis formulations, products, flashy strain names, and patient safety concerns.

For example, the use of strain (or brand) names is prevalent, but studies have shown that there are genetic inconsistencies among products with the same strain name.[1-4] Furthermore, the lack of consistency in state cannabis labeling requirements, along with the lack of involvement of healthcare professionals, has given rise to labeling practices that risk patient safety. Thus, it is difficult for dispensaries to provide patients with products that are clearly labeled, which is a critical component for safe and reproducible effects.

Components of Medical Cannabis

Cannabis sativa has many phenotypes (strains) that include hundreds of chemicals (cannabinoids) produced in varying amounts based on the strain and growing conditions. As a comparison, think of all the varieties and tastes of apples, including regional varieties, crab apples, and genetic hybrids such as "grape-apples." The two most notable cannabinoids are tetrahydrocannabinol (THC) and cannabidiol (CBD), although cannabis has many other physiologically active molecules whose effects are not fully understood.

THC is associated with psychoactivity (or psychotoxicity), including euphoria, relaxation, pain relief, anxiety, and memory impairment. The psychoactive effects tend to be dose limiting, and taking too much can make patients feel uncomfortable. When talking to patients, it is helpful to describe the psychoactive effects as impairment or intoxication and to caution that it might cause light-headedness and postural hypotension, increasing the risk of falls. THC has been associated with cannabis use disorder, while CBD has not.

continued on page 2—Medical cannabis >

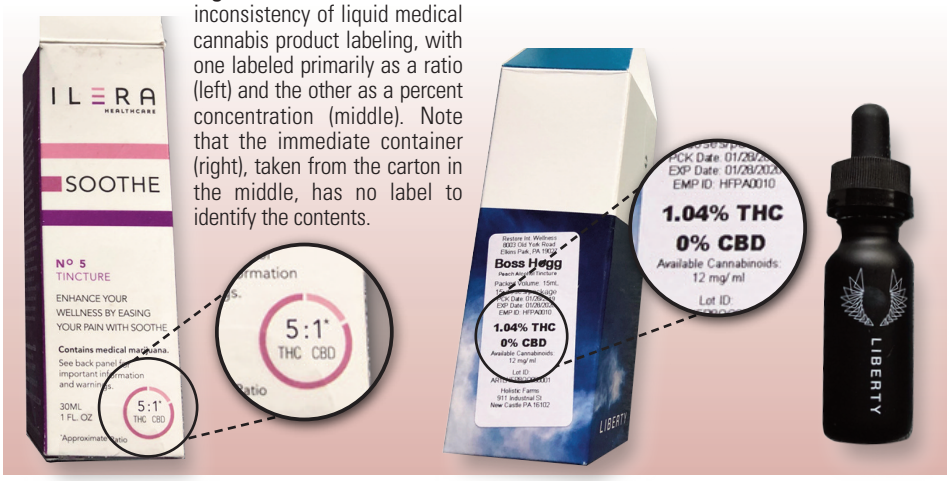


Figure 1. Photo illustrates inconsistency of liquid medical cannabis product labeling, with one labeled primarily as a ratio (left) and the other as a percent concentration (middle). Note that the immediate container (right), taken from the carton in the middle, has no label to identify the contents.

Sidebar: Example of labeling issues with medical cannabis

The following report provides an example of the difficulty healthcare providers might encounter during medication reconciliation in determining a patient's dose of medical cannabis taken at home due to the absence of label standards.

A hospitalized patient reported taking medical cannabis at home to ease her pain and help her sleep. She removed a dropper bottle from her purse and showed the healthcare provider the cannabis liquid, which had a wrap-around label on it (**Figure 1**). The label noted that the product was a "330 mg tincture" and listed the contents as a "hybrid" with a "1:10" ratio. Patient directions for use were NOT included on the label.

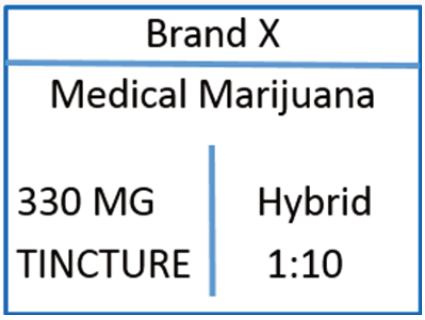


Figure 1. Wrap-around label on a dropper bottle of cannabis liquid (with the commercial name redacted and replaced with Brand X).

When the patient was asked the dose she takes daily, she said half a dropperful at bedtime and that the bottle contained a 30-day supply. The dropper had 0.5 mL and 1 mL calibrations.

So how much THC and CBD did the patient take with each dose? The label does not list a volume corresponding to the "330 mg" tincture, making it difficult to determine the mg per mL concentration. Per the patient's verbal recall of her daily dose of half a dropperful (0.5 mL), the healthcare provider might multiply each 0.5 mL dose by the

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> Medical cannabis—continued from page 1

CBD is not psychoactive, and preclinical data suggests it has anti-inflammatory, analgesic, anti-nausea, antiemetic, antipsychotic, anxiolytic, and antiepileptic properties. Patients may take escalating doses of CBD because they do not feel any cognitive impairment. Common side effects include headache, diarrhea, restlessness, and/or somnolence.

Both THC and CBD may interact with other medications. Examples include interactions with epilepsy medications and warfarin. While the dose of THC is directly correlated with cognitive and motor function effects, the dose of CBD may be more predictive of the magnitude of possible drug interactions.

Dosage Forms

There are a variety of medical cannabis dosage forms, producing different pharmacokinetic and pharmacodynamic effects. Common formulations include capsules and liquids for oral use, vaporized products (extracts and raw flower), sublingual drops, transmucosal adhesives, topical creams/ointments, transdermal patches, and suppositories.

Nonstandard, Confusing Labeling

All state laws require products to be assayed and labeled by the grower, and ideally verified by an accredited third-party lab, for at least the two major cannabinoids currently of interest, THC and CBD. While the total cannabinoid content must be listed on the label, only THC and CBD individual quantities must be expressed on the label. The amounts of these two cannabinoids are clinically relevant for managing patients' symptoms. However, the way these components are expressed on labels is not standardized (**Figure 1**, page 1) and can lead to errors.

Ratio expressions. The two primary cannabinoids are often expressed as a ratio of either THC:CBD or CBD:THC. So, the first problem is that no international or national standard exists governing which cannabinoid is listed first when presented as a ratio, and most state regulations do not dictate a formal convention. The order of components in the ratio may differ between growers and even within a grower's product line, causing confusion when determining which product to use. Look-alike product labeling (**Figure 2**), particularly within a grower's product line, has also been reported, leading to confusion between products containing different ratios of THC and CBD.

Percent concentrations. In addition to (or in place of) ratio expressions, some products are labeled with the percent concentration. This makes it difficult for staff in dispensaries and patients to calculate the amount of THC and/or CBD in the product. For example, would you be able to easily identify the amount of THC and/or CBD in 0.5 mL of a 0.037% product, especially if the mg/mL amount is not clearly listed? With some products, the mg amount of each primary ingredient can be found on container labels, which is preferred for dosing and consistency but could still cause confusion in patients who are more familiar with ratio expressions. It is critical to know the actual mg amount of each primary component, especially THC, which is most likely to elicit clinical and/or adverse effects. But too often, the mg amount of a liquid product is listed without a corresponding volume, preventing the ability to determine the concentration. And again, there is no standard. The **Sidebar** (right column, page 1) provides an example of this problem along with several other labeling issues.

Figure 2. A patient reported frequently confusing these products with different ratios of THC and CBD because the labels look so similar. Also note the bottle on the left contains a 10:1 ratio, and the bottle on the right contains a 1:1 ratio, but both are labeled as a 330 mg tincture.

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> Sidebar—continued from page 1

patient-reported 30-day supply in the bottle to obtain a presumed strength of 330 mg/15 mL, or 22 mg of cannabinoids/mL. Of course, this is an unreliable method of determining the mg/mL amount.

The label also does not specify whether the ratio of 1:10 is THC:CBD or CBD:THC. So how much THC is in each dose compared to CBD? Because the patient said she takes the product for pain and sleep, one might assume the primary cannabinoid is THC. In that case, 1:10 would signify CBD:THC, or 2 mg CBD and 20 mg of THC per mL of tincture based on the prior error-prone calculation. Based on the patient's self-reported dose of 0.5 mL, she appeared to be taking 10 mg of THC and 1 mg of CBD with each dose. However, when the patient's husband brought in the outer carton of the product the next day, it was clear that the presumed dosing information was incorrect. The dispensary label indicated that there was no CBD at all in the product, despite displaying a 1:10 ratio.

SAFETY briefs

Fasting during Ramadan and safe drug administration. Fasting during Ramadan, a month in the Islamic calendar, is one of the Five Pillars of Islam. This year, Ramadan begins the second week of May and ends the first week of June. During this time, Muslims who fast refrain from certain activities, including eating, drinking, and smoking from dawn until sunset. Their meals are before the break of dawn (suhoor) and at sunset (iftar). The Qur'an, the holy book for Muslims, states several exemptions from fasting, including if it is detrimental to one's health (e.g., diabetes, immunocompromised condition, pregnancy, the frail and elderly, children). However, many Muslims with medical conditions choose to fast during Ramadan, which may affect how they take their prescribed medications. Thus, healthcare professionals should be prepared to help these patients manage their medication regimens safely while fasting.

If patients decide to fast, they must be educated regarding the best time to take any oral medications that reach the stom-

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> Medical cannabis—continued from page 2

Labeling of the immediate container. For some liquid products and almost all vaporization cartridges, only the outer carton is labeled, and the immediate container (bottle or cartridge) is not labeled at all (**Figure 1**, page 1). If the carton is discarded or lost, the unlabeled product may be confused with something else.

Label contents. Certain dosage forms also lack important ingredient and label information. For example, the labeling of tinctures does not always include the alcohol content, and frequently the term tincture is misapplied to products that do not contain alcohol. Transdermal patches often do not include key information such as onset and duration of effect, delivered dose, and cautions about possible systemic effects. It should also be mentioned that there are terpenes present in essential oils of the marijuana plant that give it its fragrance, which are also physiologically active molecules that have been known to have clinical effects—from anxiolytic to anti-inflammatory effects, and more.[5] Product assays will sometimes list plant terpenes, but not all states require this.

Safe Practice Recommendations: To promote patient safety, labeling standards are needed for medical cannabis products, at the very least to specify THC and CBD contents and concentrations accurately in metric units, and healthcare providers need to know how to interpret the label information. Because ratio expressions are predominantly used today, medical cannabis products must conform to some type of labeling convention to signify whether THC or CBD is listed first in a ratio expression. However, we are not convinced that ratio expressions should be used at all given the potential for errors as seen with other medications previously expressed this way (e.g., **EPINEPH**rine 1:10,000), which is now prohibited on most medication labels.

The common practice of expressing concentrations as percentages, without a total volume or the mg amount per mL, introduces significant risk of error when calculating the dose, especially one based on a nonstandard serving size. Clearly mandating the expression of strengths and concentrations of the THC and CBD contents in metric units (e.g., mg, g, mg/mL) would provide the safest communication to both patients and healthcare providers. Additionally, all immediate product containers should be labeled, not just the outer packaging.

Ensuring that all inactive ingredients, especially additives, in a product are included in the labeling is critical to mitigate allergic reactions to dyes and flavoring agents. Drug-drug binding interactions can result from the product's vehicle (e.g., sesame oil) and other herbal products (e.g., melatonin) that are sometimes added. This information could be provided on a side panel to avoid clutter on the primary display panel.

The US Food and Drug Administration (FDA) approved a single cannabidiol product, **EPIDIOLEX** (Greenwich Biosciences) in June 2018 for the treatment of seizures associated with Lennox-Gastaut and Dravet syndromes in patients age 2 and older. It is available by prescription only. However, for all other forms of medical cannabis, healthcare providers interacting with patients should clearly communicate that these products are not approved by FDA for any medical conditions; thus, therapy is considered investigational, and safety, including reproducibility of response between products, is not fully understood. Further, CBD-only products that are routinely sold on the internet and in retail establishments have not been evaluated by FDA for potency, purity, or safety. There are many reports of CBD-only products containing either no detectable CBD, or significantly more CBD than is on the label. Based on studies, approximately 1 in 5 CBD-only products contains detectable amounts of THC, putting patients unknowingly at risk of impairment as well as testing positive on urine drug screens for THC.[6,7]

ISMP and FDA would like to learn more about labeling and packaging problems or other practice issues with medical cannabis. Please report all hazards, close calls, and errors with medical cannabis to the ISMP National Medication Errors Reporting Program

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ach, particularly if drug absorption can be affected by food intake. As a general rule, medications that are dosed once or twice daily can be taken before or with the morning meal (suhoor) and/or with or after the evening meal (iftar). A physician will need to assess the risk vs. benefit profile of medications that require three or more daily doses and determine the safest administration plan, including the possibility of switching to a slow-release or once daily medication. Patients should be advised to consult a pharmacist if they have questions.

Because each Islamic school of teaching may differ regarding which routes of medication administration nullify the fast, specifically ask your patients what routes of administration are acceptable for use without breaking their fast. For example, some schools of teaching may allow administration of eye and ear drops, nasal sprays, asthma inhalers, skin creams, transdermal patches, or subcutaneous injections while fasting, whereas others may not.

For patients with diabetes who choose to fast, dose modifications for insulin or other antidiabetic medications may be necessary. Blood glucose testing should occur throughout the day, and patients should be instructed to break the fast for a blood glucose level less than 70 mg/dL or greater than 300 mg/dL, for symptoms of hypoglycemia or hyperglycemia, or if acute illness occurs. Additional suggestions for managing medications for fasting patients with diabetes, cardiovascular disease, gastrointestinal health issues, or renal disease can be found at: www.ismp.org/ext/252. Also, examples of handouts for patients with diabetes can be found at: www.ismp.org/ext/253 (English) and www.ismp.org/ext/254 (Arabic).

HIGH-ALERT

A mitoMYcin-mitoXANTRONE mix-up.

A patient with goblet cell cancer of the appendix and carcinomatosis presented to the operating room for cytoreduction and hyperthermic intraperitoneal chemotherapy with mitoMYcin. However, while processing the order, pharmacy staff selected mitoXANTRONE from the shelf and dispensed the drug in a brown overwrap believing it was light-sensitive mitoMYcin. With the brown overwrap, it was not immediately recognized that the drug was

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(ISMP MERP, www.ismp.org/MERP), and ISMP will forward the reports to FDA. Look for more about medication safety issues with medical cannabis (e.g., duplicate therapy, drug interaction checking, managing hospitalized patients who use medical cannabis at home) in subsequent newsletters throughout the year.

*ISMP thanks **Christine Roussel**, PharmD, BCOP, Director of Pharmacy at Doylestown Hospital in PA, for providing this article.*

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Payer-driven biosimilar requirements: New risks in patients with cancer and chronic diseases

Problem: With the advent of biosimilar drugs, payers are often determining which biosimilars are to be administered to outpatients treated in hospitals and clinics. Manufacturers' rebates are largely driving these decisions. This would be analogous to determining which manufacturer's generic drug can be dispensed based on the patient's insurance. If this were the case, organizations would need to stock payer-specific generics and ensure that the right generic was dispensed to the right patient. For example, this would require stocking 5 different acetaminophen products for 5 different payers.

At the current time, pegfilgrastim (**NEULASTA**) has 2 biosimilars, pegfilgrastim-jmdb (**FULPHILA**) and pegfilgrastim-cbqv (**UDENYCA**). There is also **NEULASTA ONPRO**, which is delivered with an on-body injector, bringing the total to four products. The competition among the biosimilar and originator manufacturers for preferential status designation by payers has begun, and at least one payer has designated which pegfilgrastim product is to be administered to new patients to prevent febrile neutropenia.

While there are currently only 18 biosimilars approved in the US, there are 260 approved in international markets and 188 more in development.[1,2] The names of biosimilars combine a core name with a 4-letter distinguishing suffix presented in lowercase letters that is devoid of meaning, creating look- and sound-alike risks.[3] In 2019, cancer treatment is at center stage with the approval of multiple biosimilar products: ri**TUX**imab has 1 approved biosimilar, trastuzumab has 4 biosimilars, and bevacizumab has 1 biosimilar. If the current rebate-driven payer incentives designate which chemotherapy drug is to be given, this will significantly increase the complexity of the medication use process by adding steps to the already complex processes of checking chemotherapy medications.

Most electronic health records (EHR) contain chemotherapy regimens specific to the cancer diagnosis and stage of the disease. EHRs will need to add drug records for each biosimilar product, including the various dosages and common routes. Even without the biosimilars, health systems may already have multiple drug records in the EHR—for example, 2 for the pegfilgrastim products, 3 for ri**TUX**imab, 4 for bevacizumab, and 2 for trastuzumab. Physicians will need to ensure that the correct drug record is

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dark blue, and the patient inadvertently received mito**XANTRONE** during the procedure. The error was discovered when peritoneal tissues that were stained dark blue were observed, which is atypical when mito**MY**cin is used for this procedure. A search of the chemotherapy waste bucket revealed that mito**XANTRONE** was used in error. The patient was later discharged in stable condition but was unable to return for a repeat procedure using the correct medication due to her poor prognosis.

During investigation of the event, the pharmacy workflow system scanning process (DoseEdge by Baxter) was reviewed. Each drug in the workflow system has available routes assigned to it. When a drug is scanned with an ordered route that does not match the available routes, a "wrong route" error displays. The technology showed that the pharmacy technician had scanned the mito**XANTRONE** vials three times and received the same error message of "invalid route," as the mito**MY**cin had been prescribed by the intraperitoneal route, while mito**XANTRONE** is administered intravenously (IV).

DoseEdge displays only one validation error message at any given scan. "Invalid route" displayed because mito**XANTRONE** (instead of the intended mito**MY**cin) had been scanned, and intraperitoneal was not a route set up for this drug. A validation failure, like "invalid route" triggers a hard stop in the workflow and does not allow dose preparation to continue within DoseEdge. Since the workflow was stopped, a "wrong drug" alert did not occur, and the pharmacy team bypassed the IV workflow safety system. The technician was unfamiliar with mito-**XANTRONE**, so the dark blue color of the solution didn't put a halt to dispensing, either.

A request has been made to Baxter to revise the software so that identification of the wrong drug takes priority, although a "wrong route" message is also important and should immediately be investigated. Change in the expected appearance of a drug and unexpected workflow system error messages can be important clues for detecting potential medication errors and must be fully investigated. In situations where IV workflow system controls are

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selected based on the product determined by the patient's insurance. Since each chemotherapy and supportive care drug with one or more US Food and Drug Administration (FDA)-approved biosimilars will have multiple drug records, the risk of making a wrong-selection error is significantly increased. What if the regimen contains 3 drugs that all have biosimilars? Will the pharmacist also need to verify that each biosimilar has been correctly selected based on the payer's preference, in addition to making sure the correct regimen was selected at the right dose, route, and cycle number for the cancer diagnosis and stage? How will the drug inventory be labeled to ensure the right biosimilars are selected for compounding and dispensing based on the patient's insurance?

A requirement to use a payer-specific biosimilar would demand significant resources to procure and maintain separate inventory, as well as to prescribe, label, compound (depending on the medication), and dispense the right medication to the patient. Given the number of biosimilars expected to become available, these additional steps would significantly increase the risk of harmful medication errors. Furthermore, patients switched from one product to another due to payer decisions risk experiencing an immune reaction given that biosimilars are made from different living organisms, even though they are considered therapeutically equivalent. Also, billing errors are possible (each biosimilar has a different billing code), and if the wrong payer-specific biosimilar is administered, the health facility and patient would incur financial liability.

Safe Practice Recommendations: While the practice of payers making rebate-driven formulary decisions has been in place for many years, the scope has been primarily limited to self-administered drugs. In health systems, decision-making authority regarding the drugs used for patient care is defined by regulatory and accrediting agencies as part of the formulary process (**Table 1**). The question of whether payers should be able to direct health system formulary management needs to be addressed, not only from a regulatory and accrediting perspective, but more importantly from a patient safety perspective. The promise of biosimilars as a solution to rising drug costs cannot be realized at the expense of patient safety. Payers can achieve lower drug costs by allowing health systems to determine which biosimilars are available for patient use based on their formulary process and providing reimbursement regardless of which drug is selected.

*ISMP thanks **Rita Shane**, PharmD, Chief Pharmacy Officer at Cedars-Sinai Medical Center, and Professor of Medicine/Assistant Dean at the UCSF School of Pharmacy, for providing this article.*

Table 1. Regulatory/accrediting requirements for formulary decisions associated with the availability of medications

Agency	Reference	Excerpt
The Joint Commission (TJC)	Medication Management Standard MM.02.01.01	Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients. The hospital maintains a formulary, including medication strength and dosage.
Centers for Medicare & Medicaid Services (CMS)	Conditions of Participation 482.25(b)(9)	A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

References

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2) Charting the global biosimilar pipeline 2018: biosimilars in development for a range of therapy areas from cancer and diabetes to ophthalmology and respiratory – ResearchAndMarkets.com. *BusinessWire*. June 15, 2018. www.ismp.org/ext/249
3) FDA. Nonproprietary naming of biological products: update guidance for industry. March 2019. www.ismp.org/ext/250

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bypassed, manual quality checks must be performed according to hospital policy. Also, ISMP has previously recommended tall man letters for both mito**XANTRONE** and mito**MY**cin. The FDA list includes mito**XANTRONE** but not mito**MY**cin, and the manufacturer's label for mito**MY**cin does not include tall man lettering with the drug name, while companies that sell mito**XANTRONE** do. In this case, the tall man letters on the label of mito**XANTRONE** did not help prevent the error.

Special Announcement

FREE ISMP webinar

On **June 20, 2019**, ISMP will present a **FREE** webinar thanks to support from Novartis on ***Back to the Basics: Preventing Administration of Neuromuscular Blocking Agents to Unventilated Patients***. Join our ISMP speakers as they describe key vulnerabilities with neuromuscular blockers that have led to errors and patient harm. The speakers will then define the best practices for safeguarding neuromuscular blockers and present targeted, national compliance data from associated surveys and self-assessment tools. Participants will be able to reflect on their level of compliance and make plans to implement strategies that will prevent this type of event from happening within their organization. For details, visit: www.ismp.org/node/1523.

ISMP Medication *Safety Alert!* Acute Care (ISSN 1550-6312)

Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit our website at: www.ismp.org/MERP or www.ismp.org/VERP. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

How Big Pharma Suppresses 'Biosimilars'

Deals with insurers and pharmacy benefit managers at patient and taxpayer expense.

By
Denny Lanfear
June 23, 2019 3:17 pm ET

Biologic drugs—pharmaceuticals produced from living organisms—are at the forefront of medical innovation and hold tremendous potential to improve and save lives. Unfortunately, their pricing has been a driver of rapidly escalating, unsustainable drug costs.

Congress recognized the need for competition to slow price growth, and in 2010 passed the Biologics Price Competition and Innovation Act. That opened the door to the development of biosimilars—lower-cost versions of brand-name biologics that are interchangeable in clinical efficacy and safety. Yet nearly 10 years later, brand-name manufacturers are using a combination of coercive, anticompetitive tactics to box out biosimilars and maintain their monopolies. If policy makers want to reduce drug prices and maintain patient access, it's time to end the manipulative practices that take choice away from physicians and patients.

In 2017 biologic medicines made up 2% of U.S. prescriptions but 37% of Americans' drug spending. In the absence of direct competition, prices on products such as Enbrel, launched in the 1990s at about $10,000 a year, were raised aggressively—and with impunity—to more than $60,000 a year. Patients are now paying up to 20% of these drugs' list prices as copayments.

Medical pills. PHOTO: GETTY IMAGES/ISTOCKPHOTO

It doesn't have to be this way. In Europe biosimilars have been rapidly adopted, offering the benefits of biologics at a much lower cost to patients and the health-care system. Given the choice, physicians and patients choose value.

Earlier this year, my company, Coherus BioSciences , brought to market Udenyca, a biosimilar of Amgen 's Neulasta, which stimulates white-blood-cell production for cancer patients receiving strong chemotherapy. Our product is equally effective and priced 33% below the list price of Neulasta. Launched in January, Udenyca is off to a good start, with strong acceptance by oncologists and their patients, and it is substantially reducing costs.

Not everyone is happy about that. A cheaper option for patients cuts into Amgen's profits. In response to our success, Amgen made a deal with UnitedHealth Group , the nation's largest health insurer, and its pharmacy benefit manager, OptumRx, that would force physicians to prescribe the most expensive product, Neulasta, blocking the two less-expensive biosimilars. That's great for Amgen,

OptumRx and UnitedHealth Group, but terrible for patients, health care providers and the taxpayers who fund Medicare. All will pay higher prices than they should. Amgen's tactics aren't original—they're adapted from the playbook Johnson & Johnsonused to block biosimilar competition to its Remicade therapy. Johnson & Johnson provides insurers with back-end rebates on a range of their products in return for the insurer's blocking physician and patient access to less-expensive options. Johnson & Johnson is happy to collect its artificially inflated prices, and the insurer and pharmacy benefit manager are happy to pocket "savings" they've negotiated. Meanwhile, competition and choice wither, and the rest of us get stuck with the bill. Monopolies benefit only the monopolists.

Congress and the Food and Drug Administration have done their part by enabling the creation of biosimilars, improving the regulatory-approval pathway at the FDA, and providing a framework for addressing patent issues. The problem is backroom, bundled-rebate contracts between Big Pharma, major insurers and pharmacy benefit managers.

Policy makers are taking notice. Former FDA Commissioner Scott Gottlieb said Amgen is "using their market power to thwart an avenue to competition." Secretary of Health and Human Services Alex Azar says that favoring high-rebate drugs over biosimilars creates "perverse incentives" and "costs seniors and taxpayers more."

Washington has the opportunity—and obligation—to ensure that biosimilars are allowed to do the job they were intended to do: provide a check on Big Pharma's big prices.

Earlier this month, the nonprofit advocacy group Patients for Affordable Drugs Now called on the Federal Trade Commission to investigate coercive bundled-rebate contracts that keep patients in the dark and force them to purchase more-expensive products when cheaper options exist. The FTC has every reason to investigate. Patients need access to products they can afford, and these secret contracts keep prices high and prevent doctors from maximizing patient benefit.

Washington wants to lower drug prices, and that's the right aim. There's an easy first step: Allow biosimilars to compete.

Mr. Lanfear is president, CEO and chairman of Coherus BioSciences.

Letter to the Editor Response to Wall Street Journal Op-Ed by Rita Shane

Regarding Denny Lanfear's "How Big Pharma Suppresses "Biosimilars" (op-ed, June 24): Aggressive pharma rebates to insurers to drive use of drugs is not limited to brand products and is not exclusively an economic issue; it is a significant patient-safety issue. Cancer is at center stage because of increasing availability of biosimilars with 574 in the pipeline and because rebate-driven insurance requirements specifying which companies' drugs are covered will significantly encumber the complex systems of checks used to prevent tragic medication errors. For intravenous chemotherapy, 57 checks are performed.

As of June, trastuzumab, used for breast cancer, has five biosimilars and pegfilgrastim used to prevent life-threatening infections in cancer patients has two biosimilars. By using rebates, each of the eight companies which make these two drugs can secure insurer-preferred status creating a new paradigm for treatment. Besides prescribing the most effective chemotherapy regimen, physicians will need to verify that the drugs are correct, based on the patient's insurance. For these two drugs, cancer clinics will need to stock 11 products (with varying amounts per vial) versus four, increasing the risk of mixups since biosimilars look-alike. Clinicians will need to ensure insurance-specific drugs are prepared, dispensed and administered correctly. If the clinic doesn't have the required drug(s) available, treatment will be delayed, which with pegfilgrastim can be life-threatening. Imagine four people ordering steak at a restaurant requiring that each steak is sourced from a different beef producer as a condition of paying for the meal. Rebate-driven insurance requirements by drug manufacturers not only increase health-care costs, they also increase the risk of harm to vulnerable patients.

Prof. Rita Shane, Pharm.D.
Cedars-Sinai Medical Center
Los Angeles

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 17, 2019

TO: Medication Safety Committee Members

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

SUBJECT: Medication Safety Tool Review

SUMMARY

It is time for the items in the Medication Safety Tool to be reviewed and updated. Attached is a speadsheet outlining the tools, workgroup and last action.

ACTION REQUESTED

- Review and update.

Attachments: Medication Safety Tool Spreadsheet

BJB:br

Medication Safety Tools - Update			7/11/2019
Tool Title	**Workgroup**	**Date Finalized**	**Last Action**
Anticoagulant Tool (Parts I and II)	Sarah Stephens, Dan Ross, BJ Bartleson	2017	
ED Management	Jeannette Hanni, BJ Bartleson, Rory Jaffe	not finalized	Jeannette to review and finalize
Improving Safe Opioid Tools	Dan Ross, Vicki Ferraresi	not finalized	Dan Ross had comments on the latest version - not finalized.
Insulin Safe Practice	Eddie Avedikian, Dan Ross Jonathan Nelson	2017	
Medication Reconciliation	Rita Shane (infographic)	2017	
Nusing Sterile Compounding	BJ Bartleson, Lori Nolan	not finalized	October 2018 meeting BJ Bartleson and Lori Nolan to create a workgroup
Reducing Adverse Drug Events (ADEs)	no workgroup assigned	not finalized	this was not part of the original toolkit plan
Reducing Controlled Substance Diversion in Hospitals	Rita Shane, Candace Fong, Jeannette Hanni, Amy Gutierrez	2017	
Sterile Compounding		2018	
Track and Trace Law FAQs	Doug O'Brien	not finalized	Doug to update with new law info.
Additional information outside of committee work			
Drug Product Shortages	outside references		
High Alert Medication Tools	outside references		
Improving Safe Opioid Use	outside references		
Nusing Sterile Compounding	outside reference		needs updated

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

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

SUBJECT: CURES Information Exchange Web Service Issues

SUMMARY

Several hospital systems in the state, including Adventist Health, Dignity Health, Kaiser Permanente, Stanford Medical Center, Sutter health, and others have requested that CHA work with the Department of Justice (DOJ) to revise the MOU for health information exchange. The attached letter represents the letter submitted to the DOJ and the response returned.

The purpose of the MOU is to confirm the relationship between the CURES Program and the health information technology (HIT) community through RESTful web services.

CHA was contacted by a non-profit organization representing community health centers regarding their concerns with several issues in the MOU.

DISCUSSION

1) Are your HIT vendors working with CURES to develop direct access between your EMR and CURES?
2) What feedback can you provide CHA on this process?
3) Do you need CHAs advocacy in this work?

ACTION REQUESTED

- Information and feedback to CHA for advocacy efforts.

Attachments: Memorandum of Understanding
CHA Letter to DOJ, 2-27-19

BJB:br

Memorandum of Understanding
18MOU-BCIIS-CURES-XXX

Controlled Substance Utilization Review and Evaluation System (CURES) Information Exchange Web Service

BETWEEN

California Department of Justice
California Justice Information Services Division
Bureau of Criminal Identification and Investigative Services (BCIIS), CURES

AND

Insert Name of Entity

FOR OFFICIAL USE ONLY

October 2018

Version No.: 1.0

1. Background

The Controlled Substance Utilization Review and Evaluation System (CURES) is a database containing information about Schedule II, III, and IV controlled substance prescriptions dispensed to patients, as reported by the dispensing pharmacy, clinic, or other dispenser pursuant to Health and Safety Code section 11165(d). The CURES Program grants authorized health care practitioners and pharmacists access to query the CURES database to assist them in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances.

Assembly Bill 40 requires the Department of Justice to establish a method of system integration whereby approved health care practitioners and pharmacists may use a qualified health information technology system to access information in the CURES database. As a prerequisite to system integration, each entity that operates a heath information technology system must certify that it has entered into a memorandum of understanding with the California Department of Justice (DOJ) addressing the technical specifications of the system to ensure the security of CURES data in the CURES database and the secure transfer of CURES data from the CURES database.

2. Purpose

The California Department of Justice, California Justice Information Services (CJIS) Division, Bureau of Criminal Identification and Investigative Services (BCIIS), Controlled Substance Utilization Review and Evaluation System, referred to collectively herein as "STATE," and, the entity operating the health information technology system (including its officers, employees, and agents), referred to herein as "ENTITY," enter into this memorandum of understanding (MOU) in accordance with Assembly Bill 40. Chaptered on October 9, 2017, Assembly Bill 40 is codified in Health and Safety Code section 11165.1, and will be cited accordingly in this MOU. STATE and ENTITY may be collectively referred to herein as the "PARTIES," and individually referred to as "PARTY."

Pursuant to Health and Safety Code (HSC) section 11165.1(a)(1)(E), an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology (HIT) system if the entity that operates the HIT system can certify all of the following:

(i) The entity will not use or disclose CURES data for any purpose other than delivering the CURES data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.
(ii) The HIT system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the HIT system submits the following data regarding the query to CURES:
  (I) The date of the query.
  (II) The time of the query.
  (III) The first and last name of the patient queried.
  (IV) The date of birth of the patient queried.
  (V) The identification of the CURES user for whom the system is making the query.
(iii) The HIT system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into an MOU with the department that solely addresses the technical specifications of the HIT system to ensure the security of the CURES data in the CURES database and the secure transfer of CURES data from the CURES database. The technical specifications shall be universal for all HIT systems that establish a method of system integration to retrieve CURES data from the CURES database. The MOU shall not govern, or in any way impact or restrict, the use of CURES data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

Consistent with Health and Safety Code section 11165.1(a)(1)(E), the objective of this MOU is to address the technical specifications of the HIT system to ensure the security of the CURES data in the CURES database and the secure transfer of CURES data from the CURES database. As used herein, the term "MOU" shall be understood to include this document and all exhibits identified in Paragraph 8.

STATE's method of system integration developed to meet the requirements of Assembly Bill 40 shall be referred to in this MOU as the "CURES Information Exchange Web Service."

"CURES data," as such term is used in this MOU, shall include:

(i) Information reported to the Department of Justice by dispensing pharmacies, clinics, or other dispensers pursuant to Health and Safety Code section 11165(d); and,

(ii) All Sensitive Information and Personal Information, as those terms are defined in Exhibit E, obtained by a health information technology system, or the entity that operates it, from the Department of Justice through the CURES Information Exchange Web Service.

3. Services and Responsibilities

A. ENTITY will be responsible for complying with all requirements described in this Paragraph 3.A. By signing the MOU, ENTITY certifies, warrants, and represents its compliance with these requirements. ENTITY shall immediately notify STATE if, at any point during the Term, ENTITY fails to comply or is unable to maintain compliance with any requirement described in this Paragraph 3.A.

i. Certifying compliance, and maintaining compliance throughout the duration of this MOU, with Health and Safety Code section 11165(a)(1)(E)(i), which prohibits ENTITY from using or disclosing CURES data received from the CURES database for any purpose other than delivering the CURES data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

ii. Certifying compliance, and maintaining compliance throughout the duration of this MOU, with Health and Safety Code section 11165(a)(1)(E)(ii), which contains two distinct requirements.

a. The HIT system is required to authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database. This is a requirement that the HIT system operated by ENTITY verify the identification of the health care practitioner or pharmacist initiating the query, or on whose behalf the HIT system is initiating the query. For purposes of complying with this requirement, there can only be one health care practitioner or pharmacist identified with each query.

b. The HIT system is required to submit the following data regarding the query to CURES at the time of the query:
   - The date of the query.
   - The time of the query.
   - The first and last name of the patient queried.
   - The date of birth of the patient queried.
   - The identification of the authorized health care practitioner or pharmacist for whom the system is making the query. For purposes of complying with this requirement, there can only be one health care practitioner or pharmacist identified with each query.

iii. Submitting to CURES a notification confirming receipt of the CURES data by the health care practitioner or pharmacist identified in Paragraph 3.A.ii. For purposes of complying with this requirement, there can only be one health care practitioner or pharmacist identified with each query, and the submissions required by Paragraph 3.A.ii and 3.A.iii must reflect the same individual. If ENTITY cannot comply with this requirement at commencement of the Term, then ENTITY must submit with the MOU a plan, including a detailed timeframe, for becoming compliant with this requirement.

iv. Ensuring compliance of its HIT system with the format standards specified in the most current CURES Information Exchange Web Service Implementation Guide, which may be periodically updated by STATE, located on the CURES web page at www.oag.ca.gov/cures/iews.

v. Certifying that ENTITY is either a "covered entity" or "business associate," as such terms are defined in the federal Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 17931 et seq., and its implementing regulations found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations, with respect to any CURES data its HIT system receives from STATE through the CURES Information Exchange Web Service.

vi. Certifying compliance, and maintaining compliance throughout the duration of this MOU, with Health and Safety Code section 11165(a)(1)(E)(iii), which requires the HIT system to meet applicable patient privacy and information security requirements of state and federal law, including, but not limited to, the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

vii. Certifying compliance, and maintaining compliance throughout the duration of this MOU, with Health and Safety Code section 11165(a)(1)(E)(iv), which, as a condition

precedent to system integration, requires ENTITY to enter into and maintain an active MOU with STATE that addresses the technical specifications of the HIT system to ensure the security of the CURES data in the CURES database and the secure transfer of CURES data from the CURES database.

viii. Timely payment of fees, as provided in EXHIBIT D, associated with establishing and maintaining integration with the CURES database pursuant to Health and Safety Code section 11165(a)(1)(H).

ix. Compliance with all terms, provisions, and exhibits of this MOU.

B. STATE will be responsible for complying with all requirements described in this Paragraph 3.B.

i. Verifying that health care practitioners and pharmacists who submit queries to the CURES database through a HIT system, or on whose behalf a HIT system submits queries, are authorized or approved CURES users. As used herein, the terms "authorized" or "approved," when used to describe health care practitioners, pharmacists, or subscribers, shall mean those health care practitioners or pharmacists who have submitted an application to and been approved by the Department of Justice for access to CURES data pursuant to Health and Safety Code section 11165.1(a)(1)(A).

ii. Prohibiting, suspending, or terminating integration with an ENTITY and its respective HIT system(s) if at any time during this MOU such ENTITY (including any officer, employee or agent of ENTITY) fails to meet the requirements of Paragraph 3.A of this MOU.

iii. Transmitting CURES data to ENTITY in a manner consistent with EXHIBIT C.

4. Responsible Parties

For STATE:

Name, Title, Agency	Role
Joe Dominic, Chief, California Justice Information Services Division, Department of Justice	Division Chief/Executive Officer
Jenny Reich, Bureau Director, Bureau of Criminal Identification and Investigative Services, Department of Justice	Executive Sponsor
Audra Opdyke, Assistant Bureau Director, Department of Justice	Business Sponsor/BCIIS
Tina Farales, Staff Services Manager II, Department of Justice	Business Manager/CURES Program

Rodney Smith, Bureau Director, Application Development Bureau	Bureau IT Project Sponsor
Todd Ibbotson, Information Security Officer	Bureau IT Project Sponsor
Bhaskar Rudrakshala, Information Technology Manager I	CURES IT Manager

For ENTITY:

Name, Title, Agency	Role	Business Address	Phone/Email

5. Term of Agreement

This MOU will commence on the date it is fully executed by all PARTIES, as established by the latest signature date, and expire on June 30, 2022, which shall constitute the "Term." This MOU will be reviewed 90 days prior to the end of the Term to renew and/or evaluate changes. If renewing, a new MOU with updated signatures and current dates will be required. During the Term, STATE may amend this MOU pursuant to Paragraph 7, and the PARTIES may terminate this MOU pursuant to EXHIBIT B.

6. Notices

All notices hereunder may be sent by U.S. certified or registered mail, postage prepaid, return receipt requested, or by Federal Express or other overnight courier which obtains a signature upon delivery for next business day delivery, or by hand delivery, or electronic mail provided that a copy is also sent on the same day by one of other the methods set forth above, with a copy to follow

addressed to such PARTY at the address of such PARTY set forth below or at such other address as such PARTY shall designate from time to time by notice:

If to STATE:

CURES Program
P.O. Box 160447
Sacramento, CA 95816
Attention: CURES Manager
E-mail: cures@doj.ca.gov

If to ENTITY:

Name: _____
Address: _____
_____
Attention: _____
E-mail: _____

With a copy to: (which shall not constitute notice)

Name: _____
Address: _____
_____
Attention: _____
E-mail: _____

Notices shall be deemed served if by electronic mail upon receipt of a transmittal confirmation (if received during normal business hours, otherwise on the next business day) and provided that a copy is sent by U.S. mail, and in the case of overnight courier or hand delivery, on the date actually delivered to or rejected by the intended recipient, except for notice(s) which advise the other PARTY of a change of address of the PARTY sending such notice, which notices shall not be deemed served until actually received by the PARTY to whom such notice(s) are addressed or delivery is refused by such PARTY. Notwithstanding the foregoing provisions of this Paragraph, notices served by hand delivery shall be deemed served on the date of delivery if delivered at or prior to 5:00 P.M. on a business day and on the next business day if delivered after 5:00 P.M. on a business day or at any time on a non-business day.

7. Amendments

STATE shall have the express unilateral right to change or add any provisions, terms, or conditions of or to this MOU. The types of changes may include, but shall not be limited to, updated security requirements or formats and/or versions of technical data/processes associated with HIT system integration.

STATE shall provide to ENTITY advance written notice prior to amendments made to the MOU. For non-technical changes, STATE shall provide no less than thirty (30) days advance written notice. For technical changes, STATE shall provide no less than ninety (90) days advance written notice. Notice shall be provided to ENTITY in the manner prescribed by Paragraph 6. ENTITY shall execute and return to STATE any amendment to the MOU issued by STATE within fifteen (15) calendar days from receipt thereof (as determined by the notice provisions of Paragraph 6 of the MOU). Failure of ENTITY to timely execute and return to STATE any amendment to the MOU

issued by STATE shall constitute a violation of Paragraph 3.A., and STATE may, as a result, terminate the ability of ENTITY and its HIT system to retrieve data from through the CURES Information Exchange Web Service.

No amendment or variation of the terms of this MOU shall be valid unless made in writing and pursuant to this paragraph. No oral understanding or agreement not incorporated in the MOU is binding on any of the PARTIES.

8. Exhibits

All applicable exhibits are included with this MOU. ENTITY agrees to accept and abide by the requirements outlined in each exhibit.

List of Exhibits

EXHIBIT A. Special Terms and Conditions

EXHIBIT B. Miscellaneous Provisions

EXHIBIT C. CURES Information Exchange Web Service Implementation Overview

EXHIBIT D. Fees and Payment

EXHIBIT E. Confidentiality and Information Security Requirements

This MOU may be executed in one or more counterparts, and with counterpart e-mail signature pages, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument.

STATE and ENTITY warrant that each has full power and authority to enter into and perform this MOU, and that the person signing this MOU for each PARTY has been properly authorized and empowered to enter into this MOU on behalf of such PARTY.

IN WITNESS WHEREOF, the parties hereto have executed this MOU on the day and year as indicated:

Joe Dominic, Chief
Department of Justice
California Justice Information Services Division

Date

Jenny Reich, Bureau Director
Department of Justice
California Justice Information Services Division
Bureau of Criminal Identification and Investigative Services

Date

Rodney Smith, Bureau Director
Department of Justice
California Justice Information Services Division
Application Development Bureau

Date

Todd Ibbotson, Information Security Officer
Department of Justice
California Justice Information Services Division

Date

Insert Representative Name
Insert Representative Title
Insert ENTITY Name

Date

Insert Representative Name
Insert Representative Title
Insert ENTITY Name

Date

EXHIBIT A
SPECIAL TERMS AND CONDITIONS

1. Employee Access to Information

The entity will not use or disclose CURES data for any purpose other than delivering the CURES data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

2. Data Fidelity

STATE does not independently verify the accuracy of the CURES data in the CURES database. The CURES database contains Schedule II, Schedule III, and Schedule IV prescription information reported by California licensed pharmacies and direct dispensers, and is therefore only as accurate as the information provided by these entities.

3. Safeguard Review

During the term of this MOU, STATE may require ENTITY to provide information to STATE demonstrating its use of CURES data complies with the Health Insurance Portability and Accountability Act of 1996.

4. Maintenance of an Active CURES User Account

It shall be the responsibility of healthcare practitioners and pharmacists to verify through the CURES portal that their CURES account profiles are current, which shall include, at a minimum, completion of the annual update, and that they possess active CURES accounts. The failure of healthcare practitioners and pharmacists to complete the annual update or maintain an active CURES account status will result in rejection of their queries.

EXHIBIT B
MISCELLANEOUS PROVISIONS

1. Applicable Law

This MOU shall be governed by and shall be interpreted in accordance with the laws of the State of California; venue of any action brought with regard to this MOU shall be in Sacramento County, Sacramento, California.

2. Termination

A. Right to Terminate.
   i. For convenience. ENTITY shall have the right to terminate this MOU if it determines that termination is in its interest.
   ii. For cause. Either PARTY may terminate this MOU if the PARTY determines the other PARTY is not in compliance with Paragraph 3 of the MOU.

B. Notice of Termination. A PARTY shall terminate this MOU by delivering to the other PARTY a Notice of Termination specifying the termination and the effective date thereof. If the termination is "for cause," the Notice of Termination shall include a statement of that cause.

C. Responsibilities of the PARTIES on the effective date of termination.
   i. STATE shall terminate the ability of ENTITY and its HIT system to retrieve CURES data from the CURES database.
   ii. ENTITY shall be responsible for all fees accrued on or before the effective date of the termination, pursuant to EXHIBIT D.
   iii. ENTITY shall maintain continuing obligations under the terms of this MOU, notwithstanding the termination or expiration thereof, with respect to any CURES data retained by ENTITY or its HIT system.

3. Indemnification

ENTITY agrees to indemnify, defend and save harmless STATE, its officers, agents and employees from any and all third party claims, costs (including without limitation reasonable attorneys' fees), and losses due to the injury or death of any individual, or the loss or damage to any real or tangible personal property, resulting from the violation of any state or federal privacy or security law or regulation applicable to ENTITY'S use of CURES data, the willful misconduct or negligent acts or omissions of ENTITY or any of its affiliates, agents, subcontractors, employees, or officers in connection with the performance of this MOU. Such defense and payment will be conditional upon the following:

A. STATE will notify ENTITY of any such claim in writing and tender the defense thereof within a reasonable time; and

B. ENTITY will have sole control of the defense of any action on such claim and all negotiations for its settlement or compromise; provided that (i) when substantial principles of government or public law are involved, when litigation might create precedent affecting the future STATE operations or liability, or when involvement of STATE is otherwise mandated by law, STATE may participate in such action at its own expense with respect to attorneys' fees and costs (but not liability; (ii) where a settlement would impose liability on STATE, affect principles of California government or public law, or impact the authority of STATE, STATE will have the rights to approve or disapprove any settlement or compromise, which approval will not unreasonably be withheld or delayed; and (iii) STATE will reasonably cooperate in the defense and

in any related settlement negotiations.

4. Confidentiality of Data

CURES data shall be protected by ENTITY from unauthorized use and disclosure through the observance of the provisions of this MOU and applicable state and federal laws and regulations including, but not limited to, the Health Insurance Portability and Accountability Act of 1996.

5. News Releases

Unless otherwise exempted, news releases, endorsements, advertising, and social media content pertaining to this MOU shall not be made without prior written approval of STATE.

6. Change Management Process

ENTITY agrees to notify STATE in advance of any changes associated with this MOU or access to the CURES data that will affect or impact the technical environment of the HIT system, including, but not limited to, technical or system changes involving major modifications to infrastructure or disconnection from the CURES database by ENTITY, and modifications to agreed upon configurations or outages. Contacts for such notification are listed in Paragraph 6 (Notices) of the MOU.

7. Issue Resolution Procedures

If ENTITY or STATE has a concern regarding the services, deliverables, invoicing, or MOU terms and conditions which cannot be informally resolved, ENTITY or STATE will document its concern and advise the responsible parties. Once an issue has been identified, a meeting will take place within thirty (30) calendar days, between ENTITY and STATE to discuss and resolve the issue. If the dispute persists, ENTITY shall submit to STATE Division Chief or designee a written demand for a final decision regarding the disposition of any dispute between the PARTIES arising under, related to or involving this MOU. ENTITY's written demand shall be fully supported by factual information. STATE Division Chief or designee shall have 30 days after receipt of ENTITY's written demand invoking this Paragraph (Disputes) to render a written decision. Contacts for such notification are listed in Paragraph 6 (Notices) of the MOU. In the event of an unresolved issue, ENTITY and STATE agree that they will continue to carry out all their MOU responsibilities that are not affected by the issue.

EXHIBIT C

California Department of Justice
CURES Information Exchange Web Service
Overview

October 2018

EXHIBIT C

The purpose of this document is to provide an overview of the CURES Information Exchange Web Service. Outlined below is a brief explanation of the technology, as well as the use cases, associated with this web service.

The CURES Program will provide systems integration with the Health Information Technology (HIT) community through RESTful web services. For the initial phase, the following web services will be available to serve the following functions:

- Searches for a patient for a given timeframe
- Retrieves a patient controlled substance history
- CURES and a HIT system's user account status
- Notification confirming receipt of CURES data by the health care practitioner or pharmacist who submitted the query

Information will be exchanged using NCPDP SCRIPT XML REST-based format. Searches can be executed for a period using partial or exact match modes.

EXHIBIT C

Search Patient and Generate Report

The CURES web service will support two patient search use cases:

- Query Use Case 1 – Single Request/Response
  - Use Case 1 follows the NCPDP standard where every search patient request returns either no match or a single match. The result will be either an error message stating there is no match, or will return all of the prescription history associated to the matched entity.

Figure 1 – Single Request/Response

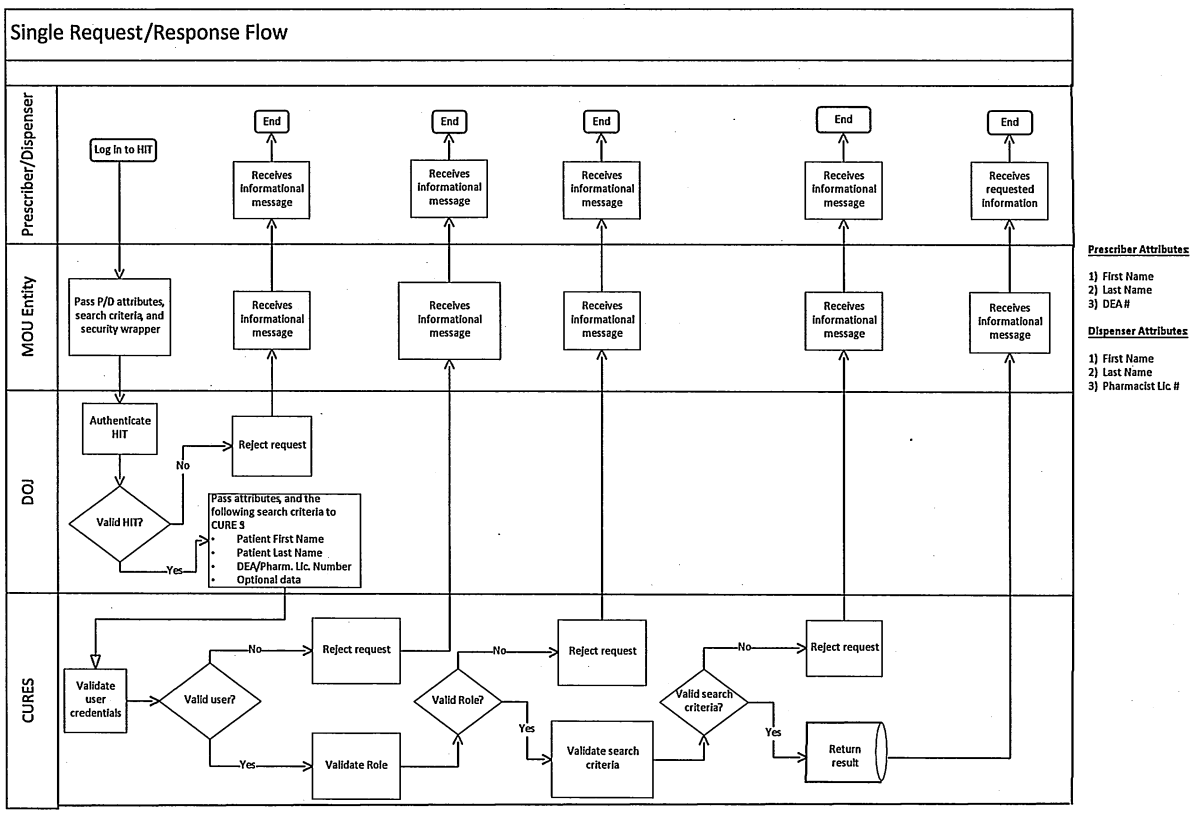


EXHIBIT C

- Query Use Case 2 – Multiple Matches (Picklist)
  - Use Case 2 supports multiple matches, via a pick list. In this use case, a patient search returns multiple entities using a NCPDP-like message structure. The requesting entity would then send one or multiple single requests to retrieve the prescription history associated to the matched entity.
  - For those HIT systems that cannot support this functionality, a response message redirecting the health care practitioner/pharmacist to the CURES web application is returned.

Figure 2 – Multiple Request/Response

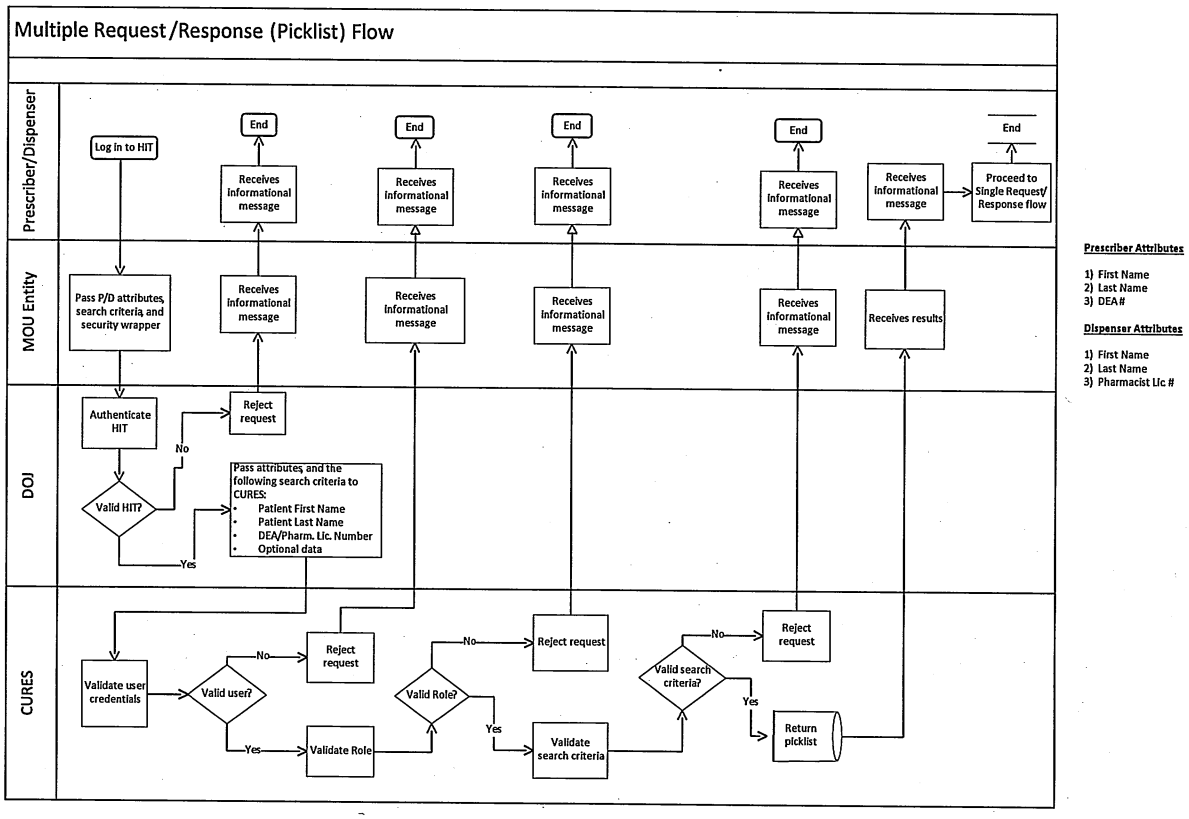


EXHIBIT C

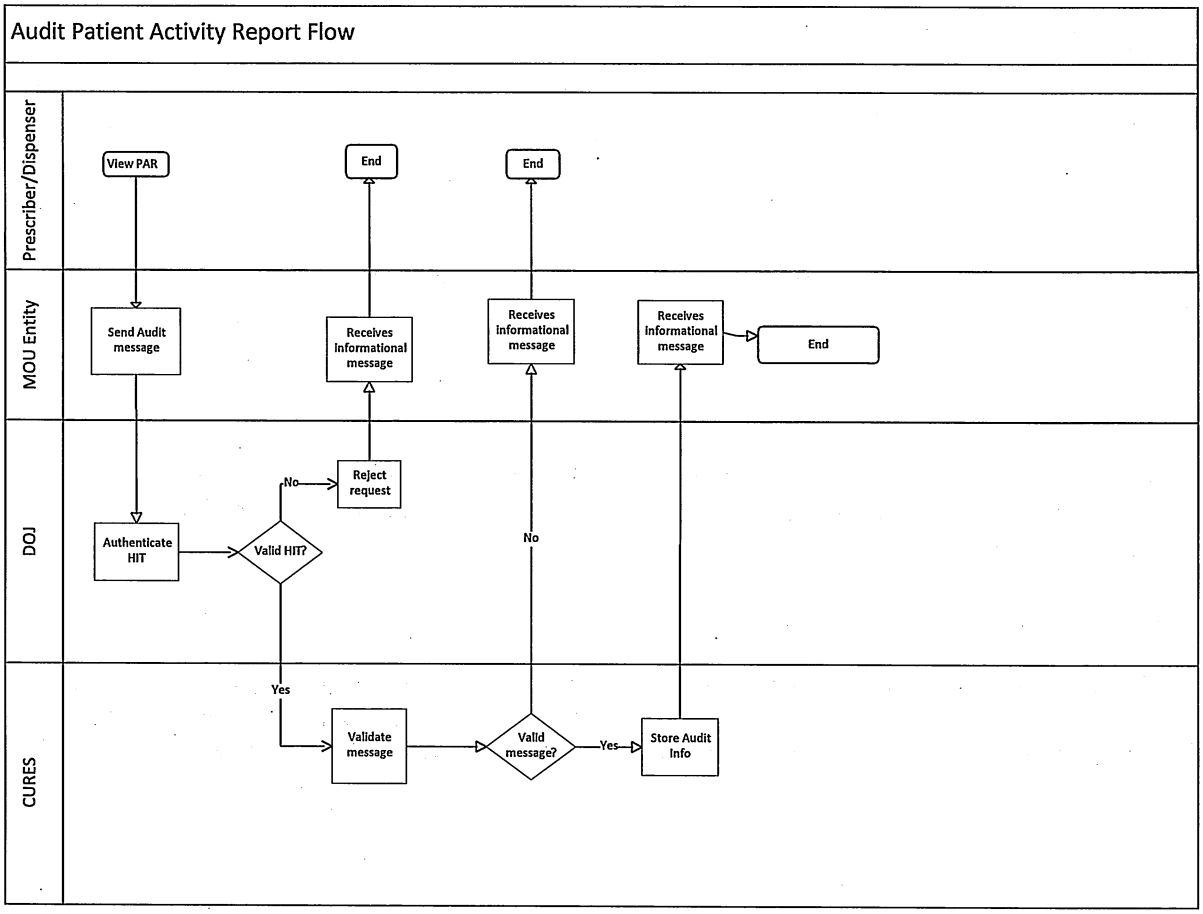
Account Status Check

In addition to the query use cases, the CURES web services will provide web services to query for account status. The first allows the HIT systems to query for the CURES user account status. The second allows the HIT systems to query for their own account status. These services allow the HIT systems to troubleshoot and alter process flows based on account status.

Audit Patient Activity Report

HIT systems are required to submit a notification confirming the receipt of CURES data by the health care practitioner or pharmacist who submitted the query. For purposes of complying with this requirement, there can be only one health care practitioner identified with each query, and, the health care practitioner or pharmacist receiving the CURES data must be the health care practitioner or pharmacist who submitted the initial query.

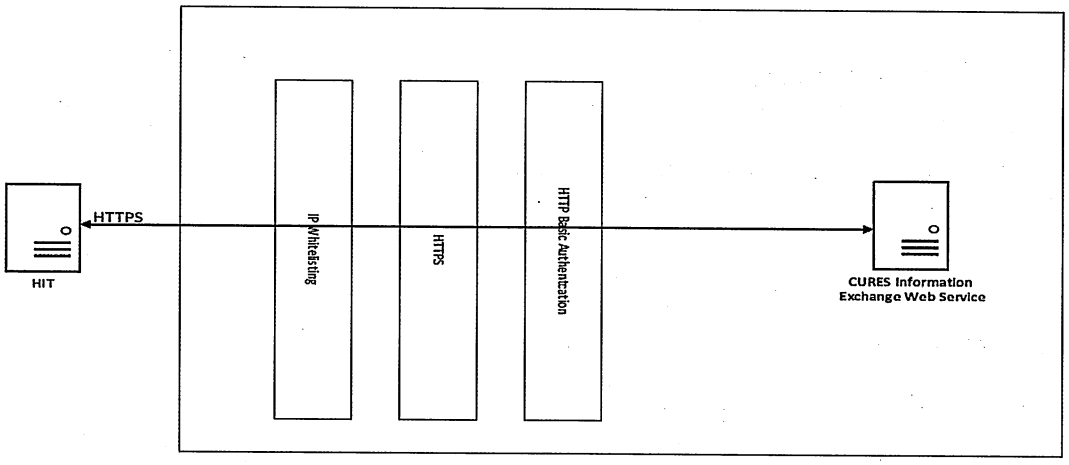
Figure 3 – Audit Patient Activity Report



Security

The CURES web service has three layers of security. Each layer is built on top of the previous to ensure the secure exchange of information. Each REST endpoint is stateless, resulting in every request going through all three layers.

Figure 4 – Security Layers



Network Security

IP whitelisting will ensure only enrolled HIT systems can communicate with the CURES web service.

Communication Security

Communication between the CURES web service and the HIT systems will be over the Internet. As a result, Transport Layer Security (TLS) is required to ensure secure communication between CURES Web services and HIT.

Access Security

After entering into an MOU with the Department of Justice, HIT systems will be provisioned with a CURES web service account. Every RESTful web services request should be accompanied with the credentials and will be validated to ensure the account is valid and in good standing.

EXHIBIT D
FEES AND PAYMENT

Pursuant to Health and Safety Code section 11165.1(a)(1)(H), an entity that operates a HIT system "that is requesting to establish integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database."

1. Fee to Establish Integration (Connectivity Fee)

The Connectivity Fee is a mandatory, one-time, on-boarding fee to cover the cost of connecting ENTITY's HIT system to the CURES Information Exchange Web Service, and is a condition to such integration. The Connectivity Fee amount is fifteen hundred dollars ($1,500). The Connectivity Fee is due with ENTITY's signed memorandum of understanding (MOU). If STATE does not approve ENTITY's MOU, the Connectivity Fee shall be returned to ENTITY. The Connectivity Fee must be paid by check, made payable to the California Department of Justice.

2. Fee to Maintain Integration (Maintenance Fee)

The Maintenance Fee is a mandatory annual fee to cover the cost of maintaining ENTITY's HIT system integration with the CURES Information Exchange Web Service. The Maintenance Fee shall be the established rate multiplied by the number of healthcare practitioners and pharmacists who utilize the CURES Information Exchange Web Service through ENTITY's HIT system. The rate shall be established on an annual basis by STATE. STATE projects the rate to be between five dollars ($5) and twenty dollars ($20) per healthcare practitioner or pharmacist, but this merely reflects an approximation and represents neither a ceiling nor a floor. A healthcare practitioner or pharmacist shall be deemed to have used the CURES Information Exchange Web Service if he or she submits one or more queries through the HIT system during the applicable period.

The Maintenance Fee shall represent a prepayment by ENTITY for its use of the CURES Information Exchange Web Service in the applicable fiscal year. The due date for payment of the Maintenance Fee shall depend upon whether ENTITY is requesting commencement or continuation of HIT system integration with the CURES Information Exchange Web Service.

A. ENTITY Year One Maintenance Fee

For an ENTITY operating a HIT system initially requesting integration with the CURES Information Exchange Web Service, that is paying its first Maintenance Fee, the Maintenance Fee shall be due with submission of its signed MOU. Payment of the Maintenance Fee is a condition of integration. The Maintenance Fee for an ENTITY commencing integration shall be pro-rated based upon the date that such ENTITY submits its signed MOU to STATE. The proration shall be in quarterly brackets, aligned with the fiscal year (which reflects STATE's billing cycle), as depicted in the below table.

Quarter	Date Range	Proration
1	July 1 – Sept. 30	fee × 1.0
2	Oct. 1 – Dec. 31	fee × 0.75
3	Jan. 1 – Mar. 31	fee × 0.50
4	Apr. 1 – June 30	fee × 0.25

ENTITY shall calculate the Maintenance Fee for the first fiscal year of ENTITY's use based on the estimated number of healthcare practitioners and pharmacists that will utilize the CURES Information Exchange Web Service in the initial fiscal year multiplied by the established Maintenance Fee rate. The Maintenance Fee must be paid by check, made payable to the California Department of Justice. A "true-up" process, described in Paragraph 2.C, will reconcile any difference between the estimated number of fiscal year one users and the actual number of users during the applicable fiscal year. There is no proration after fiscal year one.

Example

Fiscal Year	Date MOU Signed/Submitted	Fiscal Quarter	Sample Maintenance Fee Rate	Estimated Users from Onboarding Questionnaire	Calculation	Proration	**Due**
1	Nov. 15, 2020	Q2	$15	100	$15×100=$1,500	$1,500×0.5	$750

(Note: For ENTITIES that establish connection prior to June 30, 2019, the Maintenance Fee will be waived for the period up to June 30, 2019.)

B. ENTITY Year Two (and Thereafter) Maintenance Fee

STATE shall calculate the Maintenance Fee for the second fiscal year, and thereafter, based on ENTITY's actual number of healthcare practitioners and pharmacists that utilized the CURES Information Exchange Web Service in the prior applicable fiscal year multiplied by the established Maintenance Fee rate. A "true-up" process, described in Paragraph 2.C, will reconcile any difference between the number of users in the prior fiscal year and the actual number of users in the applicable fiscal year.

For the second fiscal year, and thereafter, STATE shall invoice ENTITY for the Maintenance Fee. Such invoice shall be sent to ENTITY in a manner consistent with the notice provisions of Paragraph 6 of the MOU. ENTITY shall pay to STATE the invoiced Maintenance Fee within forty-five (45) days receipt thereof. The Maintenance Fee must be paid by check, made payable to the California Department of Justice. Timely payment of the Maintenance Fee is a condition of continued integration.

C. Maintenance Fee True-Up Process

Maintenance Fees are calculated using the actual number of users in the preceding fiscal year (except for fiscal year one, where ENTITY estimates the number of users for that year). The "true-up" is a process whereby STATE reconciles any discrepancies between the projected number of users and actual number of users for each fiscal year. The true-up occurs after the close of each applicable fiscal year, such that STATE can ascertain the actual number of users during that fiscal year.

If an ENTITY's actual number of users at the close of a fiscal year is fewer than the preceding fiscal year, which was used by STATE to calculate the Maintenance Fee, STATE shall deduct from the subsequent Maintenance Fee an amount equivalent to the difference in the number of actual users multiplied by the established Maintenance Fee rate.

Conversely, if an ENTITY's actual number of users at the close of a fiscal year is greater than the preceding fiscal year, which was used by STATE to calculate the Maintenance Fee, STATE shall add to the subsequent Maintenance Fee an amount equivalent to the difference in the number of actual users multiplied by by the established Maintenance Fee rate.

EXHIBIT E
CONFIDENTIALITY AND INFORMATION SECURITY REQUIREMENTS

This Confidentiality and Information Security Requirements Exhibit (hereinafter referred to as "this Exhibit") sets forth the information security and privacy requirements the ENTITY is obligated to follow with respect to CURES data pursuant to the MOU. The STATE and ENTITY desire to protect the privacy and provide for the security of CURES data in compliance with state and federal statutes, rules and regulations.

1. Confidentiality of Information.

A. Definitions. The following definitions apply to this Exhibit and relate to STATE Confidential, Sensitive, and/or Personal Information.

i. "The Security Rule," as defined in 45 CFR Part 160, establishes national standards to protect individuals" electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

ii. Security Rule of 45 CFR Part 164 defines "confidentiality" to mean that e-PHI is not available or disclosed to unauthorized persons. The Security Rule's confidentiality requirements support the Privacy Rule's prohibitions against improper uses and disclosures of Protected Health Information. The Security rule also promotes the two additional goals of maintaining the integrity and availability of electronic-Protected Health Information. Under the Security Rule, "integrity" means that e-PHI is not altered or destroyed in an unauthorized manner. "Availability" means that electronic-Protected Health Information is accessible and usable on demand by an authorized person.

iii. "Sensitive Information" is information maintained by the STATE, which is not confidential by definition, but requires special precautions to protect it from unauthorized access and/or modification (i.e., financial or operational information). Sensitive information is information in which the disclosure would jeopardize the integrity of the STATE (i.e., STATE's operations).

iv. "Personal Information" is information, in any medium (paper, electronic, or oral) that identifies or describes an individual (i.e., name, social security number, driver's license, home/mailing address, telephone number, financial matters with security codes, medical insurance policy number, Protected Health Information, electronic-Protected Health Information etc.) and must be protected from inappropriate access, use or disclosure and must be made accessible to information subjects upon request. It can also be information in the possession of the Department in which the disclosure is limited by law or contractual Agreement (i.e., proprietary information, etc.).

v. Protected Health Information (PHI) is health data created, received, stored, or transmitted by HIPAA-covered entities and their business associates in relation to the provision of healthcare, healthcare operations and payment for healthcare services. PHI, or in the case of electronic health information, ePHI, includes all individually identifiable health information, including

demographic data, medical histories, test results, insurance information, and other information used to identify a patient or provide healthcare services or healthcare coverage. The information relates to an individual's past, present, and future physical and mental health, the provision of healthcare to an individual, or past, present, and future payments for healthcare. "Protected" means the information is protected under the HIPAA Privacy Rule.

vi. "Breach" is
   1. the unauthorized acquisition, access, use, or disclosure of CURES data in a manner which compromises the security, confidentiality or integrity of the information; or
   2. the same as the definition of "breach of the security of the system" set forth in 45 CFR 164.402.

vii. "Information Security Incident" is
   1. an attempted breach;
   2. the attempted or successful unauthorized access or disclosure, modification or destruction of CURES data, in violation of any state or federal law or in a manner not permitted under the MOU including this Exhibit; or
   3. the attempted or successful modification or destruction of, or interference with, ENTITY's system operations in an information technology system, that negatively impacts the confidentiality, availability or integrity of CURES data.

B. CURES data which may become available to the ENTITY as a result of the implementation of the MOU shall be protected by the ENTITY from unauthorized access, use, and disclosure as described in this Exhibit and consistent with the requirements of the Health Insurance Portability and Accountability Act of 1996.

C. ENTITY is notified that unauthorized disclosure of CURES data may be subject to civil and/or criminal penalties under state and federal law, including but not limited to:
   - California Welfare and Institutions Code section 10850
   - Information Practices Act 1977- California Civil Code section 1798 et seq.
   - California Penal Code Section 502
   - Health Insurance Portability and Accountability Act of 1996 ("HIPAA") - 45 C.F.R. § 160.408.
   - Safeguarding Information for the Financial Assistance Programs - 45 CFR Part 205.50

2. ENTITY Responsibilities

A. General Rules - Health Insurance Portability and Accountability Act of 1996 ("HIPAA") - 45 CFR Parts 160 and 164

The Security Rule requires ENTITY to maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting e-PHI. Specifically, ENTITY must:

i. Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit;

ii. Identify and protect against reasonably anticipated threats to the security or integrity of the information;
iii. Protect against reasonably anticipated, impermissible uses or disclosures; and
iv. Ensure compliance by their workforce.

B. Subpoena. If ENTITY receives a subpoena or other validly issued administrative or judicial notice requesting the disclosure of CURES data, ENTITY will immediately notify the STATE Program Contract Manager and the STATE Information Security and Privacy Officer. In no event should notification to STATE occur more than three (3) business days after receipt by ENTITY's responsible unit for handling subpoenas and court orders.

3. Risk Analysis and Management

A. The Administrative Safeguards provisions in the Security Rule require ENTITY to perform risk analysis as part of their security management processes. The risk analysis and management provisions of the Security Rule are addressed separately here because, by helping to determine which security measures are reasonable and appropriate for a particular ENTITY, risk analysis affects the implementation of all of the safeguards contained in the Security Rule.

B. A risk analysis process includes, but is not limited to, the following activities:
i. Evaluate the likelihood and impact of potential risks to e-PHI,
ii. Implement appropriate security measures to address the risks identified in the risk analysis.
iii. Document the chosen security measures and, where required, the rationale for adopting those measures and
iv. Maintain continuous, reasonable, and appropriate security protections.

Risk analysis should be an ongoing process, in which an ENTITY regularly reviews its records to track access to e-PHI and detect security incidents, periodically evaluates the effectiveness of security measures put in place, and regularly reevaluates potential risks to e-PHI.

4. Administrative Safeguards

A. **Security Management Process**. As explained in the previous section, an ENTITY must identify and analyze potential risks to e-PHI, and it must implement security measures that reduce risks and vulnerabilities to a reasonable and appropriate level.

B. **Security Personnel.** An ENTITY must designate a security official who is responsible for developing and implementing its security policies and procedures.

C. **Information Access Management.** Consistent with the Privacy Rule standard limiting uses and disclosures of PHI to the "minimum necessary," the Security Rule requires An ENTITY to implement policies and procedures for authorizing access to e-PHI only when such access is appropriate based on the user or recipient's role (role-based access).

D. **Workforce Training and Management.** An ENTITY must provide for appropriate authorization and supervision of workforce members who work with e-PHI. An ENTITY must train all workforce members regarding its security policies and procedures, and must have and apply appropriate sanctions against workforce members who violate its policies and procedures.

E. **Evaluation**. An ENTITY must perform a periodic assessment of how well its security policies and procedures meet the requirements of the Security Rule.

5. Technical Safeguards

A. **Access Control.** An ENTITY must implement technical policies and procedures that allow only authorized persons to access e-PHI.

B. **Audit Controls.** An ENTITY must implement hardware, software, and/or procedural mechanisms to record and examine access and other activity in information systems that contain or use e-PHI.

C. **Integrity Controls.** An ENTITY must implement policies and procedures to ensure that e-PHI is not improperly altered or destroyed. Electronic measures must be put in place to confirm that e-PHI has not been improperly altered or destroyed.

D. **Transmission Security.** An ENTITY must implement technical security measures that guard against unauthorized access to e-PHI that is being transmitted over an electronic network.

E. **ENTITY Responsibilities.** If an ENTITY knows of an activity or practice of ENTITY that constitutes a material breach or violation of ENTITY's obligation, ENTITY must take reasonable steps to cure the breach or end the violation. Violations include the failure to implement safeguards that reasonably and appropriately protect e-PHI.

6. Information Security Incidents and/or Breaches

If an ENTITY knows of an activity or practice of ENTITY that constitutes a material breach or violation of ENTITY's obligation, ENTITY must take reasonable steps to cure the breach or end the violation. Violations include the failure to implement safeguards that reasonably and appropriately protect e-PHI.

A. **Information Security Incidents and/or Breaches Response Responsibility**. ENTITY shall be responsible for facilitating the Information Security Incident and/or Breach response process as described in 45 CFR 164.308

B. **Discovery and Notification of Information Security Incidents and/or Breaches**. ENTITY shall notify the STATE Program Contract Manager and the STATE Information Security Officer immediately by telephone call and email upon the discovery of the Information Security Incident and/or Breach affecting the security of CURES data if the CURES data was, or is reasonably believed to have been, acquired by an unauthorized person, or there is an intrusion, potential loss,

actual loss, or unauthorized use or disclosure of the CURES data is in violation of this MOU, this provision, or applicable state or federal law.
ENTITY shall take:

i. Prompt corrective action to mitigate the risks or damages involved with the Information Security Incident and/or Breach and to protect the operating environment; and
ii. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.

C. **Investigation of Information Security Incidents and/or Breaches.** ENTITY shall promptly investigate such Information Security Incidents and/or Breaches. STATE shall have the right to participate in the investigation of such Information Security Incidents and/or Breaches. STATE shall also have the right to conduct its own independent investigation, and ENTITY shall cooperate fully in such investigations.

D. **Updates on Investigation**. ENTITY shall provide regular (at least once a week) email updates on the progress of the Information Security Incident and/or Breach investigation to the STATE Program Contract Manager and the STATE Information Security Officer until they are no longer needed, as mutually agreed upon between the ENTITY and the STATE Information Security and Privacy Officer.

E. **Written Report**. ENTITY shall provide a written report of the investigation to the STATE Program Contract Manager and the STATE Information Security Officer within 72 hours of the discovery of the Information Security Incident and/or Breach. To the extent ENTITY has such information, the report shall include but not be limited to the following:

i. ENTITY point of contact information;
ii. Description of what happened, including the date of the Information Security Incident and/or Breach and the date of the discovery of the Information Security Incident and/or Breach, if known;
iii. Description of the types of CURES data that were involved and the extent of the information involved in the Information Security Incident and/or Breach;
iv. A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed CURES data;
v. A description of where the CURES data is believed to have been improperly transmitted, sent, or utilized;
vi. A description of the probable causes of the improper use or disclosure;
vii. Whether Civil Code sections 1798.82, 45 CFR Part 160 and 164 or any other federal or state laws requiring individual notifications of breaches are triggered; and
viii. Full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the Incident and/or Breach.

F. **Cost of investigation and Remediation.** ENTITY shall be responsible for all costs incurred by STATE due to Information Security Incidents and/or Breaches resulting from ENTITY's failure to perform or from negligent acts of its personnel, and resulting in the unauthorized disclosure, release, access, review, or destruction; or loss, theft or misuse of an information asset. These costs include,

but are not limited to, notice and credit monitoring for impacted individuals, STATE staff time, material costs, postage, media announcements, and other identifiable costs associated with the Information Security Incident, Breach and/ or loss of data.

VII. Contact Information. To direct communications to the above referenced STATE staff, the ENTITY shall initiate contact as indicated herein. STATE reserves the right to make changes to the contact information below by giving written notice to the ENTITY. Said changes shall not require an amendment to this Exhibit or the MOU.

DOJ Program Manager	**DOJ Information Security Officer**
California Department of Justice CURES Program 4949 Broadway Sacramento, CA 95820 Email: CURES@doj.ca.gov Telephone: (916) 210-3187	California Department of Justice Information Security Officer 4949 Broadway Sacramento, CA 95820 Email: dojiso@doj.ca.gov Telephone: (916) 210-5045

DOJ Confidentiality and Security Compliance Statement

CALIFORNIA DEPARTMENT OF JUSTICE
CONFIDENTIALITY AND SECURITY COMPLIANCE STATEMENT v 2018 01

Information resources maintained by the California Department of Justice (DOJ) and provided to your entity may be confidential, sensitive, and/or personal. CURES data is not open to the public and requires special precautions to protect it from wrongful access, use, disclosure, modification, and destruction.

We hereby acknowledge that the confidential and/or sensitive records of the DOJ are subject to strict confidentiality requirements imposed by state and federal law, which may include, but is not limited to, the following; the California Welfare and Institutions Code §10850, Information Practices Act - California Civil Code §1798 et seq., Public Records Act - California Government Code §6250 et seq., California Penal Code §502, 11140-11144, 13301-13303, Health Insurance Portability and Accountability Act of 1996 ("HIPAA") - 45 CFR Parts 160 and 164, and Safeguarding Information for the Financial Assistance Programs - 45 CFR Part 205.50. ENTITY agrees to comply with the laws applicable to the DOJ CURES data received.

Project Representative

Name (Printed): _____
Title: _____
Organization: _____
Email Address: _____
Phone: _____
Signature: _____
Date Signed: _____

Information Security Officer or designee

Name (Printed): _____
Title: Information Security Officer or Designee
Organization: _____
Email Address: _____
Phone: _____
Signature: _____
Date Signed: _____

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

February 27, 2019

Joe Dominic
Chief
Department of Justice
California Justice Information Services Division

VIA EMAIL to Joe.Dominic@doj.ca.gov

Dear Mr. Dominic:

The California Hospital Association (CHA) — representing more than 400 hospitals and health systems and 97 percent of patient beds in the state — is writing today to express our concerns with the October 2018 Memorandum of Understanding (MOU) your department sent to California hospitals. Several hospital systems in the state, including Adventist Health, Dignity Health, Kaiser Permanente, Stanford Medical Center, Sutter Health, and others, have requested that CHA work with the department to revise the MOU.

As you know, Health and Safety Code Section 11165.1 restricts the scope of the MOU:

> 11165.1(a)(1)(E)(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

The hospital systems noted above created a workgroup and identified the following requested revisions to the MOU:

1. Page 3. Definition of "CURES data" – Revise to read as follows:

> "CURES data shall mean patient activity reports, patient alerts, and other individually identifiable information obtained through query of the CURES system. CURES data excludes source data submitted by ENTITY that may be incorporated into reports generated by CURES."

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

2. Page 7. Paragraph 7 – delete first paragraph entirely. In the second paragraph, revise the fifth sentence to read as follows:

> "ENTITY shall execute and return to STATE any amendment to the MOU issued by STATE within ~~fifteen (15)~~ sixty (60) calendar days from receipt thereof (as determined by the notice provisions of Paragraph 6 of the MOU)."

3. Exhibit A. Paragraph 2 – Revise header to read as follows: Data ~~Fidelity~~ Verification

4. Exhibit A. Paragraph 3 – Delete for hospital entities. The California Department of Public Health and the U.S. Department of Health and Human Services, Office for Civil Rights enforce hospitals' compliance with HIPAA. A third enforcement agency is not needed.

5. Exhibit B. Paragraph 3 – Delete the paragraph in its entirety.

6. Exhibit B. Paragraph 6 – Revise first line to read as follows:

> "ENTITY agrees to notify STATE in advance of any material changes associated with this MOU or …"

7. Exhibit E. Delete in its entirety. It is not necessary to outline the laws with which hospitals must comply.

I appreciate your willingness to work with CHA on this important issue and look forward to hearing from you. I may be reached at (916) 552-7611.

Thank you very much.

Sincerely,

Lois J. Richardson
Vice President & Legal Counsel

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

FROM: Sarah Stephens, Pharm.D., CDPS, CPPS, Medication Safety Coordinator, Kaweah Delta Health District

SUBJECT: Labetalol Administration

SUMMARY

Due to drug shortages and subpar quality of the manufacturer, the following unsafe practices noted in the attachment are being recommended.

DISCUSSION

1) How is this affecting your practice and quality of care?

ACTION REQUESTED

- Information and feedback to CHA for advocacy efforts

Attachment: Hospira – Important Safety Information – Notice of New Special Handling Instructions due to Potential for Cracked Needle Hubs and Particulate in Multiple Capuject Luer Lock Glass Syringe Products
Urgent Notice – Labetalol Injection

BJB:br

May 2018

URGENT: Important Safety Information

Subject: Notice of New Special Handling Instructions due to Potential for Cracked Needle Hubs and Particulate in Multiple Carpuject™ Luer Lock Glass Syringe Products

Dear Health Care Provider,

Hospira, a Pfizer company (Hospira) is issuing this Important Safety Information Letter to alert Health Care Providers to the potential of cracked needle hubs and particulate in multiple products manufactured in the **Carpuject™ Luer Lock Glass Syringe Products** ("Carpuject syringe ") currently in your control listed in Table 1.

Table 1. Impacted Carpuject Products

Product Description	Presentation	NDC Number
Heparin Sodium Injection, USP (Preservative Free)	5,000 USP Heparin Units/0.5 mL Carpuject™ Luer Lock Glass Syringe	0409-1316-32
Hydromorphone Hydrochloride Injection, USP, CII	1 mg/mL Carpuject™ Luer Lock Glass Syringe	0409-1283-31
	2 mg/mL Carpuject™ Luer Lock Glass Syringe	0409-1312-30
Labetalol Hydrochloride Injection, USP	20 mg/4 mL Carpuject™ Luer Lock Glass Syringe	0409-2339-34
Lorazepam Injection, USP, CIV	2 mg/mL Carpuject™ Luer Lock Glass Syringe	0409-1985-30
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	2 mg/mL Carpuject™ Luer Lock Glass Syringe	0409-1890-01

In order to minimize the potential risk of adverse events with these products, special handling directions described below are required prior to administering the affected products to patients. To help alleviate the critical drug shortage of these products, Hospira has evaluated product lots in its control and, in coordination with FDA, is releasing the impacted lots listed in Appendix 1.

Special handling instructions in this letter only apply to Carpuject lots described in Appendix 1. All other Carpuject lots may be administered following routine procedures.

Please ensure your staff and any provider in your institution who may be involved in the administration of the products in Table 1 receives a copy of this letter and specifically reviews the special handling directions in the Directions for Health Care Provider section below.

Cracked needle hubs and particulate were identified either during routine inspection or during routine quality checks of products in the Carpuject syringe. Although the probability of cracked needle hubs and/or particulate is low, all production lots and component receivers within site control were placed on hold, stopping the release of products in the Carpuject syringe.

The root cause of the cracked needle hubs and particulate has been identified, and corrective and preventative actions are now in place.

Figure 1. Magnification of Cracked Needle Hubs

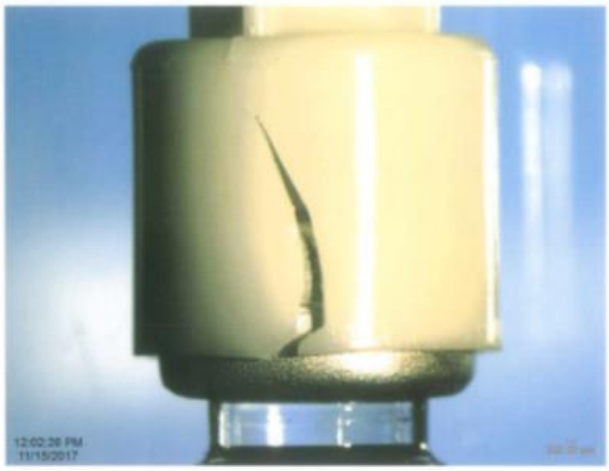
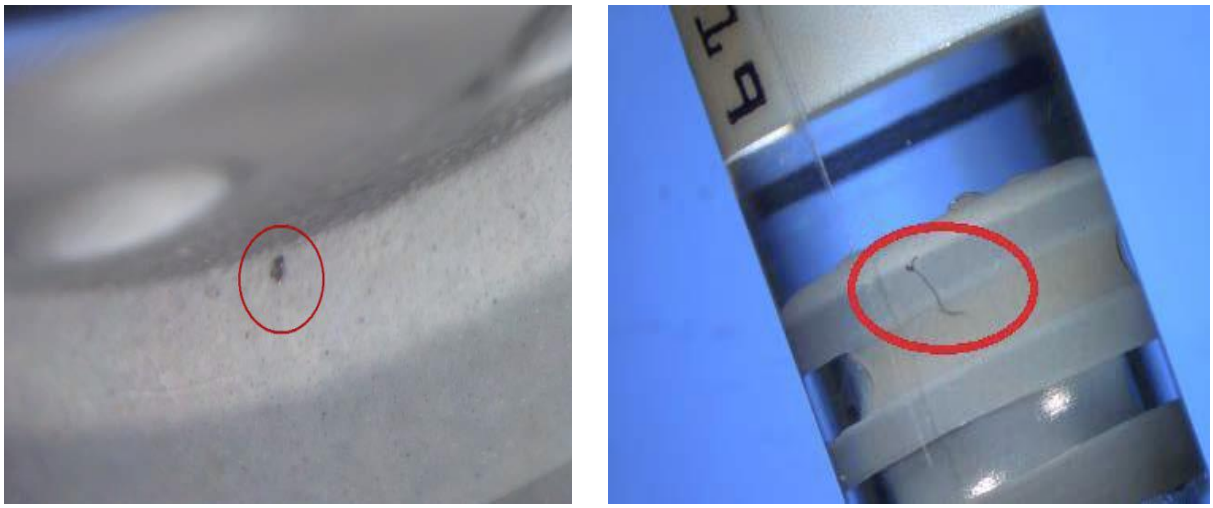


Figure 2. Magnification of Potential Particulate



Potential Safety Risk of Adverse Events

For Carpuject product lots impacted, a damaged needle hub assembly has the potential to impact the sterile pathway during product delivery. The potential for patient exposure occurs through the use of the split Luer Lock II hub assembly.

With intravenous injection, injected particulate matter may result acutely in local inflammation or phlebitis. It may also lead to micro-embolic effects in other tissue, most commonly the lungs. If extensive, this can result in chest pain or respiratory symptoms. Chronically, following sequestration, granuloma formation is possible.

Subcutaneous or intramuscular injection of particulate may result in local inflammation or tissue injury.

Directions for Wholesalers/Distributors

If you have distributed the product listed in this Dear Health Care Provider (DHCP) letter, please notify your impacted accounts of this Important Safety Information notification.

Directions for Health Care Provider

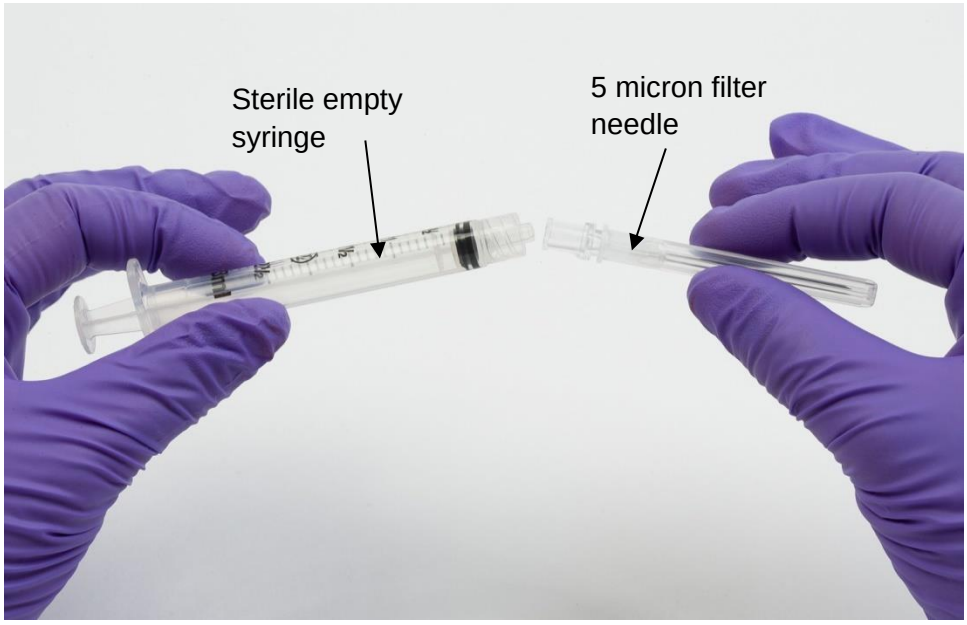
After opening the carton or box, visually inspect the cartridge to confirm there are no cracks or damage to the needle hub and that there is no visible particulate matter. Per the package insert, parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution or container permits. Please note that the instructions described below to use the Carpuject cartridge as a vial is not routine, and is advised because of the critical drug shortage.

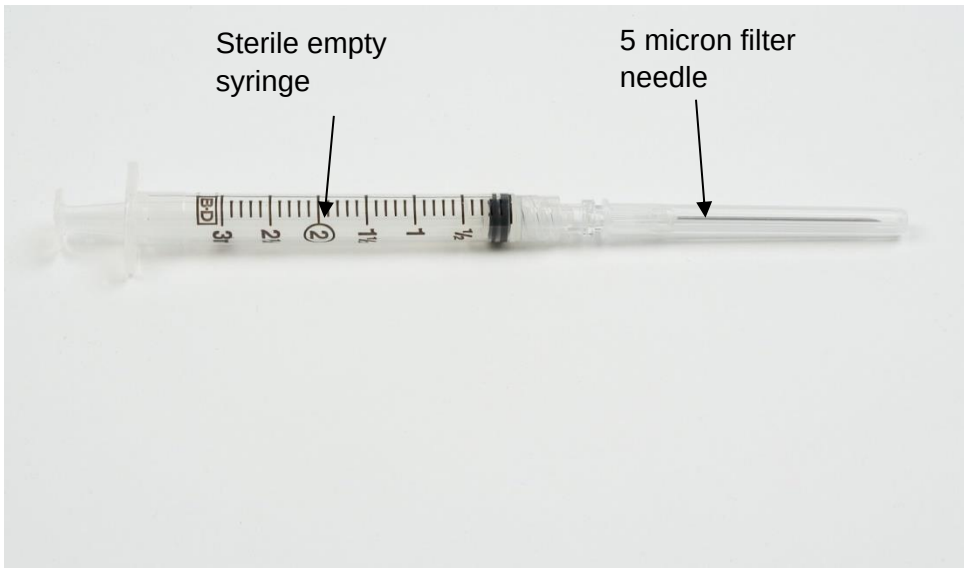
As a precaution, use a 5 micron filter needle (BD REF 305200 or equivalent) to prepare the drugs listed in this letter for administration. The following steps are recommended to remove the Carpuject cartridge from the Carpuject Hub assembly and prepare the drug solution for administration using a filter needle with these products:

1. Remove Carpuject cartridge from packaging
2. Perform a visual inspection of the Carpuject cartridge prior to use.

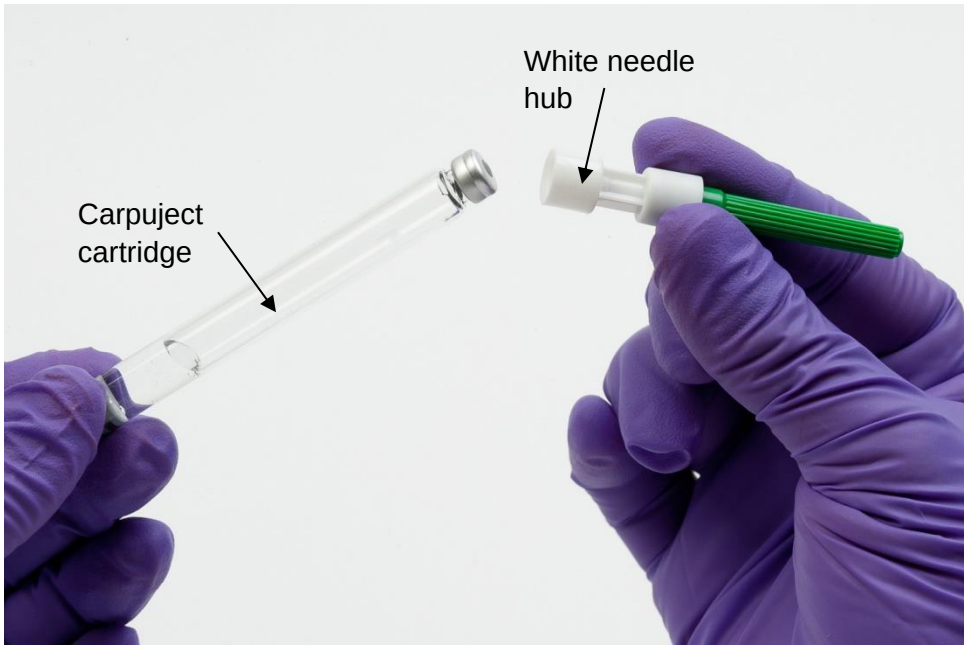
DO NOT USE IF PARTICULATES ARE VISIBLE, AND DISCARD CARTRIDGE PER YOUR INSTITUTION'S POLICY. USE A NEW CARPUJECT CARTRIDGE.

3. If no particulates are visible, as a precaution, attach a filter needle with 5 micron filter to a sterile empty syringe

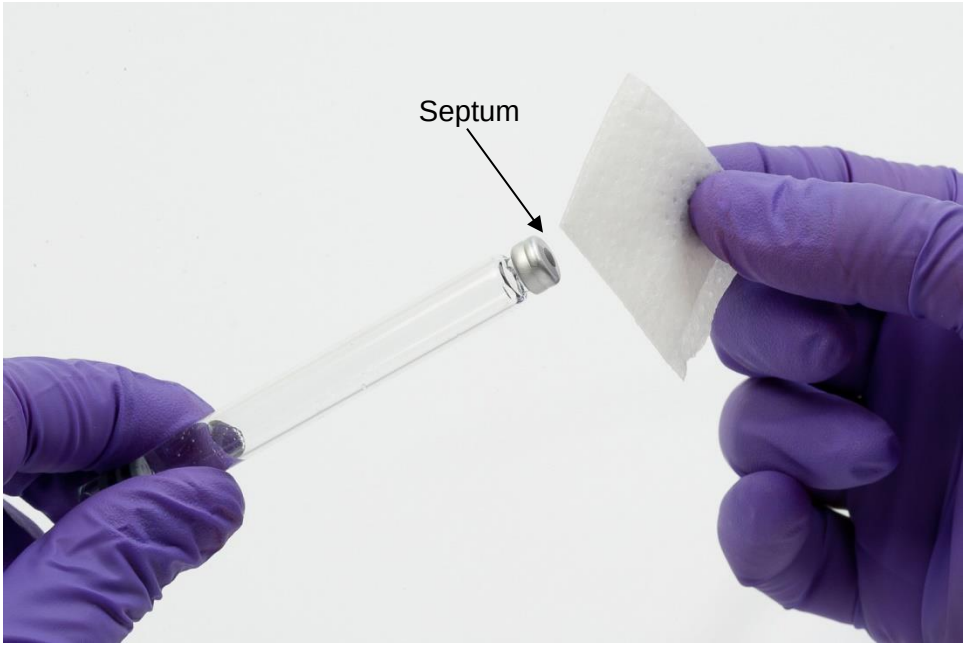




4. Remove white needle hub from Carpuject cartridge and discard per hospital procedure



5. Swab the septum of the Carpuject cartridge with sterile alcohol pad



6. Insert syringe into Carpuject cartridge septum.

7. Withdraw intended dose from Carpuject cartridge purging air from filter to help maximize amount withdrawn
8. Remove 5 micron filter needle and discard per hospital procedure
9. Attach needle if applicable and administer drug or connect syringe to a port that does not require needle access and administer drug.

NOTE: Immediately prior to intravenous use, **Lorazepam Injection, USP, CIV** must be diluted with an equal volume of compatible solution.

This letter is not intended as a complete description of the benefits and risks related to the use of these Carpuject products Full Prescribing Information including BOXED WARNING if applicable is available at www.pfizerinjectables.com/products.

Please contact Hospira customer Service at 1-844-646-4398 (Mon.-Fri. 8am-7pm ET) or your Hospira representative for any questions you may have regarding this notification.

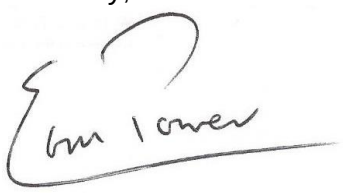
To report adverse reactions or quality issues, contact Hospira at 1-800-438-1985.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

This letter is being issued with the knowledge of the U.S. Food and Drug Administration.
We thank you for your attention to this important matter.

Sincerely,



Eddie G M Power PhD MBA
Vice President, US Medical Affairs, Chief Medical Office
Pfizer Essential Health

Appendix 1. Impacted Carpuject Product Lot Numbers with Potential Cracked Needle Hub and/or Particulate Matter

NDC Number	Product Description	Lot Numbers	Lot Expiration Date
0409-1316-32	Heparin Sodium Injection, USP, 5,000 USP Heparin Units/0.5 mL in 2.5 mL Carpuject, Luer Lock	81530LL	03/01/2019
		81580LL	03/01/2019
		81585LL	03/01/2019
		81600LL	03/01/2019
		81605LL	03/01/2019
		82505LL	04/01/2019
		82655LL	04/01/2019
		82665LL	04/01/2019
		82730LL	04/01/2019
		82735LL	04/01/2019
		82755LL	04/01/2019
		82770LL	04/01/2019
		83610LL	05/01/2019
		83665LL	05/01/2019
		83670LL	05/01/2019
		83705LL	05/01/2019
		84505LL	06/01/2019
		84595LL	06/01/2019
0409-1283-31	Hydromorphone HCl Injection, USP 1 mg/mL in 2.5 mL Carpuject, Luer Lock CII	80570LL	08/01/2019
		80650LL	08/01/2019
		80795LL	08/01/2019
		81555LL	09/01/2019
		81560LL	09/01/2019
		82520LL	10/01/2019
		82565LL	10/01/2019
		82580LL	10/01/2019
		83625LL	11/01/2019
		83660LL	11/01/2019
0409-1312-30	Hydromorphone HCl Injection, USP 2 mg/mL in 2.5 mL Carpuject, Luer Lock CII	82740LL	10/01/2019

NDC Number	Product Description	Lot Numbers	Lot Expiration Date
0409-2339-34	Labetalol Hydrochloride Injection., USP, 20 mg/4 mL in 5 mL Carpuject, Luer Lock	74630LL	02/01/2019
		76640LL	04/01/2019
		77670LL	05/01/2019
		77725LL	05/01/2019
		77775LL	05/01/2019
		78590LL	06/01/2019
		78605LL	06/01/2019
		79515LL	07/01/2019
		81545LL	09/01/2019
		83535LL	11/01/2019
		83560LL	11/01/2019
0409-1985-30	Lorazepam Injection, USP, 2 mg/mL in 2.5 mL Carpuject, Luer Lock CIV	82760LL	10/01/2019
		83520LL	11/01/2019
		83695LL	11/01/2019
0409-1890-01	Morphine Sulfate Injection, USP 2 mg/mL in 2.5 mL Carpuject, Luer Lock CII	78580LL	06/01/2019
		80645LL	08/01/2019
		80740LL	08/01/2019
		81550LL	09/01/2019
		82525LL	10/01/2019
		82745LL	10/01/2019
		83620LL	11/01/2019
		83690LL	11/01/2019

Sent: Friday, January 25, 2019 5:29 PM
To: *Patient Care Managers; *Charge Nurses; *Clinical Nursing Educators; Pharmacists; Pharmacy Technicians
Cc: *Patient Care Leadership
Subject: URGENT NOTICE: Labetalol injection
Importance: High

Situation

- Labetalol carpuject require filtration (5 micron filter needle) prior to use due to potential for particulate matter
- Due to the national labetalol shortage, FDA is allowing filtration prior to use instead of recalling the product
- Attached is the official notification from the manufacturer

REQUIRED STEPS

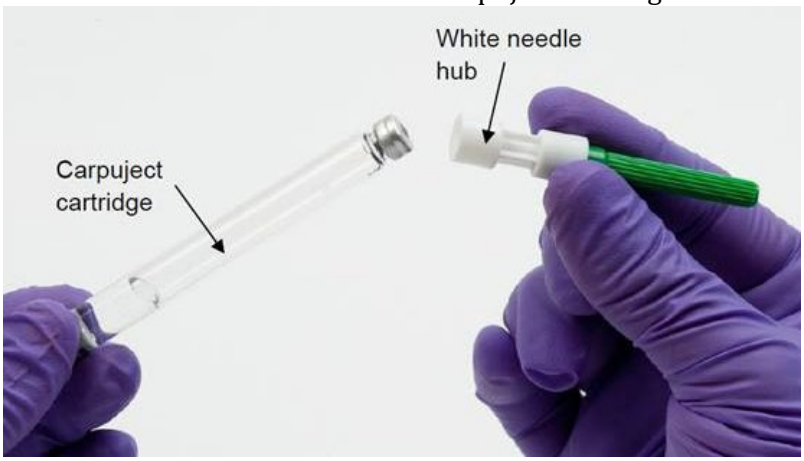
As a precaution, use a 5 micron filter needle to prepare the drug

1. Remove Carpuject cartridge from packaging

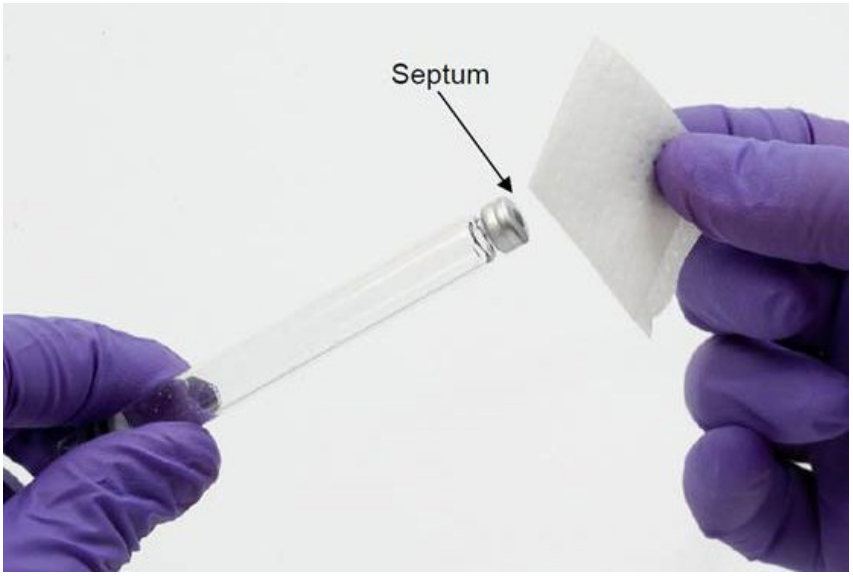
2. Visually inspect Carpuject cartridge prior to use. DO NOT USE IF PARTICULATES ARE VISIBLE - DISCARD CARTRIDGE & USE A NEW CARPUJECT CARTRIDGE.

3. If no particulates are visible, attach 5 micron filter needle to a sterile empty syringe

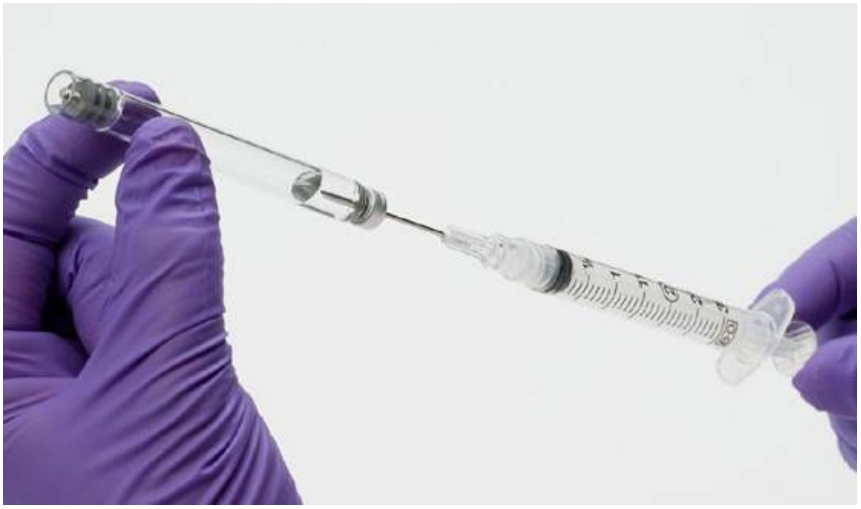
4. Remove white needle hub from Carpuject cartridge and discard



5. Swab the septum of the Carpuject cartridge with sterile alcohol pad



6. Insert syringe with filter needle into Carpuject cartridge septum



7. Withdraw intended dose from Carpuject cartridge purging air from filter to help maximize amount withdrawn

8. Remove 5 micron filter needle and discard per hospital procedure

9. Connect syringe to a leur-lock port for administration

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 17, 2019

TO: Medication Safety Committee Members

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

SUBJECT: AB 528 - CURES

SUMMARY

AB 528 (Low) adds Schedule V drugs to the Controlled Substances Utilization Review and Evaluation System (CURES)- it changes the required timeframe in which pharmacists are required to report dispensed prescriptions from seven days to the following business day.

Several systems with retail pharmacies are supportive yet concerned with this bill in that the current CURES system is not readily available to a dispensing pharmacy or capable of providing the information entered into CURES data process immediately available. For example:

1) A pharmacist enters the information into the CURES system data repository for reformatting
2) The information then goes through Atlantic Associates, a contracted prescription collection and data processing and analytics service. While prescribers and pharmacists have an NPI (National Provider Identifier) numbers, patients have no unique or universal identifiers. Atlantic Associates uses the patient information from the prescription entered into the CURES Data base and uses an established algorithm to identify the patient for whom the prescription was dispensed. This process uses various data elements to attempt to identify a patient so that all relevant data is aggregated to the appropriate patient. There are numerous potential ways that the ability of the system to correctly identify the patient can be negatively impacted. This process generally takes multiple days. "
3) Upon completion of the process, Atlantic Associates then uploads the information into the CURES system. Based on this process there is functional "real time" information available in the data base. "Today, this system requires the transmission of the information outside of the normal business processes of a pharmacy and does not allow a physician to review the data as part of their normal chart review process when examining a patient

DISCUSSION

1) How does the one day turn around affect hospital pharmacies?
2) Do we need to offer amendments to the bill reflective of any issues identified?

ACTION REQUESTED

- Information for CHA relative to potential amend or position on the bill

Attachment: AB 528

BJB:br

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Steven Glazer, Chair
2019 - 2020 Regular

Bill No:	AB 528	**Hearing Date:**	July 1, 2019
Author:	Low		
Version:	June 19, 2019		
Urgency:	No	**Fiscal:**	Yes
Consultant:	Sarah Mason		

Subject: Controlled substances: CURES database

SUMMARY: Adds Schedule V drugs to the Controlled Substances Utilization Review and Evaluation System (CURES); changes the required timeframe in which pharmacists are required to report dispensed prescriptions from seven days to the following business day; and makes other technical changes.

Existing law:

1) Establishes various practice acts in the Business and Professions Code (BPC) governed by various boards within the Department of Consumer Affairs (DCA) which provide for the licensing and regulation of health care professionals including: physicians and surgeons (under the Medical Practice Act), dentists (under the Dental Practice Act), veterinarians (under the Veterinary Medicine Practice Act); registered nurses, nurse practitioners (NP) and certified nurse-midwives (CNM) (under the Nursing Practice Act); physician assistants (PA) (under the Physician Assistant Practice Act); osteopathic physicians and surgeons (under the Osteopathic Medical Practice Act); naturopathic doctors (ND) (under the Naturopathic Doctors Act); optometrists (under the Optometry Practice Act); doctors of podiatric medicine (under the Podiatric Act) and; pharmacies, pharmacists and wholesalers of dangerous drugs or devices (under the Pharmacy Law). (Business and Professions Code (BPC) §§ 500 *et seq*.)

2) Defines "dispense" as the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or ND or upon an order to furnish drugs or transmit a prescription from a CNM, NP, PA, ND, or pharmacist acting within the scope of his or her practice. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, podiatrist, or veterinarian, or by a CNM, NP, ND, PA or pharmacist acting within the scope of his or her practice. (BPC § 4024)

3) Specifies certain requirements regarding the dispensing and furnishing of dangerous drugs and devices, and prohibits a person from furnishing any dangerous drug or device except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian or ND. (BPC § 4059)

4) Establishes the Uniform Controlled Substances Act which regulates controlled substances and defines an opiate as any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. (Health and Safety Code (HSC) § 11020)

5) Classifies controlled substances into five schedules according to their danger and potential for abuse. (HSC §§ 11054-11058)

6) Prohibits any person other than a physician, dentist, podiatrist, veterinarian, ND (according to certain supervision and protocol requirements), pharmacist (according to certain authorization and according to certain policies and procedures), CNM (if furnished or ordered incidentally to the provision of family planning services, routine health care or perinatal care, or care rendered consistent with the CNM's practice; occurs under physician and surgeon supervision; and is in accordance with standardized procedures or protocols as specified), NP (if it is consistent with a NP's educational preparation or for which clinical competency has been established and maintained; occurs under physician and surgeon supervision; and is in accordance with standardized procedures or protocols as specified); a pharmacist or registered nurse or PA acting within the scope of an experimental health workforce project authorized by the Office of Statewide Health Planning and Development (HSC §§ 128125 *et seq*.); an optometrist licensed under the Optometry Practice Act, or an out-of-state prescriber acting in an emergency situation from writing or issuing a prescription for a controlled substance. (HSC § 11150)

7) Establishes CURES for the electronic monitoring of Schedule II, III and IV controlled substance prescriptions. CURES provides for the electronic transmission of Schedule II, III and IV controlled substance prescription information to the Department of Justice (DOJ) no more than seven days from the time prescriptions are dispensed. (HSC § 11165)

8) States that the purpose of CURES is to assist law enforcement and regulatory agencies in controlling diversion and abuse of Schedule II, III and IV controlled substances and for statistical analysis, education and research. (HSC § 11165 (a))

9) Establishes privacy protections for patient data and specifies that the operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations. Specifies that CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Specifies that data obtained from CURES can only be accessed by appropriate state, local and federal persons or public agencies for disciplinary, civil or criminal actions. Specifies that CURES data shall also only be provided, as determined by DOJ, to other agencies or entities for educating practitioners and others, in lieu of disciplinary, civil or criminal actions. Authorizes non-identifying CURES data to be provided to public and private entities for education, research, peer review and statistical analysis. Requires DOJ, by July 2020, to adopt regulations regarding the access and use of the information within CURES, in consultation with stakeholders, that address the process for approving, denying, and disapproving individuals or entities seeking

access to information in CURES; the purposes for which a health care practitioner may access information in CURES; the conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation and; the process by which information in CURES may be provided for educational, peer review, statistical, or research purposes. (HSC §§ 11165 (c) (1), (c) (2) (A), and (c) (3))

10) Requires DOJ to upgrade CURES to allow health information technology systems that meet certain patient privacy and data security requirements to interoperate with the database, allowing prescribers and dispensers to make queries through their electronic health record applications. (HSC § 11165.1)

11) Requires health care practitioners in receipt of a federal Drug Enforcement Administration (DEA) registration providing authorization to prescribe controlled substances, as well as pharmacists, to register for access to the CURES database. (HSC § 11165.1(a))

12) Authorizes a health care practitioner to provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and authorizes a health care practitioner to keep a copy of the report in the patient's medical record. (HSC § 11165 (c)(3))

13) Requires certain health care practitioners to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient, with certain exceptions. (HSC § 11165.4)

14) Establishes, pursuant to the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), certain requirements relating to the provision of health insurance, including provisions relating to the confidentiality of health records. HIPAA prohibits a covered entity that uses electronic means to perform HIPAA-covered transactions, from using or disclosing personal health information except pursuant to a written authorization signed by the patient or for treatment, payment, or health care operations. Notwithstanding those provisions, HIPAA allows a covered entity to maintain a directory of patients in its facility for specified purposes, and to disclose the protected health information of a patient to family members, relatives, or other persons identified by the patient, if certain conditions are met. Covered entities include health plans, health care clearinghouses, such as billing services and community health information systems, and health care providers that transmit health care data in a way that is regulated by HIPAA. HIPAA further provides that if its provisions conflict with a provision of state law, the provision that is most protective of patient privacy prevails. (Public Law 104–191, 104th Congress)

15) Prohibits, pursuant to the state Confidentiality of Medical Information Act (CMIA), a provider of health care, a health care service plan, a contractor, a corporation and its subsidiaries and affiliates, or any business that offers software or hardware to consumers, including a mobile application or other related device, as defined, from

intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. A violation of the provisions of this act that results in economic loss or personal injury to a patient is a crime. (Civil Code Sections (CC) 56, *et seq*.)

16) Defines, for purposes of the CMIA, "medical information" to mean "any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment." "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity." (CC § 56.05(g))

This bill:

1) States Legislative intent that state laws regarding the operation and use of prescription drug monitoring programs continue to empower health care-oriented technology solutions to the opioid crisis.

2) Expands the drugs required to be reported and monitored in CURES to include Schedule V controlled substances.

3) Delays the requirement for DOJ to adopt regulations regarding the access and use of the information within CURES until January 2020.

4) Adds the conditions under which an insurer providing workers' compensation coverage may access information in CURES for purposes of reviewing a workers' compensation claim, which shall at a minimum prohibit an insurer from using information obtained from the CURES database as the sole factor in evaluating a claim for approval or denial, to the issues that the regulations noted in 9) above must address.

5) Changes the required timeframe in which dispensers are required to report dispensed prescriptions from seven days to one working day. Clarifies that veterinarians are not subject to this timeframe and authorized to report information as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.

6) Authorizes a licensed physician and surgeon who does not hold a DEA registration to submit an application to obtain approval to access CURES information.

7) Clarifies patient activity report authority for individuals delegated by prescribers or dispensers to access information.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Counsel.

COMMENTS:

1. **Purpose.** The Author is the Sponsor of this bill. According to the Author, "Because prescriptions for Schedule V drugs have been deemed by the DEA to represent those regulated by the Controlled Substances Act with the lowest potential for abuse, an argument has been made that the state's PDMP has no need to track them. However, assertions that Schedule V drugs like cough syrup with codeine are not susceptible to abuse or diversion were ultimately proven to be drastically misguided. Abuse of prescription-strength cough syrup containing codeine exploded as recreational use of the drug became popularized by hip-hop culture. Referred to through common slang terms like "purple drank," "sizzurp," "lean," and "dirty sprite," it has been widely reported that the theft of cough syrup containing codeine is one of the most prevalent causes for pharmacy break-ins."

   The Author states that "consistently requiring dispensers to report all Schedule V drugs is the most straightforwardly implementable way of expanding existing reporting requirements for pharmacies…Tracking the drugs in the database will significantly assist health professionals, regulators, and law enforcement in investigating cases of theft and abuse among these controlled substances.

   "Reducing the amount of time provided to dispensers to report prescriptions to CURES from up to 7 days down to within the next business day will significantly improve the database's reliability for practitioners seeking to identify multi-prescriber seeking behavior among their patients. The change would not substantially change current practice for the vast majority of pharmacies. It will, however, ensure that doctor shoppers are not able to take advantage of a time delay when seeking to obtain multiple prescriptions."

   "With the state's PDMP query in place for thousands of physicians and other prescribers, a need has been identified to better integrate CURES data utilization within the clinical team environment. Empowering delegates with greater access to CURES will enable them to support physicians and streamline their review of patients' prescription histories so that practitioners may incorporate that information more smoothly into their assessment of a patient's needs."

   "Authorizing health care professionals to query CURES on behalf of workers compensation coverage providers will provide for additional safeguards against the abuse and diversion of prescription drugs, potentially saving patient lives by allowing for a more holistic understanding of a patient's prescription history when controlled substances reimbursements are being approved."

2. **Background.**

   Controlled Substances, PDMPs and CURES. Through the Controlled Substances Act of 1970, the federal government regulates the manufacture, distribution and dispensing of controlled substances. The act ranks into five schedules those drugs known to have potential for physical or psychological harm, based on three

considerations: (a) their potential for abuse; (b) their accepted medical use; and, (c) their accepted safety under medical supervision.

Schedule I controlled substances have a high potential for abuse and no generally accepted medical use such as heroin, ecstasy, and LSD.

Schedule II controlled substances have a currently accepted medical use in treatment, or a currently accepted medical use with severe restrictions, and have a high potential for abuse and psychological or physical dependence. Schedule II drugs can be narcotics or non-narcotic. Examples of Schedule II controlled substances include combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), morphine, methadone, Ritalin, Demerol, Percocet, Percodan, fentanyl and Oxycontin.

Schedule III and IV controlled substances have a currently accepted medical use in treatment, less potential for abuse but are known to be mixed in specific ways to achieve a narcotic-like end product. Examples include Tylenol with codeine, testosterone, Xanax, Ambien and other anti-anxiety drugs.

Schedule V drugs have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.

With rising levels of prescription drug abuse, prescription drug monitoring programs (PDMPs) assist law enforcement and regulatory bodies with their efforts to reduce drug abuse and diversion. In California, CURES is an electronic tracking program that reports all pharmacy (and specified types of prescriber) dispensing of certain schedules of controlled drugs by drug name, quantity, prescriber, patient, and pharmacy. Data from CURES is managed by DOJ. Information tracked in CURES contains the patient name, prescriber name, pharmacy name, drug name, amount and dosage, and is available to law enforcement agencies, regulatory bodies, prescribers, dispensers, and qualified researchers. CURES provides information to identify if a person is “doctor shopping” (when a patient, often a prescription-drug addict, visits multiple doctors to obtain multiple prescriptions for drugs, or uses multiple pharmacies to obtain prescription drugs). The system can also report on the top drugs prescribed for a specific time period, drugs prescribed in a particular county, doctor prescribing data, pharmacy dispensing data, and is a critical tool for assessing whether multiple prescriptions for the same patient may exist.

Every dispenser of controlled substances and every health practitioner authorized by the DEA to prescribe controlled substances is required to obtain a login for access to CURES. For each dispensed Schedule II, III, or IV drug, pharmacists and other dispensers are required to report basic information about the patient and their prescription within 7 days. This information is then made available to other system users in a variety of possible contexts. For example, physicians may query a patient’s prescription history prior to writing a new prescription; pharmacists can check the system before agreeing to fill a prescription for a controlled substance; regulators may review a licensee’s prescribing practices as part of a disciplinary

investigation; and law enforcement can incorporate a search of the system into a potential criminal case of drug diversion.

Over 50 million prescription records have been uploaded into the system by dispensers since the beginning of the CURES program. As of January 1, 2018, 170,422 users had been approved for access to the system. Last year, close to 10 million activity reports had been processed by practitioners, pharmacists, law enforcement, and regulatory users. The vast majority of these searches (over 99%) were queries made by prescribers and dispensers seeking to review a patient's prescription history as a component of exercising informed clinical judgment before providing access to opioids or other controlled substances.

Health practitioners are required to consult the CURES database prior to writing a prescription for a Schedule II, III, or IV drug for the first time, and then at least once every four months as long as the prescription continues to be renewed. Other recently enacted statutes require the DOJ to facilitate interoperability between health information technology systems and the CURES database, subject to a memorandum of understanding setting minimum security and privacy requirements.

As attention to the opioid crisis continues to grow, CURES and other PDMPs are regularly mentioned as powerful tools for curbing the abuse of prescription drugs.

3. **PDMP Access**. Information in CURES is not available to just anyone. Data can only be accessed by:

    - A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, and Schedule IV controlled substances;

    - Appropriate state, local and federal persons or public agencies for disciplinary, civil or criminal actions;

    - Other agencies or entities, as determined by DOJ, for educating practitioners and others, in lieu of disciplinary, civil or criminal actions; and

    - Non-identifying CURES data may be provided to public and private entities for education, research, peer review and statistical analysis

    The question of whether a warrant should be required for searches of CURES has extended into investigations by regulatory boards for purposes of disciplinary actions against licensees. This practice has existed since the early iterations of the database, though SB 482 (Lara, Chapter 708, Statutes of 2016) expressly limited DCA investigator searches to regulatory boards whose licensees prescribe, order, administer, furnish, or dispense controlled substances. Each month, DCA investigators run hundreds of activity reports – still a very small relative portion of overall user activity – to determine whether prescribers and other licensees are misusing their professional privileges. Regulatory user activity is virtually unfettered

and does not always result in the same type of auditable logging that other users incur when searching the system.

In 2008, the Medical Board of California (MBC) began an investigation into Dr. Alwin Carl Lewis, a licensed physician who recommended a controversial diet in which patients were encouraged to eat two meals consisting of only five bites of food each day. As part of this inquiry, MBC investigators ran a search for Dr. Lewis in CURES to determine if he had misused his prescribing privileges in addition to offering questionable nutritional advice. The search resulted in MBC filing additional charges for overprescribing. Dr. Lewis immediately sought to have the overprescribing charges dismissed on the basis that because the allegations against him relating to his diet recommendations were irrelevant to his drug prescribing history, the MBC did not have good cause to conduct the CURES search without a warrant.

Years of litigation resulted from this dispute. Dr. Lewis's objections to the CURES search were rejected by an administrative law judge, the Los Angeles County Superior Court, and the Court of Appeal, respectively. Eventually, the case was granted review by the Supreme Court of California in *Lewis v. Superior Court*. The Court conducted a thorough analysis of the Legislature's intent in creating CURES, the privacy rights implicated by searches of the system, and whether the MBC had violated any state or federal protections in its use of the database to investigate Dr. Lewis.

In its opinion issued in July of 2017, the Court ruled in favor of the MBC. The Court found that patients did indeed have a privacy interest in their prescription records, and that the MBC's search encroached upon this interest. However, the Court held that "even assuming the Board's actions constituted a serious intrusion on a legally protected privacy interest, its review of these records was justified by the state's dual interest in protecting the public from the unlawful use and diversion of a particularly dangerous class of prescription drugs and protecting patients from negligent or incompetent physicians." The balancing test employed by the Court in Lewis reflects generally the priorities that must be weighed for any CURES policies invoking patient privacy rights.

The use of CURES data remains a sensitive issue. A *Los Angeles Times* series, "Dying For Relief," highlighted the role of prescription drugs in overdose deaths as determined through the examination of coroners' reports. Reporters conducted an analysis of coroners' reports for over 3000 deaths occurring in four counties (Los Angeles, Orange, Ventura and San Diego) where toxicology tests found a prescription drug in the deceased's system, usually a painkiller, anti-anxiety drug or other narcotic; coroners' investigators reported finding a container of the same medication bearing the doctor's name, or records of a prescription; the coroner determined that the drug caused or contributed to the death. The analysis found that in nearly half of the cases where prescription drug toxicity was listed as the cause of death, there was a direct connection to a prescribing physician. The Times created a database linking overdose deaths to the doctors who prescribed drugs, and found that more than 80 of the doctors whose names were listed on prescription bottles found at the home of or on the body of a decedent had been the

prescribing physician for 3 or more dead patients. Their analysis found that one doctor was linked to as many as 16 dead patients.

Following the veto of 2013 legislation (SB 62, Lieu), which was introduced in response to the series, and that would have required coroners in California to report to the Medical Board of California (MBC) when they receive information, based on findings that were reached by, or documented and approved by, a pathologist, indicating that the cause of death was due to a Schedule II, III, or IV drug, MBC entered into a data use agreement with the California Department of Public Health (CDPH) to receive death certificate data when the death was related to opioids. According to MBC's 2017-2018 annual report, the "death certificate project" uses information from death records to identify physicians that may be inappropriately prescribing opioids to their patients. MBC has used information from CDPH to investigate licensees who may have violated the law and has reviewed CURES prescription information, leading to matches of patients and prescribers. According to MBC, "the Board understands that just because a patient death occurred, it does not automatically mean the physician deviated from the standard of care or violated the Medical Practice Act. However, in cases where the Board determines a violation occurred, the Board takes appropriate action."

The response to this effort has not been entirely positive. A January 2019 Kaiser Health News article noted that "Critics of the project call it a 'witch hunt' and an 'inquisition.' Many doctors said it is causing them or their peers to refuse patients' legitimate requests for prescription painkillers out of fear their practices will come under disciplinary review."

4. **Related Legislation This Year**. AB 149 (Cooper, Chapter 4, Statutes of 2019) clarifies the specifications for the uniquely serialized number required in the printing of new prescription forms by security printers approved by the DOJ.

   AB 714 (Wood) would clarify current law requiring prescribers to offer a prescription for naloxone hydrochloride (NH) by specifying that the requirement only applies when an opioid or benzodiazepine is prescribed and exempts patients in inpatient facilities and patients who are terminally ill from having to receive the NH prescription and education on overdose prevention. (Status: *This measure is currently pending in the Senate Committee on Appropriations.*)

5. **Prior Related Legislation.** CURES has been the focus of ongoing discussions in the Legislature, as California and the nation face an epidemic of prescription drug abuse and related overdose deaths.

   SB 1240 (Stone) of 2018 would have expanded the drugs required to be reported and monitored in CURES to include all dangerous drugs and Schedule V controlled substances and would have required inclusion of a description of the diagnosis, condition, or purpose for which the prescription was issued and the directions for use to the list of information pharmacies are required to report to CURES for each prescription. (Status: *This bill died in the Senate Committee on Business and Professions.*)

AB 1751 (Low, Chapter 478, Statutes of 2018) provided a framework for CURES to connect with other states that comply with California's patient privacy and data security standards.

AB 1752 (Low) of 2018 included the provisions of this bill related to Schedule V controlled substances. (Status: *The measure was held under submission in the Senate Committee on Appropriations.*)

AB 1753 (Low, Chapter 479, Statutes of 2018) would limit the number of security printers authorized to manufacture prescription pads and linking uniquely serialized pads with CURES.

AB 2086 (Gallagher, Chapter 274, Statutes of 2018) would allow prescribers of controlled substances to review a list of patients for whom they are listed as being the prescriber.

AB 40 (Santiago, Chapter 607, Statutes of 2017) authorized an entity that operates a health information technology system to establish an integration with, and submit queries to CURES, on either a user-initiated basis or automated basis, according to certain requirements.

SB 641 (Lara) of 2016 would have prohibited the DOJ from releasing data in CURES to a law enforcement agency except pursuant to a warrant. (Status: *The measure did not move from the Assembly Committee on Public Safety.*)

SB 482 (Lara, Chapter 708, Statutes of 2016) required a health care provider authorized to prescribe, order, administer, or furnish a controlled substance to consult CURES prior to prescribing a Schedule II, III or IV drug to a patient for the first time and at least once every four months thereafter if the substance remains part of the patient's treatment. The bill provided exemptions from the responsibility to consult the CURES system, including while a patient is admitted to a certain type of facility, if a patient receives a non-refillable five-day supply or less prescription in conjunction with a surgery, and in the event of a technological failure or inability to access the CURES system.

SB 1258 (DeSaulnier) of 2014 would have made several changes to the ways that controlled substances are prescribed and tracked in the CURES and would have required medical providers to use electronic prescribing systems, would have required additional reporting of controlled substance prescribing, and would have placed additional restrictions on the prescribing of controlled substances. (Status: *The bill was held in the Senate Committee on Appropriations.*)

SB 809 (De Saulnier, Chapter 400, Statutes of 2013) established a funding mechanism to update and maintain CURES, required all prescribing health care practitioners to apply to access CURES information, and established processes and procedures for regulating prescribing licensees through CURES and securing private information.

SB 151 (Burton, Chapter 406, Statutes of 2003) made the CURES program permanent.

AB 2655 (Matthews, Chapter 345, Statutes of 2002) extended the CURES program to 2008 and provided access to CURES data by licensed health care providers.

SB 1308 (Committee on Business and Professions, Chapter 655, Statutes of 1999) extended the sunset date on the CURES program to July 1, 2003 and required DOJ to submit annual status reports on the program to the Legislature.

AB 3042 (Takasugi, Chapter 738, Statutes of 1996) established a three year pilot program, beginning in July 1997, for the electronic monitoring of prescribing and dispensing of Schedule II controlled substances.

3. **Arguments in Support.** According to the County of San Diego, "Misuse of prescription opioids contributes to the ongoing opioid epidemic and AB 528, by improving CURES reporting requirements from seven days to one working day, may help prevent misuse, addiction and overdose. Having access to real-time, up-to-date prescription information in CURES will help doctors and pharmacies quickly identify efforts to potentially misuse prescription medication."

   According to the California Medical Association, "Combatting California's opioid crisis requires the utilization of all types of available resources, one of those critical components being the CURES system. The system, however, is only as effective as a resource as the data contained within it. Currently, pharmacists have up to seven days to update the CURES system after dispensing a controlled substance to a patient. Under AB 528, pharmacists would be required to update the system within one working day of dispensing a controlled substance to a patient. AB 528 also contains critical fixes to the "mandatory check" requirement for physicians of the CURES system. These fixes ensure that physicians avoid duplicative work, such as logging into the system multiple times within the same day for the same patient, allow for delegates to actually pull the patient record from CURES, which is saved in the medical record and currently accessed by the delegate anyways, and removes onerous administrative requirements that do not serve to protect patients, but add time to appointments and additional overall costs to the healthcare system."

   The California Pharmacists Association (CPhA) supports this bill if it is amended. According to CPhA, "we are compelled to clarify how [CURES] works and the current inability to meet the objectives of the sponsors for immediate accessibility of information entered into CURES. The current system is not readily available to a dispensing pharmacy or capable of providing information entered into CURES data process available immediately. Information entered in the system requires the following steps:

   "1. A pharmacist must enter the information into the CURES system data repository for scrubbing or reformatting.

   "2. The information then goes through Atlantic Associates, Inc., a contracted prescription collection and data processing and analytics service. While

prescribers and pharmacists have an NPI (National Provider Identifier) numbers, patients have no unique or universal identifiers. Atlantic Associates uses the patient information from the prescription entered into the CURES Data base and uses an established algorithm to identify the patient for whom the prescription was dispensed. This process uses various data elements to attempt to identify a patient so that all relevant data is aggregated to the appropriate patient. There are numerous potential ways that the ability of the system to correctly identify the patient can be negatively impacted. This process generally takes multiple days.

"3. Upon completion of the process, Atlantic Associates then uploads the information into the CURES system. Based on this process there is functional "real time" information available in the data base.

"Today, this system requires the transmission of the information outside of the normal business processes of a pharmacy and does not allow a physician to review the data as part of their normal chart review process when examining a patient.

"While we support the goals of the bill, CPhA strongly objects to the inclusion of health plans access to the CURES system. CURES was not developed as a means for insurance companies to access patient's personal information for purposes of claims review. We believe this will reverse years of progress in protecting the privacy of Californians' medical information by allowing health plans to access this privileged information. CPhA respectfully requests an amendment to strike this language from the bill."

4. **Arguments in Opposition.** The American Civil Liberties Union of California is opposed to AB 528 unless it is amended. They argue that, "AB 528 would take large steps backwards in protecting the privacy of Californians' medical information by expanding the list of prescription medications that must be tracked in CURES. Additionally, CURES may fall outside of the state and federal medical privacy statutes because neither the database itself nor the DOJ, which administers the CURES database, fall under any of the categories of entities that must keep medical information private, and thus these medical privacy laws may not provide privacy guarantees for the extremely sensitive information in CURES. By adding more prescriptions to CURES without addressing its privacy gaps, AB 528 would exempt from these privacy protections even more sensitive medical information for even more Californians." The ACLU cites examples of sensitive information that could be exposed, such as prescription testosterone injections revealing a person is a transgender man, prescriptions for anti-anxiety medications revealing a mental illness diagnosis, or a prescription for Marinol indication a person may be fighting weight loss associated with HIV/AIDS.

Additionally, the ACLU argues that the CURES database has existing privacy issues, thus its scope should not be expanded. They request amendments to add a warrant requirement to prevent various agencies from accessing personal information in CURES without probably cause and to delete the addition of schedule V drugs to the CURES database.

The California Dental Association is also in opposition to AB 528 unless it is amended. They argue that "Allowing workers' compensation companies to access the CURES database will do nothing to prevent opioid abuse, as claim denials will only determine whether a patient will need to pay out of pocket for a prescription and not whether the patient will be able to access the prescription. A workers' compensation company, if given access to CURES, will be able to review a patients' prescription history out of context and is irrelevant to the incident of care on which the claim is based….

"Permitting workers' compensation companies to determine whether a prescription for a controlled substance is inappropriate significantly changes the scope and purpose of the CURES system."

5. **Policy Questions and Suggested Amendments.**

What is the rationale for authorizing physicians and surgeons who do not hold a DEA registration to have access to CURES? CURES requirements and access privileges apply to a number of health care professionals who have the authority to prescribe and dispense controlled substances. Regulatory boards also use information from CURES to determine, pursuant to an investigation, whether prescriptions were issued and dispensed in accordance with the law and according to the standard of care for a specific profession. It would be helpful for the Committee to better understand the rationale for the changes proposed in this bill authorizing access to non-DEA authorized prescribers, as well as how DOJ will be able to determine whether a physician or surgeon is accessing information about "a patient under their care" as the bill allows. AB 2086 (Gallagher, Chapter 274, Statutes of 2018) already authorized a prescriber of controlled substances to review a list of patients for whom they are listed as being the prescriber in order to provide all prescribers, not just physician and surgeon prescribers, with the ability to have a clear picture of their patients' controlled substance prescription history. *Given that it is not clear how consumers, patients, and the public will benefit from authorizing "a licensed physician and surgeon who does not hold a DEA registration" to "electronically access information regarding the controlled substance history of the patient", and given that the provision only applies to physicians and surgeons while there are many other licensed health professionals with prescribing authority, the Author should continue to work with interested parties to determine the potential impacts stemming from this change and to provide a clear rationale for this new authority and this expanded CURES access.*

CURES access to private third-parties. By requiring the AG to address "The conditions under which an insurer providing workers' compensation coverage may access information in CURES for purposes of reviewing a workers' compensation claim…", this bill establishes a new precedent for access to CURES. Many entities have desired similar access, including pharmaceutical manufacturers seeking to have clearer information about prescriptions for their manufacturers. Given the significance of the potential implications to provide CURES access to private third parties, the bill should be amended to strike this authority according to the following:

On page 5, strike lines 7-10 inclusive.

~~The conditions under which an insurer providing workers' compensation coverage may access information in CURES for purposes of reviewing a workers' compensation claim, which shall at a minimum prohibit an insurer from using information obtained from the CURES database as the sole factor in evaluating a claim for approval or denial.~~

SUPPORT AND OPPOSITION:

Support:

American Property Casualty Insurance Association
California Academy of Child and Adolescent Psychiatry
California Academy of Family Physicians
California Chapter of the American College of Emergency Physicians
California Chiropractic Association
California Medical Association
California Narcotic Officers' Association
California Radiological Society
California Pharmacists Association
California State Board of Pharmacy
California Veterinary Medical Association
County Behavioral Health Directors Association
County of San Diego
Medical Board of California
Zenith Insurance Company

Opposition:

American Civil Liberties Union of California
California Dental Association

-- END --

AB 149 **(Cooper D) Controlled substances: prescriptions.**

Status: 3/11/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 4, Statutes of 2019.

Summary: Current law classifies certain controlled substances into designated schedules. Current law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the department, as specified. Current law requires those prescription forms to be printed with specified features, including a uniquely serialized number. This bill would delay the requirement for those prescription forms to include a uniquely serialized number until a date determined by the Department of Justice that is no later than January 1, 2020. The bill would require, among other things, the serialized number to be utilizable as a barcode that may be scanned by dispensers.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
S		AH, MS*	BJ*, LR	Pharmacy

AB 387 **(Gabriel D) Task force: adverse drug events: prescriptions.**

Status: 7/8/2019-From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (July 8). Re-referred to Com. on APPR.

Summary: Would create the Prescription Labeling and Adverse Drug Event Prevention Advisory Task Force, with membership as prescribed, to develop specified information and make recommendations to the boards and to the Legislature on the ways to increase adherence to prescription medication and decrease adverse drug events. The bill would require the task force to report on its findings and recommendations. The bill would require each board, following submission of the report, to adopt regulations to implement recommendations in the report that are within the jurisdiction of the relevant board to enact through regulation if, in the independent determination of the board, the regulations will achieve the goals of improving the patient opt-in process, increasing the prevalence of patient opt-in, and reducing the prevalence of adverse drug events.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		KAS*, MS	BJ	Medical Staff-Physician and Peer Review, Pharmacy

AB 528 **(Low D) Controlled substances: CURES database.**

Status: 7/5/2019-Withdrawn from committee. Re-referred to Com. on APPR.

Summary: Would require 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. The bill would similarly require the dispensing of a controlled substance included on Schedule V to be reported to the Department of Justice using the CURES database.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

AB 690 **(Aguiar-Curry D) Pharmacies: relocation: remote dispensing site pharmacy: pharmacy technician: qualifications.**

Status: 7/2/2019-Read second time. Ordered to third reading.

Summary: Would authorize relocation of a pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, if no changes are made to the management and control, or ownership, of the pharmacy, and all applicable laws and regulations are followed, and require that the board be notified of the relocation immediately upon identification of the new location. The bill would specify the qualifications for a registered pharmacy technician to work at a remote dispensing site pharmacy, relating to licensing, certification, education, and minimum work experience, including completion of at least 2,000 hours of experience within the previous 2 years.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

AB 714 **(Wood D) Opioid prescription drugs: prescribers.**

Status: 7/2/2019-Read second time. Ordered to third reading.

Summary: Current law requires a prescriber, as defined, to offer to a patient a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression when certain conditions are present, including if the patient presents with an increased risk for overdose or a history of substance use disorder, and to provide education on overdose prevention to patients receiving a prescription and specified other persons. This bill would make those provisions applicable only to a patient receiving a prescription for an opioid or benzodiazepine medication, and would make the provisions specific to opioid-induced respiratory depression, opioid overdose, opioid use disorder, and opioid overdose prevention, as specified. The bill, among other exclusions, would exclude from the above-specified provisions requiring prescribers to offer a prescription and provide education prescribers when ordering medications to be

administered to a patient in an inpatient or outpatient setting.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
S		AH, MS*	BJ	Pharmacy

AB 824 **(Wood D) Business: preserving access to affordable drugs.**

Status: 7/11/2019-Read second time and amended. Re-referred to Com. on APPR.

Summary: Would provide that an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, is to be presumed to have anticompetitive effects if a nonreference drug filer receives anything of value, as defined, from another company asserting patent infringement and if the nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time, as specified.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

AB 973 **(Irwin D) Pharmacies: compounding.**

Status: 7/11/2019-Read third time. Passed. Ordered to the Assembly. (Ayes 39. Noes 0.). In Assembly. Concurrence in Senate amendments pending. May be considered on or after August 9 pursuant to Assembly Rule 77.

Summary: Would require the compounding of drug preparations by a pharmacy for furnishing, distribution, or use to be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The bill, by imposing a new requirement on pharmacies, the violation of which would be a crime, would impose a state-mandated local program. The bill would authorize the board to adopt regulations to impose additional standards for compounding drug preparations.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

AB 1468 **(McCarty D) Opioid Prevention and Rehabilitation Act.**

Status: 5/20/2019-Read second time. Ordered to third reading.

Summary: Would, commencing with the 2021–22 fiscal year, require a manufacturer or wholesaler, as defined, that sells or distributes opioid drugs in this state to submit to the State Department of Public Health a report, including specified information, that details all opioid drugs sold or distributed in this state during the preceding fiscal year. The bill would, commencing with the 2021–22 fiscal year, require the department, in consultation with the board, to calculate the ratable share of a manufacturer or wholesaler, which is the individual portion of the collective sum of $50,000,000 or a lesser amount, as specified, to be paid by the manufacturers and wholesalers, based on the information reported, without double-counting the opioid drug if both a manufacturer and a wholesaler sold or distributed the drug in this state.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MR, MS*	BJ	Pharmacy

AB 1803 **(Committee on Health) Pharmacy: health care coverage: claims for prescription drugs sold for retail price.**

Status: 7/8/2019-Enrolled and presented to the Governor at 3:30 p.m.

Summary: The Pharmacy Law requires a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, except as specified, and, if the customer pays the retail price, requires the pharmacy to submit the claim to the customer's health care service plan or health insurer. This bill would instead make the provision requiring the pharmacy to submit the claim to the health care service plan or health insurer operative on January 1, 2020. The bill would also repeal a provision that is similar to the provision being amended by the bill.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	AK	Medi-Cal Managed Care, Pharmacy

ACR 105 **(Chiu D) Prescription drug prices.**

Status: 7/3/2019-From committee: Be adopted, and re-refer to Com. on APPR. Re-referred. (Ayes 11. Noes 0.) (July 2). Re-referred to Com. on APPR.

Summary: This measure would state the Legislature's commitment to lower the cost of prescription drugs for all Californians and to support the expansion of California's single-purchaser system for prescription drugs, and would encourage the Governor to engage with the States of Washington and Oregon and others who wish to partner with our state to lower prescription drug prices across the

nation.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
PR		MS	BJ	Pharmacy

SB 159 **(Wiener D) HIV: preexposure and postexposure prophylaxis.**

Status: 7/11/2019-From committee: Do pass as amended and re-refer to Com. on APPR. with recommendation: To consent calendar. (Ayes 13. Noes 0.) (July 9).

Summary: Would authorize a pharmacist to furnish preexposure prophylaxis and postexposure prophylaxis in specified amounts and would require a pharmacist to furnish those drugs if certain conditions are met, including that the pharmacist determines the patient meets the clinical criteria for preexposure prohylaxis or postexposure prophylaxis consistent with federal guidelines. The bill would require a pharmacist, before furnishing preexposure prophylaxis or postexposure prophylaxis, to complete a training program approved by the board. Because a violation of these requirements would be a crime, this bill would impose a state-mandated local program.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

SB 377 **(McGuire D) Juveniles: psychotropic medications: medical information.**

Status: 7/9/2019-From committee: Do pass and re-refer to Com. on APPR. (Ayes 19. Noes 0.) (July 9). Re-referred to Com. on APPR.

Summary: Current law requires the Medical Board of California to review specified data provided by the State Department of Health Care Services and the State Department of Social Services regarding Medi-Cal physicians and their prescribing patterns of psychotropic medications and related services for dependents and wards of the juvenile court in order to determine if any potential violations of law or excessive prescribing of psychotropic medications inconsistent with the standard of care exist and, if warranted, to conduct an investigation. This bill would require, by July 1, 2020, the forms developed by the Judicial Council to include a request for authorization by the child or the child's attorney to release the child's medical information to the Medical Board of California in order to ascertain whether there is excessive prescribing of psychotropic medication inconsistent with a specified standard of care.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH*, MS	LR, SL*	Chemical/Substance Abuse, Pharmacy

SB 569 **(Stone R) Controlled substances: prescriptions: declared local, state, or federal emergency.**

Status: 7/2/2019-Read second time and amended. Re-referred to Com. on APPR.

Summary: Would authorize a pharmacist, during a declared local, state, or federal emergency pursuant to which the California State Board of Pharmacy issues a notice that the board is waiving the application of the provisions of the Pharmacy Law, to fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the declared local, state, or federal emergency, regardless of whether the prescription form meets the above-specified requirements, if certain other requirements are met, including that the prescription is written and dispensed within the first 2 weeks of the notice issued by the board.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
S		AH, MS*	BJ	Pharmacy

SB 624 **(Wilk R) Qualified medical supplies providers: sales taxes: repayment.**

Status: 5/16/2019-May 16 hearing: Held in committee and under submission.

Summary: Would provide a procedure for a qualified medical supplies provider to submit a claim for qualified repayments, as defined, with the California Department of Tax and Fee Administration, as provided. The bill would define a qualified medical supplies provider to mean a pharmacy or durable medical equipment provider enrolled in Medi-Cal who, among other things, paid sales taxes imposed under the Sales and Use Tax Law and the California Constitution for sales of medical supplies or equipment furnished to Medi-Cal beneficiaries occurring during the period beginning June 1, 2011, and before November 1, 2013, for which a portion of payments from Medi-Cal for those sales, which included applicable sales tax reimbursement, was paid back to the State Department of Health Care Services by the pharmacy or durable medical equipment provider due to the reduction of Medi-Cal payment by specified law.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH*, BG	RW	Medi-Cal Managed Care, Pharmacy

SB 642 **(Stone R) Pharmacy benefit management: Prescription Acquisition and Adjudication Agency.**

Status: 4/24/2019-Re-referred to Com. on HEALTH.

Summary: Would, on and after July 1, 2021, prohibit a health care service plan or a health insurer from

entering into, renewing, or extending a contract for pharmacy benefit manager services, as specified.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH*, MS	AK*, BJ	Pharmacy

SB 650 **(Rubio D) Cancer Medication Advisory Committee.**

Status: 7/8/2019-Read second time and amended. Re-referred to Com. on APPR.

Summary: Would require the California State Board of Pharmacy to establish the Cancer Medication Advisory Committee for the purpose of identifying the best mechanism to enable the transfer of unused cancer medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would require the committee to be composed of 9 specified members and would require members of the committee to serve without compensation.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

SB 655 **(Roth D) Pharmacy.**

Status: 7/11/2019-Read second time. Ordered to consent calendar.

Summary: The Pharmacy Law provides for the licensing and regulation of pharmacists and pharmacies by the California State Board of Pharmacy in the Department of Consumer Affairs. That law authorizes a pharmacy technician trainee to be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacist. That law prohibits the externship from being for a period of more than 120 hours, except if a pharmacy technician trainee's externship involves the rotation between a community pharmacy and a hospital pharmacy, in which case the externship is authorized to be for a period of up to 320 hours. That law prohibits more than 120 hours of the 320 hours from being completed in a community pharmacy setting or in a single department in a hospital pharmacy. This bill would instead require the externship to be for a period of no fewer than 120 hours and no more than 140 hours.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

Total Measures: 17
Total Tracking Forms: 17

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Coalition Informational Packet

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a looming public health crisis for California

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IMPENDING RULE CHANGE
THREATENS ACCESS TO LIFE-SAVING MEDICINES

THE PROBLEM

The Department of Health Care Services' decision to implement **new Medi-Cal reimbursement rules,** adopted by the Brown Administration, and pursue two years of retroactive payments on Medi-Cal claims, will bankrupt many community pharmacies and eliminate an important health care safety net for California's most vulnerable populations.

IMPACTS ON PATIENTS

California's most vulnerable Medi-Cal beneficiaries – roughly 3 million people – stand to lose access to their life-saving medicines for HIV/AIDS, mental illness and cancer as well as those who are in long-term care facilities.

IMPACTS ON PHARMACIES

The new rules will force many smaller community-based pharmacies to choose between serving Medi-Cal patients and closing their doors.

IMPACTS ON COMMUNITIES

The rules will result in a catastrophic loss of local, community pharmacies, who have historically been the most accessible healthcare provider to Medi-Cal beneficiaries, while also burdening hospitals with increased ER wait times.

J O I N U S

Ask Governor Newsom to intervene and stop a public health crisis from developing as a result of these rules.

Go to **www.rx-fairness.org** for more information.

Cost Impact of NADAC* to Independent Community Pharmacies

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*NADAC is defined as National Average Drug Acquisition Cost

NEW MEDI-CAL REIMBURSEMENT RULES: The new methodology developed by the California Department of Health Care Services will result in denying life-saving medicines for Medi-Cal patients, resulting in catastrophic reductions to Medi-Cal reimbursement rates for hundreds of locally owned pharmacies that serve Medi-Cal patients. DHCS announced it is collecting two years of retroactive payments from community pharmacies that currently serve Medi-Cal patients, dating back to April 2017.

1 • Pharmacies purchase medicines at wholesale price.

2 • Pharmacies furnish medicines to Medi-Cal** patients.

3 • Pharmacies submit claims to Medi-Cal** for reimbursement.

4 • Medi-Cal** reimburses pharmacies less than the wholesale purchase price.

5 • Medi-Cal** also collects retroactive difference from the last 2 years through clawback.

RESULT: Pharmacies close their doors or stop furnishing medicines to patients.

**Medi-Cal is administered by the Department of Health Care Services (DHCS).

WHAT DOES THIS MEAN?

Approximately 3 million medically-fragile beneficiaries stand to lose access to their essential, life-saving medicines. Particularly those patients with: behavioral health issues, HIV, cancer, and those who are in long-term care facilities. The new state rules will bankrupt many community pharmacies, effectively eliminating this important health care safety net for California's most vulnerable populations.

ACTUAL PHARMACY COSTS VS. MEDI-CAL PAYMENTS

Drug	Quantity	Pharmacy Cost to Acquire	Medi-Cal Payments	Pharmacy Loss	
Abilify 30 mg (Behavioral Health)	30 count	$1,232.96	$1,223.20	-$9.76	Loss to pharmacy to furnish this medication to one patient for one year = $(117.12)
Abilify Maintena ER 400 mg (Behavioral Health)	1 dose	$2,096.00	$2,090.14	-$5.86	
Latuda 80 mg (Behavioral Health)	30 count	$1,192.82	$1,765.33	-$4.40	
Ziprasidone 60 mg (Behavioral Health)	60 count	$81.40	$36.97	-$44.43	
Aristada 441 mg/1.6 mL (Behavioral Health)	1 dose	$1,242.29	$1,178.02	-$64.27	
Aristada 882 mg (Behavioral Health)	28 count	$2,448.99	$2,380.99	-$68.00	Loss to pharmacy to furnish this medication to one patient for one year = $(816.00)
Aristada 1064 mg/3.9 mL (Behavioral Health)	1 dose	$2,912.45	$2,851.14	-$61.31	
Invega Trinza 410/1,315 mL (Behavioral Health)	1 dose	$3,881.01	$3,870.21	-$10.80	
Invega Trinza 819/2,625 mL (Behavioral Health)	1 dose	$7,762.18	$7,730.25	-$31.93	
Atripla 600/200/300 mg (HIV)	30 count	$2,786.12	$2,775.85	-$10.27	Loss to pharmacy to furnish this medication to one patient for one year = $(123.24)
Symtuza 800-150-200-10 mg (HIV)	15 doses	$3,601.29	$3,587.03	-$14.26	
Triumeq 600/50/300 mg (HIV)	30 count	$2,817.13	$2,808.01	-$9.12	

the impact of community pharmacy closure on patients with a behavioral health condition

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THE PROBLEM

Any mental illness defined as a mental, behavioral or emotional disorder, and can vary in impact—ranging from no impairment to mild, moderate, and even severe impairment.

Serious mental illness is defined as a mental, behavioral or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.

Mental illnesses include those that are diagnosable currently or within the past year; of sufficient duration to meet diagnostic criteria specified within the 4th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV); and, exclude developmental and substance use disorders.

The Department of Health Care Services' decision to implement new Medi-Cal reimbursement rules, adopted by the Brown Administration, and pursue two years of retroactive payments on Medi-Cal claims, will bankrupt many community pharmacies and eliminate an important health care safety net for California's most vulnerable populations.

Join Us: Ask Governor Newsom to intervene and stop a public health crisis from developing as a result of these rules.

Counties	Population*	Annual Percentage: Any Mental Illness in the Past Year among Adults Aged 18 or Older**	Annual Percentage: Serious Mental Illness in the Past Year among Adults Aged 18 or Older**	Annual Percentage: Received Mental Health Services in the Past Year among Adults Aged 18 or Older**	Number of Independent Community Pharmacies***
All	39,250,017	17.36%	3.62%	11.75%	2233
Butte, Colusa, Del Norte, Glenn, Humboldt, Lake, Lassen, Mendocino, Modoc, Plumas, Shasta, Sierra, Siskiyou, Tehama, Trinity	952,998	19.90%	4.45%	13.93%	66
El Dorado, Nevada, Placer, Sutter, Yolo, Yuba	1,052,991	18.71%	3.86%	14.30%	34
Sacramento	1,514,460	18.00%	3.58%	12.39%	46
Marin, Napa, Solano, Sonoma	1,346,094	15.82%	3.30%	13.29%	38
San Francisco	870,887	19.19%	4.06%	14.05%	26
Santa Clara	1,919,402	15.66%	3.29%	11.21%	57
Contra Costa	1,135,127	18.15%	3.40%	12.45%	18
Alameda	1,647,704	18.91%	3.95%	12.86%	55
San Mateo	764,797	15.81%	3.08%	12.09%	23
Santa Barbara, Ventura	1,295,908	17.18%	3.93%	12.94%	72
Los Angeles County	10,137,915	17.09%	3.56%	11.18%	902
Alpine, Amador, Calaveras, Mono, San Joaquin, Tuolumne	885,119	17.85%	3.79%	10.87%	30
Imperial, Riverside	2,568,624	17.21%	3.57%	11.18%	133
Orange	3,172,532	16.28%	3.43%	10.95%	296
Fresno	979,915	17.95%	3.75%	10.59%	45
San Diego	3,317,749	18.00%	3.70%	12.14%	127
Inyo, Kern, Kings, Tulare	1,513,154	17.67%	3.84%	11.22%	73
San Bernardino	2,140,096	16.94%	3.50%	10.48%	128
Madera, Mariposa, Merced, Stanislaus	982,339	18.72%	3.87%	11.19%	30
Monterey, San Benito, San Luis Obispo, Santa Cruz	1,052,206	16.57%	3.65%	12.23%	34

* based on US Census Data Estimates for July 2016

**Annual Average Percentages Based on 2014, 2015, and 2016 National Surveys on Drug Use and Health (NSDUHs) From: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2014, 2015, and 2016.

*** As of June 30, 2018, Board of Pharmacy

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patients at risk with community pharmacy closure

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County	Independent Community Pharmacies	Patients Diagnosed with: HIV*	Cancer**
Alameda	55	6,419	6,485
Alpine	0	2	-
Amador	1	219	261
Butte	0	273	4,181
Calaveras	3	45	295
Colusa	2	11	63
Contra Costa	18	2,648	5,314
Del Norte	0	26	156
El Dorado	4	196	1,102
Fresno	45	1,969	3,406
Glenn	2	22	142
Humboldt	10	230	659
Imperial	13	329	689
Inyo	2	21	123
Kern	46	1,672	3,117
Kings	6	182	385
Lake	7	146	423
Lassen	1	26	115
Los Angeles	897	51,487	38,305
Madera	3	192	613
Marin	9	813	1,631
Mariposa	1	18	102
Mendocino	7	180	468
Merced	13	294	835
Modoc	0	1	63
Mono	0	8	57
Monterey	12	730	1,640
Napa	5	273	778
Nevada	4	124	671
Orange	296	7,294	13,388
Placer	0	350	2,110
Plumas	10	19	121
Riverside	120	9,017	9,608
Sacramento	46	4,405	6,744
San Benito	1	50	244
San Bernardino	128	4,401	7,656
San Diego	127	13,900	13,625
San Francisco	26	13,072	3,865
San Joaquin	23	1,344	2,792
San Luis Obispo	15	424	1,560
San Mateo	23	656	3,570
Santa Barbara	15	544	2,026
Santa Clara	57	3,502	7,319
Santa Cruz	6	526	1,229
Shasta	11	220	1,237
Sierra	1	5	17
Siskiyou	3	62	249
Solano	6	1,317	2,060
Sonoma	18	1,490	2,712
Stanislaus	13	776	2,088
Sutter	6	90	417
Tehama	6	51	386
Trinity	1	19	92
Tulare	19	448	1,379
Tuolumne	3	47	369
Ventura	62	1,122	3,905
Yolo	5	284	755
Yuba	4	91	318
Licensed, working outside California		N/A	
TOTAL	2233	134,082	160,920

*As of 2017.

**These numbers represent actual cancer cases diagnosed in 2014, the year for which most recent data is available. Counts of 10 or less are suppressed.

IMPACTS ON PATIENTS

California's most vulnerable Medi-Cal beneficiaries – roughly 3 million people – stand to lose access to their life-saving medicines for HIV/AIDS, behavioral health and cancer as well as those who reside in long-term care facilities.

IMPACTS ON COMMUNITIES

The rules will result in a catastrophic loss of independent community pharmacies, who have historically been the most accessible healthcare provider to Medi-Cal beneficiaries, while also burdening hospitals with increased ER wait times.

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The new rules will force many smaller independent community-based pharmacies to choose between serving Medi-Cal patients and closing their doors.

Join Us: Ask Governor Newsom to intervene and stop a public health crisis from developing as a result of these rules.

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pharmacies and pharmacists by assembly district

californians for access to life-saving medicine

A PRESCRIPTION FOR FAIRNESS

		Independent Community Pharmacies		
		Pharmacists		Population of District
1	Assembly Member Dahle	336	26	466,514
2	Assembly Member Wood	367	26	463,404
3	Assembly MemberGallagher	297	30	468,983
4	Assembly Member Aguiar-Curry	308	16	466,385
5	Assembly Member Bigelow	284	16	463,049
6	Assembly Member Kiley	795	11	468,939
7	Assembly Member McCarty	665	18	464,310
8	Assembly Member Cooley	599	16	463,773
9	Assembly Member Cooper	765	16	468,512
10	Assembly Member Levine	439	17	465,831
11	Assembly Member Frazier	338	6	466,986
12	Assembly Member Heath	322	13	461,766
13	Assembly Member Eggman	475	17	461,772
14	Assembly Member Grayson	478	6	466,848
15	Assembly Member Wicks	552	15	469,144
16	Assembly Member Bauer-Kahan	1001	11	465,945
17	Assembly Member Chiu	806	15	467,501
18	Assembly Member Bonta	475	18	469,665
19	Assembly Member Ting	727	16	467,767
20	Assembly Member Quirk	680	18	461,362
21	Assembly Member Gray	199	17	461,301
22	Assembly Member Mullin	719	14	462,734
23	Assembly Member Patterson	574	23	468,185
24	Assembly Member Berman	553	12	464,599
25	Assembly Member Chu	595	11	461,206
26	Assembly Member Mathis	311	21	470,166
27	Assembly Member Kalra	581	17	464,103
28	Assembly Member Low	717	17	466,090
29	Assembly Member Stone	352	14	465,870
30	Assembly Member Rivas	240	15	465,431
31	Assembly Member Arambula	293	23	468,265
32	Assembly Member Salas	153	21	466,850
33	Assembly Member Obernolte	154	25	423,391
34	Assembly Member Fong	353	29	466,780
35	Assembly Member Cunningham	374	24	467,334
36	Assembly Member Lackey	170	17	463,038
37	Assembly Member Limón	308	24	465,431
38	Assembly Member Smith	290	40	469,883
39	Assembly Member Rivas	360	65	466,422
40	Assembly Member Ramos	508	39	462,470

		Independent Community Pharmacies		
		Pharmacists		Population of District
41	Assembly Member Holden	635	42	462,507
42	Assembly Member Mayes	415	37	462,952
43	Assembly Member Friedman	512	104	468,406
44	Assembly Member Irwin	433	36	462,271
45	Assembly Member Gabriel	760	98	467,766
46	Assembly Member Nazarian	436	60	464,441
47	Assembly Member Reyes	239	22	470,257
48	Assembly Member Rubio	345	31	461,346
49	Assembly Member Chau	1280	68	462,545
50	Assembly Member Bloom	489	62	470,048
51	Assembly Member Carrillo	460	17	465,643
52	Assembly Member Rodriguez	240	37	465,678
53	Assembly Member Santiago	301	24	463,916
54	Assembly Member Kamlager-Dove	458	25	466,445
55	Assembly Member Chen	1162	31	461,696
56	Assembly Member Garcia	150	23	465,302
57	Assembly Member Calderon	446	32	465,845
58	Assembly Member Garcia	455	46	468,258
59	Assembly Member Jones-Sawyer	452	20	465,168
60	Assembly Member Cervantes	434	24	470,287
61	Assembly Member Medina	217	28	470,325
62	Assembly Member Burke	280	27	466,713
63	Assembly Member Rendon	316	28	461,153
64	Assembly Member Gipson	376	19	466,400
65	Assembly Member Quirk-Silva	756	35	461,510
66	Assembly Member Muratsuchi	738	34	467,745
67	Assembly Member Melendez	266	14	462,769
68	Assembly Member Choi	789	32	463,053
69	Assembly Member Daly	492	51	465,317
70	Assembly Member O'Donnell	350	31	468,514
71	Assembly Member Voepel	350	13	462,584
72	Assembly Member Diep	1089	91	469,933
73	Assembly Member Brough	645	27	461,101
74	Assembly Member Petrie-Norris	1008	44	470,248
75	Assembly Member Waldron	366	20	465,548
76	Assembly Member Horvath	463	17	468,627
77	Assembly Member Maienschein	680	24	464,066
78	Assembly Member Gloria	745	23	461,885
79	Assembly Member Weber	555	22	466,416
80	Assembly Member Gonzalez	480	19	464,602

THE PROBLEM

The Department of Health Care Services' decision to implement new Medi-Cal reimbursement rules, adopted by the Brown Administration, and pursue two years of retroactive payments on Medi-Cal claims, will bankrupt many community pharmacies and eliminate an important health care safety net for California's most vulnerable populations.

DID YOU KNOW?

Pharmacists are among the most accessible and approachable healthcare providers available to Californians, particularly for underserved populations:

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patients at risk with community pharmacy closure

californians for access to life-saving medicine

A PRESCRIPTION FOR FAIRNESS

County	Independent Community Pharmacies	Patients Diagnosed with: HIV*	Cancer**
Alameda	55	6,419	6,485
Alpine	0	2	-
Amador	1	219	261
Butte	0	273	4,181
Calaveras	3	45	295
Colusa	2	11	63
Contra Costa	18	2,648	5,314
Del Norte	0	26	156
El Dorado	4	196	1,102
Fresno	45	1,969	3,406
Glenn	2	22	142
Humboldt	10	230	659
Imperial	13	329	689
Inyo	2	21	123
Kern	46	1,672	3,117
Kings	6	182	385
Lake	7	146	423
Lassen	1	26	115
Los Angeles	897	51,487	38,305
Madera	3	192	613
Marin	9	813	1,631
Mariposa	1	18	102
Mendocino	7	180	468
Merced	13	294	835
Modoc	0	1	63
Mono	0	8	57
Monterey	12	730	1,640
Napa	5	273	778
Nevada	4	124	671
Orange	296	7,294	13,388
Placer	0	350	2,110
Plumas	10	19	121
Riverside	120	9,017	9,608
Sacramento	46	4,405	6,744
San Benito	1	50	244
San Bernardino	128	4,401	7,656
San Diego	127	13,900	13,625
San Francisco	26	13,072	3,865
San Joaquin	23	1,344	2,792
San Luis Obispo	15	424	1,560
San Mateo	23	656	3,570
Santa Barbara	15	544	2,026
Santa Clara	57	3,502	7,319
Santa Cruz	6	526	1,229
Shasta	11	220	1,237
Sierra	1	5	17
Siskiyou	3	62	249
Solano	6	1,317	2,060
Sonoma	18	1,490	2,712
Stanislaus	13	776	2,088
Sutter	6	90	417
Tehama	6	51	386
Trinity	1	19	92
Tulare	19	448	1,379
Tuolumne	3	47	369
Ventura	62	1,122	3,905
Yolo	5	284	755
Yuba	4	91	318
Licensed, working outside California		N/A	
TOTAL	2233	134,082	160,920

*As of 2017.

**These numbers represent actual cancer cases diagnosed in 2014, the year for which most recent data is available. Counts of 10 or less are suppressed.

IMPACTS ON PATIENTS

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pharmacies & pharmacists by senate disctrict

californians for access to life-saving medicine
A PRESCRIPTION FOR FAIRNESS

District	Senator	Pharmacists	Independent Community Pharmacies by District
1	VACANT	986	39
2	Senator McGuire	766	48
3	Senator Dodd	791	42
4	Senator Nielsen	772	35
5	Senator Galgiani	858	29
6	Senator Pan, MD	1,472	39
7	Senator Glazer	1,373	17
8	Senator Borgeas	887	43
9	Senator Skinner	875	33
10	Senator Wieckowski	1,162	31
11	Senator Wiener	1,515	31
12	Senator Caballero	522	36
13	Senator Hill	1,222	28
14	Senator Hurtado	610	31
15	Senator Beall	1,287	35
16	Senator Grove	600	55
17	Senator Monning	766	32
18	Senator Hertzberg	955	144
19	Senator Jackson	726	49
20	Senator Leyva	690	59
21	Senator Wilk	841	47
22	Senator Rubio	955	94
23	Senator Morrell	679	67
24	Senator Durazo	955	56
25	Senator Portantino	927	145
26	Senator Allen	945	71
27	Senator Stern	918	127
28	Senator Stone, PharmD	692	48
29	Senator Chang	1613	64
30	Senator Mitchell	945	46
31	Senator Roth	676	52
32	Senator Archuleta	998	81
33	VACANT	945	60
34	Senator Umberg	1,794	134
35	Senator Bradford	956	49
36	Senator Bates	932	34
37	Senator Moorlach	1,803	79
38	Senator Jones	1,017	29
39	Senator Atkins	1,288	54
40	Senator Hueso	851	40

THE PROBLEM

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COMMITTEES
CHAIR: HEALTH
BUDGET
HOUSING AND COMMUNITY DEVELOPMENT
JOINT LEGISLATIVE AUDIT
WATER, PARKS, AND WILDLIFE

SUBCOMMITTEE
BUDGET SUBCOMMITTEE NO. 1 ON HEALTH AND HUMAN SERVICES

SELECT COMMITTEE
HEALTH CARE DELIVERY SYSTEMS AND UNIVERSAL COVERAGE

Assembly
California Legislature

JIM WOOD
ASSEMBLYMEMBER, SECOND DISTRICT

STATE CAPITOL
P.O. BOX 942849
SACRAMENTO, CA 94249-0002
(916) 319-2002
FAX (916) 319-2102

DISTRICT OFFICES
200 S SCHOOL STREET, SUITE D
UKIAH, CA 95482
(707) 463-5770
FAX (707) 463-5773

50 D STREET, SUITE 450
SANTA ROSA, CA 95404
(707) 576-2526
FAX (707) 576-2297

1036 5TH STREET, SUITE D
EUREKA, CA 95501
(707) 445-7014
FAX (707) 455-6607

May 23, 2019

Jennifer Kent
Director
Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Director Kent:

As chair of the Assembly Health Committee, I am writing to urge you to delay implementation of the new Department of Health Care Services (DHCS) actual acquisition cost payment methodology for pharmacy services in fee-for-service Medi-Cal, and not go forward with a proposed and detrimental "clawback" of prior year claims.

In the rural Assembly district I represent, I have heard from two family-owned pharmacies who have experienced below-cost Medi-Cal reimbursement for HIV and mental health medications. I have also heard similar complaints from physicians administering long-acting injectable mental health medications in several counties, and from community pharmacists in several other areas of the state, including pharmacies in San Diego, Kern, Pomona, Chino and Bakersfield.

My district already has great difficulty attracting and retaining health care providers. It is particularly egregious to ask small health care providers such as community pharmacies to provide medications at below cost reimbursement. In addition, recouping prior year claims for services provided under a reimbursement system that is retroactively applied is fundamentally unfair and amounts to changing the rules in the middle of the game.

The state is not acting in good faith as a business partner with Medi-Cal providers who are providing medications and services to low-income Californians who need these essential services. Going forward with this new rate methodology will result in low-income Medi-Cal beneficiaries who are in need of medications that address conditions such as HIV and behavioral health not being able to live full and productive lives because they will no longer have adequate access to these medically necessary medications.

I urge the Department of Health Care Services to revisit the actual acquisition cost methodology so that pharmacies can continue to provide these medications to patients, and to halt going forward with any recoupment of prior year claims.

Thank you for your consideration.

Sincerely,

JIM WOOD
Assemblymember, 2nd District

cc: Richard Figueroa, Governor's Office
Tam Ma, Governor's Office
Carol Gallegos, Deputy Director of Legislative and Governmental Affairs

california **pharmacists** association

May 30, 2019

The Honorable Holly Mitchell
Chair, Conference Committee on the Budget
State Capitol, Room 5019
Sacramento, CA 95814

Dear Chair Mitchell,

We are writing to you and the members of the Conference Committee on the Budget to raise an important issue regarding implementation of new Department of Health Care Services (DHCS) Medi-Cal pharmacy reimbursement rules. This new methodology will result in the denial of life-saving medicines to California's most vulnerable populations. These rules, promulgated by the previous Administration, are scheduled to take effect on May 31, 2019 and are going to devastate community pharmacies and the patients who rely on these specialty medications to treat HIV/AIDS, behavioral health, oncology and those in long term care.

This issue is both timely and urgent as the conference committee begins its work on the final budget. The new reimbursement formula designed by DHCS has a direct impact on the Governor's desire to move all pharmacy services to Fee For Service (FFS) under Executive Order N-01-19. CPhA is supportive of the Executive Order in concept, however, under the new rate structure pharmacies cannot provide medications to Medi-Cal beneficiaries at a loss on these specialty medications. This issue currently impacts the Medi-Cal beneficiaries in the Fee-For-Service program, therefore any policy to move pharmacy services to 100% FFS will greatly exacerbate the problem.

Background
The federal Centers for Medicare and Medicaid Services (CMS) adopted a rule in June 2016 charging states with changing the methodology for how pharmacies are reimbursed for dispensing prescription medicine to Medicaid beneficiaries. To implement the new federal rule, CMS required every state to adopt new rules but did not dictate how each state should establish or implement their programs.

In response to the federal mandate, the California Department of Health Care Services (DHCS) received approval from CMS for its methodology in 2017 and took over two years to officially implement the new rules in February 2019. Beginning in 2017, we objected to the new methodology as it was performed by the DHCS contractor, Mercer. The data collection and analysis performed by Mercer were inadequate and highly skewed. *Due to the complexity of the survey instrument, only three (3) specialty community pharmacies were included in the data set upon which policy decisions were decided.*

With program implementation beginning February 23, 2019, the result of these exclusions are now beginning to result in catastrophic underpayment to Medi-Cal reimbursement rates for hundreds of locally-owned, community pharmacies throughout California that serve

Medi-Cal patients. *Pharmacies are literally losing money each time they fill one of these specialty prescriptions.*

Additionally, because DHCS took two years to implement their methodology, they have announced that they will be recalculating all claims going back to April 2017 (the effective date) and are pursuing two years of retroactive recoupments from community pharmacies. This "clawback" will be disastrous for community pharmacies ability to continue to provide patients with these medications, and in many cases, those providers may be forced to close their practices completely.

The state's most medically-fragile Medi-Cal beneficiaries – roughly 3 million people – will be disproportionately affected and stand to lose access to their essential, life-saving medicines. As you know, many rural communities already have trouble attracting and retaining health care providers to serve their populations. We're sure you can imagine the tragic results that will occur from pharmacies closing down, especially considering that pharmacies are routinely the most accessible health care provider.

For a state that prides itself in leading in healthcare, this is a step backward and is inconsistent with the desire to expand Medi-Cal and achieve universal coverage. We hope you will consider intervening and prevent a public health crisis from developing as a result of these rules. From San Francisco to San Diego and in all parts of California, there will be casualties associated with this policy, unless the Legislature and the Administration steps in and makes a stand for access to life-saving medicines.

Should you have any questions regarding our request, please don't hesitate to contact me at (916) 779-1400 or at jroth@cpha.com. We appreciate your attention to this critical matter.

Sincerely,

Jon R. Roth, MS, CAE
Chief Executive Officer

Cc: The Honorable Phillip Ting, Vice Chair
The Honorable Jim Nielsen
The Honorable Richard D. Roth
The Honorable Nancy Skinner
The Honorable John M.W. Moorlach
The Honorable Kevin McCarty
The Honorable Chad Mayes
The Honorable Jay Obernolte
The Honorable Shirley Weber

Coalition Action Toolkit

Below is a list of actions you can take as a member of the Californians for Access to Life-Saving Medicines coalition.

1. **Sign the coalition letter to Governor Newsom.** Click here to review and sign the letter.
2. **Share this tweet**
    - *New state rules went into effect that will put millions of vulnerable Californians at risk of losing access to their life-saving medicines. We urge Gov. @GavinNewsom to delay the implementation of these rules. http://bit.ly/rxfairness #RxFairness #caleg*

3. **Record a video to urge the Governor to take action and send it to cpha@randlecommunications.com.** This video can be shot on a smartphone – whatever is easiest. Here are some suggested talking points, but feel free to customize it to your organization:
    - I'm [NAME] with [ORGANIZATION] and we're urging the Governor to intervene to stop new Medi-Cal reimbursement rules from taking effect on May 31
    - The California Department of Health Care Services will implement new Medi-Cal reimbursement rules on May 31 that will have severe impacts on California's most vulnerable Medi-Cal beneficiaries
    - Roughly 3 million people stand to lose access to life-saving medicines
    - The new rules will force many community pharmacies out of business and eliminate a critical safety net
    - Governor Newsom, please take action now

californians for access
to life-saving medicine
A PRESCRIPTION FOR FAIRNESS

Videos

Explainer Video

https://youtu.be/sNFJKq81j8Y

New style Video

https://youtu.be/-nD9pRn4f-4

Social Media Links

Facebook/Twitter: @capharm

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