Medication Safety Committee Meeting

October 10, 2018

California Hospital Association - Boardroom

1215 K Street, Ste 800

Sacramento, CA, 95814

Conference Call Option: 800-882-3610 Passcode: 4206832#

Meeting Book - Medication Safety Committee Meeting

AGENDA

10:00	I. CALL TO ORDER/INTRODUCTIONS Hanni		
	A. Committee Roster/Member Breakdown/Member Map		Page 4
	B. Committee Guidelines		Page 10
	C. 2019 Meeting Discussion		Page 14
10:15	II. MINUTES Hanni/Fong	Recommend: Approval	
	A. April 4, 2018 Meeting Minutes (corrections made)		Page 18
	B. July 11, 2018 Meeting Minutes		Page 22
10:20	III. OLD BUSINESS		
	A. FDA Stakeholder Meeting Bartleson/Keefe		Page 27
	B. CURES Update Bartleson		Page 41
	C. Sterile Compounding Grids Bartleson		Page 72
	D. Sterile Compounding Bartleson		Page 89
	E. Tubing Connectors Bartleson/Rogers		Page 136
	F. Narcotic Inventory Reconciliation Regulations Bartleson		Page 138
	G. Nursing and Sterile Compounding Bartleson		Page 139
12:00	IV. LUNCH		
12:30	V. NEW BUSINESS		
	A. SB 1254 Education and Implementation Bartleson/Shane		Page 140
1:00	VI. LEGISLATION		

A. Pharmacy Legislation
Bartleson

1:30 VII. STANDING REPORTS

A. Board of Pharmacy
Herold

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

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

D. Collaborative Alliance for Nursing Outcomes (CALNOC)

E. Association of California Nurse Leaders (ACNL)

F. CHPSO
Jaffe

G. California Association of Health Facilities (CAHF)

1:45 VIII. OTHER BUSINESS
All

IX. NEXT MEETING

2:00 X. ADJOURNMENT
Hanni

CHA MEDICATION SAFETY COMMITTEE
2018 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

Christine Low, Pharm.D
Director Medication Safety and Pharmacy Compliance
Scripps Green Hospital
10010 Campus Pointe Dr. CPC 102
San Diego, CA 92121
(858) 678-7112
low.christine@scrippshealth.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

Chris Patty, DNP, RN, CPPS
Medication Safety Specialist
Kaweah Delta Health Care District
400 West Mineral King Avenue
Visalia, CA 93291-6263
(559) 624-2630
cpatty@kdhcd.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
Medication Safety Manager
Palomar Medical Center Escondido
2185 Citracado Parkway
Escondido, CA 92029
(442) 281-2564
diana.schultz@palomarhealth.org

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

Dan B. Dong, Pharm.D, FCSHP
Regional Director
Kaiser Permanente
1800 Harrison St. 13th Fl
Oakland, CA 94612
(510) 625-6240
dan.b.dong@kp.org

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Boulevard
Sacramento, CA 95834
(916) 574-7911
virginia_herold@dca.ca.gov

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

Dan Ross, Pharm.D
Representative
California Society of Health System Pharmacists
1314 H Street
Sacramento, CA 95814
(818) 500-8262
dross@drossconsulting.com

Kimberly Tomasi, RN, MSN
Chief Executive Officer
Association of California Nurse Leaders
2520 Venture Oaks Way
Sacramento, CA 95833
(916) 779-6949
kim@acnl.org

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

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

David Perrott, MD, DDS
Senior Vice President and Chief Medical Officer
California Hospital Association
1215 K St.
Sacramento, CA 95814
(916) 552-7574
dperrott@calhospital.org

Rory Jaffe, MD, MBA
Executive Director CHPSO
California Hospital Patient Safety Organization
1215 K St.
Sacramento, CA 95814
(916) 552-7568
rjaffe@chpso.org

Jenna Fischer, CPPS
Vice President, Regional Quality Network
Hospital Quality Institute
3480 Buskirk Avenue
Pleasant Hill, CA 94523
(925) 746-5106
jfischer@hqinstitute.org

Barbara 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 October 10, 2018

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

Contact	Position Type	Represented Organization	County (Represe
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
Chris Patty, DNP, RN, CPPS	Member	Kaweah Delta Health Care District	Tulare
Christine Low, Pharm.D	Member	Scripps Green Hospital	San Diego
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
Art Woo, Pharm.D	Ex-officio	California Department of Public Health	
Cari Lee, Pharm.D	Ex-officio	California Department of Public Health	
Dan B. Dong, Pharm.D, FCSHP	Ex-officio	Kaiser Permanente	
Dan Ross, Pharm.D	Ex-officio	California Society of Health System Pharmacists	
John Christensen, Pharm.D	Ex-officio	California Department of Public Health	
Kimberly Kirchmeyer	Ex-officio	Medical Board of California	
Kimberly Tomasi, RN, MSN	Ex-officio	Association of California Nurse Leaders	
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	
Virginia Herold	Ex-officio	California Board of Pharmacy	

GUIDELINES FOR THE
CALIFORNIA HOSPITAL ASSOCIATION
MEDICATION SAFETY COMMITTEE

I. NAME

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

II. MISSION

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

III. PURPOSE

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

IV. COMMITTEE

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

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

A. MEMBERSHIP

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

B. MEMBER RESPONSIBILITIES

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

C. COMMITTEE MEETINGS

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

D. VOTING

1. Voting rights shall be limited to members of the Committee, and each member present shall have one vote. Voting by proxy is not acceptable.
2. All matters requiring a vote of the Committee must be passed by a majority of a quorum of the Committee members present at a duly called meeting or telephone conference call.

E. QUORUM

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

F. MINUTES

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

V. OFFICERS

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

A. SUB-COMMITTEES

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

VI. GENERAL PROVISIONS

Goals, and objectives, shall be developed annually by the Committee with approval by the CHA staff liaison. Quarterly updates and progress reports shall be completed by the Committee and CHA staff.

Staff leadership at the state level shall be provided by CHA with local staff leadership provided by Hospital Council, the Hospital Association of Southern California, and the Hospital Association of San Diego and Imperial Counties. The primary office and public policy development and advocacy staff of the Committee shall be located within the CHA office.

The Committee staff liaison shall be an employee of CHA.

VII. AMENDMENTS

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

VIII. LEGAL LIMITATIONS

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

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

IX. CONFIDENTIALITY FOR MEMBERS

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

X. CONFLICT OF INTEREST

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 10, 2018

TO: Medication Safety Committee Members

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

SUBJECT: 2019 Committee and Center Schedule Change

SUMMARY

Attached is the email information from CHA CEO, Carmela Coyle. The Co-Chairs engaged in conference calls regarding the 2019 changes. The email summarizes the goals and objectives for next year's meetings.

DISCUSSION

1) When would members like to schedule the two formal meetings?
2) Are there other association meetings, such as ACNL, where members coalesce and we could consider an additional meeting?

ACTION REQUESTED

- *Confirm next year's formal meeting schedule (one face to face and one virtual).*

Attachments: Carmela Coyle email
2019 Meeting Date Suggestions

BJB:br

From: Carmela Coyle

Subject: Meeting Schedules to Change in 2019 for CHA Centers, Committees
Date: Tuesday, September 25, 2018 9:31:43 AM

Dear center and committee members:

Thank you so much for the time you commit and all that you do for CHA in your role on one of our 25 centers and committees. To ensure we continue to effectively engage members, we have developed a new proposed meeting schedule for the coming year. This schedule considers feedback we received during discussions with center and committee chairs, as well as staff leads. We have learned that:

- **Centers and committees are critical listening posts for the association.** The input we receive from all of you is essential to developing policy positions on your behalf and advocating effectively. We rely on you to identify emerging issues and guide us in response.

- **Members' availability for in-person participation is increasingly scarce.** The health care environment is changing and your roles within your organizations are even busier. Many of you fly or drive to these meetings, taking you away from critical work back home. Across CHA's centers and committees, in-person participation has declined.

- **CHA's member reach could be expanded.** Given reduced participation in these meetings, we are missing an opportunity to involve more of our 400 hospital members across the state.

- **Quarterly scheduled meetings can lead to meetings without a pressing purpose.** The need to pre-schedule meetings means they may not coincide with our need for your input on key issues or legislation.

To keep our connection strong, continue to benefit from your experiences, and make the best and most efficient use of your time, we propose to lighten the meeting load and focus on more tailored approaches to member engagement:

- Beginning in 2019, centers and committees will hold two formal meetings per year — one in-person and one virtual. Your chair and CHA staff lead will send a memo with more information for the coming year, as the timing and details will vary.

- When issues are emerging or hot, centers and committees may use additional ad hoc calls to get your input at the optimal time. This will allow us to be more nimble and relevant on your behalf.

- To engage even more leaders in our work, centers and committees may convene complementary calls with broader groups of members who share a perspective or interest (e.g., rural, behavioral health, workforce, post-acute care, certification and licensing).

By freeing up time, we hope our staff leads will have more opportunity to come to you — locally and regionally. The more we know and understand your organizations, the more effectively we can advocate for you.

The times are a changin' and technology offers us many ways to stay even more closely connected. We strive to balance togetherness, the challenges of travel and our desire to engage even more of our hospital and health system members.

If you have any questions, feel free to contact me at ccoyle@calhospital.org or (916) 552-7547, or your

center or committee chair.

Carmela Coyle
President & CEO
California Hospital Association

To unsubscribe from CHA communications, please send an e-mail to info@calhospital.org.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

September 19, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC

SUBJECT: Proposed 2019 Meeting Schedule

Following is the proposed meeting schedule for 2019 Medication Safety Committee meetings:

January 9, 2019	Sacramento, CHA Offices Board Room
April 10, 2019	Sacramento, CHA Offices Board Room
July 17, 2019	Sacramento, CHA Offices Board Room
October 16, 2019	Sacramento, CHA Offices Board Room

You will receive a save-the-date approximately one month prior to each meeting to verify your attendance/participation.

Thank you and if you have any questions, please feel free to call me directly at (916) 552-7537.

BJB:br

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
April 4, 2018 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present:	Dan Dong, Candace Fong, Kathy Ghomeshi, Amy Gutierrez, Virginia Herold, Rory Jaffe, Randy Kajioka, Christine Low, Doug O'Brien, Christopher Patty, Dan Ross, Diana Schultz, Sarah Stephens
Members on Call:	Eddie Avedikian, Carolyn Brown, John Christensen, Jeannette Hanni, Susan Herman, Lori Nolan, Richard Rabens, Rita Shane, Art Woo
Members Absent:	Katie Choy, Loriann DeMartini, Kevin Dorsey-Tyler, Mary Foley, Lisa Hall, Nasim Karmali, Cari Lee, Lisa O'Connell
Guest:	Randi Abate (student with Kathy Ghomeshi), Margarita Chernova (student with Sarah Stephens), Vicky Ferraresi, Michael Tou
CHA Staff:	BJ Bartleson, William Emmerson, Jennifer Lopez, Amber Ott, Debby Rogers, Barb Roth

I. CALL TO ORDER/INTRODUCTIONS – Hanni/Fong

The committee meeting was called to order by chair Ms. Fong at 10:00 a.m. Ms. Fong briefly reviewed operational items.

II. REVIEW OF PREVIOUS MEETING MINUTES –Fong

The minutes of the January 10, 2018, Medication Safety Committee meeting were reviewed. Amy Gutierrez abstained as she was not present for the January 10, 2018 meeting.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: Minutes approved as presented*

III. New Members:
New member Kim Tomasi will be replacing Pat McFarland as the representative for ACNL. Deepak Sisodiya is the Administrative Director of Pharmacy Services at Stanford Health Care. After discussion the membership voted to approve Mr. Sisodiya's membership.

- *ACTION: Ms. Bartleson to contact Mr. Sisodaya regarding membership in the Medication Safety Committee.*

III. OLD BUSINESS

A. 340B Update (Ott)

The Governor's budget proposal was released in January of this year which includes changes to the 340B Drug Discount Program. CHA is opposed to this proposal. A hearing was held on

Thursday, March 28. Three members of the committee asked many questions and do not appear to be pleased with the proposal. CHA is requesting information from member hospitals in 340B areas on how this proposal will affect them.

- *ACTION: Please send stories to Ms. Ott (aott@calhospital.org) about how this affects your community (3-4 sentences).*

B. CHPAC (Emmerson)

William Emmerson with CHA's Legislative Team presented CHPAC. CHA is encouraging everyone to contribute to the CHA Political Action Committee. Any level of donation is acceptable.

C. Medication Safety Toolkit Update – Bartleson/Roth

Ms. Roth demonstrated how to locate the Medication Safety Toolkit on the CHA website. Ms. Bartleson requested members to forward outstanding items to her and she will ensure they get posted.

- *ACTION: Ms. Bartleson and Mr. Jaffe to discuss collaboration with CHA/HQI for Medication Safety Toolkit.*
- *ACTION: Sterile Compounding grids – Mr. O'Brien to send the completed grids to CHA for distribution and approval by the committee prior to being added to the toolkit.*

D. Sterile Compounding (Fong/Herold)

Ms. Herold discussed continued refinements on the sterile compounding regulations including compounding definitions, facilities and equipment.

- *ACTION: Information Only.*

E. Board of Pharmacy/CAU-CDPH/OSHPD Construction Waiver (Rogers)

CHA is sponsoring AB 2798 which would provide timelines for CDPH to approve/deny applications within 45 days. There will be a committee meeting on this bill in two weeks.

CDPH is proposing to raise hospital fees again. This would be an increase of 103% in last 4 years.

CHA will be hosting two upcoming webinars. The Sterile Compounding webinar on April 17 will be recorded and Medication Safety Committee members will have access to the recording.

- *ACTION: Information only.*

F. AHA Leadership Summit

Special committee recognition of outstanding efforts made by Sarah Stephens, Kathy Ghomeshi and Rita Shane on their proposal submissions to AHA. Although their proposals were not accepted, CHA Medication Safety Committee appreciates their efforts.

- *ACTION: Awards presented.*

IV. LEGISLATION AND REGULATORY

A. SB 1254 (Bartleson/Shane)

Several areas in the bill could cause problems at the hospital level (primarily regarding a potential increase in resources) and the Board of Pharmacy (regarding current staffing regulations). CHA has not made a decision regarding support or opposition of this bill prior to

obtaining input from the committee. The committee agreed to review the bill with the following amendments:

1. **Release of the Pharm tech ratio.**
2. **Add the 100 bed limitation.**
3. **Regulation would only be in effect during hours when the pharmacy is open.**
4. **Regulation to apply to admission instead of discharge.**

Ms. Shane has prepared a wealth of information regarding the importance the approval of this bill. A toolkit for the hospitals, making this information visible to leadership, would be beneficial.

- *ACTION: Ms. Shane to submit recommended amendments for committee review.*

B. SB 1447 (Bartleson)

This Board of Pharmacy (BoP) bill regarding the licensing of Automated Drug Dispensing (ADD) machines. It would allow patients to obtain prescription medication from an ADD machine if they opt into the system at a facility with a healthcare provider. The BoP has control over where the ADD machines are located. Questions about hospital locations to be answered by Ms. Herold.

- *ACTION: Information only.*

C. Legislation (Bartleson)

- *ACTION: Information only.*

V. NEW BUSINESS

A. Opioid Drug Shortages (Herold/Bartleson)

ASHP recently released a helpful document regarding the shortage. It was agreed that switching between products and strengths can be dangerous. Although it may take a crisis to make a change, it was recommended that committee members contact our two senators regarding this problem.

ASHP - ISMP is requesting the filing of incident reports on issues to prove the point. Reports can be filed anonymously.

- *ACTION: Committee members to send a couple of sentences or a paragraph indicating that this is a crisis or catastrophic situation in the making to Ms. Bartleson.*
- *ACTION: Ms. Bartleson to contact CHA Federal office with input from committee members.*

B. **Incidents of Smart Pump Malfunctioning (Bartleson)**

Mr. Woo advised that the brand of pump is being reported is by Alerus. There is not a recall at this time, however this has been problem for a couple of years. The MAUDE device database houses reports from providers on device problems. This is a public database.

- *ACTION: Information only.*

V. STANDING REPORTS

A. Board of Pharmacy (BoP) – Herold

The Board of Pharmacy has originated several new bills this session.

B. CHPSO – Jaffe

Update on data provided to the committee.

VI. OTHER BUSINESS

VII. NEXT MEETING

Wednesday, July 11, 2018

VIII. ADJOURNMENT

Having no further business, the committee adjourned at 1:10 PM

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
July 11, 2018 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: Dan Dong, Kevin Dorsey-Tyler, Candace Fong, Jeannette Hanni, Virginia Herold, Kimberly Kirchmeyer, Christine Low, Doug O'Brien, Deepak Sisodiya

Members on Call: Carolyn Brown, Loriann DeMartini, Randy Kajioka, Lori Nolan, Dan Ross, Diana Schultz, Rita Shane, Sarah Stephens,

Members Absent: Eddie Avedikian, John Christensen, Kathy Ghomeshi, Amy Gutierrez, Nasim Karmali, Cari Lee, Lisa O'Connell, Chris Patty, Kim Tomasi, Richard Rabens, Art Woo

Guests: Janette Wackerly

CHA Staff: BJ Bartleson, Rory Jaffe, Claire Manneh, Barb Roth

I. CALL TO ORDER/INTRODUCTIONS – Hanni/Fong
The committee meeting was called to order by chair Ms. Hanni at 10:05 a.m. Ms. Hanni briefly reviewed operational items.

II. REVIEW OF PREVIOUS MEETING MINUTES –Hanni
The minutes of the April 4, 2018, Medication Safety Committee meeting were reviewed.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: Minutes to be updated with the following corrections.*
- *Add Candace Fong as attendee.*
- *Identify CURES action.*
- *Identify Sterile Compounding action.*

III. OLD BUSINESS

A. CURES (Bartleson)
Ms. Bartleson reminded the committee that the effective date for CURES utilization is October 2, 2018 and asked if there were any issues occurring relative to their EMR or provider usage. The group felt that issues would surface after the October date and at this point there were no active issues.

- *ACTION: Information Only*

B. Drug Shortages (Bartleson)
With the help of Senator Feinstein, Ms. Bartleson and Ms. Herold were able to speak with an assistant administrator at DEA. Unfortunately, the DEA was not able to provide assistance.

Ms. Herold advised that if there is an outsourcer from which someone wants to purchase drugs, please let her know and she will do what she can to get them online and approved. Ms. Shane suggested a related future topic for committee discussion: the unintended

consequences on the over-reliance on outsourcing.

- *ACTION: Information only.*

C. Medication Application in Outpatient Setting (Manneh)

The Gordon and Betty Moore Foundation supports patient safety and is supporting the HQI Conference. The Foundation also funded a large grant to look at medication safety in outpatient settings. They are interested in participating with committees and workgroups looking at this issue. Julie Lawrence is the Program Officer. The Scope of Nursing Practice workgroup might be a good workgroup for their participation. CHA will invite Ms. Lawrence to the meeting.

- *ACTION: Ms. Manneh to send contact information and introduction to Ms. Bartleson.*
- *ACTION: Ms. Bartleson to invite Ms. Lawrence to participate with the workgroup.*

D. Medication Safety Toolkit Update (Bartleson/Roth)

The Sterile Compounding Grids are included in the packet and will be sent to the committee electronically for review and comments. Some items for the Toolkit are still outstanding.

- *ACTION: Ms. Roth to send PDF of the Sterile Compounding Grids to the committee for review and approval by August 1, 2018.*
- *ACTION: Still needed - ED Management, Reducing Adverse Drug Events (ADEs), Track and Trace Law FAQs.*

E. Sterile Compounding Update (Bartleson)

Ms. Bartleson reiterated there had been issues raised on the re-licensing of pharmacies that are dormant due to construction.

- *ACTION: The Board of Pharmacy is working to resolve this issue.*

F. Sterile Compounding Grids (Hanni/O'Brien/DeMartini)

The committee acknowledged the outstanding work of the workgroup in putting together the Sterile Compounding Grids. Ms. Herold advised she will send the grids to their staff at the Board of Pharmacy and ask their inspectors to review for any potential problems. Ms. Hanni suggested that the committee approve the grids pending a review by August 1, 2018.

- *ACTION: Ms. Roth to send PDF of the Sterile Compounding Grids to the committee.*
- *ACTION: Motion made to approve Grids pending review by August 1, 2018. Motion approved.*

G. Sterile Compounding FAQs (Bartleson)

Information provided as requested from the last meeting regarding how to locate the FAQs online.

- *ACTION: Information only.*

H. Sterile Compounding Clean Room (Bartleson)

AFL 18-20 clarifies the licensing pathway for mobile units and new construction.

- *ACTION: Information only.*

I. 340B Update (Ott)

The final budget did not include this proposal. Covered entities will work with the department to find a way to avoid duplicate discounts. Most hospitals are already doing this. The plans have to be ready to receive the modifier and flag it so that it is not claimed by the state. This is a reasonable solution, however, the problem occurs when a contract pharmacy is being used to administer340B drugs and the plan has something in place to replace those drugs. Twenty percent of hospitals are using contract pharmacies (mostly in rural areas).

The GAO released a report last week to focus on this area of concern at the federal level. CHA provided the state with language for the Budget Trailer Bill regarding how to solve the problem. An email from state indicated that they are going to use their administrative authority to solve the problems. The state wants the rebate, the hospitals want the discount.

- *ACTION: Information only.*

IV. LEGISLATION

A. Legislation (Bartleson)

SB 1254 – Medication Profile List. The bill identifies high-risk patients only at this time, however, some legislators actually asked for more – some wanted all patients. When this bill passes, it will take effect January 1, 2019. Education may be needed for the independent hospitals who may be uninformed about this legislation. Ms. Shane will have information for education purposes. Ms. DeMartini advised that CHSP is willing to provide education, perhaps a toolkit and/or training for technicians.

SB 1447 – Automatic Drug Dispensing Systems. These machines are where many patients will be getting their drugs in the future. The refill machines must be adjacent to the pharmacy. A potential use would be in a hospital ED to provide drugs when the pharmacist is gone – the machine would allow 3-day dispensing. Either the MD or the Pharmacist must be available to talk with the patient. There is currently a pilot at UCSD Sharp in San Diego.

- *ACTION: AB 1254 – Ms. Bartleson to discuss education with Ms. Shane.*

V. NEW BUSINESS

A. Prescriptions to Manage Opioid Withdrawal for Patients Admitted for Medical Conditions (Garman)

There is inconsistency between Federal regulations and State law for the treatment of patients in withdrawal who have been admitted for medical conditions. California Health and Safety Code Section 11217 – generally prohibits treating an addict for treatment unless in a specific list of facilities. Only one provision in the statute could encompass a non-public setting. Use of the word "and" means that is has to be a General Acute Care Hospital or Psychiatric Facility AND a chemical dependency facility. Hospitals are currently viewing this regulation with varying degrees of aggression.

Ms. Garman is submitting this to the committee for consideration for next year's legislative session. It was suggested that Dr. Wood might be interested in looking at this.

- *ACTION: Discussion and information.*

B. **Narcotic Inventory Reconciliation Regulations (Fong/Shane)**

The Board of Pharmacy (BoP) is requiring a quarterly reconciliation (inventory) to reduce drug losses. Pharmacies were showing that they were losing 300,000-400,000 pills before they even knew they were missing.

It is important for the pharmacy to check what is ordered vs. what is received. Dignity Health invested in a program to do monthly inventories. If the hospital can show over time that they are doing this duplicative work – after some time of having data, they should take it to the BoP to show they are complying with an adequate alternate system. CHA has not been advised that any hospital has been cited for this.

- *ACTION: Members to discuss further.*

C. **Nursing and Sterile Compounding (Wackerly)**
The Board of Registered Nursing (BRN) wants to inform nurses in California about the changes that have occurred related to nursing. The BRN helps to define where the application of nursing compounding is OK and where it is not allowed.

USP is currently undergoing revision and much will be different. Ms. Bartleson suggested the committee create a task force, led by Ms. DeMartini and to include some nurses, to see what is going on in the field regarding definitions, FAQs, etc.

- *ACTION: Create a taskforce led by Ms. DeMartini.*

V. STANDING REPORTS

A. Board of Pharmacy - BoP (Herold)
BoP will have a Board Meeting at the end of July

- Sterile Compound Committee – discussing whether to publish citations and fines online.
- Pharmacy closure process will be reviewed. Currently, when a pharmacy closes, the records are to be kept in a licensed premises for 3 years. Sometimes, those records end up in a storage facility. If payments are not kept up, the contents are then open for auction.
- Preliminary discussion regarding the transition from board requirements to USP.
- Reviewing the job analysis for the 2 pharm tech programs.
- Legislation and regulations will be discussed.
- Training for the board regarding conflict of interest.

B. California Department of Public Health - CDPH (Lee, Woo, Christensen)
No report.

C. California Society of Health-System Pharmacists - CSHP (Dong)
No report.

D. CALNOC
No report.

E. Association of California Nurse Leaders – ACNL (Tomasi)
No report.

F. CHPSO (Jaffe)

CHPSO has received a Gordon and Betty Moore Foundation grant, along with IHI and Brigham and Woman's Hospital. They are reviewing outpatient medication prescribing safety. The findings from outpatient medication reports:

1. Outpatient infusion centers are dominating the safety events.
2. There are immunization issues.
3. Outpatient events have bigger communication and timing issues than inpatient.

The third year of the grant will develop an implementation plan to improve prescribing safety for outpatient areas.

CHPSO is also conducting an analysis of medication events. The combination of opioids and benzodiazipines have adverse outcomes. Insulin events have lower level issues. Encourage all to subscribe to the CHPSO newsletter.

G. California Association of Health Facilities – CAHF (Owens)
No report.

VI. OTHER BUSINESS

VII. NEXT MEETING
Wednesday, October 10, 2018

VIII. ADJOURNMENT
Having no further business, the committee adjourned at 1:53 PM

Further Discussion Item:

Work with the BoP and CDPH on USP 800 so there are options on how to manage the 3rd category as was discussed will be essential.
Determine how to provide the evidence to the BoP regarding quarterly CII reconciliation will be important. Will defer to you as to how to organize the members to do this. Happy to have my folks participate in both of these if that is the direction you want to take. The outsourcing sterile compounding is a lofty topic since drug shortages, manufacturer dating requirement and outsourcing risk are all linked and represent challenging issues that warrant examination. Perhaps engage UCSF School of Pharmacy's Outcomes Program to conduct an evidence-based evaluation of negative consequences of these issues on patient care. This is a big topic that may be beyond the scope of this group but these certainly impact us all.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 10, 2018

TO: Medication Safety Committee

FROM: Alyssa Keefe, Vice President Federal Regulatory Affairs

SUBJECT: Request for Member Engagement on Drug Shortage Issues

Action Item
The committee is asked to review and discuss the attached notice and background memo and let us know of their interest in participating in this member engagement process.

Background
California Hospitals have been actively engaged with our national association partners in giving voice to the issues related to drug shortages. Below is a quick summary of our action to date:

- After Hurricane Maria hit Puerto Rico in the fall of 2017, California hospitals reported shortages on intravenous (IV) fluid mini-bags. CHA urged the FDA to resolve the shortage and offered recommendations on ways to expedite the resolution. CHA has worked with its Medication Safety Committee, state agencies and the American Hospital Association to develop best practices for hospitals as well as policy recommendations that address these ongoing and persistent shortages.

- During CHA's Congressional Action Program, Sen. Dianne Feinstein expressed a deep concern over the continuing intravenous opioid shortage and a strong interest in finding a quick solution. To illustrate the issue, CHA developed an online survey that allowed hospitals to describe the direct effects of the shortage. Sen. Feinstein's staff continued to be actively engaged and facilitated a call between the DEA and CHA to hear directly from California hospitals.

- The DEA recently issued a notice of proposed rulemaking on aggregate production quotas for Schedule I and II controlled substances. In response, CHA requested that the DEA reconsider the reduction of manufacturing quotas to help address the current drug shortages that are prevalent in hospitals. CHA urged the agency to reconsider its proposal to reduce manufacturing quotas specific to injectable medications used in hospitals rather than other dosage forms or opioid products.

Action Requested
In response to the growing voices calling for Congress and FDA to implement more long-term policies to address the numerous drug shortages that plague our hospitals every day, the FDA has committed to an interagency and stakeholder engagement process. **As their first step in this process, FDA will hold a**

public meeting on Nov. 27 to discuss the underlying causes of drug shortages and offer an opportunity for stakeholders to provide ideas on ways to resolve the ongoing shortages. The FDA taskforce will use stakeholder input in a report to Congress that will include recommendations the FDA or other federal agencies could use to end drug shortages.

CHA is requesting member engagement on this important issue in anticipation of submitting comments ahead of the meeting to help set its agenda. Discussion topics are outlined in the attached meeting notice and include questions on adverse consequences of drug shortages, underlying systemic causes and drivers and policies and strategies that may help to prevent or mitigate shortages. This is the opportunity for hospitals to tell their stories of the challenges faced on a daily basis and to inform policy efforts at the federal level. All submissions will remain confidential and this is a voluntary effort.

Attachment: FDA -2018-N-3272 – Notice of public meeting; request for comments

AK/BJ:br

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3272]

Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." The purpose of the meeting is to give stakeholders, including health care providers, patients, manufacturers, wholesalers, pharmacists, pharmacy benefit managers, veterinarians, public and private insurers, academic researchers, and the public, the opportunity to provide input on the underlying systemic causes of drug shortages, and make recommendations for actions to prevent or mitigate drug shortages. Members of Congress have asked the Agency to examine the root causes and drivers of these shortages, and to recommend measures that will provide more enduring solutions. To this end, the Commissioner has convened an inter-Agency task force of senior Federal officials of FDA, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, and the Department of Defense. After receiving input from stakeholders, the task force intends to provide a report to Congress regarding the root causes of drug shortages. The report will also include recommendations regarding new authorities FDA or other Federal agencies could use to help provide enduring solutions to shortages.

DATES: The public meeting will be held on November 27, 2018, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public meeting by January 11, 2019. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the Washington Marriott at Metro Center, 775 12th St., NW, Washington, D.C. 20005. The hotel's phone number is 202-737-2200.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 11, 2019. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of January 11, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-3272 for "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its

consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michie Hunt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6153, Silver Spring, MD 20993, 301-796-3504.

SUPPLEMENTARY INFORMATION:

I. Background

Drug shortages are among the greatest challenges health care providers and patients face. These shortages can affect treatment options and require practitioners to make difficult decisions

that can compromise care, such as rationing supplies or using less desirable, but more readily available, alternative therapies. FDA has acted within its statutory authority to prevent and mitigate drug shortages. By working with industry and other parties, the Agency has helped to steadily reduce the number of new shortages since a peak of 251 new shortages occurred in 2011, as detailed in the Agency's "Report on Drug Shortages for Calendar Year 2017," which is available at https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM610662.pdf.

Despite this success in preventing or mitigating individual cases, more can and must be done to better understand and address the underlying systemic factors that are leading to shortages of medically necessary drugs. Members of Congress have asked the Agency to examine the root causes and drivers of these shortages, and to recommend measures that will provide more enduring solutions. To this end, the Commissioner has convened an inter-agency task force of senior federal officials of FDA, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, and the Department of Defense. After receiving input from stakeholders, the task force intends to provide a report to Congress regarding the root causes of drug shortages. The report will also include recommendations regarding new authorities FDA or other federal agencies could use to help provide enduring solutions to shortages.

II. Topics for Discussion at the Public Meeting

We are soliciting input from stakeholders concerning the adverse consequences of drug shortages, the underlying systemic causes and drivers of these shortages, and the policies and strategies that may help to prevent or mitigate them. We welcome any relevant information that stakeholders wish to share, as all factors contributing to shortages are matters of concern. We are particularly interested in stakeholder input in the following areas:

A. Assessing the Adverse Consequences of Drug Shortages to Patients, Health Care Providers, and the Drug Supply Chain

1. Drug Shortages' Impact on Patients

a. What clinical impacts have patients experienced: e.g., adverse events, treatment delays, accelerated disease progression, or worsened outcomes due to patients' to using less effective or less safe alternatives?

b. What economic impacts have patients affected by drug shortages experienced?

c. Do drug shortages affect patients disproportionately by geographic region, age, disease or condition, socioeconomic status, or other factors? Are there specific times of year or classes of drugs that see episodic, more frequent or more severe shortages? If so, why does this happen?

2. Drug Shortages Impact on Health Care Providers

a. What economic impacts (including increased inventory management costs, substitution of more expensive drugs for drugs in shortage, and increased liability from adverse events) have health care providers, including veterinarians, experienced because of drug shortages?

b. Do the adverse consequences of shortages affect providers disproportionately by, for example, geographic region, clinical area, or other characteristics?

3. Drug Shortages' Impact on the Supply Chain

a. What economic effects have shortages had on key links in the drug supply chain: e.g., wholesalers, distributors, and pharmacies?

b. Have certain links in the supply chain been disproportionately affected by shortages? If so, which ones?

4. Do available data accurately capture the differences among shortages (e.g., their severity and duration) that may affect their clinical and economic adverse consequences? If not, what additional data would be needed to better capture these differences?

B. Identifying the Root Causes and Drivers of Drug Shortages

1. What factors affect the likelihood, severity, and duration of shortages? Are these factors mostly related to raw materials, management, and resilience of production facilities, or other factors such as contracting or market structure? Do they differ for various drugs?

2. What government policies and regulations may contribute to drug shortages, and how could these be modified to prevent or limit impacts of drug shortages?

3. How do manufacturers contribute to drug availability or shortages, including responses to shortages?

a. What factors do generic and brand manufacturers consider when making decisions about whether to seek approval for certain drugs, to produce and market a drug for which they already hold an approved new drug application or abbreviated new drug application, or to discontinue marketing a drug? How do those decisions contribute (directly or indirectly) to shortages?

b. How do manufacturers monitor for situations that may result in a drug shortage? Are there certain indicators that are monitored? If so, are the potential triggers the same for all drugs, for example brand and generic sterile injectable drugs?

c. When manufacturers recognize a potential shortage, what options do they have for averting one? How easy or difficult is it to implement these options, and how costly is it to implement them? What is the impact of government policy or regulation on these options?

d. What factors play a role in manufacturers' decisions to make capital investments to expand capacity or to modernize infrastructure?

e. When manufacturers are remediating or upgrading a facility, how can shortages related to production slowdowns and shutdowns be avoided?

4. Drug supply is controlled through contracts among manufacturers, distributors, and end users. What features of contracts used throughout the supply chain contribute to drug availability and shortages, including responses to shortages?

a. What is the effect of duration and scope (how many and what types of drug products are covered by each contract, and whether non-drug products are bundled into the contract), on drug availability or shortage?

b. How commonly do these contracts include incentives such as contingency clauses, performance requirements, failure-to-supply clauses, or restrictions on limiting downstream price increases? How large are these incentives currently? Are there institutional or informational impediments limiting greater use of such incentives or performance clauses?

c. What are the implications of markups on inventory management throughout the supply chain? How might these markups contribute to shortages, and to response to shortages?

d. How have the characteristics of contracts, and markups at different points in the supply chain, changed over the past 15 years?

e. What are the implications of these contracting provisions and their changes for the probability, severity, and duration of drug shortages?

f. How much competition exists throughout the supply chain? Over the past 15 years, have there been challenges to competition and if so, what factors are responsible for these challenges? For example, has consolidation in different parts of the supply chain created market

barriers to entry and reduced competition? If so, what effect has the reduction in competition had on drug shortages?

C. Identifying Strategies for Preventing or Mitigating Drug Shortages

1. What policies could the Federal Government adopt, and what strategies could it implement, that would reduce the likelihood, severity, and duration of shortages? Would additional authorities be necessary or helpful? For example:

a. Establish a list of "essential medicines" for use in preventing and mitigating shortages. If such a list were established, what should be the criteria for inclusion? And how should such a list be maintained and administered?

b. Provide financial incentives, such as tax credits or revised reimbursement policies: e.g., to allow additional payments for drugs in or at risk of shortage or to encourage investment to expand manufacturing capacity or to modernize aging infrastructure, to enhance process capability and variability control, or to prevent manufacturing problems that affect product availability;

c. Allow other entities (e.g., contract manufacturers) to fill gaps in supply;

d. Require risk management plans to help manufacturers prepare to respond efficiently and effectively to potential shortages;

e. Require the extension of expiration dates for drugs in shortage or at risk of shortage, where scientifically justified;

f. Revise trade policies and authorities: e.g., to allow federal purchasers to buy imported drugs or raw materials to prevent or mitigate a shortage;

g. Heighten scrutiny of proposed mergers and acquisitions that increase market concentration or the likelihood of shortages;

h. Revise payment policies and authorities: e.g., that would be coupled with a requirement to establish contingency plans for supplying medicines that go into shortage; and

i. Federal investment in production capacity for essential medicines directly related to national security, emergency preparedness, and defense.

2. In designing new policies to prevent or mitigate shortages, how can the Federal Government avoid creating perverse incentives or negative cascading effects in the health care financing and delivery system? For example, how might changes to government payment and reimbursement affect the other sectors of the market?

3. Are there lessons for the Federal Government, or practices that it can emulate, from strategies used to prevent or mitigate shortages in other commodity markets that face shortage issues?

4. What challenges does the global nature of drug manufacturing and marketing pose for efforts to prevent shortages in the U.S. market?

5. As drug shortages are a national problem, what are the sources of funding that can be applied to provide incentives to remedy the root causes?

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: https://healthpolicy.duke.edu/events/drug-shortage-task-force. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by Wednesday, November 21, 2018, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If

you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. The Duke-Margolis Center for Health Policy will post on its website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (phone: 202-791-9561, email: sarah.supsiri@duke.edu) no later than November 20, 2018.

Streaming webcast of the public workshop: This public workshop will be webcast live. Persons interested in viewing the live webcast may register ahead of the event by visiting https://healthpolicy.duke.edu/events/drug-shortage-task-force. The live webcast will also be available at the website above on the day of the event without pre-registration. Archived video footage will be available at the Duke-Margolis website following the workshop.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm.

Other Issues for Consideration: A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Washington Marriott at Metro Center, 775 12th St., NW, Washington, D.C. 20005.

All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website at https://healthpolicy.duke.edu/events/drug-shortage-task-force.

Dated: September 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-19612 Filed: 9/7/2018 8:45 am; Publication Date: 9/10/2018]

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 10, 2018

TO: Medication Safety Committee Members

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

SUBJECT: CURES Update and Information

SUMMARY

The Department of Justice (DOJ) wants CHA's assistance to make sure hospitals are aware of the CURES requirements (of AB 40 and SB 482- which mandates prescribing providers to use the CURES system by 10/2/2018 and requires DOJ to create electronic access to CURES by 10/1/18

DOJ MOU's

DOJ is developing an MOU to access CURES electronically– which could be between: DOJ and an organization (including a provider/physician) or from DOJ and an HIE that would provide the link to CURES or perhaps HIT vendors and DOJ. The DOJ should have an MOU completed by the end of August. It is unclear when providers/others would sign the MOU.

EMR Utilization

DOJ is working w/ a group of stakeholders – including Dr. Lane and the Epic User Group. They said they are working w/ Epic, Cerner, CMT, Doctor First and EDIE. The DOJ fee to access CURES will be paid by providers/hospitals/vendors. DOJ is modeling options and does not know what it might be. There will be a one-time connection fee and an annual fee.

Accessing other States

DOJ stated existing law does not authorize DOJ to access other states' data. AB 1751 will allow this – and was passed this year.

DOJ Education/Webinars

DOJ plans bi-monthly webinars on CURES. The ED will be exempted from use. However, the law will be applicable for non-surgical inpatients/observation patients that are discharged with an opioid prescription.

QUESTIONS:

1) If the hospital/provider is using the EHR vendor access to CURES – which entity would sign the MOU? What about a system of hospitals – could the MOU be implemented for the entire system?

2) What about other hospital system vendors such as Meditech. How are they to interface with the CURES database ?

3) What do they expect from medical staff monitoring of compliance

ACTION REQESTED

- Information only.

Attachments: CURES Mandatory Use Informational Sheet

BJB:br

CURES 2.0
MANDATORY USE
BEGINS OCTOBER 2, 2018

The Controlled Substance Utilization Review and Evaluation System (CURES) was certified for statewide use by the Department of Justice (DOJ) on April 2, 2018. Therefore, the mandate to consult CURES prior to prescribing, ordering, administering, or furnishing a Schedule II–IV controlled substance becomes effective on October 2, 2018. Visit www.mbc.ca.gov/CURES for detailed information regarding CURES 2.0.

Note: The phrase "controlled substance" as used in this guide refers to a Schedule II, Schedule III, or Schedule IV controlled substance.

WHEN MUST I CONSULT CURES?

- The first time a patient is prescribed, ordered, administered, or furnished a controlled substance, unless one of the exemptions on back apply.
- Within the twenty-four hour period, or the previous business day, before prescribing, ordering, administering, or furnishing a controlled substance, unless one of the exemptions on back apply.
- Before subsequently prescribing a controlled substance, if previously exempt.
- At least once every four months if the controlled substance remains a part of the patient's treatment plan.

> "First time" is defined as the initial occurrence in which a health care practitioner intends to prescribe, order, administer, or furnish a controlled substance to a patient and has not previously prescribed a controlled substance to the patient.
>
> *— Health and Safety Code (HSC), § 11165.4(a)(1)(B)*

ARE THERE ANY PROTECTIONS FOR PRESCRIBERS?

- There is no private cause of action for a prescriber's failure to consult CURES.
- For complete information on the mandatory requirement to consult CURES, please read HSC § 11165.4.
- If you have any further questions, please seek legal counsel.

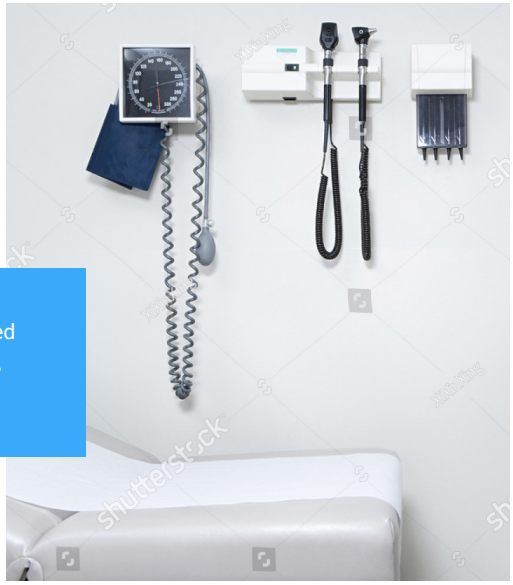
HOW CAN I GET HELP WITH CURES?

For general assistance with CURES, including training and CURES usage support, contact the California DOJ at (916) 210-3187 or CURES@doj.ca.gov. For Direct Dispensing assistance, contact Atlantic Associates, Inc. at (800) 539-3370 or cacures@aainh.com.

WHAT EXEMPTIONS ARE THERE TO CONSULTING CURES?

- A health care practitioner is exempt from consulting the CURES database before prescribing, ordering, administering, or furnishing a controlled substance in any of the following circumstances:
  - While the patient is admitted to, or during an emergency transfer between a
    - Licensed Clinic, or
    - Outpatient Setting, or
    - Health Facility, or
    - County Medical Facility
  - In the emergency department of a general acute care hospital, and the controlled substance does not exceed a non-refillable seven-day supply.

> The facilities listed are specifically defined in statute commencing with HSC § 1200, § 1248, § 1250, and § 1440, respectively.



  - As part of a patient's treatment for a surgical procedure, and the controlled substance does not exceed a non-refillable five-day supply when a surgical procedure is performed at a
    - Licensed Clinic, or
    - Outpatient Setting, or
    - Health Facility, or
    - County Medical Facility, or
    - Place of Practice
  - The patient is receiving hospice care.

> "Place of Practice" is defined as a Dental Office pursuant to Business and Professions Code § 1658.

- What if it is not reasonably possible for a prescriber to access the information in CURES in a timely manner?
  - If another individual with access to CURES is not reasonably available, a five-day supply of the controlled substance can be prescribed, ordered, administered, or furnished as long as there is no refill allowed. In addition, the prescriber must document in the medical records the reason for not consulting CURES.
- What if I determine that consulting CURES would result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition?
  - A prescriber may provide a non-refillable five-day supply if they make this determination. The prescriber must document in the medical records the reason for not consulting CURES.

WHAT IF I EXPERIENCE TECHNICAL DIFFICULTIES WITH CURES?

There are exemptions to consulting CURES if there are technical difficulties accessing CURES, such as CURES is temporarily unavailable for system maintenance, or you experience temporary technological or electrical failure and CURES cannot be accessed (e.g., power outage due to inclement weather).

A prescriber should contact the CURES Help Desk at (916) 210-3187 or cures@doj.ca.gov for assistance accessing their CURES account.

Note: A prescriber must, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within their control.

CURES 2.0

MEDICAL BOARD OF CALIFORNIA
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

CONTACT
(916) 263-2382
www.mbc.ca.gov
webmaster@mbc.ca.gov

FOLLOW
@MedboardOfCA
@MedicalBoardCA
@MedboardOfCA

CURES 2.0

California's Prescription Drug Monitoring Program (PDMP)

CURES 2.0

Prescriber / Dispenser Overview

August 16, 2018

CURES 2.0

Controlled Substance

Utilization

Review and

Evaluation

System

CURES 2.0

System and Requirements

The CURES Program is the prescription drug monitoring program for the state of California.

The CURES database contains information about Schedule II, III, and IV controlled substance prescriptions dispensed to patients, as reported by those dispensers.

CURES data reflects dispensing information exactly as it is reported to the Department of Justice. The reporting dispenser creates and owns the prescription records submitted. The Department of Justice is a custodian (and not editor) of these aggregated prescription records.

CURES 2.0

System and Requirements

The Health and Safety Code requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES):

- To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances.
- To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances.
- And for statistical analysis, education, and research.

California Health and Safety Code section § 11165(a)

CURES 2.0

History

1939	The California Triplicate Prescription Program (TPP) was created, capturing Schedule II prescription information.
1997	CURES pilot program was initiated, operating in parallel with the TPP's Automated Triplicate Prescription System (ATPS) to evaluate the comparative efficiencies between the two systems.
2005	TPP/ATPS decommissioned after Senate Bill 151 eliminated the triplicate prescription requirement for Schedule II controlled substances. CURES became permanent.
2009	A searchable, client-facing application was introduced as a component of CURES.
2011	DOJ's Bureau of Narcotic Enforcement dissolved and the CURES Program de-funded.
2013	The State Budget Act allocated funds for the CURES 2.0 build. Senate Bill 809 mandates CURES registration by prescribers and dispensers and established an on-going funding mechanism to support costs for operating and maintaining the CURES system.
2016	CURES 2.0 universally released.
2018	CURES 2.0 was certified for statewide use by the Department of Justice. Mandate to consult CURES prior to prescribing, ordering, administering, or furnishing a Schedule II–IV controlled substance becomes effective on October 2, 2018.

Mandatory Reporting

CURES MANDATORY REPORTING

Health and Safety Code Section 11165, subdivision (d)

The dispensing pharmacy, clinic, or other dispenser, including direct dispensing prescribers, are required to report dispensations of Schedules II, III, and IV controlled substances to the Department of Justice, in a format specified by the Department of Justice, as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.

California Health and Safety Code section § 11165(d)

Mandatory Registration: SB-809

CURES MANDATORY REGISTRATION

Senate Bill 809 (Stats 2013, Ch 400, DeSaulnier)

Senate Bill 809, amended, in part, by Assembly Bill 679, and codified in Health and Safety Code section 11165.1(a)(1)(A), requires the following licensees to register for access to the CURES database by July 1, 2016:

- All California licensed pharmacists, upon licensure.
- All California licensed health care practitioners authorized to prescribe, order, administer, furnish, or dispense controlled substances in California, upon receipt of a federal DEA registration.

Mandatory Use: SB-482

CURES MANDATORY USE

Senate Bill 482 (Stats 2016, Ch 708, Lara)

Mandatory Use: SB-482

What is the mandatory use requirement of SB-482?

With specified exceptions, a prescriber shall consult the CURES database no earlier than 24 hours, or the previous business day, before prescribing a Schedule II-IV controlled substance to a patient for the first time, and at least every four months thereafter if the substance remains part of the treatment of the patient.

When does mandatory use become effective?

Mandatory use of CURES becomes effective on October 2, 2018.

To whom does mandatory use apply?

Prescribers with a DEA Controlled Substance Registration Certificate AND a valid license issued by a professional licensing board of the California Department of Consumer Affairs. Examples include:

- Dentist
- Optometrist
- Podiatrist
- Medical Physician
- Osteopathic Doctor
- Naturopathic Doctor
- Physician Assistant
- Registered Certified Nurse Midwife (furnishing)
- Registered Nurse Practitioner (Furnishing)

Mandatory Use: SB-482

To whom does mandatory use not apply?

Mandatory use does not apply to veterinarians or pharmacists.

Are there situational exceptions?

Yes, there are numerous situational exceptions to the mandatory use requirement of SB-482. Prescribers should review the full text of SB-482 (Health and Safety Code 11165.4), which contains an exhaustive list of exceptions to the mandatory use requirement.

Who is responsible for enforcing the mandatory use requirement?

It is the responsibility of the respective state professional licensing board to enforce compliance with the mandatory use requirement.

What are the consequences of non-compliance with mandatory use?

It is the responsibility of the respective state professional licensing board to determine administrative sanctions for health care practitioners who fail to consult the CURES database as required.

Mandatory Use: SB-482

Is mandatory use required in my practice?

Questions regarding the application of this requirement to the particulars of your practice should be referred to your respective licensing board to guide your compliance with this legislation.

What is required to properly document compliance?

Questions regarding the proper documentation of compliance with the mandatory use requirement should be directed to your respective professional licensing board.

Can CURES usage be electronically audited?

Consistent with Health and Safety Code section 11165.2(a), the CURES Program has the ability to audit the activity of users within the system.

What if I experience technical difficulties accessing CURES?

There are exceptions to mandatory use if technical difficulties are experienced when accessing CURES. For example, if CURES is temporarily unavailable for system maintenance, or if temporary technological or electrical failures prevent CURES from being accessed. (See Health and Safety Code 11165.4(c)(6),(7) for details.)

CURES 2.0 Other Issues Addressed by SB-482

Can health care practitioners provide CURES reports to their patients?

A health care practitioner may provide a patient with a copy of the patient's CURES patient activity report, if in accordance with federal and state privacy laws and regulations, to the extent that no additional CURES data is provided.

Can health care practitioners put a copy of a CURES report in the patient's medical record?

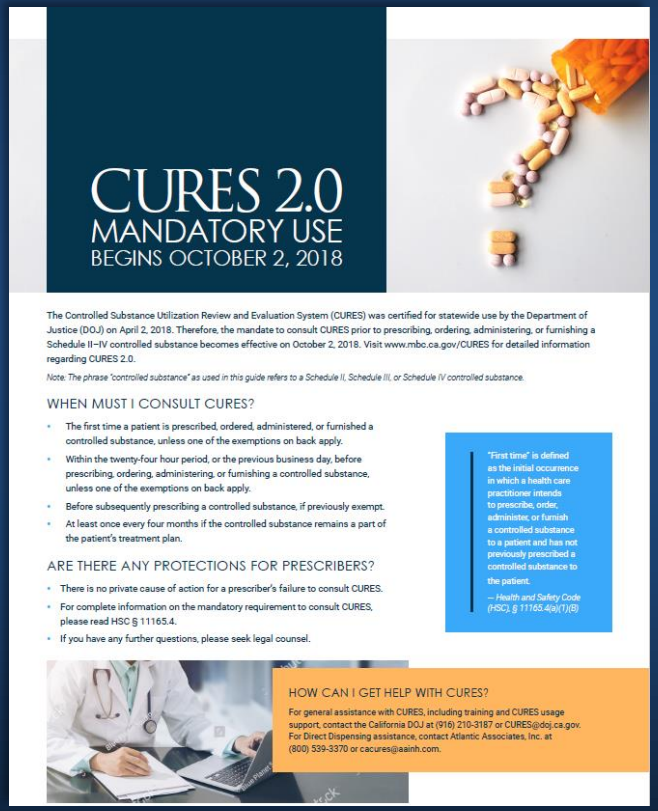
A health care practitioner may put a copy of the patient's CURES patient activity report in the patient's medical record, if in accordance with federal and state privacy laws and regulations.

Can all regulatory boards access CURES data?

Only regulatory boards whose licensees prescribe, order, administer, furnish, or dispense controlled substances may access CURES data.

Mandatory Use: SB-482

Additional resources can be found on the CURES Dashboard, the OAG CURES webpage, linked below, and the MBC website.



CURES 2.0
MANDATORY USE
BEGINS OCTOBER 2, 2018

The Controlled Substance Utilization Review and Evaluation System (CURES) was certified for statewide use by the Department of Justice (DOJ) on April 2, 2018. Therefore, the mandate to consult CURES prior to prescribing, ordering, administering, or furnishing a Schedule II–IV controlled substance becomes effective on October 2, 2018. Visit www.mbc.ca.gov/CURES for detailed information regarding CURES 2.0.

Note: The phrase "controlled substance" as used in this guide refers to a Schedule II, Schedule III, or Schedule IV controlled substance.

WHEN MUST I CONSULT CURES?

- The first time a patient is prescribed, ordered, administered, or furnished a controlled substance, unless one of the exemptions on back apply.
- Within the twenty-four hour period, or the previous business day, before prescribing, ordering, administering, or furnishing a controlled substance, unless one of the exemptions on back apply.
- Before subsequently prescribing a controlled substance, if previously exempt.
- At least once every four months if the controlled substance remains a part of the patient's treatment plan.

"First time" is defined as the initial occurrence in which a health care practitioner intends to prescribe, order, administer, or furnish a controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

— Health and Safety Code (HSC), § 11165.4(a)(1)(B)

ARE THERE ANY PROTECTIONS FOR PRESCRIBERS?

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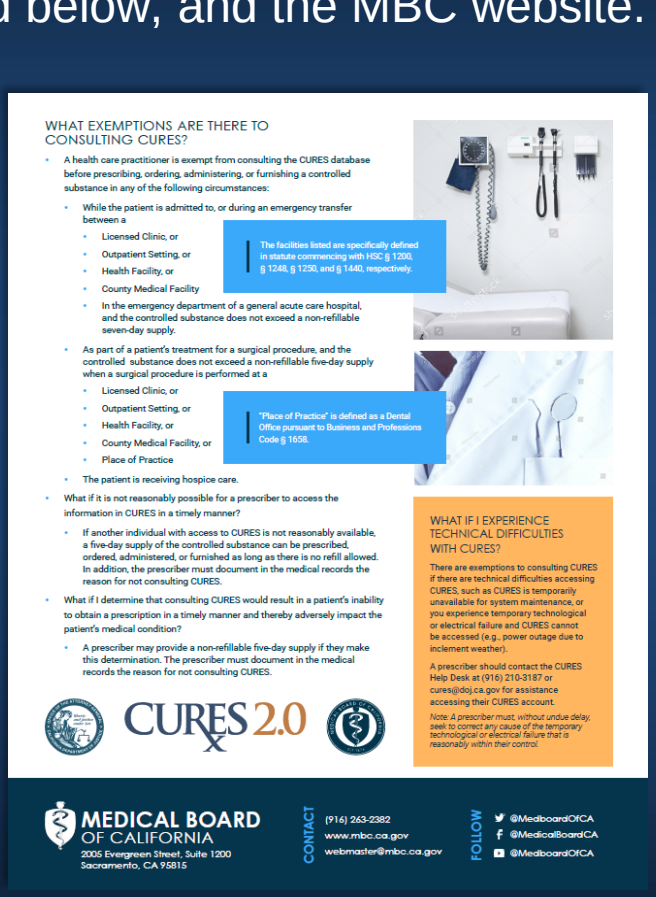

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- A health care practitioner is exempt from consulting the CURES database before prescribing, ordering, administering, or furnishing a controlled substance in any of the following circumstances:
  - While the patient is admitted to, or during an emergency transfer between a
    - Licensed Clinic, or
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    - County Medical Facility
    - In the emergency department of a general acute care hospital, and the controlled substance does not exceed a non-refillable seven-day supply.

The facilities listed are specifically defined in statute commencing with HSC § 1200, § 1248, § 1250, and § 1440, respectively.

  - As part of a patient's treatment for a surgical procedure, and the controlled substance does not exceed a non-refillable five-day supply when a surgical procedure is performed at a
    - Licensed Clinic, or
    - Outpatient Setting, or
    - Health Facility, or
    - County Medical Facility, or
    - Place of Practice

"Place of Practice" is defined as a Dental Office pursuant to Business and Professions Code § 1658.

  - The patient is receiving hospice care.
- What if it is not reasonably possible for a prescriber to access the information in CURES in a timely manner?
  - If another individual with access to CURES is not reasonably available, a five-day supply of the controlled substance can be prescribed, ordered, administered, or furnished as long as there is no refill allowed. In addition, the prescriber must document in the medical records the reason for not consulting CURES.
- What if I determine that consulting CURES would result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition?
  - A prescriber may provide a non-refillable five-day supply if they make this determination. The prescriber must document in the medical records the reason for not consulting CURES.

CURES 2.0

WHAT IF I EXPERIENCE TECHNICAL DIFFICULTIES WITH CURES?

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@MedboardOfCA

https://oag.ca.gov/cures

Assembly Bill 40

AB 40 (Stats 2017, Ch 607, Santiago)

Assembly Bill 40 (AB-40), chaptered on October 9, 2017, and codified in Health and Safety Code section 11165.1, 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.

Assembly Bill 40

CURES INTEGRATION

Assembly Bill 40 (Stats 2017, Ch 607, Santiago)

- Stakeholder Webinars
- Technical documentation
- Memorandum of Understanding
- Integration Solution Release

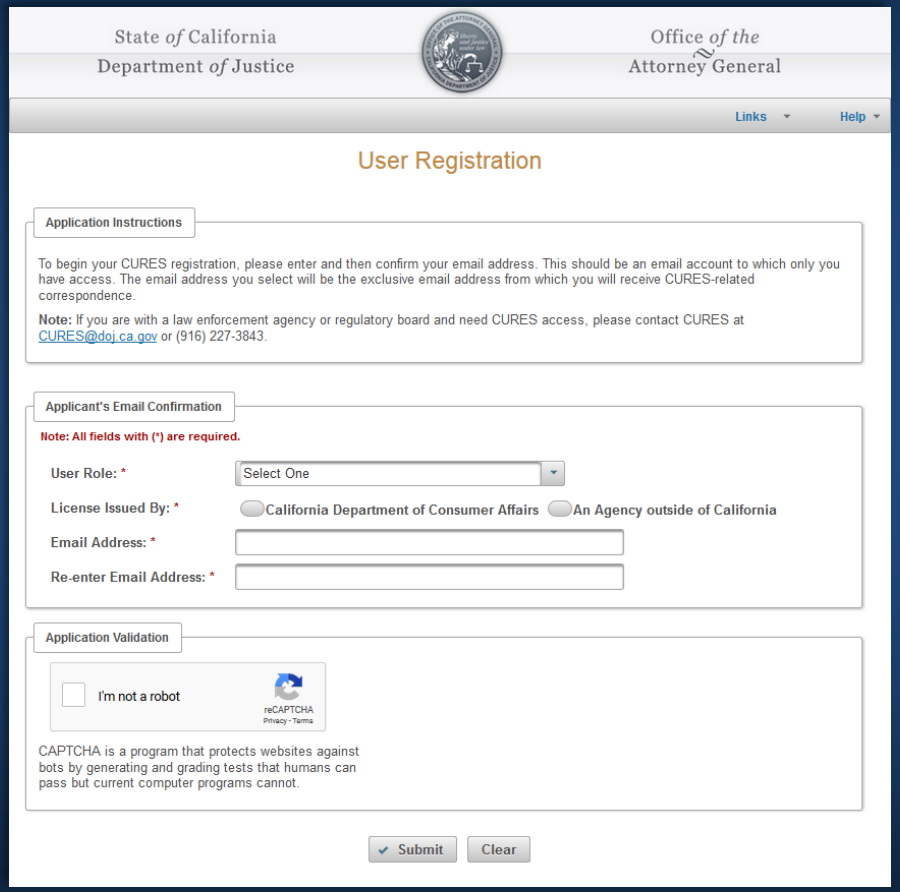
CURES 2.0

CURES 2.0 provides an improved user interface; fast, robust performance; analytics; and innovative PDMP informational features.

Prescriber & Dispenser Registration

Automated Registration

CURES 2.0 provides a web-based electronic registration process that can be accessed from the Office of the Attorney General website.

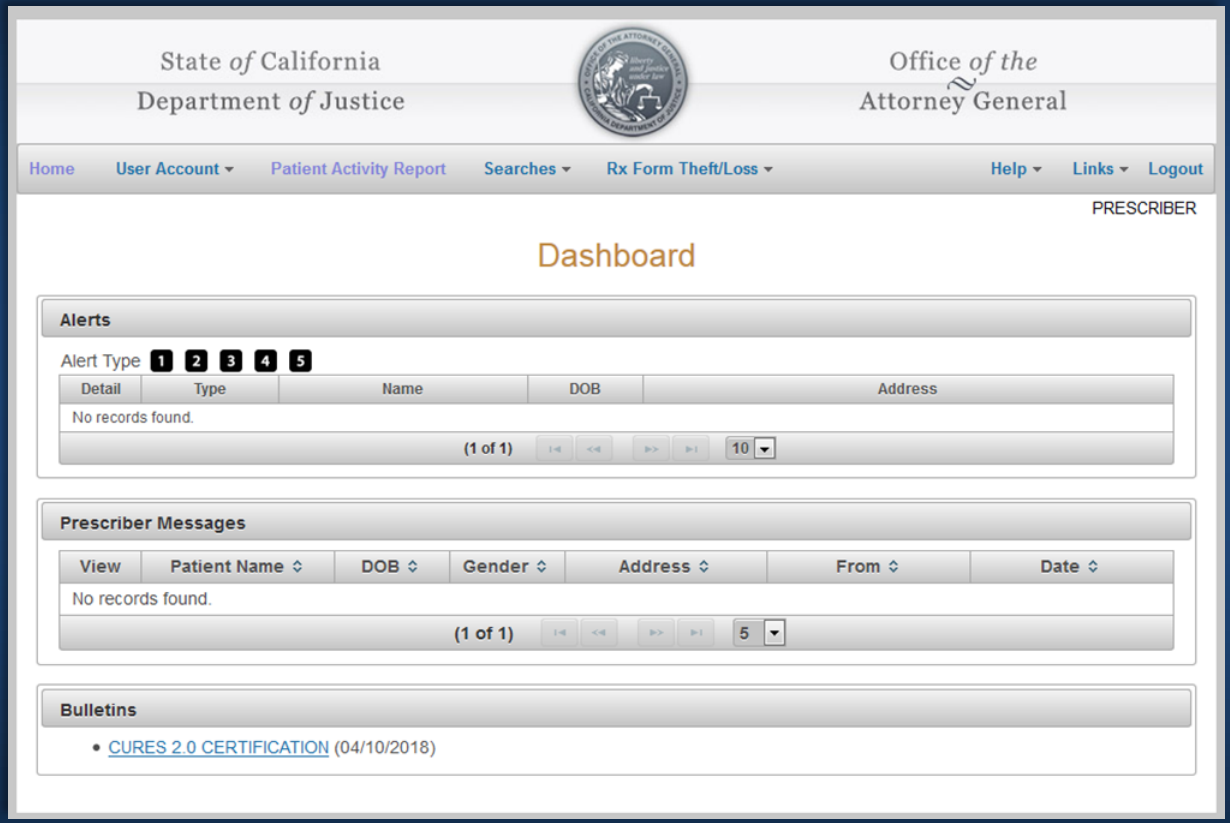


CURES 2.0 Features

Dashboard

The Dashboard is the landing page for all users upon login to CURES 2.0. From this page, users can access all features contained within CURES 2.0, including:

- Alerts
- Prescriber Messages
- Bulletins
- Global Navigation Bar

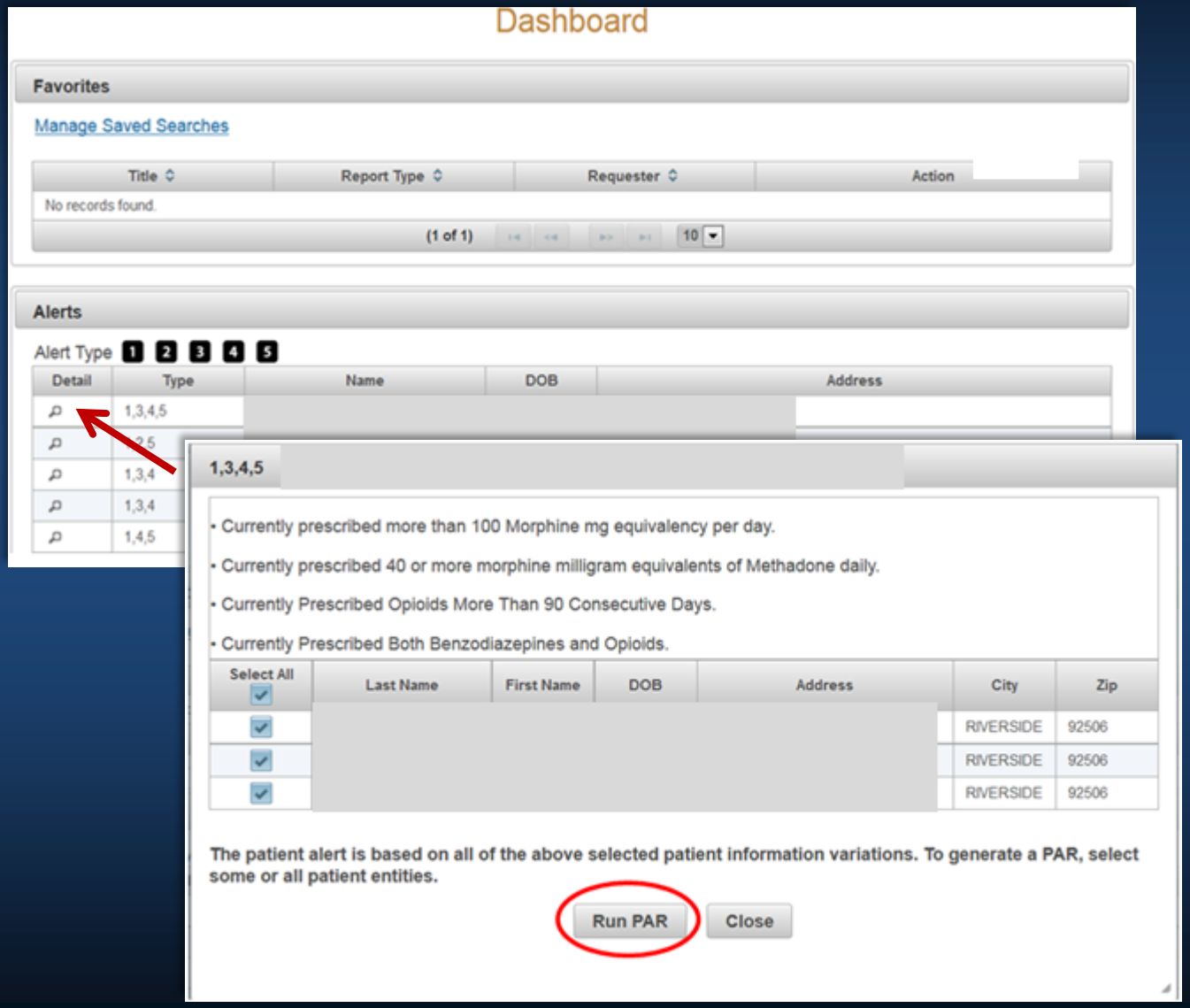


CURES 2.0 Features

Alerts

Based on patterns indicative of at-risk patient behavior.

Alerts are informational and providers must determine if any action is necessary.



CURES 2.0

CURES 2.0 Features

Patient Safety Alerts

1. Rx Recipients Who are Currently Prescribed More than 90 Morphine Milligram Equivalency Per Day

2. Rx Recipients Who Have Obtained Prescriptions from 6 or More Prescribers or 6 or More Pharmacies During Last 6 Months

3. Rx Recipients Who Are Currently Prescribed More than 40 Milligrams Methadone Daily

4. Rx Recipients Who Are Currently Prescribed Opioids More Than 90 Consecutive Days

5. Rx Recipients Who Are Currently Prescribed Both Benzodiazepines and Opioids

CURES 2.0 Features

Global Navigation Bar

User Account
Update Profile
Manage Delegates
Change Password

Patient Activity Reports (PARs)
Generate Report
PDF or Excel Format

Searches
Delegate Searches
Saved Searches

Prescription Form Theft/Loss
Create Reports
Search Self-Reports

CURES 2.0 Features

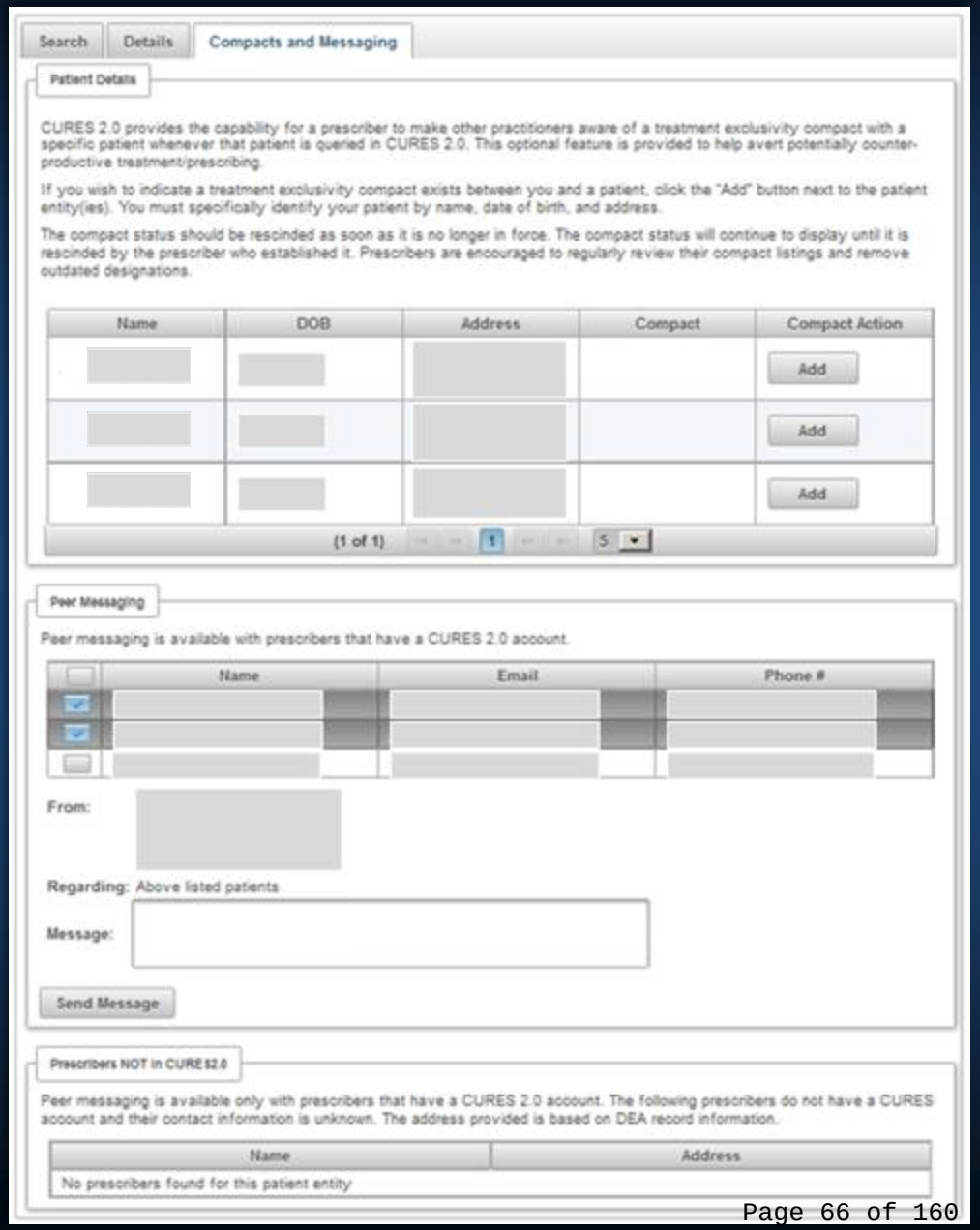
Compacts

Prescribers can easily notate their patients with treatment exclusivity compacts, forewarning other providers that additional prescribing to these patients can be potentially counter-productive to their existing treatment regimen. Users can view if a compact exists for a patient.

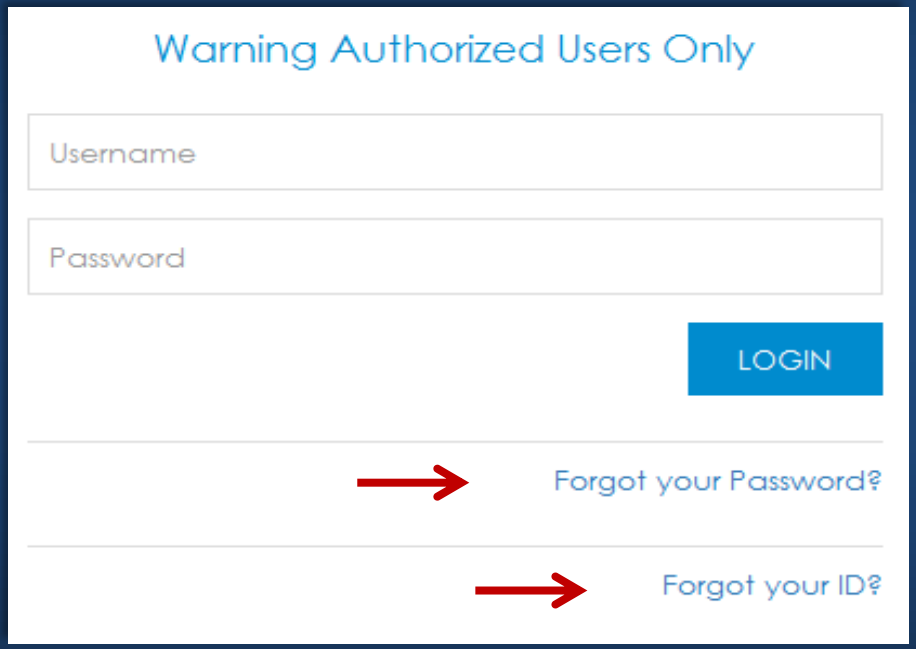
Peer-to-Peer Communication

Users can view prescriber contact information. Prescribers and dispensers can securely send messages to prescribers concerning mutual patients within CURES 2.0.

Messages are encrypted in transit and at rest.



CURES 2.0 Self-Service

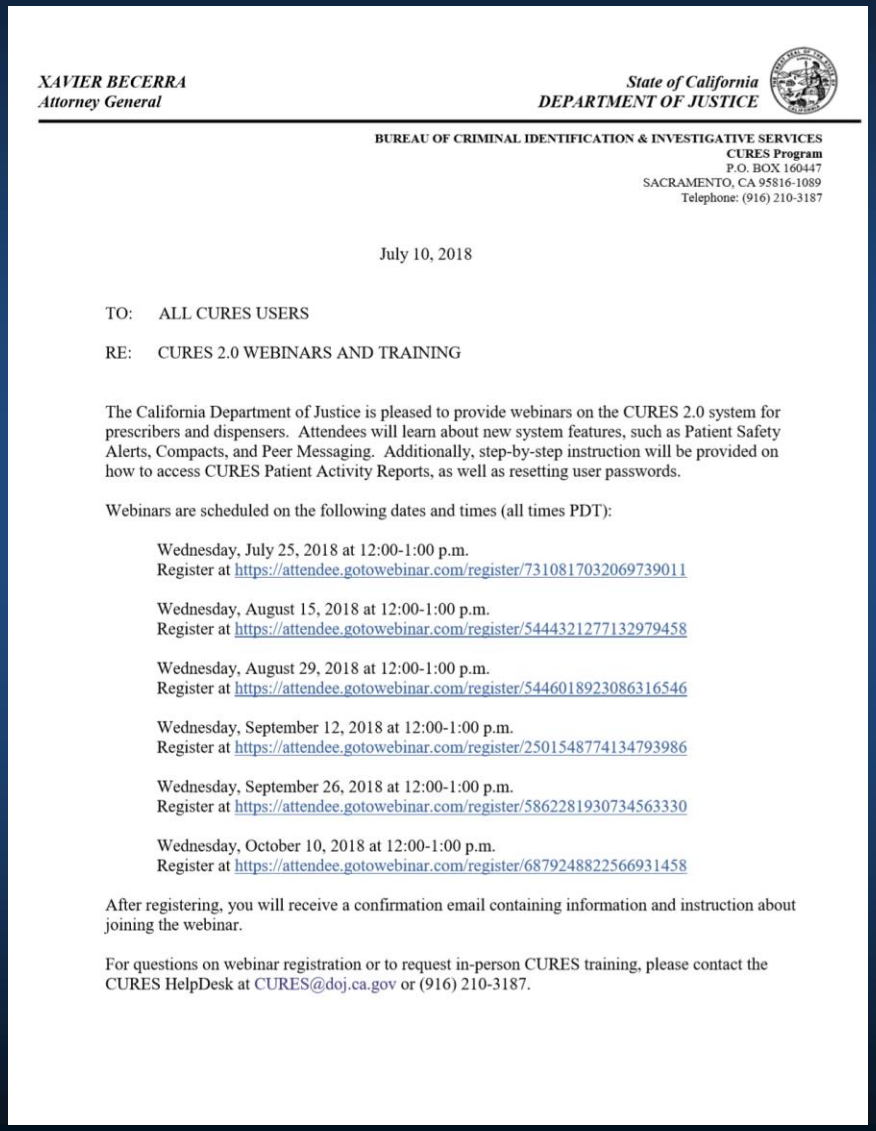


Password resets are required every 90 days.

Reminder emails are sent to the user prior to the password expiration date.

CURES 2.0

Resources



XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

BUREAU OF CRIMINAL IDENTIFICATION & INVESTIGATIVE SERVICES
CURES Program
P.O. BOX 160447
SACRAMENTO, CA 95816-1089
Telephone: (916) 210-3187

July 10, 2018

TO: ALL CURES USERS

RE: CURES 2.0 WEBINARS AND TRAINING

The California Department of Justice is pleased to provide webinars on the CURES 2.0 system for prescribers and dispensers. Attendees will learn about new system features, such as Patient Safety Alerts, Compacts, and Peer Messaging. Additionally, step-by-step instruction will be provided on how to access CURES Patient Activity Reports, as well as resetting user passwords.

Webinars are scheduled on the following dates and times (all times PDT):

Wednesday, July 25, 2018 at 12:00-1:00 p.m.
Register at https://attendee.gotowebinar.com/register/7310817032069739011

Wednesday, August 15, 2018 at 12:00-1:00 p.m.
Register at https://attendee.gotowebinar.com/register/5444321277132979458

Wednesday, August 29, 2018 at 12:00-1:00 p.m.
Register at https://attendee.gotowebinar.com/register/5446018923086316546

Wednesday, September 12, 2018 at 12:00-1:00 p.m.
Register at https://attendee.gotowebinar.com/register/2501548774134793986

Wednesday, September 26, 2018 at 12:00-1:00 p.m.
Register at https://attendee.gotowebinar.com/register/5862281930734563330

Wednesday, October 10, 2018 at 12:00-1:00 p.m.
Register at https://attendee.gotowebinar.com/register/6879248822566931458

After registering, you will receive a confirmation email containing information and instruction about joining the webinar.

For questions on webinar registration or to request in-person CURES training, please contact the CURES HelpDesk at CURES@doj.ca.gov or (916) 210-3187.

Upcoming Webinars

In-person Training

Additional Resources

https://oag.ca.gov/cures/publications

CURES 2.0

Questions?

DOJ Contact Information

Tina Farales
Phone: (916) 210-3171
Email: Tina.Farales@doj.ca.gov

CURES Help Desk and General Questions
Phone: (916) 210-3187
Email: CURES@doj.ca.gov

http://oag.ca.gov/cures

CURES 2.0

Thank you!

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 10, 2018

TO: Medication Safety Committee Members

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

SUBJECT: Sterile Compounding Grids

SUMMARY

The CSHP Sterile Compounding Task Force reviewed final comments from the committee and has completed an enormous amount of work by updating all the tools. The final grids are a hallmark example of the extraordinary collaborative work amongst the medication safety community to streamline sterile compounding efficiency and effectiveness in hospital pharmacies.

An announcement has been published in CHA News and the grids have been posted in the Medication Safety Toolkit on the CHA website.

ACTION REQESTED

- Please see grids attached.

Attachments: Sterile Compounding Grids

BJB:br

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 – 2.2º	2º	8º 7.7º	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		20º 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		

This tool is intended for hospital and health care pharmacists in charge (PIC) 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.

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

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 September 17, 2018

Facilities and Engineering Controls: Hazardous Drugs

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

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

Last Revised 9/17/2018

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

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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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Last Revised 9/17/18

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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Last Revised 9/17/18

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

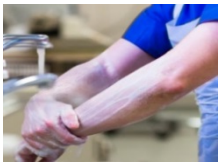
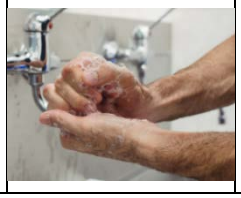
1) **Put on TWO pairs of shoe covers on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD**
2) **Repeat for 2nd foot**

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.

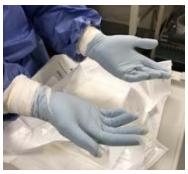
NOTE: HD-gowns must be changed, at a minimum, every 3 hours OR immediately after a spill or splash

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

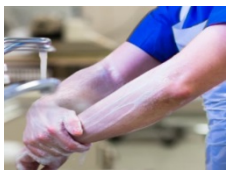
1) **Put on shoe cover on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD.**
2) **Repeat for 2nd foot**

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

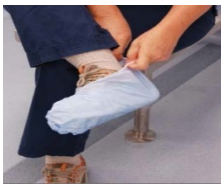
DOFFING SEQUENCE

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 10, 2018

TO: Medication Safety Committee Members

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

SUBJECT: **Sterile Compounding Drug Modifications , Notice of Modified Text, Title 16 of the California Code of Regulations, Sections 1735.1, 1735.2, 1735.6, 1751.1, 1751.4 Comment Period: September 26, 2018 to October 11, 2018.**

SUMMARY

CHA did not submit written comments to the proposed text, however did testify using written comments from both Providence St. Joseph Health and Cedars-Sinai, (See Attachments). There are still concerns regarding the temperature language in 1751.4. Several issues brought to the BoP's attention during testimony, such as "separate versus non separate BSI exhaust" and "continuous ventilation enclosure" were not taken. The BoP is willing to work on temperature language.

Comments are due on October 11, and CHA will submit concerns expressed by the committee today.

In addition, Dr. Perrott, CHA Medical Director, shared the Joint Commission information on survey material for sterile compounding.

QUESTIONS:

1) What issues remain that need to be addressed?
2) How are hospital pharmacies doing regarding waivers and sterile compounding conforming requirements?
3) What other issues does CHA need to address from a sterile compounding policy perspective?

ACTION REQESTED

- Information only.

Attachments: Notice of Proposed Action
Initial State of Reasons
Availability of Modified Text
Modified Text
PSJH Compounded Drug Preparations Comment Letter
CaBOP Title 16 Proposed Text Comments
Campbell Sterile Medication Compounding

BJB:br

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office not later than 5:00 p.m. on September 17, 2018.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Sections 4005 and 4127 of the Business and Professions Code authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The board proposes to clarify and make specific the standards for pharmacies and pharmacists compounding drug preparations.

Business and Professions Code (B&P) section 4001.1 specifies that protection of the public is the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. It also specifically authorizes it to adopt regulations: relating to the sanitation

of persons and facilities licensed by the board; pertaining to licensed facilities wherein any drug is compounded, prepared, furnished or dispensed; pertaining to minimum equipment for licensed facilities; and for the proper and effective enforcement and administration of Pharmacy Law.

B&P section 4127 generally authorizes the board to adopt and amend regulations establishing standards for compounding sterile drug products in a pharmacy.

B&P section 4029 established the definitions of a hospital pharmacy and a hospital satellite compounding pharmacy.

B&P section 4036 establishes the definition of a pharmacist.

B&P section 4037 establishes the definition of a pharmacy.

B&P section 4051 generally specifies those functions and duties relating to dangerous drugs or dangerous devices, including compounding, which must be performed by a pharmacist.

B&P section 4052 further specifies general functions a pharmacist may perform, including how a pharmacist may furnish drugs to a prescriber and those functions a pharmacist may perform in a health care facility, clinic or in other health care settings.

California Code of Regulations, title 16, division 17, articles 4.5 and 7 specify the conditions under which pharmacies and pharmacists may compound drug preparations.

The regulations proposed in this rulemaking would modify the requirements for a pharmacy and pharmacist compounding drug preparations, including how pharmacists may establish beyond use dates (BUD) for compounded drug preparations. The proposed amendments would also clarify definitions of compounding terms used, clarify standards relating to equipment used in compounding (including biological safety cabinets), and clarify standards for facilities performing sterile compounding (including smoke studies).

The regulations regarding BUDs for compounded drug preparation were also the subject of an emergency regulation that took effect on December 19, 2017.

Anticipated Benefits of the Proposed Regulations

The broad objective of this proposal is to ensure that compounding is performed in a manner and under conditions that ensure the compounded drug preparations dispensed to the public by a pharmacy and pharmacist are safe and effective. The specific benefits anticipated by the proposed amendments are to protect the public from risks of unsafe and or ineffective compounding of drug preparations. Unsafe compounded drug preparations pose risks to patients, including a risk of death. Ineffective compounded drug preparations can pose a risk to patients if the patient does not receive the

prescribed dose of a medicine. A pharmacist's expanded ability to extend the BUD for non-sterile compounded drug preparations makes such preparations more accessible, and therefore makes patients healthier by increasing the compliance with a doctor's directions. It also includes benefits such as the protection of public health and safety, worker safety, the environment, and the increase in openness and transparency in business and government.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact and Related Estimates

The board has made the following initial fiscal impact determinations:

Local Mandate: None

Fiscal Impact on Public Agencies:

- Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None
- Costs/Savings to State Agencies: Minimal cost savings
- Nondiscretionary Costs/Savings to Local Agencies: None
- Costs/Savings in Federal Funding to the State: None

Significant Statewide Adverse Economic Impact Directly Affecting Businesses (If Any):

The board has made an initial determination that the proposed regulatory action would have no significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The board concludes that it is:

(1) Unlikely that the proposal will create or eliminate any jobs within California;
(2) Unlikely that the proposal will create new, or eliminate existing, businesses in California;

(3) Unlikely that the proposal will expand businesses currently doing businesses within the state;
(4) The benefits to the public are for consumer protection and increased assurance that any compounding services will be provided safely and effectively with minimal risk, that patients will have better access to nonsterile compounded medications, that workers and environments will be protected during the compounding of drugs and that the board will be better able to monitor compliance.

Benefits of the Proposal:

The board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and the state's environment. Unsafe or inadequately prepared or handled compounded medications pose risks to consumers' health; drugs compounded in an unsafe manner pose risks to employees and the environment. By regulating the circumstances under which a pharmacy and pharmacist may compound drug preparations and provide them to consumers, the board makes it more likely compounded drugs are safe and effective for consumers and makes it more likely that the employees and the environment are protected. The proposed amendments modify how pharmacists and pharmacies can compound drug preparations, which will increase patient access to these products, will ensure they are safely prepared, will ensure that workers and the environment are protected, and that the board can appropriately monitor for compliance.

Cost Impact on Representative Private Person or Business:

The board anticipates that the regulatory proposal could result in patients receiving a larger supply of medication at one time and could result in fewer visits to the doctor and/or pharmacy and therefore lower patient costs. Pharmacies may also experience cost savings due to decreased testing requirements to extend the duration of a drug preparation's usefulness. It anticipates minimal, if any, additional costs in pharmacy recordkeeping and storage when a pharmacy documents its extension of a beyond use date.

Business Reporting Requirement

The proposal requires pharmacies and pharmacists extending the BUD for nonsterile compounded drug preparations to create a record of their analysis and to keep it in the pharmacy's files. For the health, safety, or welfare of the people of the state, the board finds that it is necessary that proposed section 1735.2(i)(1)(G) apply to businesses.

Effect on Small Business:

The board believes this regulation will impact small businesses. Although the board does not have nor maintain data to define if any of its licensees (pharmacies) are a "small business" as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. This is based on the determination that the regulatory proposal could result in existing pharmacies, some of which are likely small businesses, offering more nonsterile compounding services, lower costs for those services, patients receiving a larger supply of medication at one time, and fewer patient visits to the doctor and/or pharmacy. Pharmacies that are small businesses may experience cost savings due to decreased testing requirements to extend the duration of a drug preparation's usefulness; it is also possible that they may experience a very minor increase in costs related to record keeping in so doing.

Consideration of Alternatives

The board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention (1) would be more effective in carrying out the purpose for which the action is proposed, (2) would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or (3) would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The board invites interested persons to present statements or arguments with respect to the alternatives to the proposed regulations during the public comment period.

Availability of Initial Statement of Reasons, Text of Proposed Regulations and Rulemaking File

The board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address above. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, the initial statement of reasons, and all of the documents upon which the proposal is based.

Availability of the Final Statement of Reasons

Upon its completion, you may obtain a copy of the final statement of reasons by accessing the website listed below or by contacting the person named below.

Contact Person

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Lori Martinez
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Phone No.:	(916) 574-7917
Fax No.:	(916) 574-8618
E-Mail Address:	Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Phone No.:	(916) 574-7910
Fax No.:	(916) 574-8618
E-Mail Address:	Anne.Sodergren@dca.ca.gov

Website Access

Copies of this notice, the initial statement of reasons, and the text of the proposed regulations in underline and strikeout can be found at the California State Board of Pharmacy's website: www.pharmacy.ca.gov.

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Compounded Drug Preparations

Sections Affected: Amend Section 1735.1 of Article 4.5 of Division 17 of Title 16, California Code Regulations
Amend Section 1735.2 of Article 4.5 of Division 17 of Title 16, California Code Regulations
Amend Section 1735.6 of Article 4.5 of Division 17 of Title 16, California Code Regulations
Amend Section 1751.1 of Article 7 of Division 17 of Title 16, California Code Regulations
Amend Section 1751.4 of Article 7 of Division 17 of Title 16, California Code Regulations

Problems Addressed

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies and pharmacists. (Bus. & Prof. Code, (B&P) § 4000, et seq.) The board's mandate and its mission is to protect the public. (B&P § 4001.1.) Pharmacies and pharmacists are permitted to compound drug preparations for patients. (B&P §§ 4029, 4036, 4037, 4051, 4052, 4127, 4129.) If, however, compounding is done in an unsafe or unsanitary manner, a compounded drug preparation can pose a significant and potentially fatal threat to the public. A pharmacist is required to label any prescription dispensed with the expiration date of the effectiveness of the drug dispensed. (B&P § 4076.) To minimize unnecessary risks to the public, the board establishes standards for compounding including, but not limited to, how to establish beyond use dates (BUDs) for compounded drug preparations, and standards for the locations and environment where compounding occurs.

On January 1, 2017, following three years of discussion and development, the board's regulations related to compounded drug preparations were extensively amended. (California Code of Regulations, tit. 16, div. 17, articles 4.5 and 7.) Following implementation of the amended regulations, the board and the public identified concerns, and requested clarifications and amendments to the compounding regulations. Specifically, the regulations relating to BUDs for non-sterile compounded drug preparations adversely impacted patient accessibility to the drugs. In addition, there was confusion between use of the terms "venting" and "exhaust"; concern about the methods for venting air from devices during hazardous drug compounding; confusion about which compounding environments require smoke studies and the necessary frequency for conducting the studies; and the board sought to clarify the maximum temperature for a sterile compounding area consistent with national standards.

Benefits

The anticipated benefits of proposed amendments to the regulations include: protecting the health and safety of the public, worker and environmental safety, and increasing openness and transparency in business and government. More specific benefits include: keeping drug compounding safe for the public, making it more likely that individuals compounding the drugs are safe, making compounded drugs more accessible to patients, making the drug compounding standards clearer to the regulated public and other agencies, and making the standards easier for the board to enforce.

The regulations would also create certainty about specified standards for compounding drugs that were adopted as an emergency effective December 19, 2017.

Specific Purpose of Proposed Changes and Rationale

Each regulation section being amended is discussed in turn below.

Proposed Change to Amend 16 CCR Section 1735.1, Compounding Definitions:

Subdivisions (c) and (f) would be amended to change the terminology from "ventilation" and "venting" to "exhausting" and "exhaust." The changes clarify that, where hazardous drugs are being compounded in a biological safety cabinet or an isolator, the exhaust air must be removed from the device by external building exhaust. This will clarify that exhaust air must travel from the device to the outside of the building.

Rationale for board's determination that the changes are necessary: The Office of Statewide Health Planning and Development (OSHPD), which has a role in reviewing construction projects at licensed hospitals, explained to the board that the correct industry term in the California Mechanical Code used to describe this specific type of air flow or movement out or away from a hood or biological safety cabinet is "exhaust." The word exhaust means air is being expelled, pushed or moved through the opening or outlet to the outside. This exhausting requirement is required to ensure worker safety. Additionally, OSHPD advises that in the California Mechanical Code the term venting is only used for heat producing or fuel burning applications like a gas range and therefore is not the most appropriate term in these contexts. This change should also help to avoid any confusion from or by pharmacies regulated both by the board and OSHPD.

Proposed Change to Amend 16 CCR Section 1735.2, Compounding Limitations and Requirements; Self-Assessment:

Subdivision (i)(1)(D) would be amended from "180 days for non-aqueous formulations," to "for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation." This change permits a pharmacist, using professional judgment, to extend the BUD for a non-aqueous formulation beyond 180 days, based on the pharmacist's research, analysis and documentation. The nature of the research, analysis, and documentation is further clarified in subdivision (G). A pharmacist's ability to extend the BUD for the specified

formulation will make the drug preparations more readily available to public. The pharmacist's exercise of professional judgment under the circumstances should adequately protect the public from any risks associated with the extended BUD.

Subdivision (i)(1)(E) would be amended from "14 days for water-containing oral formulations, and" to "for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation." This change permits a pharmacist, using professional judgment, to extend the BUD for a water-containing oral formulation, beyond 14 days based on the pharmacist's research, analysis and documentation. The nature of the research, analysis, and documentation is further clarified in subdivision (G). A pharmacist's ability to extend the BUD for the specified formulation makes will make the drug preparations more readily available to public. The pharmacist's exercise of professional judgment under the circumstances should adequately protect the public from any risks associated with the extended BUD.

Subdivision (i)(1)(F) would be amended from "30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations" to "for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation." This change permits a pharmacist, using professional judgment, to extend the BUD for a water containing topical/dermal and mucosal liquid and semisolid formulations beyond 30 days based on the pharmacist's research, analysis and documentation. The nature of the research, analysis, and documentation is further clarified in subdivision (G). A pharmacist's ability to extend the BUD for the specified formulation will make the drug preparations more readily available to public. The pharmacist's exercise of professional judgment under the circumstances should adequately protect the public from any risks associated with the extended BUD.

Subdivision (i)(1)(G) would be added to read:

> "A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:
>
> (i) the nature of the drug and its degradation mechanism,
> (ii) the dosage form and its components,
> (iii) the potential for microbial proliferation in the preparation,
> (iv) the container in which it is packaged,
> (v) the expected storage conditions, and
> (vi) the intended duration of therapy.
>
> Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula."

Subdivision (i)(1)(G) would be added to clarify how the pharmacist must use professional judgment to research, analyze and document his or her findings in extending a BUD pursuant to one of the identified subdivisions. It requires the pharmacist to research, at a minimum, by consulting and applying drug-specific and general stability documentation and literature. It requires the pharmacist, at a minimum, to analyze the identified documentation and literature, as well as items (i) – (vi) above, before reaching a conclusion. The board determined that items (i) – (vi) were the appropriate standards based on the factors specified in Chapter <795> of the United States Pharmacopeia - National Formulary (USP <795>) for determining BUDs. The board requires the pharmacist to exercise professional judgment in these ways because it is less likely under these circumstances that the public will be harmed by an extended BUD. The section also requires that the pharmacist maintain documentation of his or her research, analysis and conclusion, and to maintain such documents as part of the master formula in a readily retrievable format. The board requires the documentation and maintenance so that the board can readily inspect and verify whether the pharmacist complied with the regulation, and so that the board can take action if it finds that any non-compliance poses a risk to the public.

Subdivision (i)(3) would be amended to add "For sterile compounded drug preparations," to the beginning of the subdivision. This was done to clarify that, with the changes described above, this subdivision, which specifies a different method for extending a BUD, will only apply to sterile compounded drug preparations, and will not apply to non-sterile compounded drug preparations. The standards in subdivision (i)(3) are more appropriate to, and are practically feasible only for, sterile compounded preparations. The board determined that if it did not clarify that subdivision (i)(3) applies only to sterile compounding, the changes the board is proposing to subdivision (i)(1) would create confusion about the means to extend a BUD for both sterile and non-sterile compounded drug preparations.

Rationale for board's determination that the above changes are necessary: After implementation of the revised regulations, the board received significant testimony from the public that patients were not able to receive timely access to medications because of the restrictive BUD for non-sterile compounded preparations. The board's concern was so significant that it adopted emergency regulations on this subject effective December 19, 2017. The analysis below describes the impact of the board's regulations prior to the emergency rulemaking.

The most notable example of direct patient impact was in the area of pediatric oral suspensions where the board's then-current BUD requirements were impacting patient access and ability to maintain appropriate drug therapy. According to the United Network of Organ Sharing (UNOS) online database system (UNet), there were over 1,800 transplants in patients under the age of 18 in 2016 nationwide (based on Organ Procurement and Transplantation Network data as of November 24, 2017). Pediatric patients who have undergone an organ transplant use a compounded medication to prevent the body from rejecting the transplant. Failure to have timely and consistent access to this medication may result in transplant rejection.

For pediatric patients with autism, compounded medications play a vital role. When nutritional therapy is required, pharmacies combine vitamins, minerals, and supplements in specific dosage forms for such patients. According to the Professional Compounding Centers of America, children affected by autism often have unique physical or psychological challenges that can be exacerbated by ingredients found in food and medicine. Compounded medications are necessary to overcome these challenges.

Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients (humans and animals) whose health care needs cannot be met by manufactured medications. Compounding preserves the prescribers' ability to prescribe medications that best fit the needs of their patients. Pharmacies may either cease compounding, or they pass the costs associated with the higher testing standards to extend BUDs on to patients. The BUDs and high-test standards also restrict access to compounded drugs. Accordingly, patients may have suffered under the board's regulations because they paid higher costs than necessary and had limited access to necessary medications. In the context of less risky, non-sterile compounded drugs, the potential consequences of the decreased access to compounded medications far outweigh the additional public protections that come with the more restrictive BUD.

Another impact described was on the compounded medications that are available for prescriber office use. Under board regulations, a pharmacy may provide a reasonable quantity of a medication to a prescriber for office use. Specific to veterinary practices, most non-sterile compounded medications for animals are aqueous, or water-containing, oral formulations. Such medications had a BUD of 14 days. Because the patient population in a veterinary practice ranges in species and sizes (from birds to horses), the reasonable quantity a veterinarian might need to keep on hand varies greatly, and the supply cannot easily be managed without the ability of the compounder to extend the BUD of non-sterile compounded products beyond 14 days. Without the appropriate supply, the veterinarian cannot easily provide sufficient medication to the animal patient until the regular prescription can be filled.

Under the existing regulation, the restrictive BUDs mean that the medication is less accessible for patients because 1) patients can obtain only a limited quantity and must return to the pharmacy more frequently for refills, 2) the expense required to extend BUDs makes drugs prohibitively expensive for patients, or 3) the expense required to extend BUDs will mean that fewer pharmacies will compound and patients will have a harder time finding a pharmacy from which to obtain medications. The patients' restricted access, in turn, directly impacts patients' medication adherence. Patient medication adherence, where the patient takes medication in the dosage and in the pattern prescribed, is necessary for patient health. The lack of ready access to medications decreases patient medication adherence and, consequently, patient health.

This proposal is necessary to allow for the extension of the BUD of non-sterile compounded drug preparations in a manner consistent with national practice standards,

eliminate possible confusion about the means to extend a BUD for both sterile and non-sterile compounded drug preparations, and ensure timely access to non-sterile compounded drug preparations.

Proposed Change to Amend 16 CCR Section 1735.6 Compounding Facilities and Equipment:

Subdivision (e) was amended to change "vented" to "exhausted" for consistency with the changes in 16 CCR section 1735.1.

Subdivision (e)(1) would be amended to change the abbreviation from "hrs" to "hours." This is a non-substantive change made for grammatical clarity.

Subdivision (e)(3) would delete the word "PEC" (Primary Engineering Control) and replaces it with "BSC" (Biological Safety Cabinet). This provision would specify the type of PEC that must be externally vented. The board is providing clarity to this section by adding the more specific compounding terminology of BSC.

Rationale for board's determination that the above changes are necessary: The word PEC is a broad term as defined in 16 CCR section 1735.1(ab). When compounding with hazardous drugs one should only use a negative pressure PEC. A negative pressure PEC is a BSC. The use of a negative pressure PEC is already required in 16 CCR section 1735.4(g).

Subdivision (e)(3) would also be amended to add "except that a BSC used only for nonsterile compounding may use a redundant-HEPA filter in series" to permit a BSC used for nonsterile compounding to use redundant-HEPA filters in series. Additionally, this subdivision was further amended to change "vented" to "exhausted" for consistency with the changes in 16 CCR section 1735.1.

Rationale for board's determination that the above changes are necessary: External exhaustion protects worker safety by removing any contaminants from the immediate air where compounding is occurring. In series filtering of the air is, however, also an accepted air filtering method in USP <800> for nonsterile compounding (see section 5.3.1). This means there would be more than one HEPA filter linked together, each of which would filter the air before it could be recirculated into the compounding room, thereby further cleansing the air for the safety of employees and the environment. The board would be aligning its regulations with the current national compounding practice standards by updating this language. This will continue to protect the public while providing more options to protect worker safety during nonsterile compounding of hazardous drugs.

Proposed Change to Amend 16 CCR Section 1751.1 Sterile Compounding Recordkeeping Requirements:

Subdivision (a)(5) would be amended to add "Biannual" and "Class 5" to the requirements of the video smoke studies. This language is added to clarify the

frequency of the smoke studies and the class environment where the smoke studies must be performed. These changes further align the board's regulation with USP <797>. Smoke studies are used to verify air flow within a specified area. For purposes of this regulation, the smoke study is conducted to verify unidirectional airflow and sweeping action over and away from the compounding area and must be conducted under dynamic conditions.

Rationale for board's determination that the above changes are necessary: The board determined that biannual, meaning twice a year, was the appropriate frequency to perform such studies as it is the same requirement for smoke studies in an ISO Class 5 area and is consistent with USP <797>. The smoke studies help ensure public, worker and environmental protection by demonstrating the airflow in the compounding environment. The smoke study requires that fire alarm systems in a hospital to be turned to test mode (turns off the fire alarm) and it closes the compounding room for the duration of the test. On balance, the benefits of more frequent testing do not outweigh the time, effort and expense of the study; less frequent testing poses an unacceptable risk that the public and workers could be exposed to potentially harmful particles from air circulation.

Proposed Change to Amend 16 CCR Section 1751.4 Facility and Equipment Standards for Sterile Compounding:

Subdivision (k) would be amended to remove the higher figure in the temperature range (24 degrees (Celsius) and 75 degrees Fahrenheit, respectively), leaving only a single maximum temperature for the room where the sterile compounding occurs.

Rationale for board's determination that the above changes are necessary: The temperature where compounding occurs must be comfortable for all employees working in all required protective compounding garments and equipment so that the employees do not perspire; perspiration can expose the area, ingredients and drug products to contaminants. The prior room temperature range requirement was based on the conditions for an operating room. The revised maximum room temperature, 20 degrees Celsius (and its equivalent of 68 degrees Fahrenheit), is a reasonable temperature for a person when garbed for compounding, and it also consistent with USP <797>, which suggests 20 degrees Celsius as the maximum room temperature. (See USP <797>, *Environmental Quality Control* section, under the subheading *Facility Design and Environmental Controls*.)

Underlying Data

1. Relevant Meeting Materials and Minutes from Board Meeting held January 24-25, 2017
2. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held April 18, 2017
3. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held June 2, 2017

4. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held July 12, 2017
5. Relevant Meeting Materials and Minutes from Board Meeting held July 25-26, 2017
6. Chapter <795> of the United States Pharmacopeia - National Formulary (USP37 - NF32 through 2nd Supplement) (37th Revision, Effective December 1, 2014).
7. Chapter <797> of the United States Pharmacopeia - National Formulary (USP37 - NF32 through 2nd Supplement) (37th Revision, Effective December 1, 2014).
8. Chapter <800> of the United States Pharmacopeia - National Formulary (USP37 - NF32 through 2nd Supplement) (40thRevision, Effective December 1, 2017).
9. United Network for Organ Sharing (UNOS) Organ Procurement and Transplantation Network (OPTN) as of November 24, 2017 (https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#)

Business Impact

The board has made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, the proposed amendments more closely align the board's regulations with national practice standards for compounding in USP <795>, <797>, and <800>, allow for the extension of the BUD of non-sterile compounded drug preparations, eliminate possible confusion about the means to extend a BUD for both sterile and non-sterile compounded drug preparations, and ensure timely access to non-sterile compounded drug preparations. These amendments will positively impact California businesses.

Economic Impact Assessment/Analysis

There are approximately 7,627 pharmacies licensed in the state. There are approximately 7,150 licensed California community and outpatient pharmacies and 477 licensed hospital pharmacies. Each of these pharmacies may perform nonsterile compounding in accordance with board regulations.

The proposed changes to the terms "exhaust" and "vent" in the definitions of BSC and CACI are for clarity and to avoid confusion, and the board believes its licensees are currently following industry standards, which are consistent with these clarifications. It does not believe pharmacies will actually modify the equipment or facilities based on these changes. As a result, the board anticipates no economic impact from these changes, including the creation or elimination of jobs, businesses, or the expansion of businesses doing business with the state.

The proposed changes that reduce the standards for establishing a BUD for nonsterile compounded drug preparations will make it possible for pharmacies to use a longer BUD date and allow patients to get larger supplies of a drug at one time. This proposal will restore and codify the prior standard, which is consistent with national industry

standards for nonsterile compounding. The proposal will make it easier to extend BUDs for nonsterile compounded drugs, meaning the medications may be used for a longer period of time. The board anticipates lower costs for patients because they will obtain a larger supply of medications (fewer visits to the pharmacy), and possible lower health care costs overall because patients who can easily access and follow prescription regimens should have better health and need fewer health care interventions (doctor visits and treatments) long term. Fewer visits to the doctor and pharmacy could result in fewer co-pays, and could result in savings to the State for patients receiving Medi-Cal benefits. Based on public testimony, the board also anticipates that pharmacies will find it easier to continue to provide nonsterile compounding as a result of the change. Several pharmacies provided public comment that complying with the current regulation would be prohibitively expensive, and speculated that they may cease to provide nonsterile compounding services if the regulation was not modified. Fewer pharmacies providing these services may result in less competition in the marketplace.

The pharmacy and pharmacist may expend some additional resources in preparing the record when they exercise professional judgment to extend a nonsterile BUD, but those resources were likely being incurred prior to the board's revisions of its compounding regulation by diligent compounders acting consistent with industry practice. Because the board believes most pharmacy licensees to be diligent, it does not anticipate a significant cost associated with that requirement. The clarification that the existing text of the regulation for BUDs continues to apply to sterile compounding is also not anticipated to have an economic impact because it only makes it clearer that the existing standard still applies to that type of compounding. Therefore, the proposed amendments will not result in the creation or elimination of jobs, businesses, or the expansion of businesses doing business with the state.

The clarification that a biological safety cabinet may be used for nonsterile compounding with redundant, in series HEPA filters, rather than external venting, is unlikely to result in an economic change because it will restore the prior standard with respect to ventilation for nonsterile hazardous compounding. While it may be less expensive for a pharmacy that performs only nonsterile hazardous compounding, the board does not believe that many pharmacies perform only that unique type of compounding. Pharmacies that engage in sterile hazardous compounding will still have to invest in the more elaborate external venting. It is more likely that the modification will enable a nonsterile compounder to sometimes perform the nonsterile hazardous compounding for patients in a cost-effective manner without referring a prescription to another compounding pharmacy. Because this restores the prior industry standard for the unique type of compounding, and because the board believes most of its licensed pharmacies are compliant with such standards, the board does not anticipate an economic impact of this regulation on pharmacies. It is possible that patients may save time by being able to obtain their prescriptions from a pharmacy closer to their home.

The change to the standards to the smoke studies is made for clarification. Because the board believes that most of its licensees are diligent compounders, and existing industry standards require twice yearly studies only in ISO Class 5 environments, it does not anticipate pharmacies will be changing their practices. Without a change to

practices, the board does not anticipate an economic impact in the creation or elimination of jobs, businesses, or the expansion of businesses doing business with the State.

The change to the room temperature standard to remove the upper end of the range (leaving only the lower figure of 20 degrees Celsius) is not anticipated to have an economic impact on pharmacies. Similar to prior analysis, existing national industry standards would require the room temperature for sterile compounding to be not more than 20 degrees Celsius. The board believes that most licensed sterile compounding pharmacies are diligent and follow existing industry standards; without a change to the pharmacies' practices, the board does not anticipate an economic impact based on that change.

The board concludes that it is:

(1) Unlikely that the proposal will create or eliminate any jobs within California;
(2) Unlikely that the proposal will create new, or eliminate existing, businesses in California;
(3) Unlikely that the proposal will expand businesses currently doing businesses within the state;
(4) The benefits to the public are for consumer protection and increased assurance that any compounding services will be provided safely and effectively with minimal risk, that patients will have better access to nonsterile compounded medications, that workers and environments will be protected during the compounding of drugs and that the board will be better able to monitor compliance.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law begin implemented or made specific. The only alternative identified would be to not implement the proposed changes. This is not reasonable as it would not mitigate the possible patient harm with the restriction of extending beyond use dates.

AVAILABILITY OF MODIFIED TEXT

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed additional modifications to the text of Title 16 CCR §§ 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, related to Compounded Drug Preparations. Any person who wishes to comment on the proposed modifications may do so by submitting written comments beginning September 26, 2018 and ending at 5pm on October 11, 2018, to the following:

Contact Person: Lori Martinez
Agency Name: California State Board of Pharmacy
Address: 1625 North Market Blvd, Suite N 219
Sacramento, CA 95834
Email: Lori.Martinez@dca.ca.gov
Fax: (916) 574-8617

Please limit your comments to the new modifications to the text.

Any responses to comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons.

Title 16. Board of Pharmacy
Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language. Additionally, text in [brackets] indicates language that is not being amended.

Note: The board adopted an emergency regulation affecting regulation section 1735.2 effective December 19, 2017. The strikethrough and underline to the text of that section reflects changes from the board's non-emergency regulation.

Amend section 1735.1, subdivisions (c) and (f), in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

[…]

(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ~~ventilation~~ exhausting. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI.

[…]

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ~~ventilation~~ exhaust. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

[…]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.2, subdivision (i), in Article 4.5 of Division 17 of Title 16 California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

[…]

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation~~;~~,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,
(v) the expected storage conditions, and
(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, ~~E~~ extension of a beyond use date is only allowable when supported by the following:
(A) Method Suitability Test,
(B) Container Closure Integrity Test, and
(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

[…]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.6, subdivision (e), in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

[…]

(e) Hazardous drug compounding shall be completed in an externally ~~vented~~ exhausted physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 ~~hrs~~ hours or less or when non sterile products are compounded; and
(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and
(3) (A) For sterile compounding, each ~~Each PEC~~ BSC or CACI ~~in the room~~ shall ~~also~~ be externally ~~vented~~ exhausted. ~~except that a BSC used only~~
(B) ~~f~~For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either ~~may~~ use a redundant-HEPA filter in series or be externally exhausted. ~~; and~~ For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

[…]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

Amend section 1751.1, subdivision (a)(5), in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile Compounding Recordkeeping Requirements.

(a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:
[…]
(5) Biannual ~~V~~ video of smoke studies in all ISO Class 5 certified spaces.
[…]

[…]

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1751.4, subdivision (k), in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile Compounding.

[…]

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically includes a room temperature of 20 ~~-24~~ degrees Celsius (68 ~~-75~~ degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

[…]

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

Providence St. Joseph Health
20555 Earl Street
Torrance, CA 90503

October 3, 2018

California Board of Pharmacy
Attn: Ms. Lori Martinez
1625 N. Market Blvd., N219
Sacramento, CA 95834

SUBJECT: Compounded Drug Preparations, Notice of Modified Text, Title 16 of the California Code of Regulations, Sections 1735.1, 1735.2, 1735.6, 1751.1, 1751.4. Comment Period: September 26, 2018 to October 11, 2018.

Dear Ms. Martinez:

Providence St. Joseph Health appreciates the efforts by the California Board of Pharmacy to develop a temperature standard that seeks to address the concerns we raised in our original comment letter. We are submitting additional comments on the modified text for your consideration.

PSJH Recommendation

In reference to the proposed modifications to Section 1751.4(k), Providence St. Joseph Health urges the Board to provide guidance to inspectors on how they will interpret a "typical" temperature if the cleanroom is measured above 20 degrees Celsius during an inspection. Inspectors should consider a variety of factors, including a daily temperature log, drug storage requirements, and seasonal temperatures, to ensure consistency in the application of the new standard. It may be helpful to consider what is *atypical* when defining and/or interpreting the room temperature standard.

Thank you for carefully considering our comments on the modified text.

Sincerely,

Michael Tou
Director, Government Relations

cc: Providence St. Joseph Health Pharmacy Directors
BJ Bartleson, California Hospital Association

	Proposed text	Comments
1735.1. (f) Compounding Definitions.	Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ~~ventilation~~ exhausting. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI.	USP 800 does not require each BSC be separately exhausted. This would be prohibitive in both cost and physical feasibility since it would be very challenging to have multiple vents.
1751.4. Facility and Equipment Standards for Sterile Compounding	(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20~~-24~~ degrees Celsius (68~~-75~~ degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.	Recommend changing language to " approximately 20 degrees Celsius" to be consistent with USP 797 which states a comfortable temperature such as 68 degrees
1735.6. Compounding Facilities and Equipment.	(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors);	Measuring negative pressure differential above the ceiling is not required by USP 800 and would be difficult to measure since pharmacies generally have solid ceilings to prevent diversion.
	(3) Each ~~PEC~~ BSC in the room shall also be externally ~~vented~~ exhausted except that a BSC used only for nonsterile compounding may use a redundant-HEPA filter in series; and	Need to insert "Hazardous" after non-sterile.

Enhanced Sterile Medication Compounding Evaluation

Robert Campbell, PharmD

Pharmacist, Standard Interpretation

Division of Healthcare Improvement

The Joint Commission

The Joint Commission

Contents

Reducing Risk Associated with Sterile Medication Compounding

Accreditation chapters utilized

- Environment of Care
- Human Resources
- Infection Control
- Leadership
- Medication Management

No new standards were written for hospital accreditation program

- Proper aseptic technique
- Proper PPE
- Media Fill Competency
- Finger tip testing competency
- Didactic Competency
- Hazardous Medication Competency

Personnel

Product

- Proper product storage
- Proper product labeling
- Appropriate BUD assignment
- Correct complexity level assessment

Leadership

- Oversight - Accountability
- Policy Implementation
- Knowledge

Environment

- Proper PEC placement
- Proper Testing and Certification
- Correct ISO level designations
- Reduction of highly pathogenic organisms
- Reduction of excessive CFU bacterial growth

Survey process

- Competencies
- Evaluation of environment
- Review of test/certification reports of engineering controls
- Observation of compounding process
- Labeling and storage

Competencies

Competencies

- Fingertip testing
  - Initial and ongoing
- Media fill test
  - Match most complex level of compounding
- Didactic test
  - Must establish a passing level
- Observation of handwashing and donning PPE

Competencies frequency

- Low-Risk and Medium-Risk Sterile
  - Annually for staff performing
    - defined as every 12 months +/- one month
- High-Risk Sterile Compounding
  - Every 6 months

Evaluation of the Compounding Environment

Compounding environment

Walls

- Surface should be smooth
- Resistant to cleaning activities
- Where flooring meets walls should be evaluated
  - Typical installation leaves a ledge that creates risk for dusk accumulation

Floors

- Must be solid

Ceilings

- Either solid surface or if drop in tiles
  - Tiles must be sealed
  - Tiles must be caulked into the support framing
- Sprinkler heads

Testing/Certification Reports Review

Primary Engineering Control (PEC) Certification/Testing Requirements

The Joint Commission

Test every 6 months (or if the PEC is relocated or moved)	Result Required
ISO Level	5 or better (less)
Air Microbial Sampling	≤ 1 cfu/cubic meter [1000 liters] of air per plate *
Surface Microbial Sampling	≤ 3 cfu/ contact plate *
Air velocity	Per Manufactures Requirements
HEPA filter leak test	No leak greater than 0.01%

*Evidence of remediation along with re-culturing is required when CFU count is exceeded or for any CFU of highly pathogenic organisms.

Secondary Engineering Control (SEC) Certification/Testing Requirements

The Joint Commission

Test every 6 months	Ante Room Requirement	Buffer Room Requirement
ISO level	8 or better	7 or better
HEPA filter leak test	PASS	PASS
Room air exchanges	30 ACPH	30 ACPH (no more than 15 can be supplied by hood)
Room pressurization	+	N.H. +0.02" w/c H - 0.01" w/c
Surface microbial sampling	≤ 100 cfu/ contact plate *	≤ 5 cfu/ contact plate *
Air microbial sampling	≤ 100 cfu/cubic meter *	≤ 10 cfu/cubic meter *

*Evidence of remediation along with re-culturing is required when CFU count is exceeded or for any CFU of highly pathogenic organisms.

Compounding Direct Observation

Compounding Observation

- Item placement
- Protecting critical sites
- Single dose vial use and labeling
- Large volume bag use and labeling
- Correct Primary Engineering Control used

Labeling and Storage

Labeling and storage

- Beyond use date (BUD) application
- BUD must match compounding complexity and storage
- Evaluating items returned to the pharmacy
- Addressing re-dispensed items

Suggested Compliance Tactics

- Perform a GAP analysis of Engineering Control Testing and Certification
- Perform a GAP analysis of Compounding Operations
- Complete periodic evaluations of practices occurring in the compounding suite
- Develop a quality dashboard for Sterile Compounding
- Make Sterile Compounding an organizational priority

Frequently Asked Questions

Posted Frequently asked questions

Medication - Concentrated KCL definition

Medication - Licensed Independent Practitioner Controlled - Pharmacy Review

Featured ! **New** ! Medication - Sterile Compounding - Compounding Staff Competency Requirements

Featured ! **New** ! Medication - Sterile Compounding - Exending Beyond Use Dates (BUD) with Closed System Transfer Devices (CSTD)

Featured ! **New** ! Medication - Sterile Compounding - Low Volume Hazardous Medication Preparation

Featured ! **New** ! Medication - Sterile Compounding - Nurse Competency Requirements

Featured ! **New** ! Medication - Sterile Compounding - Personal Protective Equipment (PPE) Requirements with Compounding Isolators

Featured ! **New** ! Medication - Sterile Compounding - Primary Engineering Control (PEC) Testing/Certification Requirements

Featured ! **New** ! Medication - Sterile Compounding - Secondary Engineering Control (SEC) Testing/Certification Requirements

Featured ! **New** ! Medication - Sterile Compounding - Segregated Compounding Area (SCA)

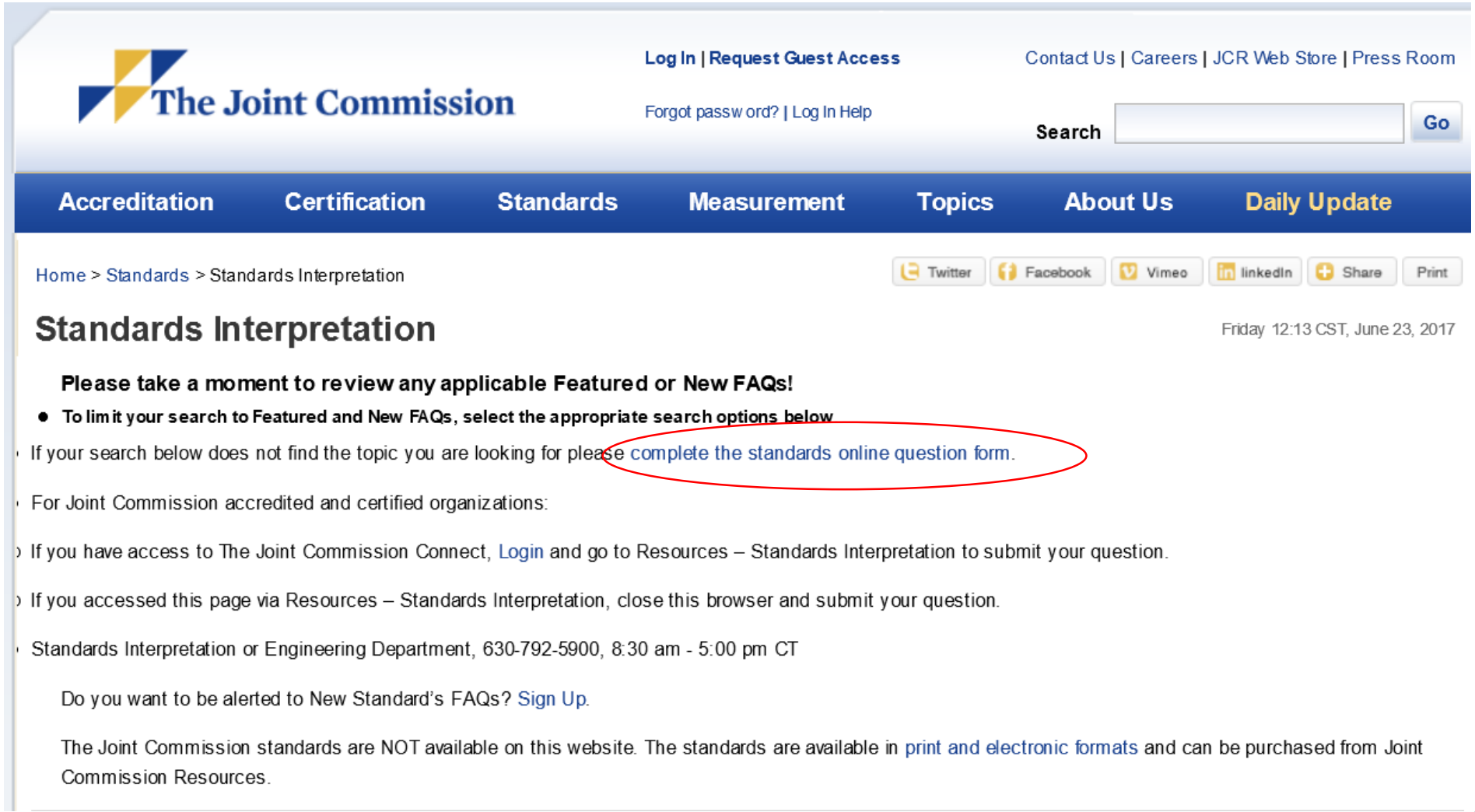
Featured ! **New** ! Medication - Sterile Compounding - Testing/Certification Remediation Requirements for Primary and Secondary Engineering

Featured ! **New** ! Medication - Sterile Compounding - Unit Dose Alcohol Swabs

Featured ! **New** ! Medication - Sterile Compounding - Using Primary and Secondary Engineering Controls with Testing/Certification Failures

Medication Administration - Incorporating Patient Preference Into Medication Administration Practices

Have Questions..... Need Answers?



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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 10, 2018

TO: Medication Safety Committee

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

SUBJECT: Prohibition on Universally-Connectable Tubing Connectors

CHA has heard from hospitals that some of the reengineered tubing connectors leak when drawing up medications. This is particularly important when drawing up/administering hazardous medications.

SUMMARY

The U.S. Food and Drug Administration (FDA) has issued a guidance letter in response to continued reports of misconnections with enteral devices. The FDA recommends that hospitals and clinicians use enteral devices with connectors that meet the International Organization for Standardization (ISO) 80369-1 or ISO 80369-3 standard, or that are otherwise designed to reduce the risk of misconnections. (The FDA also notes that some currently marketed enteral connectors that meet the 80369-3 standards use the tradename ENFit).

The letter also recommends that health care professionals:

- Check the labeling or check with the distributor or manufacturer to determine whether connectors meet the ISO standards.
- Organize a plan to implement the use of these new devices.
- Do not modify or adapt devices, because that may defeat their safety system.
- Minimize the use of transition adapters.
- Do not use cross-application connectors.
- Trace all lines back to their origin when reconnecting devices.
- Route tubes and catheters that have different purposes in unique and standardized directions to avoid accidental misconnections.

A California law prohibits hospitals and skilled-nursing facilities from using epidural, intravenous or enteral feeding connectors that can fit into connection ports other than the type for which they were intended. Hospitals and skilled-nursing facilities are now required to use reengineered tubing connectors, which work to prevent misconnections, eliminate human error and facilitate patient safety.

Hospitals are encouraged to develop a careful and methodical transition to the new connectors, and should also review their patient safety plans to ensure they adequately address the prevention of

misconnecting intravenous, enteral and epidural lines. More details about patient safety plan requirements are available in Chapter 19 of CHA's *Consent Manual*. For more details about tubing connectors, visit the FDA website.

DISCUSSION

1. Has your hospital experienced connector leakage while drawing up medications using the re-engineered connectors?
2. Has your hospital completely transitioned to reengineered epidural and enteral connectors?
3. Has your hospital(s) included sustained product availability in the hospital's patient safety plan?

Attachment: FDA Guidance Letter

DBR:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 10, 2018

TO: Medication Safety Committee Members

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

SUBJECT: **Narcotic Inventory Reconciliation Regulations**

SUMMARY

At our last meeting we discussed the duplicative processes hospitals use to meet regulations to monitor controlled substances and prevent diversion. Ms. Herold and the BoP asked us to use data to demonstrate the efficacy of using a different method to prevent diversion in order to change the regulations and allow institutions that have real-time processes to be exempt from the present manual reconciliation requirement.

CHA suggests we form a subcommittee and or use existing resources to monitor the data to show that institutions that use automated perpetual inventory systems can be exempt from the quarterly manual reconciliation regulation since reconciliation is performed in real time.

QUESTIONS:

1) How would the Committee like to proceed?

ACTION REQESTED

- Next steps for Narcotic Inventory Reconciliation Regulations

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 10, 2018

TO: Medication Safety Committee Members

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

SUBJECT: Nursing and Sterile Compounding

SUMMARY

At our last meeting, Jeannette Wackerly, RN, from the Board of Registered Nursing attended to work with them to clarify and develop FAQ's on how sterile compounding applies to nursing practice outside of the pharmacy setting. For example, how does the BoP compounding definition below apply to nurses who are reconstituting or mixing drugs at the bedside, particularly in light of drug shortages when alternative methods of dispensing and delivery are necessary?

1735. Compounding in Licensed Pharmacies. (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription: (1) Altering the dosage form or delivery system of a drug (2) Altering the strength of a drug (3) Combining components or active ingredients (4) Preparing a compounded drug preparation from chemicals or bulk drug substances (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability. (c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.). Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions C.

At our last meeting, the committee determined to initiate a subcommittee and address RN compounding through education and FAQ's.

QUESTIONS:

1) Who needs to be on the subcommittee and who will chair?

ACTION REQESTED

- Next steps for Nursing and Sterile Compounding

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 10, 2018

TO: Medication Safety Committee Members

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

SUBJECT: **SB 1254, Medication Profile Legislation Passes!**

SUMMARY

Congratulations go out to author Rita Shane, the CHA Medication Safety Committee, and the BoP, for their collaboration and compromise to support SB 1254.

Next steps as far as implementation and education need to be addressed.

QUESTIONS:

1) How will hospital pharmacies be made aware of the new law?
2) Do we need a subcommittee to prepare education, handouts, or a webinar to help hospitals implement and or understand the requirements?

ACTION REQESTED

- Information only.

Attachments: SB 1254

BJB:br

Senate Bill No. 1254

CHAPTER 697

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

[Approved by Governor September 22, 2018. Filed with Secretary of State September 22, 2018.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1254, Stone. Hospital pharmacies: medication profiles or lists for high-risk patients.

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

This bill would require a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission of the patient under specified circumstances. The bill would authorize an intern pharmacist or a pharmacy technician to perform the task of obtaining an accurate medication profile or list for a high-risk patient if certain conditions are satisfied. The bill would require the hospital to establish criteria regarding who is a high-risk patient for purposes of the bill's provisions, and determine a timeframe for completion of the medication profile or list, based on the populations served by the hospital. The bill would exclude the State Department of State Hospitals from the bill's provisions.

By placing new requirements on a pharmacist, this bill would expand the scope of an existing crime and would, therefore, impose a state-mandated local program.

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

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

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

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

4118.5. (a) A pharmacist at a hospital pharmacy shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patient under the following conditions:

(1) The hospital has more than 100 beds.

(2) The accurate medication profile or list may be acquired by the pharmacist during the hospital pharmacy's hours of operation.

(b) Notwithstanding any other law, a pharmacy technician or an intern pharmacist may perform the task of obtaining an accurate medication profile or list for a high-risk patient if both of the following conditions are satisfied:

(1) The hospital pharmacy has a quality assurance program to monitor competency.

(2) The hospital has established policies and procedures for training and proctoring pharmacy technicians or intern pharmacists by the hospital pharmacy department and the pharmacy technician or intern pharmacist has completed that training and proctoring.

(c) The hospital shall establish criteria regarding who is a high-risk patient for purposes of this section, and shall determine the timeframe for completion of the medication profile or list, based on the patient populations served by the hospital.

(d) The board may adopt rules and regulations to carry out the purposes and objectives of this section.

(e) This section shall not apply to the State Department of State Hospitals.

(f) Nothing in this section shall be construed to prohibit a healing arts licensee licensed pursuant to this division from obtaining an accurate medication profile or list.

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

O

File name: CHA

CA AB 315

AUTHOR: Wood [D]
TITLE: Pharmacy Benefit Management
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/06/2017
ENACTED: 09/29/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-905
SUMMARY:

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, unless the pharmacy automatically charges the customer the lower price. Requires the pharmacy to submit a claim to a plan or insurer when a customer pays the retail price. Imposes additional requirements on health care service plans with regard to contracted pharmacy providers and benefit managers.

STATUS:

09/29/2018 Chaptered by Secretary of State. Chapter No. 2018-905
INDEX: 39, 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 587

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

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

STATUS:

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

CA AB 1751

AUTHOR: Low [D]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 01/03/2018
ENACTED: 09/18/2018

DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-478
SUMMARY:

Requires the Department of Justice, no later than a specified date, to adopt regulations regarding the access and use of the information within CURES by consulting with stakeholders, and addressing certain processes, purposes, and conditions in the regulations. Authorizes the Department to enter into an agreement with any entity operating an interstate data sharing hub or prescription drug monitoring program in another state.

STATUS:

09/18/2018 Signed by GOVERNOR.
09/18/2018 Chaptered by Secretary of State. Chapter No. 2018-478
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F, X

CA AB 1752

AUTHOR: Low [D]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 01/03/2018
LAST AMEND: 06/20/2018
DISPOSITION: Failed - Adjourned
LOCATION: Senate Appropriations Committee
SUMMARY:

Adds Schedule V controlled substances to the Controlled Substances Utilization Review and Evaluation System, or CURES database. Requires a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than a working day after a controlled substance is dispensed.

STATUS:

08/16/2018 In SENATE Committee on APPROPRIATIONS: Held in committee.
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA AB 1753

AUTHOR: Low [D]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 01/03/2018
ENACTED: 09/18/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-479
SUMMARY:

Authorizes the Department of Justice to reduce or limit the number of security printers approved by the Department. Requires the prescription forms for controlled substance prescriptions to have a uniquely serialized number, in a

manner prescribed by the Department. Requires a printer to submit specified information to the Department for all prescription forms delivered.

STATUS:

09/18/2018	Signed by GOVERNOR.
09/18/2018	Chaptered by Secretary of State. Chapter No. 2018-479

INDEX: 89

ISSUES: BJ*, DP

LOBBYIST: AH

POSITION: F

CA AB 1998

AUTHOR: Rodriguez [D]

TITLE: Opioids: Safe Prescribing Policy

FISCAL COMMITTEE: yes

URGENCY CLAUSE: no

INTRODUCED: 02/01/2018

LAST AMEND: 07/02/2018

DISPOSITION: Failed - Adjourned

LOCATION: Senate Appropriations Committee

SUMMARY:

Requires every health care practitioner, with the exception of veterinarians, who prescribes, administers, or furnishes opioids classified as Schedule II and Schedule III to adopt, review, and periodically update a safe opioid prescribing policy. Prohibits the safe opioid prescribing policy from placing a limitation on the prescription, ordering, administration, or furnishing of opioids to patients with prescribed conditions.

STATUS:

08/16/2018	In SENATE Committee on APPROPRIATIONS: Held in committee.

INDEX: 73, 89

ISSUES: BJ, DP*

LOBBYIST: AH

POSITION: PR, X

CA AB 2037

AUTHOR: Bonta [D]

TITLE: Pharmacy: Automated Patient Dispensing Systems

FISCAL COMMITTEE: yes

URGENCY CLAUSE: yes

INTRODUCED: 02/06/2018

ENACTED: 09/21/2018

DISPOSITION: Enacted

LOCATION: Chaptered

CHAPTER: 2018-647

SUMMARY:

Amends the Pharmacy Law relating to automated drug delivery systems. Provides an alternative program to authorize a pharmacy to provide pharmacy services to the patients of covered entities that are eligible for discount drug programs through the use of an automated patient dispensing system. Provides that the pharmacy is responsible for the maintenance of the program. Provides that the pharmacy is responsible for obtaining a license.

STATUS:

09/21/2018	Signed by GOVERNOR.
09/21/2018	Chaptered by Secretary of State. Chapter No. 2018-647

INDEX: 89

ISSUES: AO, BJ*, DP
LOBBYIST: AH*, BG
POSITION: F, X

CA AB 2086

AUTHOR: Gallagher [R]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/07/2018
ENACTED: 09/06/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-274
SUMMARY:

Allows prescribers to access the Controlled Substance Utilization Review and Evaluation System, or CURES, for a list of patients for whom that prescriber is listed in the database.

STATUS:

09/06/2018 Signed by GOVERNOR.
09/06/2018 Chaptered by Secretary of State. Chapter No. 2018-274
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: S, X

CA AB 2384

AUTHOR: Arambula [D]
TITLE: Medication Assisted Treatment
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/14/2018
VETOED: 09/23/2018
DISPOSITION: Vetoed
LOCATION: Vetoed
SUMMARY:

Requires a health insurer or a health care service plan, including a MediCal managed care plan, to cover, at a minimum, at least one version of each medication assisted treatment, relapse prevention, and overdose reversal approved prescription drug for opioid use disorder. Provides that at least one version of each treatment, relapse prevention, and overdose reversal prescription drug is not subject to specified requirements of a service plan or health insurance policy.

STATUS:

09/23/2018 Vetoed by GOVERNOR.
INDEX: 65, 89
ISSUES: AM, BJ, DG*, SL
LOBBYIST: AH*, BG
POSITION: F

CA AB 2576

AUTHOR: Aguiar-Curry [D]
TITLE: Emergencies: Health Care
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018

ENACTED: 09/23/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-716
SUMMARY:

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

STATUS:

09/23/2018 Chaptered by Secretary of State. Chapter No. 2018-716
INDEX: 31, 89
ISSUES: AK, BJ, CLH*, DG, RY, SL
LOBBYIST: AH, KAS*
POSITION: F

CA AB 2624

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

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

STATUS:

02/15/2018 INTRODUCED.
INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA AB 2741

AUTHOR: Burke [D]
TITLE: Prescription Drugs: Opioid Medications: Minors
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
LAST AMEND: 06/13/2018
DISPOSITION: Failed - Adjourned
LOCATION: Senate Business, Professions & Economic Development Committee
SUMMARY:

Prohibits a prescriber, as defined, from prescribing more than a certain supply of opioid medication to a minor unless the prescription is for specified uses, with certain exceptions. Requires a prescriber to take certain steps before prescribing a minor a course of treatment with opioid medication, including discussing risks and obtaining verbal consent, except in specified instances.

Makes unprofessional conduct a violation and subjects the prescriber to disciplinary action by their licensing board.

STATUS:

06/18/2018	In SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT: Not heard.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 2760

AUTHOR:	Wood [D]
TITLE:	Prescription Drugs: Prescribers: Naloxone Hydrochloride
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2018
ENACTED:	09/10/2018
DISPOSITION:	Enacted
LOCATION:	Chaptered
CHAPTER:	2018-324

SUMMARY:

Requires a prescriber to offer 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 to a patient when certain conditions are present. Requires the prescriber to provide education on overdose prevention and the use of naloxone hydrochloride or another drug to the patient and specified others. Provides for administrative sanctions for violating these provisions.

STATUS:

09/10/2018	Signed by GOVERNOR.
09/10/2018	Chaptered by Secretary of State. Chapter No. 2018-324
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F, X

CA AB 2789

AUTHOR:	Wood [D]
TITLE:	Health Practitioners: Prescriptions: Electronic Data
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2018
ENACTED:	09/17/2018
DISPOSITION:	Enacted
LOCATION:	Chaptered
CHAPTER:	2018-438

SUMMARY:

Requires health care practitioners authorized to issue prescriptions to have the capability to transmit electronic data transmission prescriptions. Requires pharmacies to have the capabilities to receive those transmissions. Requires a pharmacy to transfer or forward the prescription to another pharmacy at the request of the patient. Requires that a health care practitioner, pharmacist, or pharmacy who fails to meet applicable requirements be referred for administrative sanctions.

STATUS:

09/17/2018 Signed by GOVERNOR.
09/17/2018 Chaptered by Secretary of State. Chapter No. 2018-438
INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F, X

CA AB 2863

AUTHOR: Nazarian [D]
TITLE: Health Care Coverage: Prescriptions
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
ENACTED: 09/26/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-770
SUMMARY:

Limits the amount a health care service plan or health insurer may require an enrollee or insured to pay at the point of sale for a covered prescription to the lesser of the applicable cost sharing amount or the retail price. Provides that a payment rendered by an enrollee or insured would constitute the applicable cost sharing.

STATUS:

09/26/2018 Chaptered by Secretary of State. Chapter No. 2018-770
INDEX: 89
ISSUES: AK, DP, RY*
LOBBYIST: AH
POSITION: F

CA SB 212

AUTHOR: Jackson [D]
TITLE: Solid Waste: Pharmaceutical and Sharps Waste
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/01/2017
ENACTED: 09/30/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-1004
SUMMARY:

Establishes a stewardship program, under which a manufacturer or distributor of covered drugs or sharps, distributor, or other entity defined to be covered by the bill, would be required to establish and implement a stewardship program for covered drugs or for sharps. Authorizes an operator of a stewardship program, after the stewardship plan has been approved, to establish a mail back or other collection program for covered products for a county in which it operates.

STATUS:

09/30/2018 Chaptered by Secretary of State. Chapter No. 2018-1004
INDEX: 75, 89
ISSUES: BJ*, LR
LOBBYIST: AH
POSITION: N, X

CA SB 528

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

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

STATUS:

09/01/2017 In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.

INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA SB 716

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

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

STATUS:

07/19/2017 In ASSEMBLY Committee on APPROPRIATIONS: Not heard.

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

CA SB 1021

AUTHOR: Wiener [D]
TITLE: Prescription Drugs
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/07/2018
ENACTED: 09/26/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-787
SUMMARY:

Amends existing law relating to drug formularies. Requires a prescription drug benefit to provide that an enrollee or an insured is not required to pay more than the retail price for a prescription drug if a pharmacy's retail price is less than the applicable copayment or coinsurance amount, and the payment

rendered by an enrollee or insured would constitute the applicable cost sharing, as specified.

STATUS:

09/26/2018	Chaptered by Secretary of State. Chapter No. 2018-787

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

CA SB 1229

AUTHOR: Stone [R]
TITLE: Pharmacists: Opioid Medications: Consultation
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
LAST AMEND: 04/09/2018
DISPOSITION: Failed - Adjourned
LOCATION: Senate Business, Professions & Economic Development Committee

SUMMARY:

Requires a pharmacist, on dispensing any opioid medication to a patient for the first time, to provide oral consultation before dispensing the medication. Prohibits the pharmacist from dispensing the medication if the patient declines the consultation.

STATUS:

04/09/2018	From SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT with author's amendments.
04/09/2018	In SENATE. Read second time and amended. Re-referred to Committee on BUSINESS, PROFESSIONS & ECONOMIC DEVELOPMENT.

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

CA SB 1240

AUTHOR: Stone [R]
TITLE: Prescription Drugs: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
LAST AMEND: 04/09/2018
DISPOSITION: Failed - Adjourned
LOCATION: Senate Business, Professions & Economic Development Committee

SUMMARY:

Requires a prescription, if in writing or transmitted electronically, to include an ICD 10 Code or a legible clear notice of the condition or purpose for which the drug is being prescribed, unless the patient requests this information to be omitted and would require a prescription transmitted orally to include either the code or a description of the condition or purpose for which the drug is being prescribed. Requires a pharmacy to immediately convey prescription profile data to the requesting pharmacy.

STATUS:

04/16/2018	In SENATE Committee on BUSINESS, PROFESSIONS AND

ECONOMIC DEVELOPMENT: Not heard.

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

CA SB 1254

AUTHOR: Stone [R]
TITLE: Hospital Pharmacies: Medication Profiles
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
ENACTED: 09/22/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-697
SUMMARY:

Requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile for each high risk patient upon admission of the patient, under specified circumstances. Authorizes an intern pharmacist or pharmacy technician to perform the task of obtaining an accurate medication profile, or list, for a high risk patient, if certain conditions are satisfied. Requires the hospital to establish criteria regarding who is a high risk patient and determine completion of such profile or list.

STATUS:

09/22/2018 Chaptered by Secretary of State. Chapter No. 2018-697
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: S, X

CA SB 1264

AUTHOR: Stone [R]
TITLE: MediCal: Hypertension Medication Management
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
LAST AMEND: 05/01/2018
DISPOSITION: Failed - Adjourned
LOCATION: Assembly Appropriations Committee
SUMMARY:

Includes providing specified hypertension medication management services as a covered pharmacist service under the Medi-Cal program.

STATUS:

08/16/2018 In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.
INDEX: 65, 89
ISSUES: AK*, BJ
LOBBYIST: AH, BG*
POSITION: F

CA SB 1285

AUTHOR: Stone [R]
TITLE: Health Care Coverage: Advanced Practice Pharmacist
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no

INTRODUCED: 02/16/2018
DISPOSITION: Failed - Adjourned
LOCATION: Senate Health Committee
SUMMARY:

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

STATUS:

04/25/2018	In SENATE Committee on HEALTH: Failed passage.
04/25/2018	In SENATE Committee on HEALTH: Reconsideration granted.

INDEX: 39, 89
ISSUES: BJ, DG*, DP
LOBBYIST: AH
POSITION: F

CA SB 1286

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

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

STATUS:

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

INDEX: 57, 89
ISSUES: BJ, GBS*
LOBBYIST: AH*, KAS
POSITION: F, X

CA SB 1404

AUTHOR: Stone [R]
TITLE: Pharmacists: Exemption From Overtime Regulations
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Failed - Adjourned
LOCATION: Senate Labor and Industrial Relations Committee
SUMMARY:

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

STATUS:

	04/25/2018	In SENATE Committee on LABOR AND INDUSTRIAL RELATIONS: Not heard.
	INDEX:	57, 89
	ISSUES:	BJ, CM
	LOBBYIST:	AH*, KAS
	POSITION:	F, X

CA SB 1426

AUTHOR:	Stone [R]
TITLE:	Pharmacists: Authority To Prescribe and Dispense
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2018
LAST AMEND:	03/22/2018
DISPOSITION:	Failed - Adjourned
LOCATION:	Senate Business, Professions & Economic Development Committee

SUMMARY:

Requires the State Board of Pharmacy to convene a Public Health and Pharmacy Formulary Advisory Committee to advise the board in promulgating regulations to establish a formulary of drugs and devices that an advanced practice pharmacist may furnish to a patient. Requires the Board to establish a formulary of dangerous drugs and devices that an advanced practice pharmacist may furnish to a patient. Authorizes an advanced practice pharmacist to furnish a dangerous drug or device included on the formulary.

STATUS:

04/04/2018	Re-referred to SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F, X

CA SB 1442

AUTHOR:	Wiener [D]
TITLE:	Community Pharmacies: Staffing
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2018
ENACTED:	09/19/2018
DISPOSITION:	Enacted
LOCATION:	Chaptered
CHAPTER:	2018-569

SUMMARY:

Prohibits a community pharmacy from requiring a pharmacist to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located is made available to assist the pharmacist at all times.

STATUS:

09/19/2018	Signed by GOVERNOR.
09/19/2018	Chaptered by Secretary of State. Chapter No. 2018-569
INDEX:	57, 89
ISSUES:	BJ, GBS*
LOBBYIST:	AH*, KAS

POSITION: F, X

CA SB 1447

AUTHOR: Hernandez [D]
TITLE: Pharmacy: Automated Drug Delivery Systems
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
ENACTED: 09/21/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-666
SUMMARY:

Repeals provisions and conditions for Automated Drug Delivery Systems located in a health facility. Requires an ADDS to meet specified requirements in order to be installed, leased, owned, or operated in the state, including a license issued by the Board of Pharmacy to the holder of an in state valid active pharmacy license. Requires additional conditions for an Automated Patient Dispensing System. Exempts an Automated Unit Dose System from licensure requirements, as provided.

STATUS:

09/21/2018 Chaptered by Secretary of State. Chapter No. 2018-666
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F, X

CA SB 1495

AUTHOR: Health Cmt
TITLE: Health
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/28/2018
ENACTED: 09/14/2018
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2018-424
SUMMARY:

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

STATUS:

09/14/2018 Signed by GOVERNOR.
09/14/2018 Chaptered by Secretary of State. Chapter No. 2018-424
INDEX: 89
ISSUES: BJ, DP, LR*
LOBBYIST: AH
POSITION: F

File name: CHAP/VETO2017

CA AB 40

AUTHOR: Santiago [D]

TITLE:	CURES Database: Health Information System
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	yes
INTRODUCED:	12/05/2016
ENACTED:	10/09/2017
DISPOSITION:	Enacted
LOCATION:	Chaptered
CHAPTER:	2017-607

SUMMARY:

Requires the Department of Justice to make the electronic history of controlled substances dispensed to an individual under a health care practitioner's care, based on data contained in the CURES database, available to the practitioner, or a pharmacist. Authorizes a practitioner or pharmacist to submit a query on an online internet web portal or an authorized health information technology system, under certain conditions. Requires a maintenance fee to establish an integration with the CURES database.

STATUS:

10/09/2017	Signed by GOVERNOR.
10/09/2017	Chaptered by Secretary of State. Chapter No. 2017-607
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	S, X

CA AB 265

AUTHOR:	Wood [D]
TITLE:	Prescription Drugs: Prohibition on Price Discount
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/31/2017
ENACTED:	10/09/2017
DISPOSITION:	Enacted
LOCATION:	Chaptered
CHAPTER:	2017-611

SUMMARY:

Prohibits a person who manufactures a prescription drug from offering any discount, repayment, product voucher, or other reduction in an individual's out of pocket expenses, including a copayment, coinsurance, or deductible, for any prescription drug if a lower cost generic drug is covered under the individuals health insurance, health care service plan, or other health coverage on a lower cost sharing. Authorizes a manufacturer to offer a pharmaceutical product free of charge to patients and insurers.

STATUS:

10/09/2017	Signed by GOVERNOR.
10/09/2017	Chaptered by Secretary of State. Chapter No. 2017-611
INDEX:	89
ISSUES:	DG
LOBBYIST:	AH
POSITION:	F

CA AB 401

AUTHOR:	Aguiar-Curry [D]
TITLE:	Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy
FISCAL COMMITTEE:	yes

URGENCY CLAUSE: no
INTRODUCED: 02/09/2017
ENACTED: 10/07/2017
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2017-548
SUMMARY:

Prohibits the Board from issuing specified licenses to clinics that share a clinic office space until the board is provided with documentation relating to MediCal financing and other regulatory issues. Authorizes primary care clinics and specialty clinics to operate, as specified, in shared clinic space with the government clinics.

STATUS:

10/07/2017 Chaptered by Secretary of State. Chapter No. 2017-548
INDEX: 89
ISSUES: BJ*, PW
LOBBYIST: AH
POSITION: F

CA AB 532

AUTHOR: Waldron [R]
TITLE: Drug Courts: Drug and Alcohol Assistance
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/13/2017
VETOED: 09/28/2017
DISPOSITION: Vetoed
LOCATION: Vetoed
SUMMARY:

Clarifies that a court may collaborate with outside organizations on a program to offer mental health and addiction treatment services to women who are charged in a complaint that consists only of misdemeanor offenses or who are on probation for one or more misdemeanor offenses. Excludes from these provisions a woman who is charged with a felony or who is under supervision for a felony conviction.

STATUS:

09/28/2017 Vetoed by GOVERNOR.
INDEX: 89
ISSUES: SL
LOBBYIST: AH
POSITION: F

CA SB 17

AUTHOR: Hernandez [D]
TITLE: Health Care: Prescription Drug Costs
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 12/05/2016
ENACTED: 10/09/2017
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2017-603
SUMMARY:

Requires health care service plans or health insurers that file certain rate information to report specified cost information regarding covered prescription

drugs, including generic drugs, brand name drugs, and specialty drugs. Requires the publication of a certain report. Establishes notification requirements for certain manufacturers with a specified wholesale acquisition cost of a prescription drug that is purchased or reimbursed by specified purchasers. Makes an appropriation.

STATUS:

10/09/2017	Signed by GOVERNOR.
10/09/2017	Chaptered by Secretary of State. Chapter No. 2017-603

INDEX: 65, 89
ISSUES: AO, DG*
LOBBYIST: AH*, BG
POSITION: S, X

CA SB 351

AUTHOR: Roth [D]
TITLE: Hospital Satellite Compounding Pharmacy: License
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/14/2017
ENACTED: 10/09/2017
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2017-623

SUMMARY:

Authorizes the State Board of Pharmacy to issue a license to a hospital satellite compounding pharmacy meeting specified requirements. Redefines a hospital pharmacy to include a pharmacy that is located in any physical plant regulated as a general acute care hospital. Authorizes the board to issue a license to a hospital satellite compounding pharmacy meeting specified requirements. Requires a hospital satellite compounding pharmacy to compound sterile drug products for registered patients on the premises.

STATUS:

10/09/2017	Signed by GOVERNOR.
10/09/2017	Chaptered by Secretary of State. Chapter No. 2017-623

INDEX: 89
ISSUES: BJ*, PW
LOBBYIST: AH
POSITION: S, X

CA SB 443

AUTHOR: Hernandez [D]
TITLE: Pharmacy: EMS Automated Drug Delivery System
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/15/2017
ENACTED: 10/10/2017
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2017-647

SUMMARY:

Authorizes a pharmacy, or licensed wholesaler that is also an emergency medical services provider agency, to restock dangerous drugs or devices into an emergency medical services automated drug delivery system that is licensed by the board, if specified conditions are met. Requires the provider agency to obtain a license from the board to operate the system.

STATUS:

10/10/2017	Signed by GOVERNOR.
10/10/2017	Chaptered by Secretary of State. Chapter No. 2017-647

INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: S, X

CA SB 510

AUTHOR: Stone [R]
TITLE: Pharmacies: Compounding
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/16/2017
ENACTED: 10/10/2017
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2017-649
SUMMARY:

Repeals a provision under the Pharmacy Law which requires a pharmacy to compound sterile products from one or more nonsterile ingredients in prescribed environments.

STATUS:

10/10/2017	Signed by GOVERNOR.
10/10/2017	Chaptered by Secretary of State. Chapter No. 2017-649

INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA SB 752

AUTHOR: Stone [R]
TITLE: Pharmacy: Designated Representative Reverse Distributor
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/17/2017
ENACTED: 10/08/2017
DISPOSITION: Enacted
LOCATION: Chaptered
CHAPTER: 2017-598
SUMMARY:

Amends existing law relating to requirements of licensure examinations. Provides that an applicant who fails certain licensure examinations be required to wait at a specified period of time before being permitted to retake the examination.

STATUS:

10/08/2017	Chaptered by Secretary of State. Chapter No. 2017-598

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

CA SB 800

AUTHOR: Bus, Prof and Econ Dev Cmt
TITLE: Professions and Vocations
FISCAL COMMITTEE: yes

URGENCY CLAUSE:	no
INTRODUCED:	02/17/2017
ENACTED:	10/07/2017
DISPOSITION:	Enacted
LOCATION:	Chaptered
CHAPTER:	2017-573

SUMMARY:

Amends the Pharmacy Law which provides for the licensure and regulation of pharmacies, pharmacists, and other associated persons and entities by the State Board of Pharmacy. Requires each pharmacist, intern, pharmacy technician, and designated representative 3rd-party logistics provider licensed in this state to join the board's email notification list within sixty days of obtaining a license. Relates to Licensed and Family Therapist Act.

STATUS:

10/07/2017	Chaptered by Secretary of State. Chapter No. 2017-573
INDEX:	89
ISSUES:	BJ, DP, LR*
LOBBYIST:	AH
POSITION:	F