Medication Safety Committee

July 6, 2016

California Hospital Association

CHA Boardroom

1215 K Street, Suite 800

Sacramento, CA 95814

Conference Call Option: (800) 882-3610 Access Code 4206832#

Medication Safety Committee

AGENDA

10:00 **I. CALL TO ORDER/INTRODUCTIONS** — Hanni/Fong

A. Membership

1. Member Updates
2. Member Maps
   a. MSC County Representation - Page 5
3. CHA Member Breakdown
   a. MSC Member Breakdown - Page 6
4. CHA MSC Guidelines for Committee
   a. MSC Guidelines - Page 7
5. CHA MSC Goals and Objectives 2016
   a. MSC Goals and Objectives - Page 11

10:15 **II. MINUTES** — *Recommend: Approval* — Hanni/Fong

A. Draft Minutes - April 6, 2016 - Page 12

III. NEW BUSINESS

10:20 A. FDA - New Draft Guidelines — Low / Eastin

1. Hospital and Health System Compounding Draft Guidance - Page 20
2. Prescription Requirement Under Section 503a Draft Guidance - Page 30
3. Facility Definition Under Section 503b Draft Guidance - Page 44
4. AHA Statement for FDA on Compounding Guidance - Page 53
5. Listening Session on Drug Compounding Summary - Page 57
6. FDA Hospital and Health System Compounding Under the Federal Food, Drug and Cosmetic Act - Page 63

10:55 B. Creating an Inventory of Efforts Statewide — Munoz

(hospitals, health systems, aligned professional groups) on Addressing Opioid Use.

IV. OLD BUSINESS

11:05 A. Sterile Compounding Update — Bartleson

1. Letter From C. Duane Dauner - Page 66
2. Sterile Compounding FAQ - Page 68
3. Assessment Tool - Page 71
4. Grids - Requirements and Regulations - Page 74
5. Sterile Compounding Webinar Presentation - Page 84
6. Sterile Compounding Q&A - Page 113

11:25 B. Revision of Respiratory Monitoring of Patients Outside the ICU Guidelines of Care Toolkit Update — Munoz

11:30 C. Drug Reconciliation and Inventory Regulations — Fong

1. CHA Board of Pharmacy Inventory Letter - Page 116
2. 16 CCR 1715.65 Reconciliation and Inventory Report of Controlled Substances - Page 131
3. Reconciliation Regulations 1715.65 - Page 142
4. Controlled Substance Diversion - Page 168

11:45 D. Small Bore Connectors — Jaffe/Rogers

1. Tubing Connectors Memo - Page 184

11:55 E. Medication Safety Toolkit Manual — Bartleson

1. Production Tracking - Page 186
2. Medication Guidelines Activity Matrix - Page 188
3. Implementation of SB 1039 and Program Flex Requests - Page 192
4. Anticoagulant Guideline - Page 195
5. Reducing Controlled Substance Diversion -

Page 205

6. Insulin Recommended Safe Practice Guidelines - Page 221
7. ED Medication Management Safety Tool - Page 229
8. Recommendations for Improving Safety of Opioid use - Page 236
9. Grids - Requirements and Regulations - Page 246

12:00 **V. LUNCH**

12:45 **VI. PHARMACY LEGISLATIVE UPDATES** — Bartleson

A. Legislative Update - Pharmacy - Page 256

VII. STANDING REPORTS

1:00 A. Board of Pharmacy — Herald

1:05 B. CDPH — Lee/Woo

1:10 C. CSHP — So/Ross

1:15 D. CALNOC — Foley

1:20 E. ACNL

1:25 F. CHPSO — Jaffe

1:30 G. CAHF — Montgomery

1:30 **VIII. WORK GROUP RPEORTS**

A. Sterile Compounding

B. CURES 2.0 Browser — Bartleson

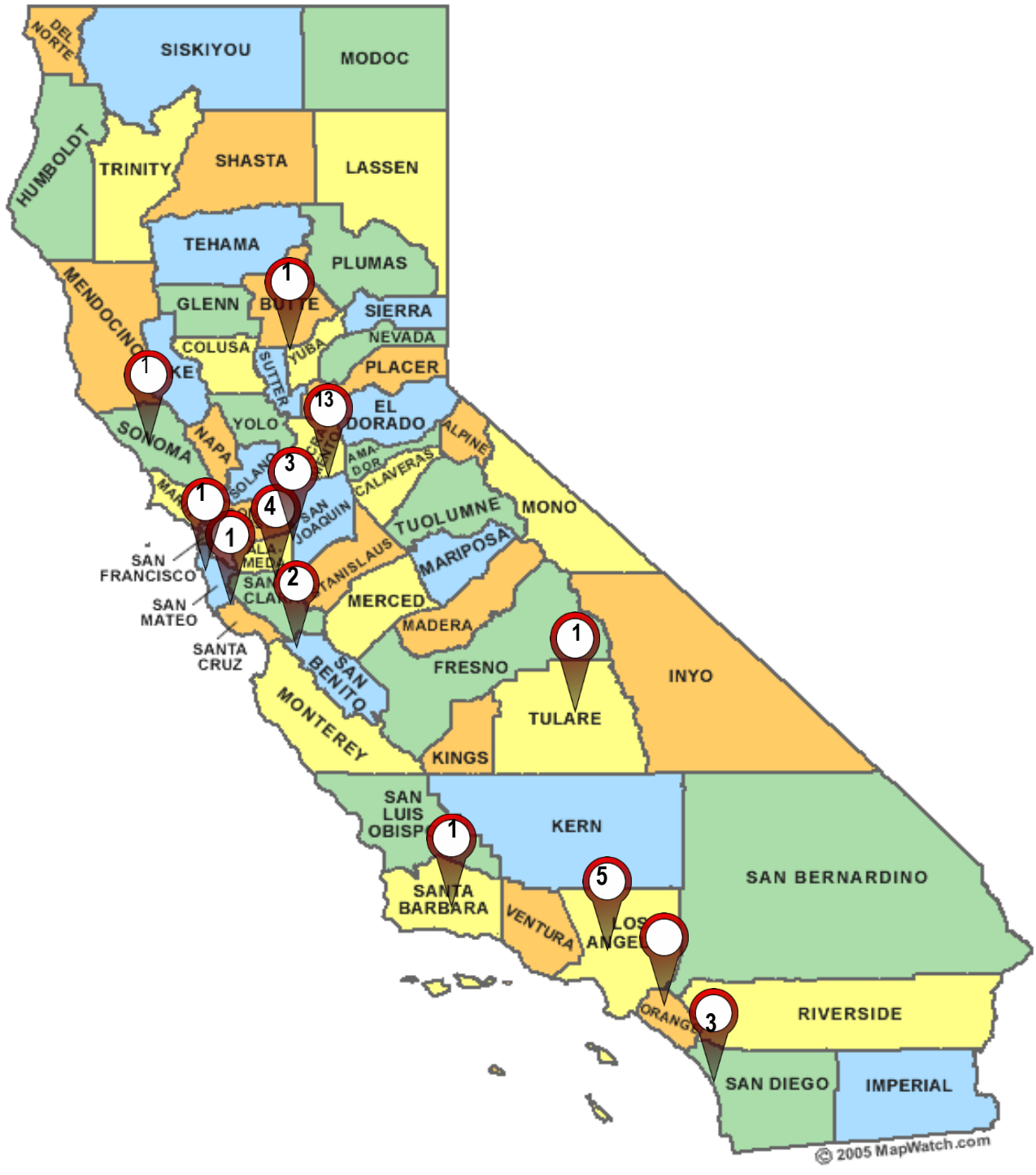
C. CHA Medication Safety Toolkit Plan

D. CHA Antineoplastic Drug Handling

2:00 **IX. ADJOURNMENT** — Hanni

Medication Safety Committee Representation

Rev. January 2015



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

Medication Safety Committee
Member Geographics - July 2016

HOSPITAL COMMITTEE MEMBERS

Candace Fong	Dignity Health	Sacramento/San Francisco
Doug O'Brien	Kaiser Foundation Hospitals	Sacramento
Sarah Stephens	Kaweah Delta Health Care District	Tulare
Carolyn Brown	Santa Clara Valley Medical Center	Santa Clara
Jeannette Hanni	Sutter Health - West and South Bay Region	Santa Clara
Nasim Karmali	Kaiser Foundation Hospital	Alameda
Kevin Dorsey-Tyler	Enloe Medical Center	Butte
Sue Reed	Adventist Health	Placer
Christine Low	Scripps System	San Diego
Eddie Avedikian	Providence Holy Cross Medical Center	Santa Barbara
Edna DeLeon	Huntington Memorial Hospital	Los Angeles
Nancy Blake	Childrens Hospital Los Angeles	Los Angeles
Lori Nolan	Providence Holy Cross Medical Center	Los Angeles
Richard Rabens	The Permanente Medical Group, Inc.	Alameda
Diane Schultz	Palomar Medical Center	San Diego
Theresa Vidals	Tri-City Medical Center	San Diego
Amy Gutierrez	LA County Department of Health Services	Los Angeles

NON-HOSPITAL COMMITTEE MEMBER:

Dan Ross	California Society of Health System	Sacramento
Jocelyn Montgomery	California Association of Health Faciliteis	Sacramento
Patricia McFarland	Association of California Nurse Leaders	Sacramento
Randy Kajioka	California Correctional Health Care	Sacramento
Robert Menet	California Department of Public Health	Sacramento
Rory Jaffe	Calfiornia Hospital Patient Safety Organization	Sacramento
Virginia Herold	California Board of Pharmacy	Sacramento
Art Woo	California Department of Public Health	Contra Costa
Cari Lee	California Department of Public Health	San Mateo
Jacalynn Blankenship	CALNOC	Contra Costa
Jenna Fisher	Hospital Council of Northern and Central	Contra Costa
Katie Choy	Washington Hospital Health Care System	Alameda
Lynn Paulsen	University of California	San Francisco
Mary Foley	Center for Nursing and Innovation	San Francisco
Alicia Munoz	Hospital Association of San Diego	San Diego
Christy Sinclain	California Society of Health System	Sacramento
Julie Slininger	Hospital Association of Southern California	Los Angeles

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 the following organizations:

California Department of Public Health
California Society of Health System Pharmacists
California Board of Pharmacy
Centers for Medi-Care and Medi-Caid Services
Association of California Nurse Leaders
California Medical Association
California HQI
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 Rehabilitation Services

Hospital Services for Continuing Care Committee
Governance
Quality Directors
Health Informatics and Technology Committee

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. Non hospital member representatives can only be appointed to the Committee at the discretion of the CHA President.

2. In addition to the Committee/Centers named above, 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.

3. Hospital members are appointed by CHA Staff.

4. Term:

(a) The initial term of office shall be three years, except that one-half of the initial members shall be appointed to two-year terms to ensure continuity of committee members in the future.

(b) As the terms of the members appointed in 2009 expire, or members otherwise leave, vacancies shall be filled to achieve the requirements of Article IV. Members are limited to two, three-year consecutive terms. An exception shall be granted in cases where a member is elected as a chair officer. Following two consecutive terms there must be a one-year interval before a member is eligible for another term.

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee.

2. Identify issues and develop possible solutions and best practices to improve the safety of medication storage and distribution administration.

3. Work cooperatively with key stakeholders to develop creative solutions.

4. Provide communication to member hospitals regarding medication safety issues.

5. Maintain/increase 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 is not acceptable.

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

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

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, Vice Chair, Immediate Past Chair and CHA staff.

The Chair shall be elected by the Committee for a two-year term, except for the initial Chair, who shall be appointed by CHA staff for one year. Should a Chair vacate his/her position prior to the end of the term, CHA staff will appoint a replacement to complete the remainder of the term.

Past-chairs will remain as a member of the Committee.

A. SUB-COMMITTEES

1. Task forces of the Committee may be formed at the discretion of the Committee

Chair and members and CHA staff for the purpose of conducting activities specific to a special topic or goal.

VI. GENERAL PROVISIONS

The strategic plan defining the goals, objectives, and work plans shall be developed annually by the Committee with approval by CHA staff. 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 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 statutes or regulations shall be declared null and void as of the date of such determination.

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

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

IX. CONFIDENTIALITY FOR MEMBERS

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

X. CONFLICT OF INTEREST

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

CHA Medication Safety Committee, Mission, Purpose and 2016 Objectives

Mission:

The mission of the CHA 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 medication.

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.

2016 Goals and Objectives

1) Develop guidance, tools, information and strategies for hospitals and pharmacists involved in medication safety to enhance quality care and patient safety.

    a) Implement workgroups where members can apply their expertise to explore, plan and suggest strategies

        i) 2016 Workgroups: Sterile Compounding , Medication Technology, CURES 2.0 Browser Workgroup, Inventory and Reconciliation, Drug Quality and Security , Antineoplastic Regulations

        ii) Finalize the Sterile Compounding Matrix Tools, disseminate and implement an informational webinar to assist members with compliance

2) Advise the CHA Board of Trustees on issues relevant to medication safety, particularly under health care reform and projected care model changes.

    a) Develop an issue brief that describes the challenges of the present environment and make strategic recommendations for the pharmacy of the future
    b) Work with CHA Finance staff to assist with regulatory advocacy on pricing issues such as the 340B Drug Pricing Program Omnibus Guidance.

3) Develop new strategies for CHA Medication Safety Tools to be disseminated and distributed among California hospitals and stakeholders.

    a) Publish the CHA Medication Safety Tool Compendium that includes the numerous tools developed by the committee and disseminate to members.

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
April 6, 2016 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: Jeannette Hanni, Candace Fong, Eddie Avedikian, Kevin Dorsey-Tyler, Mary Foley, Lisa Hall, Virginia Herold, Rory Jaffe, Randy Kajioka, Nasim Karmali, Christine Low, Patricia McFarland, Robert Menet, Lori Nolan, Doug O'Brien, Lynn Paulsen, Dan Ross, Diana Schultz, Kethen So, Sarah Stephens, Terri Vidals, Art Woo, Jenna Fischer, Alicia Munoz

Members Absent: Jacalynn Blankenship, MaryAnne Bobrow, Carolyn Brown, John Christensen, Katie Choy, Edna DeLeon, Amy Gutierrez, Cari Lee, Richard Rabens, Susan Reed, Rita Shane, Julia Slinger, David Perrot

Invited Guests: Justin Lewis, Karen Youmbi, Kathy Ghomeshi

CHA Staff: BJ Bartleson, Ronda Fricke

I. CALL TO ORDER/INTRODUCTIONS

The committee meeting was called to order by co-chair Ms. Hanni at 9:57 a.m.

Ms. Bartleson introduced Mr. Hawthorn, CHA's new lobbyist, and gave some general background on his experience. The committee then introduced themselves with an icebreaker.

A. Member Updates

Ms. Hanni reviewed the membership items included in the meeting book. Ms. Bartleson introduced the new committee members, Mses. Shane, Blake and Mr. So. She also thanked those members leaving the committee.

B. Committee Guidelines

Ms. Hanni reminded the committee guidelines and goals mentioning new members should take a moment to review them. Ms. Bartleson discussed the 2016 goals that have ongoing activity.

II. REVIEW OF PREVIOUS MEETING MINUTES

The minutes of the January 6, 2016, Medication Safety Committee meeting were reviewed as submitted.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: To approve the minutes of the January 6, 2016, Medication Safety Committee meeting.*

III. NEW BUSINESS

A. Part B Prescription Drug Model

Mr. Bartleson introduced Ms. Keefe and provided general background information on her role with CHA.

Ms. Keefe gave an overview of the Part B Prescription Drug Model and invited members to participate in an hour call on April 29, 2016, and that a registration link was noted in the memo provided in the meeting book. She mentioned there is also a summary on the CHA website.

During her overview she mentioned that CMS will begin testing new models to improve the way Medicare Part B pays for prescriptions. It is designed to test different physician and patient incentives including prescribing the most effective drugs and test new payment models that award positive patient outcomes.

Ms. Keefe discussed the current add-on of 6% and proposed add-on of 2.5% plus a flat fee payment of $16.80 per drug per day. The desired outcome is to have improved quality and value. The test is due to begin late 2016 but no earlier than 60 days after the rule is finalized.

Ms. Keefe added that the proposed rule has very little information. She mentioned that Phase 1 is concerning because of price cuts and G Code. She discussed Phase 2 and its complexity. She asked what the implications to hospitals are if CMS moves forward. She noted that high level preliminary conversation says it does not hit on the true intent. There is significant concern about high price drugs that don't have reduced price substitutions. This will come up specifically in oncology/cancer.

Public comments are due by May 9, 2016.

- *ACTION: Informational only. Alyssa Keefe will continue to monitor and provide updates.*

B. California Poison Control System

Ms. Bartleson introduced Mr. Lewis from the California Poison Control System. Mr. Lewis started his presentation by providing his background before going into the services provided by California Poison Control System. He mentioned there are 4 statewide answering centers that are managed by UCSF School of Pharmacy. The Sacramento division is located at UC Davis Medical Center. He discussed the staff that includes Clinical Pharmacists, Registered Nurses, Clinic Toxicologists, Pharmacy Technicians, Paramedics and Board Certified Physicians. He reviewed the types of calls the center receives, the free information that is available to the public and the value of poison centers. He also discussed what happens during a call, age range of victims, frequently involved substances and call center outcomes.

Mr. Lewis noted that Sacramento gets approximately 250 calls a day and 80% of those are home incidents.

- *ACTION: Informational only*

C. State Government Drug Purchasing Initiative (Drug Pricing)

Ms. Bartleson discussed the initiative's exaggerated attempt to do something about drug pricing. Mr. Bartleson noted this is mainly for information purposes, not a priority for CHA's legislative team who will continue to follow.

- *ACTION: CHA will continue to monitor the initiative.*

D. Revision of Respiratory Monitoring of Patients Outside the ICU Guidelines of Care Tool Kit

Ms. Munoz discussed potential Respiratory Monitoring of Patients Outside the ICU guidelines noting there has been interest expressed in revising the toolkit. She asked if it would be ideal for CHA and MSC to be the final approver of the revised tool kits. Ms. Munoz suggested 3 workgroups (S. Cal, N. Cal and San Diego) to assist with the revisions.

Mr. Hanni reiterated what Ms. Munoz recommended; committee review and back revisions and create workgroups to assist with the new updates. She noted that HQI would handle the grant. Ms. Munoz also suggested involving those that worked on the original tool kit. Ms. Hanni thought the request was timely and that there would be lots of interest in helping. There is a lot of work that needs to be done. Mr. So asked what the time commitment would be. Mses. Munoz and Schultz stated the meetings were quarterly and then moved to monthly towards the end of the project. Ms. Munoz added that Medtronics is very interested in supporting the revisions.

Ms. Hanni asked that the group wholeheartedly support the revisions. Ms. Bartleson stated that the revised tool kit should be available to everyone.

The members agreed the toolkit would be revised, grant support for application would go through HQI and the CHA Medication Safety Committee would review and validate the final tool kit.

- *ACTION: Committee review and validate final toolkit.*
- *ACTION: Create workgroups to assist with updates to the toolkit.*
- *ACTION: HQI to provide grant support.*

IV. OLD BUSINESS

A. CURES 2.0 Browser

Ms. Bartleson discussed the calls the CURES 2.0 workgroup has been having relative to registration and browser issues. She noted the DOJ has added tutorials on their website. Ms. Vidals mentioned she had to obtain a new password once the

system was updated but that it is much faster. It was noted that the Board of Pharmacy (BOP) has been sending cards to the pharmacists reminding them to register by July 1, 2016. Mr. So mentioned that Ms. Herold has a staff member that can assist with CURES 2.0 registration. Ms. Herold added that approximately 2/3 of those required to register have done so. Ms. Herold was glad to hear that people are able to access the system and that it is running fast.

- *ACTION: Continue to monitor CURES 2.0 usage.*

B. Drug Quality and Security Act FAQs

Ms. Hanni discussed the Frequently Asked Question document that Mr. O'Brien and Ms. Bartleson created. Ms. Bartleson thanked Mr. O'Brien for providing the initial Kaiser document and allowing her to add to it. Mr. O'Brien mentioned that he needed to confirm the implementation date. Ms. Hanni asked the group to review the document and approve with the caveat to check the implementation date.

- *ACTION: Review document for data accuracy.*

C. Sterile Compounding

Ms. Bartleson discussed the upcoming webinar scheduled for June 28, 2016. Ms. Fong asked Ms. Herold if she knew how many waivers there would be. Ms. Herold replied not at this time but OSHPOD would be able to address those issues and establish a process that works for everyone. Ms. Paulsen brought up Sections 1735.1 (a)(f) and 1735.6(e) seeking clarification on one question regarding the January 1, 2017, designation. Ms. Herold asked Ms. Paulsen to send her questions directly to her and she would answer them. There was a comment made that the two regulations are contradictory in regards to the requirement of a separate room. Ms. Hanni asked if the webinar content was sufficient. There were no comments from the members. Ms. Hanni noted it was ready to go.

Ms. Bartleson commented the Regulations in the packet were not the most current revisions, noting they could be found at www.pharmacy.ca.go. Go to the tab marked Laws and Regulations, select Pending Regulations near the bottom.

Ms. Paulsen discussed the 4 matrixes and suggested they include directions on how to use them to be compliant. Ms. Hanni thanked the committee for all their work.

Mr. Ross pointed out some conflicting information on pages 125 and 126 regarding the temperature. Ms. Paulsen said she would note it and update per USB and summit to the Board for final approval.

Ms. Paulsen will send out once the instructions and clarifications are complete. Ms. Bartleson added that this is the centerpiece of the webinar and would like this to be included on the website. Mr. O'Brien pointed out that this document will be widely used. Ms. Paulsen asked the group to review and send comments/questions directly to her.

Mr. So offered to help publicize the webinar through CSHP. There was mention that lots of negative comments were received because there was a cost associated with attending the webinar. Ms. Bartleson said she would see if the cost could be addressed.

- *ACTION: Ms. Paulsen to send questions regarding the January 1, 2017, designation to Ms. Hanni.*
- *ACTION: Send webinar information once finalized.*
- *ACTION: Ms. Paulsen will review conflicting information on temperature and update the matrixes per USB and submit to the Board for final approval.*
- *ACTION: Send the 4 matrixes and directions on how to use once finalized.*

D. Cal OSHA Antineoplastic Regulations

Ms. Bartleson discussed AB 1202 adding that Ms. Blanchard-Saiger is the lead Issue Manager and several members from this group are part of that committee. She noted to date there has been no reply to the letter and that CHA will continue to monitor. Ms. Hanni commented the letter was well written and to the point.

- *ACTION: CHA will continue to monitor.*

E. Drug Take Back Program

Ms. Bartleson discussed the City and County ordinances for prescription take back programs noting it's important to keep hospitals voluntarily participating in these programs. Ms. Bartleson thanked Ms. Gutierrez for bringing the proposed adoption issues to the members' attention so that comments could be submitted. She reviewed the comments that were submitted by CHA stressing the big emphasis is to make the program voluntary.

- *ACTION: Informational Only*

F. Drug Reconciliation and Inventory Regulations

Ms. Fong said both CHA and Dignity Health provided comments to the proposed regulations noting there were several items of concern. She mentioned specifically the requirement to perform quarterly physical inventory of narcotics. This requirement seems excessive and the Board has been asked if they would be willing to compromise on the timeframe.

Ms. Bartleson discussed Ms. Shane's Controlled Substances Best Practices. She asked the members to review the practice guide Ms. Shane compiled for any missing information. Mr. Kajioka asked if the nurses were included and asked to share responsibilities. Ms. Fong added it is a shared responsibility and that the pharmacy cannot do it alone. Mr. O'Brien thought it was a good idea to review and update.

Ms. Bartleson suggested getting on top of this now so that the Board knows a resolution is being worked on and that there may be additional comments. Ms.

Herold added that additional comments can be submitted but the Board does not have to take them into consideration when making their final decision. Ms. Bartleson suggested a workgroup to review best practice guides. The following volunteered to participate: Mses. Shane, Fong, Vidals and Messer O'Brien, Ross and So.

- *ACTION: Ms. Bartleson will schedule a call with the workgroup (Mses. Shane, Fong, Vidals and Messer O'Brien, Ross and So) to review, refresh and resubmit comments to the Board of Pharmacy.*

G. CHA Medication Safety Tools

Ms. Bartleson mentioned the hardcopy compendium is in progress and that she would like help from the members to complete it. She asked who originally helped on the sections.

Ms. Stephens stated she helped with the anti-coagulant portion and suggested an additional tool. Ms. Bartleson will connect with Ms. Stephens to discuss. Ms. Schultz offered to help Ms. Stephens with this portion of the tool.

Mr. So offered to connect Ms. Bartleson with Ms. Heidi Marie to help with the Insulin portion. Ms. Hanni will help with the ED Management section.

- *ACTION: Ms. Bartleson will connect with Ms. Stephens on the anti-coagulant portion.*
- *ACTION: Mr. So will connect Ms. Bartleson with Ms. Heidi Marie for the insulin portion.*
- *ACTION: Ms. Fricke will determine the best way to disseminate the materials so everyone will have access.*

H. Small Bore Connectors

Dr. Jaffe reminded the members there is a 90 minute Small Bore Connecter webinar in two weeks and you do need to register for it. Dr. Jaffe discussed ISO standards for small bore connections. The external feeding connector rule goes into effect on July 1, 2016, but it is recommend that you do not switch over to the new tube until you have a good supply of syringes. The old syringes cannot be used with the new tube.

Mr. O'Brien asked if the CHPSO website would be sending information to the masses. Dr. Jaffe said they would not and that GPO (Group Purchasing Organization) will be in charge of the communications.

- *ACTION: Informational Only.*

I. Hazardous Waste Pharmaceuticals

Ms. Bartleson mentioned this is for informational purposes.

- *ACTION: Informational Only.*

VI. STANDING REPORTS

A. Board of Pharmacy (BOP)

Ms. Herold reported that the drug take back requirements for SB 797 and 800 are the next big item. She also touched on the BOP Sunset review noting the report is online and can be reviewed to see what work has transpired over the last 4 years. Ms. Herold also touched on fee increases for 18 programs and why they are necessary. If fees aren't increased the BOP may lose 10 inspectors. If the bill passes, the fees won't take place until 2017.

Ms. Herold noted that the BOP is updating their website to have a new look with less clutter on its pages. They will also be performing a more thorough examination of Pharmacy Technician qualifications. There is a new video that will walk technicians through the application process. Ms. Fong asked for an update on when the BOP will begin accepting electronic renewals. Ms. Herold added a computer modification needs to take place prior to electronic renewals being offered, stating it's in the preliminary stages and not sure when the service will be available.

- *ACTION: Informational Only.*

B. CDPH

Mr. Menet stated there were no new updates. Ms. Paulsen asked if new inspections were being implemented. Mr. Menet said they have been implemented.

- *ACTION: Informational Only.*

C. CSHP

Mr. So talked about the CPHA/CSHP joint Legislative Day noting that AB 2084 Medi-Cal Medication Management passed. He added that the Government Affairs Advisement committee will be reviewing and giving recommendations and reporting out their final positions within a week. He mentioned the Professional Affairs Committee will be looking at the Take Back Program and include their position in an update to the professional policy.

- *ACTION: Informational Only.*

C. **CALNOC –** No update provided.

E. ACNL – No update provided.

F. CHPSO

Dr. Jaffe reported that an annual report would be forthcoming. He noted that if the hospital has been reporting drug class information to CALNOC the report will show the most frequent drug classes mentioned**.** Dr. Jaffe added that individual

hospitals will get an individual read if they have been providing information to CHPSO.

- *ACTION: Informational Only.*

G. CAHF – No update provided.

VII. WORKGROUP REPORTS – Tabled to discuss Legislative Update

A. Medication Technology

VIII. PHARMACY LEGISLATE UPDATE

Ms. Bartleson informed the members that Mr. Hawthorne would be handling the pharmacy items. She asked that if anyone sees a bill that is hot and needs to be watched or have comments made, please notify her directly.

Ms. Bartleson reviewed the discussion guide she provided with the various bills. She mentioned that there has been a lot of discussion on marijuana use when a patient brings it with them to the hospital.

Ms. Bartleson asked for feedback regarding AB 2144. She added to date she has only received comments from Cedars. Ms. Herold added that the BOP did not take a position on AB 2144 and that CSHP sees it as a spot bill and they will continue to watch.

Ms. Bartleson touched briefly on SB 1193 stating she hasn't looked at the report but didn't think there were any issues with it. She also noted SB 992 was a spot bill with no content.

IX. INFORMATIONAL ONLY

Ms. Bartleson briefly reviewed the articles that were provided in the meeting book.

XI. NEXT MEETING

July 6, 2016
October 5, 2016

XII. ADJOURNMENT

Having no further business, the committee adjourned at 1:49 PM.

Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman, CDER Office of Unapproved Drugs and Labeling Compliance (OUDLC) at 301-796-3110.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

April 2016
Compounding and Related Documents

Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

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Compounding and Related Documents

TABLE OF CONTENTS

Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry[1]

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I. INTRODUCTION AND SCOPE

Pharmacies located within a hospital or standalone pharmacies that are part of a health system frequently provide compounded drug products for administration within the hospital or health system. Some of these compounders have registered with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and others are state-licensed pharmacies subject to section 503A of the FD&C Act. This guidance describes how FDA intends to apply section 503A of the FD&C Act to drugs compounded by licensed pharmacists or physicians in state-licensed hospital or health system pharmacies for use within the hospital or health system.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Overview

1. Compounding Under the FD&C Act

Sections 503A and 503B of the FD&C Act address human drug compounding.

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act in 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility, or by licensed physician, to be exempt from the following three sections of the FD&C Act:

- section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements);
- section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and
- section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

A list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A of the FD&C Act appears in the guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.[2]

Section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a new category of compounders called *outsourcing facilities*. Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- section 502(f)(1);
- section 505; and
- section 582 (concerning track and trace requirements).

The guidance, *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* lists the conditions that are set forth in section 503B of the FD&C Act.

Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act, outsourcing facilities are subject to CGMP requirements, among other requirements under the FD&C Act (section 503B(a)).[3] In addition, outsourcing facilities will be inspected by FDA on a risk-based schedule (section 503B(b)(4)). An outsourcing facility is not required to be a licensed pharmacy and may or may not obtain prescriptions for identified individual patients.[4]

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[2] All FDA guidances are available on the FDA guidance Webpage at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

[3] FDA has issued a draft guidance for industry *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.* Once finalized, that guidance will represent the Agency's thinking on this topic.

[4] Although an outsourcing facility may send prescription drugs to health care facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the

2. Compounding in Hospitals and Health Systems

Compounded drug products can serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, or an elderly patient or a child who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available.

Hospital and health system[5] drug compounding and distribution practices vary. For example, some hospital pharmacies compound drugs only for use in the hospital in which the pharmacy is located (e.g., for the treatment of patients admitted to the hospital, or for use in the hospital's emergency room), while other hospital and health system pharmacies compound and distribute their compounded drug products to other facilities within their health system (e.g., to other hospitals, clinics, infusion centers, or long-term care facilities within the health system for administration or dispensing).

In some cases, a hospital or health system pharmacy compounds drugs only after receipt of a prescription or order for an identified individual patient. Hospital and health system pharmacies may also compound drugs and distribute them within the hospital or health system before the receipt of a patient-specific prescription. The hospital or health system then holds the drug products until a patient presents with a need for the drug, for example in an operating room, where emergency procedures cannot be scheduled in advance, or in emergency departments.

Many hospitals and health systems purchase compounded drug products from compounders that have registered with FDA as outsourcing facilities under section 503B of the FD&C Act. Outsourcing facilities are subject to increased federal oversight through FDA inspection on a risk-based schedule, and quality standards CGMP requirements) that help to assure the quality of their compounded drug products. Some hospital and health system compounders have registered with FDA as outsourcing facilities to serve as centralized compounding facilities where drug products are compounded with or without first receiving patient-specific prescriptions, and they then distribute the drugs within their health system or to affiliated health care facilities.

3. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In

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requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

[5] FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of "health system" that applies to all sections of the FD&C Act. However, this is the definition of a "health system" used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products they compound because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint such as a report of a serious adverse event or visible contamination.

In 2012, contaminated injectable drug products that a compounding pharmacy shipped to patients and healthcare practitioners across the country caused a fungal meningitis outbreak that resulted in over 60 deaths and over 750 cases of infection.[6] This was the most serious of a long history of outbreaks associated with contaminated compounded drugs. Since the 2012 fungal meningitis outbreak, FDA has investigated numerous other outbreaks and other serious adverse events, including deaths, associated with compounded drugs that were contaminated or otherwise compounded improperly.

FDA has also identified many pharmacies that compounded drug products under insanitary conditions whereby the drug products may have been contaminated with filth or rendered injurious to health and that shipped the compounded drug products made under these conditions to patients and health care providers in large volumes across the country.[7] The longer a compounded sterile drug product that is contaminated is held by a pharmacist or physician before distribution, or the longer it is held in inventory in a healthcare facility before administration, the greater the likelihood of microbial proliferation and increased patient harm.

As noted previously, compounders that elect to become outsourcing facilities must register with FDA, must comply with CGMP requirements, and are inspected by FDA according to a risk-based schedule. This mitigates the risk that their drug products will be contaminated or otherwise made under substandard conditions.

Because compounded drugs have not undergone premarket review for safety, effectiveness, and quality, they should only be used when an FDA-approved product is not available to meet the medical needs of an individual patient. As described further below, the exemptions under sections 503A and 503B of the FD&C Act are only available to compounded drugs that meet certain conditions.

B. The Prescription Requirement in Hospitals and Health Systems

[6] See http://www.cdc.gov/HAI/outbreaks/meningitis.html

[7] See FDA actions, including warning letters and injunctions, related to insanitary conditions at compounding facilities, on FDA's website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm

As described above, compounded drug products are not approved and, therefore, do not undergo premarket review for safety, effectiveness, and quality. In addition, drug products compounded by licensed pharmacists and licensed physicians under section 503A of the FD&C Act are exempt from CGMP requirements. As reflected in the policies set forth below, FDA believes that the conditions in sections 503A and 503B provide important protections to patients, including those treated in a hospital or other facility within a health system, from the risks associated with compounded drugs and help ensure that compounders do not operate like conventional manufacturers. Therefore, FDA generally intends to apply these conditions to compounding in health system and hospital pharmacies, and sets forth an enforcement policy below regarding the prescription requirement in section 503A.

The prescription requirement in section 503A ensures that drug products are only exempt from three key provisions of the FD&C Act designed to assure safety, efficacy, and quality if they are compounded for identified individual patients. However, as stated above, FDA recognizes that a hospital may need to maintain a supply of certain compounded drug products within the hospital but outside of the pharmacy (e.g., in an emergency department or operating room) in anticipation of a patient presenting with a critical need for the drug when there is no time for the hospital pharmacy to compound and provide the drug upon receipt of a prescription or order for that patient.

FDA also recognizes that certain characteristics of hospital pharmacies differentiate them from pharmacies that are not owned and controlled by hospitals, and from conventional manufacturers. For example, generally, the scope of distribution of drug products compounded by hospital pharmacies is limited. Hospital pharmacies usually compound drug products based on orders from practitioners who work in the hospital, distribute the drug products only within the hospital or to related healthcare facilities under common ownership and control and located within close proximity to the hospital, and administer them only to patients within the hospital or healthcare facility. Because the hospital or healthcare facility and the pharmacy are under common ownership and control, the hospital or healthcare facility is responsible for both the compounding of the drug and treatment of the patient, and the cause of any compounding-related adverse events can be more readily identified. FDA believes that the policies set forth in this guidance, based on the way a hospital pharmacy normally functions with regard to compounding for its patients, will prevent hospital pharmacies from operating like conventional manufacturers.

III. POLICY

A. Hospital or Health System Compounding Under Section 503A of the FD&C Act

To qualify for the exemptions under section 503A of the FD&C Act from sections 501(a)(2)(B), 502(f)(1), and 505(a), a drug product compounded by a licensed pharmacist in a state-licensed pharmacy or Federal facility, or by a licensed physician, must be compounded in accordance with all of the provisions of section 503A. Section 503A does not distinguish between stand-alone pharmacies and pharmacies within hospitals and health systems. Therefore, the provisions of section 503A apply to pharmacists, pharmacies, and physicians that compound drugs within a hospital or a health system that is not registered as an outsourcing facility under section 503B.

Drug products compounded by a licensed pharmacist or licensed physician that are not compounded in accordance with all of the provisions of section 503A may be subject to regulatory action for violations of the new drug approval, adequate directions for use, and CGMP requirements of the FD&C Act.

For example, under section 503A, a licensed pharmacist or a licensed physician within a hospital or health system must compound drug products for an identified individual patient. The compounding must either be (a) after the receipt of a valid prescription or order for an identified individual patient or (b) in limited quantities in advance of receipt of a valid prescription or order for an identified individual patient, and the drug must be distributed after receipt of the prescription or order.

However, FDA does not intend to take action if a hospital pharmacy distributes compounded drug products without first receiving a patient-specific prescription or order provided that:

(1) The drug products are distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are located within a 1 mile radius of the compounding pharmacy;
(2) The drug products are only administered within the healthcare facilities to patients within the healthcare facilities[8], pursuant to a patient specific prescription or order; and
(3) The drug products are compounded in accordance with all other provisions of section 503A, and any other applicable requirements of the FD&C Act and FDA regulations (e.g., the drug products are not made under insanitary conditions (section 501(a)(2)(A)) or misbranded (e.g., section 502(g)).

The 1-mile radius in our policy is intended to distinguish a hospital campus from a larger health system. As explained in section II.B of this guidance, certain characteristics of hospital pharmacies distinguish them from conventional manufacturers. However, a health system pharmacy that compounds drug products without patient-specific prescriptions for facilities within its health system across a broader geographic area could function as a large manufacturing operation, but without the necessary standards to assure drug quality. If such a pharmacy contaminates or otherwise adulterates or misbrands a compounded drug, the drug has the potential to harm many patients. Outsourcing facilities, which are subject to CGMP requirements and other conditions that help to assure drug quality, can compound and distribute drug products to healthcare facilities nationwide without first receiving prescriptions for identified individual patients.

B. Hospital or Health System Compounding Under Section 503B of the FD&C Act

A compounder can register as an outsourcing facility if it intends to provide compounded drugs to facilities such as other hospitals or clinics outside the 1 mile radius of the pharmacy in which the drug is compounded without first obtaining a prescription for an identified individual patient.

[8] This does not include dispensing a drug product to a patient for use outside the hospital.

To qualify for the exemptions under section 503B from sections 502(f)(1), 505, and 582 of the FD&C Act, hospitals and health system compounders that elect to register with FDA as outsourcing facilities must comply with all of the provisions of section 503B. Outsourcing facilities must also comply with CGMP requirements in section 501(a)(2)(B) of the FD&C Act.

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

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April 2016
Compounding and Related Documents

TABLE OF CONTENTS

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Guidance for Industry[1]

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I. INTRODUCTION AND SCOPE

This guidance sets forth the Food and Drug Administration's (FDA or Agency) policy concerning certain prescription requirements for compounding human[2] drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use (or "office stock").

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II. BACKGROUND

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA's draft guidance, *Compounding Animal Drugs from Bulk Drug Substances*. For proposed policies pertaining to mixing, diluting, and repackaging biological products, see FDA's draft guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.* For proposed policies pertaining to repackaged drug products, see FDA's draft guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*. FDA guidances are available on the FDA website at http://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

A. Overview

1. Compounding Under the FD&C Act

Sections 503A and 503B of the FD&C Act address human drug compounding.

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act in 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- section 501(a)(2)(B) (concerning CGMP requirements);
- section 502(f)(1) (concerning the labeling of drugs with adequate directions for use; and
- section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

A list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A of the FD&C Act appears in the guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

Section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a new category of compounders called *outsourcing facilities*. Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- section 502(f)(1);
- section 505; and
- section 582 (concerning track and trace requirements).

In contrast to drug products compounded under section 503A of the FD&C Act, drug products compounded by outsourcing facilities under section 503B are not exempt from CGMP requirements in section 501(a)(2)(B). Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks of the drug products they compound.

The guidance, *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, lists the conditions that are set forth in section 503B of the FD&C Act.

2. Compounding, Generally

Compounded drug products can serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form that is not otherwise available.

Drug products for identified individual patients can be compounded consistent with section 503A by licensed pharmacists in state-licensed pharmacies and Federal facilities, or by licensed physicians. Drug products can also be compounded by compounders known as *outsourcing facilities* under section 503B of the FD&C Act.

In general, when a compounded drug product is clinically necessary for a patient, a prescriber writes a prescription for a compounded drug product, and the patient brings the prescription to a pharmacy, where a licensed pharmacist fills the prescription. In an inpatient setting, such as in a hospital, a prescriber may write an order for a compounded drug product on a patient's chart. Sometimes, a physician may compound a drug in the office for administration to his or her patient after the patient presents at the physician's office with a clinical need for the compounded drug.

In other cases, a pharmacist may compound a drug product before receipt of a prescription for an identified individual patient in anticipation of receiving such a prescription, based on knowledge of what prescriptions the pharmacist has historically been asked to fill. The pharmacist then provides the drug product to a patient or a prescriber upon receipt of a prescription. Similarly, a physician may compound a drug product to hold in his or her office in anticipation of patients in his or her practice presenting with a need for the compounded drug, based on the amount of the compounded drug that the physician has historically administered or dispensed. The physician then administers or dispenses the compounded drug to his or her patients after making a notation the patients' charts.

Sometimes, it is necessary for health care practitioners in hospitals, clinics, offices, or other settings to have certain compounded drug products on hand that they can administer to a patient who presents with an immediate need for the compounded drug product. For example, if a patient presents at an ophthalmologist's office with a fungal eye infection, timely administration of a compounded antifungal medication may be critical to preventing vision loss. In such a case, the prescriber may need to inject the patient with a compounded drug product immediately, rather than writing a prescription and waiting for the drug product to be compounded and shipped to the prescriber.[3]

In other cases, compounded drug products may need to be administered by a health care practitioner in his or her office because it would not be safe for the patient to take the drug home for self-administration, and it would not be practical for the patient to bring a prescription for the compounded drug product to a pharmacy and then return to the health care practitioner for administration.

3. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means

[3] Such compounding would be subject to all of the conditions of section 503A or 503B, including provisions concerning compounding drug products that are essentially copies of commercially available drug products (section 503A(b)(1)(D)) or drug products that are essentially copies of approved drugs (section 503B(a)(5)).

they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with current good manufacturing practice (CGMP) requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products they compound (see section 3, below) because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint such as a report of a serious adverse event or visible contamination.

In 2012, contaminated injectable drug products that a compounding pharmacy shipped to patients and health care practitioners across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection.[4] This was the most serious of a long history of outbreaks associated with contaminated compounded drugs. Since the 2012 fungal meningitis outbreak, FDA has investigated numerous other outbreaks and other serious adverse events, including deaths, associated with compounded drugs that were contaminated or otherwise compounded improperly.

FDA has also identified many pharmacies that compounded drug products under insanitary conditions whereby the drug products may have been contaminated with filth or rendered injurious to health, and that shipped the compounded drug products made under these conditions to patients and health care providers across the country, sometimes in large amounts.[5] The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm. Because of these and other risks, the FD&C Act places conditions on compounding that must be met for compounded drugs to qualify for the exemptions in section 503A. Among these conditions are that:

- compounding is for an identified individual patient,
- drugs compounded in advance of receiving prescriptions are compounded only in limited quantities, and
- drugs are distributed pursuant to a patient-specific prescription.

These conditions are meant to help ensure that compounding under section 503A is based on individual patient needs, and that entities purportedly operating under section 503A are not actually operating as conventional manufacturers.

[4] See http://www.cdc.gov/HAI/outbreaks/meningitis.html.

[5] See FDA actions, including warning letters and injunctions, related to insanitary conditions at compounding facilities, on FDA's website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm

B. The Prescription Requirement in Section 503A(a) of the FD&C Act[6]

A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient." To qualify for the exemptions under section 503A, the drug product must also be compounded by a licensed pharmacist in a state-licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a)).

Section 503A(a) describes two situations in which a drug product can be compounded: (1) based on the receipt of a valid prescription order for an identified individual patient (section 503A(a)(1)); or (2) in limited quantities before the receipt of a valid prescription order for an identified individual patient (section 503A(a)(2)). As discussed further in section III.C of this guidance document, section 503A does not provide for distributing a compounded drug product before receiving a valid prescription order for an identified individual patient.

The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, not labeled with adequate directions for use, and not made in accordance with CGMP requirements, are provided to a patient only based on individual patient need.

The prescription requirement is also an important factor that distinguishes compounding by a licensed pharmacist in a state-licensed pharmacy or a Federal facility, or by a licensed physician under section 503A from compounding by an outsourcing facility under section 503B of the FD&C Act. Section 503B states that an outsourcing facility may or may not obtain prescriptions for identified individual patients (section 503B(d)(4)(C)). Outsourcing facilities, which are subject to CGMP requirements and other important conditions, can compound drug products to fulfill the needs described in section II.A.1 for health care practitioners to have drug products on hand that are not compounded for identified individual patients.

1. Compounding After Receipt of a Valid Prescription Order

As described in section II.A.1, a prescriber may write a prescription for an identified individual patient who needs a compounded drug product. In most cases, either the prescriber or the patient will then bring or send the prescription to the pharmacy, where the pharmacist will compound the drug product for the patient and provide it to the prescriber or patient according to the prescription. For a patient in an inpatient setting, a prescriber may place an order in the patient's chart for a compounded drug product, which will likely be provided by the health care facility

[6] For information concerning how the FDA intends to apply the prescription requirement in section 503A of the FD&C Act to compounding within a hospital or health system, see the draft guidance for industry, *Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act*. Once finalized, this guidance will describe FDA's current thinking on this topic.

pharmacy. In an office setting, a physician may compound a drug after making a notation in the chart of a patient in his practice who presents with a need for the compounded medication. This type of compounding is covered under section 503A(a)(1) of the FD&C Act,[7] which provides for compounding by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs.

2. Compounding Before Receipt of a Valid Prescription Order

Sometimes, based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or healthcare provider when a prescription for an identified individual patient is received. This is known as *anticipatory compounding*. Section 503A(a)(2) of the FD&C Act provides for compounding by a licensed pharmacist or licensed physician in "limited quantities before the receipt of a valid prescription order for such individual patient" if:

- The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product;

and

- The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order.

Anticipatory compounding can be beneficial because larger batch sizes can increase efficiency and reduce the likelihood of human error that is associated with compounding many small batches of a drug product after the receipt of individual prescriptions for the same drug. However, anticipatory compounding also has risks. For example, if a problem occurs during compounding, such as contaminating a drug product that is supposed to be sterile, it could affect numerous patients, and not just one. Because drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or contamination. Restricting production to limited quantities serves to limit the number of patients likely to be affected by such a mistake.

The limitations on anticipatory compounding in section 503A (i.e., compounding must be in "limited quantities" and based on an "established relationship") help to protect patients from product quality issues. These limitations on anticipatory compounding also help to distinguish licensed pharmacists or licensed physicians compounding drug products under section 503A for

[7] If applicable state and federal requirements are met, outsourcing facilities can also compound drug products pursuant to prescriptions for identified individual patients under section 503B of the FD&C Act. However, that is not the subject of this guidance document.

individual patients from conventional manufacturers, who generally produce larger quantities of drugs that are distributed without a prescription through a wholesaler to pharmacies, which then dispense them to individual patients pursuant to a prescription order.

The anticipatory compounding limitations also differentiate licensed pharmacists and licensed physicians compounding under section 503A from compounders registered as outsourcing facilities under section 503B of the FD&C Act. As explained above, outsourcing facilities are subject to increased Federal oversight and quality standards, including CGMP requirements, which reduce the risks of quality problems such as production mistakes or contamination. Under section 503B, an outsourcing facility can distribute compounded drug products to health care facilities and healthcare practitioners without first receiving prescriptions for identified individual patients.

With these principles in mind, FDA sets forth its policy with regard to the prescription requirement in section 503A.

III. POLICY

A. Receipt of a Valid Prescription Order or a Notation Approved by the Prescriber Under Section 503A

For purposes of section 503A, a *valid prescription order* for a compounded drug product means a valid prescription order from a licensed physician or other licensed practitioner authorized by state law to prescribe drugs (prescriber). It also includes a valid order or notation written by a prescriber in a patient's chart in an inpatient setting and a valid order or notation by a physician who compounds a drug for his or her own patient written in that patient's chart.[8]

If it is not obvious from a prescription order that the prescription is for a compounded drug product, a pharmacist may consult with the prescriber to determine whether the patient needs a compounded drug and make an appropriate notation on the prescription order.[9] To serve as a basis for compounding under section 503A, a notation must document the prescriber's determination that a compounded drug is necessary for the identified patient (section 503A(a)). We recommend using the following statement:

"Per [type of communication] with [name of prescriber] on [date], [name of prescriber] has advised that compounded [name of drug] is necessary for the treatment of [name of patient]."

[8] Prescription orders that are not valid would not satisfy the prescription requirement in section 503A and cannot serve as the basis for anticipatory compounding. See, in addition, section 301(ccc)(2), which states that, with respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable, is a prohibited act.

[9] FDA anticipates that in general, it will be clear whether a prescription is for a compounded drug product. An example of a circumstance in which this may be unclear, and the compounder may consult with the prescriber, is if a compounder receives a prescription for an FDA-approved drug product, but determines that the product is not medically appropriate for the patient and needs to be compounded (e.g., if the FDA-approved drug product is an oral capsule, but the patient has difficulty swallowing capsules and needs the drug in a liquid dosage form).

Furthermore, to meet the prescription requirement, a prescription must identify the patient for whom the drug has been prescribed. If the identity of the patient is not given or is not clear, it will not satisfy this requirement. For example, a prescription would not satisfy the requirement if it is written for the prescriber, when the prescriber is not also the patient. If the identity of the patient who will receive the drug is not clear from the prescription, the compounder should contact the prescriber for clarification and must not distribute the drug unless the identity of the patient is clarified.

B. When a Drug Can Be Compounded Under Section 503A

1. Compounding After Receipt of a Valid Prescription Order

Unless a drug product is compounded in limited quantities before the receipt of a valid prescription order under the conditions described in section 503A(a)(2) of the FD&C Act, which are also described in section III.B.2 of this guidance, to qualify for the exemptions under section 503A, the drug product must be compounded *after* the licensed pharmacist or licensed physician receives a valid prescription order for an individual patient. We understand this to be compounding "on" the receipt of a valid prescription order, as provided in section 503A(a)(1).[10]

2. Compounding Before Receipt of a Valid Prescription Order

If a drug product is not compounded after the receipt of a valid prescription order for an identified individual patient as described in section 503A(a)(1) of the FD&C Act and section III.B.1 of this guidance, the drug product can be compounded under section 503A of the Act by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient (section 503A(a)(2)(A)), if all of the conditions of section 503A are met, including the following conditions:

- The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders[11] for the compounding of the human drug product; and

- The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the prescriber who will write such prescription order[12] (see section 503A(a)(2)(B)).

[10] This includes a physician compounding a drug for his or her own patient after writing a prescription order (e.g., an order written in the patient's chart) for the compounded drug.

[11] This includes orders that a physician writes in the charts of his or her patients.

[12] When a physician compounds drugs for his or her own patients, FDA considers the "established relationship" provision of section 503A(a)(2) to have been satisfied because the licensed physician and the "prescriber who will write such prescription order" are the same individual.

This means that anticipatory compounding under section 503A is done in limited quantities, based on an expectation that the licensed pharmacist or licensed physician will receive a patient-specific prescription for the particular drug product, written for a patient or by a prescriber with whom the compounder has a relationship.

At this time we do not intend to consider a compounder to have exceeded the limited quantity condition in section 503A(a)(2) if:

- The compounder holds for distribution[13] no more than a 30-day supply of a particular compounded drug product (i.e., units of a compounded drug product that the compounder believes it will distribute over a 30-day period) to fill valid prescriptions it has not yet received; and

- The amount of the supply is based on the number of valid prescriptions that the compounder has received for identified individual patients in a 30-day period over the past year that the compounder selected.

Under this policy, if a compounder does not exceed the quantities described above, FDA also does not intend to determine whether anticipatory compounding was based on the expectation that the compounder would receive another prescription for the drug product for a particular patient or prescriber with whom the compounder has established a history.

The following example illustrates FDA's policy on anticipatory compounding under section 503A(a)(2):

> A compounder regularly receives valid prescription orders from a particular prescriber or prescribers, or for a particular patient or patients, for compounded drug X. The highest number of units of drug X for which the compounder has received patient-specific prescriptions in a 30-day period in the last year is 500 units. Compounding up to 500 units of drug X in advance of receiving prescriptions for the drug, and holding no more than that amount to fill new patient-specific prescriptions as the compounder receives them, would be consistent with this policy.
>
> A physician who compounds drugs for his or her own patients routinely sees patients who need compounded drug X. The highest number of units of drug X that the physician has dispensed or administered to patients after making a notation in the patients' charts in a 30-day period in the last year is 500 units. Compounding up to 500 units of drug X in advance of making such notations in patients' charts (i.e., before patients present at the physician's office with a need for the compounded drug), and holding no more than that amount to dispense or administer to patients, would be consistent with this policy.

C. When a Compounded Drug Product Can Be Distributed Under Section 503A

[13] *For distribution* means drug product that is available for immediate distribution and does not include drug product that is being held pending receipt of the results of release testing such as sterility testing.

Compounding under section 503A(a) must be "for an identified patient based on the receipt of a valid prescription order" – either "on the receipt of a prescription order for such individual patient" or, under certain conditions, "before the receipt of a valid prescription order for such individual patient." This means that for each drug compounded under section 503A, the compounder must obtain a patient-specific prescription order. We therefore understand that the compounder can fill a prescription for compounded drugs under section 503A only pursuant to such a patient-specific prescription. We recognize that some state boards of pharmacy may authorize the writing of prescriptions that do not include individual patient names. Such prescriptions, however, do not meet the requirement of a patient-specific prescription in section 503A. Under section 503B, outsourcing facilities can fill such prescriptions if they meet the requirements of applicable state and Federal laws.

D. Office Stock/Office Use

As discussed in section II.A.1 of this guidance, some compounded drug products are kept in stock by hospitals, clinics, or health care practitioners to administer to patients who present with an immediate need for a compounded drug product. Hospitals, clinics, and health care practitioners can obtain non-patient-specific compounded drug products from outsourcing facilities registered under section 503B.[14] Outsourcing facilities, which are subject to CGMP requirements, FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that provide greater assurance of the quality of their compounded drug products, may, but need not, obtain prescriptions for identified individual patients prior to distribution of compounded drug products (section 503B(d)(4)(C)).[15] Therefore, outsourcing facilities can compound and distribute sterile and non-sterile[16] non-patient-specific drug products to hospitals, clinics, and health care practitioners for office use.[17]

Section 503A(a)(2) provides a pathway for anticipatory compounding in limited quantities. A licensed pharmacist or licensed physician can compound a drug product in advance of receiving a valid prescription order for an identified individual patient, in accordance with the conditions described in section 503A(a)(2) of the FD&C Act, to have a supply of the drug product ready to provide to a patient or prescriber (or, in the case of a physician, to administer to a patient) when a patient-specific prescription order is presented for the compounded drug product. This can

[14] See also FDA's draft guidance, *Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act* for FDA's proposed policies regarding the application of section 503A of the FD&C Act to drug products compounded for use within a hospital or health system.

[15] Although an outsourcing facility may send prescription drugs to health care facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

[16] Section 503B defines *outsourcing facility*, in part, as a facility that is engaged in the compounding of sterile drugs (section 503B(d)(4)(A)(i)). Therefore, an entity that only compounds non-sterile drugs does not meet the definition of *outsourcing facility*.

[17] Distribution of compounded drug products by outsourcing facilities is subject to the limitations described in section 503B(a)(8), among other conditions.

reduce the time it would take for a compounded drug product to be made available to a patient upon receipt of a valid prescription order for that patient.

E. Recordkeeping

The licensed pharmacist or licensed physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with the prescription requirement in section 503A(a)(1) of the FD&C Act and the basis for any anticipatory compounding. For example, this includes records of valid prescription orders, and of prescription orders bearing notations that the compounded drug product is necessary for the identified individual patient as described in section III.A of this guidance and section 503A(a) of the FD&C Act.

This also includes records of the calculations performed to determine the limited quantities of drug products compounded before the receipt of valid prescription orders under the enforcement policy described in section III.B.2 of this guidance and section 503A(a)(2) of the FD&C Act. These records should clearly reflect the quantity of a particular drug product compounded in advance of receiving prescription orders for identified individual patients that the compounder has kept on hand as stock for distribution and the basis for the quantity the compounder kept in stock. Under the enforcement policy described in section III.B.2, this would include the quantity of the drug product distributed pursuant to prescription orders for identified individual patients during the reference period that the licensed pharmacist or licensed physician selected (i.e., a 30-day period within the last year).

Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2016
Compounding and Related Documents

Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

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Food and Drug Administration
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TABLE OF CONTENTS

Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended for entities that are registered or are considering registering with the Food and Drug Administration (FDA or Agency) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[2] Section 503B defines an outsourcing facility, in part, as "a facility at one geographic location or address." FDA has received questions from outsourcing facilities and other stakeholders about the meaning of this term, such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards. FDA is issuing this guidance to answer these questions.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a new category of compounders called *outsourcing facilities*. Section 503B describes the conditions that must be satisfied for human drug products compounded by or under the direct

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] A new section 503B was added to the FD&C Act by the Drug Quality and Security Act (DQSA). See Pub. L. No.113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- section 502(f)(1) (concerning labeling requirements);
- section 505 (concerning drug approval requirements); and
- section 582 (concerning Drug Supply Chain Security Act requirements).

Section 503B(d)(4) of the FD&C Act defines an outsourcing facility as a facility at one geographic location or address that— (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section. In addition, an outsourcing facility is not required to be a licensed pharmacy, and it may or may not obtain prescriptions for identified individual patients.[3] Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act, outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements.[4,5]

One of the conditions that must be met for a compounded drug to qualify for the exemptions under section 503B is that it must be compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section (section 503B(a)(11)). FDA's final guidance document, *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*,[6] clarifies that:

> If you register a facility as an outsourcing facility, you are indicating your intent for the facility's compounded drugs to be regulated under section 503B of the FD&C Act. Under section 503B(a)(11), a compounded drug can only qualify for the exemptions from sections 502(f)(1), 505, and 582 of the FD&C Act if ***all*** of the facility's compounded drugs are compounded in accordance with section 503B (page 4).

The guidance further states that:

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[3] See section 503B(d)(4)(C).

[4] See section 503B(a).

[5] FDA has issued a draft guidance entitled, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* ("Interim CGMP Guidance"). The Interim CGMP Guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

> All FDA guidances are available on the FDA guidance Webpage at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

[6] See the guidance *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

> By registering as an outsourcing facility, an entity is electing to have its compounded drugs regulated under section 503B of the FD&C Act, not section 503A. Drugs compounded at an outsourcing facility are not eligible for the exemptions provided in section 503A, even if the conditions in that section are met with respect to the particular drug (page 5).

Some outsourcing facilities compound drugs both according to patient-specific prescriptions as well as in response to orders that are not patient-specific, as section 503B permits them to do.[7] FDA has been asked whether an outsourcing facility can create a separate area within its facility for compounding according to patient specific prescriptions under section 503A, and not follow CGMP requirements in that area. For example, can the drugs be compounded according to patient-specific prescriptions in an adjacent area or room, or in a separate suite, but with the same staff and the same components used in 503B compounding? The CGMP regulations[8] contain requirements for facility design, staff training and competency testing, control of incoming components, aseptic processing, air quality, environmental monitoring, and related requirements designed to ensure the quality of the finished product. The application of different CGMP requirements or the different conditions in section 503A and 503B to commingled compounding activities can cause confusion about what requirements apply and could lead to the production of substandard drugs.

For that reason, and because it is a condition of eligibility for the exemptions in section 503B that all of the drug products compounded in an outsourcing facility must be compounded in accordance with section 503B and with CGMP requirements, this guidance clarifies what constitutes a "facility."

III. POLICY

Section 503B(d) defines an outsourcing facility, in part, as "a facility at one geographic location or address." FDA interprets "facility at one geographic location or address" to mean a business or other entity under one management, direct or indirect, engaged in human drug compounding at a geographic location or street address. The agency considers all activities, equipment, appurtenances, and materials part of such a facility if they are related to human drug compounding under the supervision of the facility's management at the same street address, or in the same building, or in buildings located in close proximity to one another.

As noted above, all drug products compounded in an outsourcing facility are regulated under section 503B[9] and subject to CGMP requirements.[10] These conditions cannot be avoided by segregating or subdividing compounding within an outsourcing facility. For example, even if an

[7] See note 3, supra.

[8] See CGMP regulations at Title 21, Parts 210 and 211 of the Code of Federal Regulations.

[9] See section 503B(a)(11).

[10] See section 503B(a).

outsourcing facility divides its site at one street address into multiple sections with temporary or permanent physical barriers, conducts patient-specific and non-patient specific compounding in different areas (e.g., in different hoods or different rooms), or conducts patient specific and non-patient specific compounding on different days or different times of the day, all of the drug products compounded at that street address must meet the conditions of section 503B or none of the outsourcing facility's drug products would qualify for the exemptions in section 503B. Furthermore, all of the drug products compounded at that street address must be compounded in accordance with CGMP requirements or the outsourcing facility could be cited for violations of section 501(a)(2)(B) of the FD&C Act.

A. Segregating Compounding of Drug Products Under Section 503A From Compounding of Drug Products Under Section 503B

FDA is interpreting facility in this way to be consistent with the intent of section 503B. To be eligible for the exemptions in section 503B(a), a drug product must be compounded in an outsourcing facility in which drugs are compounded only in accordance with section 503B (see section 503B(a)(11)). Outsourcing facilities may or may not obtain prescriptions for identified individual patients, and they are not subject to the interstate distribution restrictions in section 503A. Therefore, the intent of this provision is to ensure that all drugs compounded at an outsourcing facility without the restrictions in section 503A (e.g., the prescription requirement and the restrictions on interstate distribution) are compounded in accordance with CGMP requirements, labeled appropriately, subject to adverse event reporting, and otherwise compounded in accordance with the conditions of section 503B.

If compounding under sections 503A and 503B were to take place in the same geographic location or address, it could appear that all drug products compounded in the outsourcing facility were being made under higher standards, when in fact some or all were made under lesser controls (e.g., the drugs produced under the conditions of 503A would not be produced in accordance with CGMP requirements).

In addition, this definition is designed to prevent commingling of compounding activities under sections 503A and 503B to evade the conditions of section 503B and CGMP requirements. A drug product compounded under section 503A may be indistinguishable from a drug product compounded under section 503B except for the conditions under which it is compounded. It is important to be able to follow the production of drug products compounded in an outsourcing facility to ensure that the products are made under CGMP requirements from the time the bulk drug substances are received at the facility through production of the finished dosage form. If a firm compounds drug products in the same general location under different standards, it will be difficult to ensure that all of the products were made under the correct standards, particularly if the activities are commingled (e.g., because compounding under both standards draws on the same supplies, equipment, personnel, storage, or processing areas), or if compounded drug products are marketed under the same firm name or from the same location. And because drug products compounded under section 503A must be compounded in accordance with a prescription while drug products made under section 503B may or may not be compounded in accordance with a prescription, if the drug products are made in neighboring suites in the same

building, it may be impossible to determine whether a prescription was obtained for the a particular product before it was distributed. The agency's interpretation also provides clarity during inspections with regard to which standards apply to the location that is being inspected.

It is in the best interest of the public health to be clear about the separation between 503A and 503B facilities to ensure that those obtaining the drugs will know the standards under which they were compounded. Furthermore, the public health is best served, and an important objective of section 503B is achieved, if all drug products compounded in an outsourcing facility, whether patient-specific or non-patient specific, are compounded in accordance with CGMP requirements and other requirements imposed in section 503B of the FD&C Act.

B. Compounding Drug Products Under Section 503B and Conventionally Manufacturing Drug Products at the Same Facility

If a conventional manufacturer registers a facility as an outsourcing facility and makes both approved drug products and compounded drug products in the outsourcing facility, the compounded drug products would need to meet the conditions of section 503B to qualify for the exemptions from sections 502(f)(1), 505, and 582.[11]

All of the drug products produced at the facility would be subject to the CGMP requirements in 21 CFR parts 210 and 211. As stated above,[12] FDA has issued a draft guidance that, when finalized, will describe FDA's expectations regarding outsourcing facilities and these CGMP requirements. When a facility both manufactures conventional drug products and compounds drug products under section 503B, the policies described in this guidance would apply to the facility's compounded drug products, except with respect to CGMP requirements that must be implemented throughout a manufacturing facility and cannot be applied differently to different drug products in the same facility, such as environmental monitoring and pressure differential monitoring requirements.

The compounding of drug products under section 503B and the manufacture of approved drug products in the same facility does not present the complications described above regarding the compounding of drug products under sections 503A and 503B in the same facility. For example, an outsourcing facility could not commingle its compounded and approved drug products to avoid manufacturing the approved drug products in accordance with applicable CGMP requirements or to avoid compounding drug products in accordance with the conditions of section 503B. An outsourcing facility's compounded drug products are easily differentiated from its approved drug products; the approved drug products are the subject of approved drug applications and are listed with FDA under section 510 of the FD&C Act, while the compounded drug products are unapproved and are generally not listed. Furthermore, outsourcing facilities

[11] We do not read "compounding" in section 503B(a)(11) of the Act to refer to the manufacture of an approved drug product. Therefore, a drug product may be compounded in an outsourcing facility in accordance with section 503B even if an approved drug product is manufactured in that outsourcing facility not in accordance with section 503B.

[12] See footnote 5.

must label compounded drug products with the statement, "This is a compounded drug,"[13] so purchasers of compounded drug products from an outsourcing facility that also manufactures approved drug products will know that the drug products that they purchased were compounded. FDA verifies during inspections that outsourcing facilities are producing their compounded and approved drug products in accordance with the applicable standards, including that the drug products are labeled appropriately.

[13] See section 503B(a)(10).

STATEMENT ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Good morning and thank you for inviting us to this listening session. I am Roslyne Schulman, a Director of Policy at the American Hospital Association. Today I am accompanied by Dr. Shewan Aziz, the Senior and System Director of Pharmacy at Seton Healthcare Family in Austin, Texas, which is a member of the non-profit health care system, Ascension.

The AHA appreciates FDA's efforts to ensure that drugs are compounded in a way that protects patients and that also recognizes the challenges that the prescription requirement in 503A poses for hospitals and health systems.

As FDA notes in its draft guidance, health systems often have centralized compounding pharmacies that prepare and distribute quantities of drugs to other parts of their system before a patient-specific prescription is received. These compounded drugs are then held at the system's hospitals or its outpatient facilities until a patient presents with a need for the drug. This is intended to ensure that patients can receive the appropriate treatment in a timely manner. Centralized compounding also helps ensure that products can be prepared efficiently, safely, and in compliance with strict standards for quality and consistency. For example:

- Compounded drugs are commonly distributed this way for urgent uses in surgeries and in emergency departments.
- Also drugs that are not otherwise commercially available in the right dosages or forms are often centrally compounded by hospital pharmacies and distributed so they can be available timely for special patient populations such as those in the neonatal intensive care unit (NICU), for cancer patients or for dialysis patients, to name a few.
- Further, centralized compounding pharmacies supply the smaller/rural facilities that are part of their system, which allows these rural facilities to provide better and more convenient access to care for patients in these communities.

We appreciate FDA's intent in using its enforcement discretion to provide an exemption for hospital compounding pharmacies. However, we are concerned that the exemption, particularly the 1-mile radius standard, is too limiting for those health systems that have centralized compounding pharmacies that supply hospitals and outpatient facilities outside that radius. Unfortunately none of the other options available to health care systems are ideal:

- Building redundant compounding pharmacies within a 1-mile radius of all health system facilities would be extremely costly and would likely reduce patient safety.

- Health systems cannot purchase all their compounded products from outsourcing facilities because outsourcing facilities do not offer all the types of specialized products needed for individual patients nor can outsourcing facilities provide

health systems with compounded products with very short beyond-use dates or products needed urgently.

- Finally, becoming a 503B outsourcing facility would not be feasible for most health systems, particularly if FDA applies its proposed policy prohibiting a 503A compounding pharmacy and a 503B outsourcing facility to co-exist at the same address.

Instead, as Dr. Aziz will explain, we believe that a time-based exemption may make more sense and should be explored.

Ascension Health System (Dr. Shewan Aziz): We are concerned about the 1-mile radius exemption. Compounding sterile IV products is complex and requires compliance with very strict standards including USP, state Boards of Pharmacy regulations, Joint Commission standards, etc. After the 2012 NECC contamination situation and due to the complexity of IV sterile compounding and to assure patient quality and safety as well as reduce supply cost my health system decided to consolidate, centralize and in-source our IV sterile compounding to one of our large hospitals to operate as a central-fill pharmacy. We believe that a centralized compounding pharmacy with certified and competent staff that are dedicated to preparing sterile IV preparations will allow the benefit of economy of scale, increases patient accessibility to compounded products, improves quality assurance and reduces the potential of errors that may otherwise occur if different staff prepare these IV preparations at multiple locations or physicians and nurses compound drugs at the bedside. In addition this central fill pharmacy has helped us provide sterile IV preparations to the patients of our small hospitals that do not have pharmacy services 24/7 and has helped these small hospitals comply with USP 797, TJC, CMS and the state board of pharmacy compounding related standards.

Finalizing the 1-mile radius exemption would have a negative impact on patient quality of care, safety and will force many health systems back to the old system of each individual hospital or outpatient facility within the system doing its own compounding or, worse yet, shifting to bedside compounding by physicians and nurses particularly in hospitals without 24/7 pharmacy services. With this scenario in place IV compounding will be prepared by non-experienced staff, under non sterile environment, with no quality assurances which will increase the potential for errors, contamination, and violation of USP 797, CMA, TJC and state board of pharmacy compounding standards. The option of having these small hospitals creating their own IV sterile laboratory, purchasing compounding equipment and hiring IV experienced and certified pharmacy staff to extend compounding operation to 24/7 is not a viable option especially when these small hospitals are already facing financial difficulties due to the reduction in federal reimbursement. This means with time these hospitals will be forced to close their doors which will definitely impact the small rural community they serve. Unfortunately, the option for our central-fill pharmacy to become a 503B outsourcing facility is not workable because our health system pharmacies, particularly the one which assigned the central

fill work, still need to retain their state license to provide traditional compounding to their own patients and the FDA's draft guidance on the definition of facility in 503B will not allow us to have both a 503A compounding pharmacy as well as a 503B outsourcing facility at the same address.

There are several reasons why we could not exclusively use 503B outsourcing facilities for all our compounding needs:

- Ratability and turn around issues: While we can obtain some products from 503B outsourcing facilities, their turn-around time is too long for other products we require on shorter notice. It can take several days to get ordered products from an outsourcing facility.
- Maximum Capacity: The number of registered outsourcing facilities do not have the capacity to serve all hospitals. Currently they all have reached their maximum capacity with the number of health system they currently serve which is evident by the fact that their turn-around time for providing products have increased. We are concerned that if they tried to meet the nations' needs for additional compounded products, the pressure to serve all health care facilities would result in increases in contamination or errors.
- Outsourcing facilities do not produce all the specialized compounded products needed for patient care.
- When there is a drug shortage, the outsourcing facilities cannot provide the hospital/system with the needed product. Currently and during drug shortage our central fill hospital aliquots the drug on the shortage list and distribute to the rest of our hospitals to reduce waste, extend the supply/availability of the drug and most importantly to assure patient access to the drug. Outsourced facilities will not be able to provide this kind of service to our patients.
- Outsourcing IV preparation is costly as compared to preparing these compounded products in house. This cost increase will not only negatively impact the small hospital's operation and existence but this increase in cost will also be reflected and transferred to the patient.

We urge FDA to reconsider the proposed 1-mile radius exemption. Instead, we recommend the agency to consider a time-based standard. For instance, FDA's existing guidance for mixing, diluting or repackaging biological products outside the scope of an approved biological license application states that licensed pharmacy located in hospitals and health systems can divide a biological product into a smaller amount in order to extend the supply of the drug due to shortage and facilitate access to the drug by hospitals within health systems in advance of receipt of prescription providing that the beyond use date (BUD) is no longer than 4 hours or equal to the time within which the open products is to be used as specified in the approved labeling or whichever is shorter or up to 24 hours if the microbial studies are performed. We believe this time based standard is more appropriate knowing that with the revised USP chapter and the new USP 800 hazardous drugs chapter hospital pharmacies will have more strict IV

sterile preparation standards, including additional sterile and microbial testing requirements to comply with which will provide more assurance about the sterility of our products and the safety of our patients.

Summary of FDA Listening Session on Compounding

Attending Organizations: American Hospital Association (AHA), Ascension Health, Institute for Safe Medication Practices (ISMP); HCA; Federation of American Hospitals (FAH), Blue Cross Blue Shield Association (BCBSA), Kaiser Permanente (KP), Pharmaceutical Care Management Association (PCMA); Accreditation Commission for Health Care (ACHC); Ambulatory Surgery Center Association (ASCA); LifePoint Health, American Society of Health System Pharmacists (ASHP).

FDA Lead on Compounding: Julie Dohm.

- FDA is holding several listening sessions besides this one for providers and insurers to solicit feedback on the compounding draft guidance documents including sessions for pharmacy, medical/drug industry and 503b outsourcing facilities.
- FDA has released draft compounding guidance documents and encourages participants to provide their views in writing to those open dockets.

ASCA: Concerned that policy for office-based compounding will limit physicians' ability to get drugs.

AHA (Roslyne): Centralized compounding in health systems is intended to ensure that patients can receive the appropriate treatment in a timely manner. It also helps ensure that products can be prepared efficiently, safely, and in compliance with strict standards for quality and consistency. While we appreciate FDA's intent in using its enforcement discretion to provide an exemption for hospital compounding pharmacies, we are concerned that the exemption, particularly the 1-mile radius rule, is too limiting. Unfortunately none of the other options available to health care systems are ideal. Instead, we believe that a time-based exemption may make more sense and should be explored.

Ascension/AHA (Dr. Aziz): We are concerned about the 1-mile radius exemption. Compounding sterile IV products is complex and requires compliance with very strict standards including USP, state Boards of Pharmacy regulations, Joint Commission standards, etc. After the 2012 NECC contamination situation and due to the complexity of IV sterile compounding and to assure patient quality and safety as well as reduce supply cost my health system decided to consolidate, centralize and in-source our IV sterile compounding to one of our large hospitals to operate as a central-fill pharmacy. We believe that a centralized compounding pharmacy with certified and competent staff that are dedicated to preparing sterile IV preparations will allow the benefit of economy of scale, increases patient accessibility to compounded products, improves quality assurance and reduces the potential of errors that may otherwise occur if different staff prepare these IV preparations at multiple locations or physicians and nurses compound drugs at the bedside. In addition this central fill pharmacy has helped us provide sterile IV preparations to the patients of our small hospitals that do not have pharmacy

services 24/7 and has helped these small hospitals comply with USP 797, TJC, CMS and the state board of pharmacy compounding related standards.

Finalizing the 1-mile radius exemption would have a negative impact on patient quality of care, safety and will force many health systems back to the old system of each individual hospital or outpatient facility within the system doing its own compounding or, worse yet, shifting to bedside compounding by physicians and nurses particularly in hospitals without 24/7 pharmacy services. With this scenario in place IV compounding will be prepared by non-experienced staff, under non sterile environment, with no quality assurances which will increase the potential for errors, contamination, and violation of USP 797, CMA, TJC and state board of pharmacy compounding standards. The option of having these small hospitals creating their own IV sterile laboratory, purchasing compounding equipment and hiring IV experienced and certified pharmacy staff to extend compounding operation to 24/7 is not a viable option especially when these small hospitals are already facing financial difficulties due to the reduction in federal reimbursement. This means with time these hospitals will be forced to close their doors which will definitely impact the small rural community they serve. Unfortunately, the option for our central-fill pharmacy to become a 503B outsourcing facility is not workable because our health system pharmacies, particularly the one which assigned the central fill work, still need to retain their state license to provide traditional compounding to their own patients and the FDA's draft guidance on the definition of facility in 503B will not allow us to have both a 503A compounding pharmacy as well as a 503B outsourcing facility at the same address.

There are several reasons why we could not exclusively use 503B outsourcing facilities for all our compounding needs:

- Ratability and turn around issues: While we can obtain some products from 503B outsourcing facilities, their turn-around time is too long for other products we require on shorter notice. It can take several days to get ordered products from an outsourcing facility.
- Maximum Capacity: The number of registered outsourcing facilities do not have the capacity to serve all hospitals. Currently they all have reached their maximum capacity with the number of health system they currently serve which is evident by the fact that their turn-around time for providing products have increased. We are concerned that if they tried to meet the nations' needs for additional compounded products, the pressure to serve all health care facilities would result in increases in contamination or errors.
- Outsourcing facilities do not produce all the specialized compounded products needed for patient care.
- When there is a drug shortage, the outsourcing facilities cannot provide the hospital/system with the needed product. Currently and during drug shortage our central fill hospital aliquots the drug on the shortage list and distribute to the rest of our hospitals to reduce waste, extend the supply/availability of the drug

and most importantly to assure patient access to the drug. Outsourced facilities will not be able to provide this kind of service to our patients.

- Outsourcing IV preparation is costly as compared to preparing these compounded products in house. This cost increase will not only negatively impact the small hospital's operation and existence but this increase in cost will also be reflected and transferred to the patient.

We urge FDA to reconsider the proposed 1-mile radius exemption. Instead, we recommend the agency to consider a time-based standard. For instance, FDA's existing guidance for mixing, diluting or repackaging biological products outside the scope of an approved biological license application states that licensed pharmacy located in hospitals and health systems can divide a biological product into a smaller amount in order to extend the supply of the drug due to shortage and facilitate access to the drug by hospitals within health systems in advance of receipt of prescription providing that the beyond use date (BUD) is no longer than 4 hours or equal to the time within which the open products is to be used as specified in the approved labeling or whichever is shorter or up to 24 hours if the microbial studies are performed. We believe this time based standard is more appropriate knowing that with the revised USP chapter and the new USP 800 hazardous drugs chapter hospital pharmacies will have more strict IV sterile preparation standards, including additional sterile and microbial testing requirements to comply with which will provide more assurance about the sterility of our products and the safety of our patients.

ISMP: They support use of manufacturer developed products and restrictions on products that shouldn't be compounded. However, they recognize that certain products, such as parenteral products, need to be compounded. ISMP has guidelines for safe compounding.

The 1-mile radius proposal is a concern. Many hospitals have put time, effort and resources in expanding their facilities for compounding parenteral compounds. Their concern is that larger health systems have smaller hospitals that fall outside the 1-mile radius and this proposed policy would force their smaller hospitals outside that radius to use 503B products. Products from 503B outsourcing facilities are not only more costly, but they are concerned that, as demonstrated by FDA's inspections, these outsourcing facilities still have quality issues. Registering to be an outsourcing facility is voluntary. They are also concerned that if larger health systems are not permitted to supply their hospitals or other facilities, compounding will be done at bedside, which increases the risk of contamination and error.

KP: KP is a national integrated health system. The FDA's definition of health system doesn't fit their model. In most regions, KP has outpatient clinics that are specialty specific. They also have urgent care centers, ASCs and other types of facilities. KP has outpatient pharmacies, home IV pharmacies and oncology pharmacies. While KP often receives patient-specific prescriptions for compounded products and they prefer, to the extent possible to use commercially available products, their facilities do not always

know a physician will need a particular compounded product. The 1-mile radius rule would not work for KP and there is a concern that it would lead to more bedside compounding.

BCBSA: Their perspective is mostly on the retail pharmacy side. They are pleased to see regulation for 503A and 503B facilities. They are concerned about the number of compounded products that have hit the market and the source of these products. They are also worried about physicians having access to compounding kits. BCBSA is concerned about the number of units of compounded product that could be prepared in advance of a patient-specific prescription under FDA's proposed 30-day inventory standard for office-based compounding. They fear that this could result in a lot of product going out to patients without a prescription (?). The association feels that a 30-day inventory standard is too broad and they suggest that FDA limit the number of units as well.

Lifepoint Health/FAH: LifePoint is a health system with a rural hospital emphasis. They are concerned about the possible impact of the draft guidance. As part of their unique collaboration with the Duke Health System they have created a LifePoint Quality Program System.

Hospitals and health systems must be able to continue to be able to compound drugs for their patients. LP concerns with the draft guidance include:

- 1-mile radius: There is no clear reason or rationale for the 1-mile radius limitation. Seems arbitrary with no linkage to the health system definition. This will hurt critical access hospitals and other hospitals outside the 1-mile radius.
- Distinction between 503A and 503B: The prescription requirement should be revised to link to beyond-use dates (BUD). That is, if a compounding facility meets USP Chapter 797 standards, then the timeframe linked to BUDs should be adequate.
- Definitions and static nature of the guidance.

USP Chapter 797 and the FDA guidance are inextricably linked and USP Chapter 797 undergoing revisions. They urge FDA to wait to finalize the guidance until 797 is finalized. They note that hospitals and health systems are regulated in a number of ways, including the Medicare Conditions of Participation (CoPs), USP (which are referenced in the CoPs), systems within hospitals to ensure patient safety.

- Concerns about the distance – should look at issues looked at last year with BUDs and that should
- Current HCS system is changing. Variety of collaborative models with physicians and hospitals taking risk. Guidance documents need to fit into the new environment.
    - Concerned about prohibition of operating a 503A and 503B facility in the same area within a HC system. Concerned isn't looking at advancing technology (e.g. use of robots to do compounding).

    - Changing marketplace – critical that hospitals should be able to have separate 503A and 503B facilities.
- Trina Kaylor, HCA: Huge numbers of system facilities from CAHs to AMCs. After NECC put a lot of thought into pharmacy facilities. Looked to bring compounding in-house as much as possible and all of facilities were ensured to be 797 compliant. Leverage size to improve patient safety. Thought about whether they want to build 503B but decided not too. Leverage large 24/7 hosptials to service smaller facilities in their system. Reduces risk, optimize facilities they have built, highly trained staff. Redundancy to improve safety.
- Should use BUD instead of 1-mile radius. Optimize practices based on their risk. Challenge is majority of the HOPDs are outside of the 1-mile radius. None of those facilities has ability to cojpound or admix on daily basis. Reliability of outsourced compounders gives them concern.
- Leveraging large facilities helps garner efficiencies for higher risk services they provide: Opthalmology, TPN, Oncology.
- Anticipatory compounding: Know patterns of physiciahns. E.g. TPNs, have limited hours to allow orders to come in from physicians. So they do batch some TPN orders. Batching for a day or two. Certain amount of surgeries that they expect the next day plus emergency facilities. Don't want to push these out to outsourcing facility.
- Support 30-day period.
- As it relates to prescription requirements, EHR is how this works…so should consider changing language of "written" to encompass electronic record keeping
- Andy Cosgrove, PCMA: Supports where the draft guidance documents came out.
- Jon Pritchett: Accred Commission for HC: Inspect pharmacies on behalf of state boards and pharmacy compounding accreditation board (voluntary). State oversight of compounding varies widely. Only ½ of states require USP.
- ASHP: Jillanne Schulte/Bona Benjamin: Not particularly concerned about the 30-day limit or prescription requirement. Very concerned about the 1-mile radius. Worked really closely with state boards to set up something that works within their system and that is safe/practical. All vetted with state boards and now have central fill pharmacy or one large centralized pharmacy with best/most experienced staff. With 1-mile will have to reconsider space and care model. If you have a situation where a patient has to wait until a compounded product will take time, you are endangering your situation with CMS, patient satisfaction/etc. Looks to explore a time-based requirement. That will also provide for quality but still a closed system. Not business but just part of healthcare delivery. All internal, not looking to expand outside the system.
- 503B outsourcing facilities: Problem is they have systems set up already so can't register a 503b if they have other compounding pharmacies elsewhere on campus. Don't want bedside compounding to happen. At large central fills there are pharmacists there and lots of control over quality.

- Hospitals can't get everything from 503Bs. Things that are needed immediately. Problem with sufficiency. Shortages now, people have to wait to get product. If this expanded, delays will get worse.
- Push towards insourcing is because hospitals are responsible for outcomes. Concerned about quality issues with 503b outsourcing facilities – if FDA could ensure the quality/reliability, they would support as much of business going out to 503B's as possible.
- Can't go without 503A's in hospitals.
- FDA Q&A: 1-mile radius comes from common ownership and control.
- If they moved away from a geographical constraint to a timing constraint, how would that look?
- What is indicia for common ownership/control.
- Accrediting bodies require emergency drugs at the point of care: cardiovascular examples.
- Isuprel and Nypride are not prepared by outsourcing facilities due to short BUD. Also, can't wait for these products from outsourcing facility.
- Include "indices of system-ness" in our comments. Shared EHR, shared pharmacy ordering systems, centralized physician credentialing, treated as one unit by accrediting bodies.
- In comments, provide examples of siutations in which outsourcing facilities won't be the best.
- Why can't hospitals become outsourcing facilities: can't be both 503A and 503B
- Also provide comments on why non-hospital compounding pharmacies can't do this instead of hospital pharmacies.
- Record retention: How long do hospitals keep compounding products records? This is driven by state BOP as well as CMS. But will miss all bedside compounding.
- Also, USP 797 and 800 have record keeping requirements.
- Any other information about outsourcing facilities
- Clarifying definition of compounding: Definaition in new 797.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 6, 2016

TO: CHA Medication Safety Committee

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

SUBJECT: FDA Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

SUMMARY

The FDA has released three documents related to hospital and health system compounding under the Federal Food, Drug and Cosmetic Act. (See Attachments, Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act, Prescription Requirement Under Section 503A of the Federal Food, Drug and Cosmetic Act, and, Facility Definition Under Section 503 B of the Federal Food, Drug and Cosmetic Act.)

While FDA's guidance documents do not establish legally enforceable responsibilities, they describe the Agency's current thinking on a topic and should only be viewed as recommendations, unless specific regulatory or statutory requirements are cited.

DISCUSSION

With that being said, the new FDA guidance represents key provisions for central packaging pharmacies in California, who operate distribution from a broad mileage radius to enhance sophisticated compounding medication practices and safety across individual system facilities. Key factors in the guidance such as mileage criteria, if adopted, could imply that our present central packaging facilities are not complying with FDA 503A guidelines.

ISSUES OF CONCERN:

A. Clearly the 1-mile radius does not represent the mileage radius of our central hospital packaging pharmacies (CHPP) or our 75 mile state regulations in Article 7.6, Section 4128. Per the attached AHA document, Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act, a time-based standard is being offered as an alternative. "For instance, FDA's existing guidance for mixing, diluting or repackaging biological products outside the scope of an approved biological license application states that licensed pharmacy located in hospitals and health systems can divide a biological product into a smaller amount in order to extend the supply of the

drug due to shortage and facilitate access to the drug by hospitals within health systems in advance of receipt of prescription providing that the beyond use date (BUD) is no longer than 4 hours or equal to the time within which the open products is to be used as specified in the approved labeling or whichever is shorter or up to 24 hours if the microbial studies are performed. We believe this time based standard is more appropriate knowing that with the revised USP chapter and the new USP 800 hazardous drugs chapter hospital pharmacies will have more strict IV sterile preparation standards, including additional sterile and microbial testing requirements to comply with which will provide more assurance about the sterility of our products and the safety of our patients".

1. Is this or any other type of time standard acceptable to our systems?
2. If not a time standard, are there other options we can offer FDA that will support the continued operation of CHPP's in our state?

B. In "Prescription Requirement Under Section 503A of the Federal Food, Drug and Cosmetic Act, (see attachment) several policy areas need review.

**On page 7, there is a requirement for a receipt of a valid prescription order or a notation approved by the prescriber under section 503A. "A notation must document the prescriber's determination that a compounded drug is necessary for the identified patient. They recommend the following statement. "per (type of communication) with (name of prescriber) on (date), (name of prescriber) has advised that compounded (name of drug) is necessary for the treatment of (name of patient)"

1. What is our process for receipt of a valid prescription?
2. Is this done manually or through HER, etc.?
3. Is there another process we'd like to offer?

Compounding Before Receipt of a Valid Prescription Order, page 8 "The Compounding is a based on a history of the licensed pharmacist or physician" And, "the orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the prescriber who will write such prescription order".

1. Do both the comments on page 8 align with our processes?

*Page 9 describes a limited quantity as a 30 day supply based on the number of valid prescriptions for identified individual patients in a 30 day period over the previous year.

1. Is a 30 day supply consistent with our procedures and are they compounded similar to the formula based on page 9?
2. If not, what language can we offer?

*****Record Keeping, page 11 should maintain records to demonstrate compliance with the prescription requirement in section 503A(a)(1) of the FD&C Act and the basis for any anticipatory compounding. For example, this includes records of valid prescription orders and of prescription orders bearing notations that the compounded drug product is necessary for the identified individual patient as described in section III.A of this guidance and section 503A(a) of the FD&C Act. This also includes records of the calculations performed to determine the limited quantities of drug products compounded before the receipt of valid prescription orders under the enforcement policy described in section III.B.2 of this guidance and section 503A(a)(2) of the FD&C Act. These records should clearly reflect the quantity of a particular drug product compounded in advance of receiving prescription orders for identified individual patients that the compounder has kept on hand as stock for distribution and the basis for the quantity the compounder kept in stock. Under the enforcement policy described in section III.B.2, this would include the quantity of the drug product distributed pursuant to prescription orders for identified individual patients during the reference period that the licensed pharmacist or licensed physician selected (i.e., a 30 day period within the last year).

1. Does our CHPP's maintain records including valid prescription orders, approved notations and calculations of anticipatory prescribing?
2. Do the calculations reflect the quantity of a particular drug product?

C. Facility Definition Under Section 503B of the Federal Food, Drug and Cosmetic Act, (see attachment)

1. Do we agree that a 503A and a 503B should not be comingled?
2. Page 5 describes 503B and the "manufacture of approved drug products in the same facility is an exemption", What is a "manufacture of approved drug products"?

ACTION REQUESTED:

CHA requests alternative language from members to formulate a response letter

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

June 8, 2016

TO: CHA Member Hospital CEOs, COOs, CNOs and Pharmacists

FROM: C. Duane Dauner, President/CEO
BJ Bartleson, vice president, nursing and clinical services

SUBJECT: Important Information About Hospital Pharmacy Sterile Compounding

In response to the 2012 New England Compounding Center tragedy — where contaminated injections led to 64 deaths and hundreds of illnesses nationwide — federal and state laws have been reexamined to provide increased oversight and better safeguards for compounded pharmaceuticals. Because regulations and national standards have evolved over time, hospital leaders and pharmacists in charge (PICs) may not be aware of significant challenges that could affect their physical pharmacy plant space and engineering controls. CHA urges PICs and hospital leaders to review the new regulations immediately, perform a gap analysis and mitigate a plan to meet federal and state requirements.

CHA's Medication Safety Committee has tirelessly advocated for state regulations that closely match United States Pharmacopeia (USP) Convention standards and protect public safety, as well as leverage patient care delivery needs and the diverse hospital resources across the state. **On June 28 from 10 a.m. – noon, CHA will offer a Sterile Compounding Webinar to review the regulations and waiver process.** In addition to the details that follow, CHA and the California Society of Health-System Pharmacists have prepared an assessment tool to help hospitals assess their compliance; FAQs about the new regulations; and a set of grids describing the specific Board of Pharmacy and USP requirements and timelines – all available on the CHA website.

Changes to Standards and Regulations
There are three key changes for California hospitals:

1) **New state regulations**: The California Board of Pharmacy has developed new regulations for licensed pharmacies where sterile compounding occurs, which will go into effect January 1, 2017.
2) **USP 800, finalized this year**: The national professional standards that guide compounding practices and compounding administration of drugs are also being revised. The USP 800 was finalized in February 2016 and focuses entirely on employee safety when handling hazardous drugs; facilities will have two years to comply (July 2018). There is no waiver or mechanism to delay compliance with USP 800.
3) **USP 797, undergoing revisions**: USP 797 is due to be finalized in January 2018, when the California Department of Public Health will use it for survey purposes.

The Food and Drug Administration recently released three draft guidelines outlining the amount of drugs providers can compound without a prescription, the requirements for health system compounding pharmacies and clarification on outsourcing facility standards. Of concern is the requirement for a one-mile radius for distribution of non-patient specific compounded drugs to facilities across their service area. CHA is reviewing the draft guidelines and formulating comments to submit by the July 18 deadline.

What Hospitals Need to Know
Both the Board of Pharmacy's updated regulations and the USP standards pertain to sterile compounding of hazardous and non-hazardous drugs. The most important information your hospital should know is:

- Changes throughout the regulations and standards apply to facility configuration, frequency of cleaning, testing and personnel training, and may require significant adaptation.
- The most imminent challenge is for hospitals that conduct hazardous compounding. The state regulations will require a separate negative pressure room for hazardous sterile compounding, along with specific ventilation and air exchange requirements.
- The Board of Pharmacy may offer a temporary compliance waiver if a facility's physical construction or alteration to a facility or physical environment is necessary to meet the regulations.

Tools for Assessing Compliance
CHA's pharmacy leaders have developed a set of tools to enable PICs to perform a high-level assessment of compliance based on current available regulations and standards, including:

- FAQs that can be used with hospital stakeholders to explain the various federal and state regulatory changes for hazardous and non-hazardous sterile compounding.
- A "CHA High-Level Hazardous Drug Sterile Compounding Assessment Tool" for use in determining what, if any, changes need to be made if you perform hazardous sterile compounding.
- A set of grids developed by CHA and the California Society of Health System Pharmacy leaders. The grids describe the physical plant requirements, temperature requirements, lab testing requirements, documentation and garbing requirements in easy-to-read charts that depict both Board of Pharmacy and USP 797/800 requirements. The grids apply to all hazardous and non-hazardous sterile compounding changes.

After conducting an assessment, if your hospital needs to apply for a waiver, we urge you to begin formulating a plan immediately. The waiver format will be available in June, and a waiver request must be submitted and approved by the Board of Pharmacy before January 1, 2017. Facilities that are unable to secure a waiver should develop an alternate plan to procure prepared hazardous drugs, if needed.

Please consult with your PIC if you have not done so to be assured that your pharmacies will be prepared to meet the upcoming regulatory deadlines. If you have any questions or concerns, please contact BJ Bartleson, RN, NEA-BC, vice president of nursing and clinical services, at bjbartleson@calhospital.org or (916) 552-7537.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Frequently Asked Questions about Federal and State Sterile Compounding Regulations

June 2016

In response to the 2012 New England Compounding Center tragedy, where contaminated injections led to 64 deaths and hundreds of illnesses nationwide, federal and state laws have been revised to provide increased oversight and better safeguards for sterile compounded pharmaceuticals.

These FAQs are intended for hospital and health care providers as they attempt to comply with changing federal sterile compounding standards and new state regulations that take effect beginning January 1, 2017.

Why were the California Board of Pharmacy sterile compounding regulations changed?

The Board of Pharmacy changed its regulations to ensure they reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565). The regulations also address the problem of ensuring that board regulations are aligned with compounding standards in United States Pharmacopeia (USP) 797 and USP 800, which further ensures the safety of consumers receiving compounded drugs in California.
(See www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf.)

What are USP 797 and USP 800?

The professional compounding standards used nationally are known as the United States Pharmacopeia and The National Formulary (USP–NF). The USP specifically features monographs for drug substances, dosage forms, and compounded preparations. Its widely recognized quality standards for pharmacy compounding of sterile and nonsterile preparations, USP 797 and USP 800, reference the handling and administration of drugs that present physical or health hazards. Many states, including California, incorporate USP standards into pharmacy laws and regulations.
(See www.pharmacy.ca.gov/laws_regs/1735_nopa.pdf.)

What do pharmacies need to know about USP 797 and 800?

- **USP 800, finalized this year**: USP 800 focuses entirely on employee safety when handling hazardous drugs; facilities will have two years to comply (July 2018). There is no waiver or mechanism to delay compliance with USP 800.
- **USP 797, undergoing revisions**: USP 797 is due to be finalized in January 2018, when the California Department of Public Health will use it for survey purposes.

To what facilities do these regulations and standards apply?

- USP 797 and 800 apply to any practice site that compounds sterile products or administers hazardous drugs (e.g., doctors' offices, licensed pharmacies and clinic-based infusion centers).
- The California Board of Pharmacy regulations apply to any licensed pharmacy in California that compounds sterile products.

What about compounding facilities that ship their products to California?

Included as part of the federal Drug Quality and Security Act, which became effective on Nov. 27, 2013, are provisions that establish federal regulation and oversight of large-scale drug compounding by "outsourcing facilities." The law sets forth voluntary requirements for licensure and enforcement of these entities. However, California's law is more restrictive than the federal law in several areas. California will continue to require any pharmacy that compounds sterile products for California residents or practitioners to possess licensure with the Board of Pharmacy and comply with California requirements as sterile compounding pharmacies.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Prior to the enactment of the Drug Quality and Security Act, compounding pharmacies were regulated by their respective states of residence.

What is included in the Board of Pharmacy's recent sterile compounding regulatory changes?

Changes were made to lab testing requirements, temperature requirements, cleaning requirements, quality assurance requirements, frequency of documentation, policies and procedures, competency assessments and physical plant and facilities requirements.

The regulations amend Sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8,1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, 1751.8, and 1751.10, as well as adds Article 7.5 and Sections 1751.9, 1752, 1753, and 1754 of Division 17 of Title 16 of the California Code of Regulations.

When do the new Board of Pharmacy sterile compounding regulations go into effect?

Jan. 1, 2017. (See www.pharmacy.ca.gov.)

When do the USP revised standards go into effect?

- USP 800 goes into effect in July 2018.
- It is presumed that the draft USP 797 standards will go into effect in July 2018 along with USP 800, but that has not been confirmed by the FDA.

What if our facility won't be ready to meet the deadline?

Where compliance with the state Board of Pharmacy's Jan. 1, 2017 amendments requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical changes. (See www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf page 231- section 1735.6 [f])

What is the process for requesting a waiver from the Board of Pharmacy?

Waiver applications must be submitted by the licensee in writing, and the request must identify the provisions requiring physical construction or alteration, as well as the timeline for such changes. The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver. (See www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf).

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

CHA Hazardous Sterile Compounding High-Level Assessment Tool

The California Board of Pharmacy's newly revised sterile compounding regulations apply to both sterile hazardous and non-hazardous compounding of pharmaceuticals. Because the hazardous sterile compounding requirements include potential physical plant changes, as well as new engineering controls, CHA has developed this high-level assessment tool to help hospitals determine what — if any — changes they will need to make related to hazardous sterile compounding regulations that take effect January 1, 2017.

Because many of the necessary changes will include physical construction or alteration to a facility or physical environment, the Board of Pharmacy has included in the regulations a compliance waiver process for hospitals that may need time to complete necessary physical changes.

The tool can be used by the hospital pharmacist in charge (PIC) to determine if there are sufficient engineering controls and space, and whether changes are necessary for the facility to perform hazardous sterile compounding.

To use this assessment tool, answer the questions below and follow the instructions after each step:

Step 1: Do you perform hazardous sterile compounding in your hospital pharmacy?

- ☐ Yes – Proceed to Step 2.
- ☐ No – Stop here. You don't need to perform an assessment regarding *hazardous* sterile compounding. However, you will need to assess and compare changes that may be required for *non-hazardous* sterile compounding. Those changes can be found in the "CHA Sterile Compounding Matrices," included with this packet.

Step 2: What engineering controls and hazardous sterile compounding space do you have now? Check all that apply.

- ☐ A separate negative pressure room
- ☐ International Standard Classification Organization (ISO) class 7 or cleaner air
- ☐ A negative pressure, unidirectional airflow hood vented to the outside, **and** at least 30 air exchanges per hour

If you have checked the previous three boxes above, you will meet the January 1, 2017 requirements for the full beyond use date (BUDs) requirements. ***Stop here****. You have completed the assessment and will meet the regulatory requirements for hazardous compounding for full BUD requirements.*

Step 3: If you don't have all three of the above, do you have any of the following?

- ☐ A separate, negative pressure room
- ☐ Unclassified International Organization for Standardization (ISO) and air
- ☐ A negative pressure, unidirectional non-turbulent airflow hood, vented to the outside and at least 10 air exchanges per hour

If all three are checked, you will meet the January 1, 2017 requirements for the short BUDs (12 hours) hazardous sterile compounding, without the need for a waiver. ***Stop here****. You have completed the assessment, unless you plan to extend your BUD capabilities, in which case you will need to skip to* ***"Next Steps"*** *(see below).*

Step 4: If you don't have the engineering controls and space described in Steps 2 or 3, do you have any of the following scenarios for hazardous sterile compounding listed below? Check all that apply.

- ☐ A separate, negative pressure room
- ☐ With or without ISO Class 7 air
- ☐ A negative pressure, unidirectional airflow hood, not vented to the outside

If all three are checked, this will not meet the requirements. Proceed to ***Next Steps*** *(see below).*

Step 5: **If you do not have any of the scenarios described in Step 4, do you have following?**

- ☐ A negative pressure, unidirectional hood vented to the outside but not in a negative pressure room

If the box above is checked, this will not meet the requirements and will need to be reconfigured. If the hood is already vented, consider any space that could become a room and meet the air exchange and still use the same vent for the 12-hour BUD requirement. Proceed to ***Next Steps*** *(see below).*

Step 6: If you do not have the scenario described in Step 5, do you have following?

- ☐ A negative pressure hood not vented to the outside

If you checked the box above, this will not meet the requirements. Proceed to ***Next Steps*** *(below).*

Next Steps
If you are planning to continue sterile hazardous compounding in your facility and you currently have the engineering controls and space described in Steps 4, 5 or 6 — or if the scenarios in Step 3 apply to your facility and you want to upgrade your BUD requirements — you may want to consider the following next steps:

- ☐ Inform your senior management team of your initial assessment and potential changes needed to perform hazardous sterile compounding relative to BUD requirements. Also, inform them that the Board of Pharmacy will require a waiver for planned changes if the proposed facility changes will not meet the January 1, 2017, regulatory deadline.
- ☐ Meet with appropriate staff and your facilities manager to determine a suitable location that can become a negative pressure room with venting to the outside (one vent per hood).
- ☐ If you have a recirculating hood, add a new hood to the budget and or contact the manufacturer for a possible change.
- ☐ Engage an architect, if applicable, for construction plans/modifications.
- ☐ Confer with your facilities manager to determine a tentative budget and timeline.
- ☐ Prepare for OSHPD approval process, if applicable.
- ☐ Begin the process for capital budget and seek Capital budget approval.
- ☐ ***Submit a waiver to the Board of Pharmacy that includes:***
    - The assessment
    - The plan
    - The timeline

This tool is intended for hospital and health care PIC and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption" Sterile Compounding Regulations found at www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_leg.pdf, page 231, and designed by CHA's Medication Safety senior pharmacy leaders.

This tool is not a fixed compliance assessment that must be followed and should not be construed as entirely inclusive or exclusive of all methods that can achieve the same results. Information contained in this document should not be construed as legal advice or used to resolve legal problems.

Instructions for Using the CHA/CSHP Compounding Grids 2016

WHAT

The California Hospital Association (CHA)/California Society of Health-System Pharmacists (CSHP) Compounding Grids identify the proposed Board of Pharmacy requirements that will take effect Jan. 1, 2017, as well as describe the upcoming USP 797 and USP 800 requirements that will likely be effective July 1, 2018. There are six compounding grids: Physical Plant Requirements for Non-Hazardous Compounding, Physical Plant Requirements for Hazardous Compounding, Compounding Frequency of Documentation, Temperature Requirements and Monitoring, Required Laboratory Testing, and Non-Hazardous and Hazardous Garbing.

These tools are intended for hospital and health care pharmacists in charge (PICs) and other hospital staff as they evaluate their current sterile compounding practices. The grids are based on the Board of Pharmacy's Feb. 24, 2016, "Order of Adoption- Sterile Compounding Regulations" and interpreted by CHA's and CSHP's Medication Safety senior pharmacy leaders. The grids are not a fixed compliance assessment that must be followed, and they should not be construed as legal advice or used to resolve legal problems.

WHEN

The Board of Pharmacy regulations take effect Jan. 1, 2017. If a facility is not able to meet the physical plant requirements, a waiver will be required prior to Jan. 1, 2017. The waiver requires a plan and a proposed timeline. *Note: There is no waiver for training, testing and cleaning requirements.*

USP 800 is in its final form with an effective date of July 1, 2018. USP 797 is undergoing review and is expected to be finalized for an effective date of July 1, 2018, but there may be some changes to the proposed language.

HOW

To use the grids:

1. The Compounding Frequency of Documentation, Temperature Requirements and Monitoring, Required Laboratory Testing, and Non-Hazardous/Hazardous Garbing grids are self-explanatory.

2. The physical plant grids for non-hazardous and hazardous sterile compounding should be used as follows:

Which room	Date requirements take effect	
	January 1, 2017	**July 1, 2018**
Hazardous	Board of Pharmacy	USP <800> (CDPH requirement)
Non-hazardous	Board of Pharmacy	USP <797> still draft (CDPH requirement)

1. Look at the negative pressure, Hazardous Compounding Grid, space, equipment and the Board of Pharmacy requirements.

   a. Find the type of room in the current space (the SEC = secondary engineering control).
   b. Second, determine if you can meet the minimum requirements.
      - If yes, congratulations. Next, be sure to review the USP 800 requirements.
      - The USP requirements go into effect in two years — July 2018.
   c. If the current set up does **not** meet the Board of Pharmacy requirements, a waiver will be required prior to Jan. 1, 2017. This will require a plan and a timeline.
   d. If structural changes are necessary, be sure to review the USP 800 planned requirements and proposed changes simultaneously, especially refrigeration and storage in negative pressure spaces.

2. Repeat the same process with the positive pressure, non-hazardous space compounding grid.

WHO

CHA and CSHP created a task force in the fall of 2014 to develop a series of grids to assist health system pharmacists understand the requirements as delineated by the California State Board of Pharmacy and the current and proposed USP chapters 797 and 800. The Sterile Compounding Task Force members are:

Christine Acosta, Board of Pharmacy
Elaine Beals, CSHP Southern California Chapter, Kaiser
Corbin Bennett, CSHP Sierra Chapter, Kaiser
Darrell R. Chan, CSHP Orange County Chapter, Prime Health Care
Lucinda Chan, CSHP Diablo Chapter, Touro University
Helen Chun, CSHP Southern California Chapter, Kaiser
Candace Fong, Past Chair, CHA Medication Safety Committee, Dignity Health
Ken Fukushima, CSHP Orange County Chapter, CPS Pharmacy
Jeannette Hanni, CSHP QuatraCounty Chapter, Sutter, CHA Medication Safety Committee Chair
Stephanie Holcomb, CSHP Sierra Chapter, Community Medical
Martin Iyoya, Diablo, CSHP Board Liaison, John Muir Health
Mervyn Kalman, CSHP San Fernando Valley Chapter, Consultant
Doug. C. O'Brien, CHA Medication Safety Committee, Kaiser
Lynn Paulsen, University of California, CHA Medication Safety Committee, Chair SCTF
Maria Serpa, CSHP Sacramento Valley Chapter, Sutter
Art Woo, California Department of Public Health, CHA Medication Safety Committee
Betty Yee, CSHP Diablo Chapter, Retired

TEMPERATURE REQUIREMENTS AND MONITORING

(CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797>(7/1/18) 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> proposed	Board of Pharmacy January 1, 2018
	Min	Max	Min	Max				
Controlled Freezer Temperature (USP and BOP)	-25º	-10º	-13º	14º	Check individual monographs for specific requirements outside this range	General Notices 10.20.10		No provision for excursions §1735.1 (i)
Freezer (CDC)	-50º	-15º	-58º	5º	Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Controlled Cold Temperature	2º	8º	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)
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 for July 1, 2018	
	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 Proposed
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)
Ambient Room	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. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption Sterile Compounding Regulations" and designed by CHA's and CSHP's Medication Safety Senior Pharmacy Leaders. 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.

PHYSICAL PLANT REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) 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 • **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**	**APPLIES TO ALL**
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**			
>ISO Class 7 clean room with ISO 8 or better ante-area • No sink in clean room • Sink in ante • 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(e)(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. 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
	• Laminar Flow Hood • Biological Safety Cabinet with unidirectional flow • CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	12 hours	• 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)
	• 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
PROPOSED USP 797 - NON-HAZARDOUS DRUGS Effective July 1,2018				

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PHYSICAL PLANT REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

<table>
<tr><th>SECONDARY ENGINEERING CONTROL
• Temp = or < 20 C
• Humidity < 60%
• Controlled through HVAC
• Air enters HEPA filter in the ceiling of buffer room and returns low on the wall</th><th>PRIMARY ENGINEERING CONTROL (PEC)
ISO 5 with unidirectional flow</th><th>BEYOND USE DATES</th><th></th></tr>
<tr><td colspan="3">Category 1</td><td>Comments</td></tr>
<tr><td>Segregated compounding area (SCA)
• Not ISO classified
• Buffer/ante not meeting ISO 7/8 respectively
• Buffer/ante fails surface sampling
• Away from significant traffic flow
• Away from unsealed doors/windows that connect to outdoor
• Perimeter must be defined
• Sink must be 1 meter from PEC (greater than the 3 ft. for the BOP requirements)
• Not adjacent to construction, warehouse or food prep</td><td>ISO Class 5 PEC:
• Laminar Air Flow System (LAFS)
• Biological Safety Cabinet (BSC)
• Restricted Access Barrier System (RABS), can be CAI or CACI
• Isolator</td><td>• Less than or equal to 12 hours at Room Temp*
• Less than or equal to 24 hours at Cold Temp (Refrigerator)**</td><td>• Recertification every six months
• Endotoxin and sterility testing not required for products
• No shipping or external cartons allowed in SCA</td></tr>
<tr><td colspan="3">Category 2</td><td>Comments</td></tr>
<tr><td>PEC in ISO 7 buffer room
• With ISO 8 or better ante, separated from surrounding unclassified area
• Buffer and ante must be separate rooms with walls and doors, and controls to prevent low quality air into controlled areas
• Sink in ante
• Buffer and ante must have ACPH = or >30, at least 15 must be HEPA filtered fresh air vs. recirculated air
• Positive pressure differential at least 0.02” wc to separate each ISO classified area and from ante to general pharmacy area</td><td>ISO Class 5 PEC:
• Laminar Air Flow System (LAFS)
• Biological Safety Cabinet (BSC)
• Restricted Access Barrier System (RABS), can be CAI or CACI</td><td rowspan="2">Sterile to Sterile, No Preservatives, Aseptic Technique
<table><tr><td>Sterility Testing</td><td>Room Temp BUD</td><td>Refrigerated BUD</td><td>Freezer BUD</td></tr><tr><td>NO</td><td>6 days</td><td>9 days</td><td>45 days</td></tr><tr><td>YES</td><td>28 days</td><td>42 days</td><td>45 days</td></tr></table>BUD days start after the quarantine period for sterility testing

For: Terminal sterilization, preservatives, non-sterile to sterile compounding BUDs, please see the USP <797> document</td><td rowspan="2">• Recertification every six months
• No tacky mats in ISO classified areas
• Document pressure differential or velocity daily or use continuous recording device
• No shipping or external cartons allowed in buffer/ante
• Endotoxin testing required for CSP compounded from non-sterile ingredient(s)</td></tr>
<tr><td>PEC in ISO 8 area
• Sink can be in ISO 8 area 1 meter from PEC
• Must have ACPH = 15 ;must be HEPA-filtered fresh air vs. recirculated air
• Positive pressure differential at least 0.02”wc to separate each ISO classified area and to general unclassified area</td><td>• Isolator (must meet standards; see lines 505-511 in proposed USP <797>)</td></tr>
</table>

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NON-HAZARDOUS GARBING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

Compounding attire	Order of garbing in the anteroom	Specifications
Shoe covers	1	May be eliminated IF written documentation by CAI manufacturer
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)	May be eliminated IF written documentation by CAI mfr.
Non-shedding gown	4	
Sterile gloves Must wear sterile gloves over any CAI gauntlet gloves	5	Tested for compatibility with sterile 70% isopropyl alcohol (SIPA)
PROHIBITED ITEMS AND INDIVIDUALS		
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing with jewelry • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails • False eyelashes		Eyelash extensions are permitted
Excluded from ISO 7 and ISO 5 spaces until resolved		
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases		

HAZARDOUS GARBING: In addition to the above requirements (USP<800>)

Compounding attire	Specifications	Information
Double shoe covers		Don the second pair upon entering the buffer area. Remove upon leaving.
Sterile chemo gloves	Chemo gloves must meet ASTM standard 6978 (or its successor). NO powder.	Change every 30 minutes or when torn, punctured or contaminated.
Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	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.
Face shields	Required when working outside a C-PEC	Surgeons, spill cleanup, etc.

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REQUIRED LABORATORY TESTING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

<table>
<tr><th>Environmental Testing
Under Dynamic Conditions</th><th>USP <797></th><th>Board of Pharmacy (BOP)</th></tr>
<tr><td>Viable surface sampling

Viable air sampling by volumetric impaction: (400-1,000 liters)</td><td>Every six months: Requires identification of every colony forming units (CFUs) to the genus level and action plan for CFUs exceeding USP thresholds
<table>
<tr><th>Location</th><th>Viable airborne</th><th>Viable surface</th></tr>
<tr><td>ISO-5 (PEC)</td><td>>1</td><td>>3</td></tr>
<tr><td>ISO-7 (Buffer)</td><td>>10</td><td>>5</td></tr>
<tr><td>ISO-8 (Anteroom)</td><td>>100</td><td>>100</td></tr>
</table>
(highly pathogenic microorganisms [e.g., G(-) rods, coag (+) Staph, molds and yeasts] must be immediately remedied, regardless of CFU count)</td><td>• Every six months for low and medium risk California Code of Regulations (CCR) §1751.4 (j)
• Every six months for high risk CCR §1751.4 (j)
• Genus level identification of CFUs exceeding the threshold (facility determined) CCR §1751.4 (j)</td></tr>
<tr><td>Volumetric air sampling by impaction: non-viable particle counts</td><td>Every six months: requires action plan for particle counts exceeding ISO class as required</td><td>• Every six months as part of hood re-certification for low and medium risk
• Weekly for high risk</td></tr>
<tr><td colspan="3">Process validation: 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.</td></tr>
</table>

Personnel	When Required	What Tests Are Required (BOP and USP)
Moderate and low risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing, then 1x annually thereafter. CCR §1735.1(u)
Moderate and low risk compounding – ongoing competency	Annually as part of the competency testing process	
High risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing then semi-annually thereafter. CCR §1735.1(u)
High risk compounding – ongoing competency	Every six months as part of the competency testing process	

Lot Compounding (More than one of the identical product)	USP <797> July 1, 2018 Proposed	Board of Pharmacy: Additional Policies Required
Sterile to sterile compounding	N/A	Written policies and procedures including (1) master formulae and compounding logs, (2) appropriate documentation and (3) appropriate sterility and potency testing CCR §1751.3 (b)(1-3)
Non-sterile to sterile		Written policies and procedures including: (1) process validation for chosen sterilization methods and (2) end-product evaluation, quantitative and qualitative testing CCR §1751.3 (c)(1-2)

End Product Testing: Requirement for Sterility and Potency Testing for Lots of Low/Med Risk CSPs	Comments	USP <797> July 1, 2018	BOP January 1, 2017
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 • USP <797> revisions have different BUD	• As long as the shorter of the manufacturer insert stability and the USP <797> BUD is met, there is no batch sterility testing requirement.	• "Appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CR §1751.3 (d)
Extended BUD (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. • USP <797> does not exempt extended BUDs from sterility testing.	• 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.	• "Appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1735.2(i)(3-4)
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 • Facility policy should describe processes as determined by the PIC to assure accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(3-4)

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PHYSICAL PLANT REQUIREMENTS - HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

Hazardous Drugs - BOP				
		Beyond Use Dates		
SECONDARY ENGINEERING CONTROL • **Temp 20-24C (68-75F)** • **Externally vented** • **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 dedicated to 1 BSC or Compounding Aseptic Isolators (CACI)**	**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 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 • CACI with unidirectional flow. Air within the CACI shall not be recirculated or turbulent.	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 at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e); each hood must have a separate vent • All surfaces with the room shall be smooth, seamless, impervious and non-shedding 1735.6(e)(4) • No requirements for negative pressure drug storage
• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft. from 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 • CACI with unidirectional flow. CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	12 hours	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification at least 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces with 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) • No requirements for negative pressure drug storage
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				

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy’s 2/24/2016 “Order of Adoption Sterile Compounding Regulations” and designed by CHA’s and CSHP’s Medication Safety senior pharmacy leaders. 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.

PHYSICAL PLANT REQUIREMENTS - HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

HAZARDOUS DRUGS - USP 797				
SECONDARY ENGINEERING CONTROL **Externally vented through HEPA filtration**	**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 (greater than the 3 feet required by BoP)**	• 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	*USP <800> and <797> BUDs* *6 days at Room Temp** *9 days at Cold Temp*** *45 days Freezer Temp **** ***BUT will be overridden by the BOP BUDs unless there is a regulatory change*** **BOP BUDs** **48 hours Room Temp** **14 days Cold Temp** **45 days Solid Frozen State**	*USP <800> and <797> BUDs* *6 days at Room Temp** *9 days at Cold Temp*** *45 days Freezer Temp **** ***BUT will be overridden by the BOP BUDs unless there is a regulatory change*** **BOP BUDs** **30 hours Room Temp** **9 days 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.
• **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 HEPA filtered air** • **Sink at least 1 meter from C-PEC (greater than the 3 feet required by the BOP)**	• 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	

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

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

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

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COMPOUNDING FREQUENCY OF DOCUMENTATION

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and Proposed USP<797> (7/1/18) 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 (Twice a day for vaccines)	X	X
Freezer (Twice a day for vaccines)	X	X
Air pressure differentials or air velocity between adjoining ISO rooms	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
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
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	X
Volumetric air sampling Particle count CFUs, identified to genus. ALL CFUs identified to genus per USP <797>, only facility-determined limits for BOP	X	NA
Hood certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Media fill for employees	NA	X
ANNUAL	LOW AND MEDIUM RISK	HIGH RISK
Media fill for employees	X	NA
Competency testing Observation Written	X	X

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Meeting New Requirements for Sterile Compounding Webinar

June 28, 2016
CHA Webinar

CALIFORNIA HOSPITAL ASSOCIATION

Welcome

Liz Mekjavich
California Hospital Association

Continuing Education Requirements

Full attendance, completion of online evaluation and attestation of attendance is required to receive CEs for this webinar. CEs are complimentary and available for the registrant. Post-event survey will be sent this afternoon. Please fill out the survey — we value your input on our programs.

3

Continuing Education Offered for this Program

Compliance — This program has been approved for 2.4 Compliance Certification Board (CCB) Continuing Education Units. Granting of prior approval in no way constitutes endorsement by CCB of the program content or the program sponsor. (Note: CE recipients are solely responsible for retaining a copy for their records and for reporting credits to CCB)

Health Care Executives — CHA is authorized to award 2.0 hours of pre-approved ACHE Qualified Education credit (non—ACHE) for this program toward the advancement, or recertification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward ACHE qualified education credit should indicate their attendance when submitting application to the American College of Healthcare Executives for advancement or recertification.

Nursing — Provider approved by the California Board of Registered Nursing, CEP #11924, for 2.4 Contact Hours.

Legal — CHA is a State Bar of California-approved MCLE provider. Provider number 1980. This participatory activity has been approved for 2 hours of MCLE credit.

4

Program Overview and Introductions

BJ Bartleson, RN, NEA-BC

California Hospital Association

Faculty

Jeannette Hanni, received her Bachelor of Pharmacy degree from Washington State University. She then completed her Master's degree in Public Administration for Health Services Administration from the University of San Francisco, graduating with honors. Ms. Hanni is currently the Executive Director of Pharmacy for the Bay Area for Sutter Health, West and South Bay. In addition to overseeing the operations of her respective facilities Ms. Hanni has spent the last 10+ years becoming heavily involved in health care policy and medication safety. Ms. Hanni has served as Co-Chair of the very active CHA Medication Safety Committee since its inception in 2009. Through her association with this committee Ms. Hanni has been fortunate to be able to impact the revisions of several important State laws and regulations and to be a part of creating various tools and guidelines to aid the health care community on important medication safety initiatives and challenges. Ms. Hanni has spent many years as an active member of the California Society of Health System Pharmacists, serving as local chapter President, and as a director for the CSHP Board of Directors.

6

Faculty

Doug O'Brien received his Doctor of Pharmacy degree from the University of California, San Francisco. He completed his residency in Clinical Pharmacy at Long Beach Memorial Hospital.

Since 2008, has served as the Northern California Regional Director for Inpatient Pharmacy Services for Kaiser Foundation Hospitals. Prior to joining Kaiser Permanente he was the Director of Inpatient Pharmacy Services at Friendly Hills Regional Medical Center in La Habra, California. Dr. O'Brien's 30 years of professional experience includes roles as Director of Clinical Pharmacy Services at La Habra Community Hospital, and Vice-President of Clinical Pharmacy Consultants, Inc., providing consulting and educational services to various medical centers throughout Southern California. He currently serves as a Member of the California Hospital Association's Medication Safety Committee.

7

Faculty

Michael Ignacio, is a supervising inspector with the California Board of Pharmacy, where he provides guidance, and investigative case plans and assessments to direct investigations. In addition, Mr. Ignacio trains inspector staff, consults with executive staff on complex enforcement and licensing program activities, and has assisted in the development of revisions to California compounding regulations. Prior to joining the Board of Pharmacy, he practiced as a pharmacist, where he was involved with high-risk sterile compounding.

8

Faculty

Virginia Herold, became executive officer of the Board of Pharmacy in January 2007. Prior to this appointment, Ms. Herold served as assistant executive officer of the Board for 16.5 years, and interim executive officer for seven months.

As executive officer, Ms. Herold works closely with and advises the 13 Board of Pharmacy members in the development of policy and in the administration of the board's enforcement, licensing and regulatory programs to further the board's consumer protection mandate. The Board regulates over 130,000 licensees in 13 separate licensure classifications including pharmacists, pharmacies and drug wholesalers.

9

Faculty

Lynn Paulsen, is a pharmacist with over 40 years of experience in the spectrum of hospital pharmacy practice; rural, pediatric specialty, community and academic Medical center. She received her Pharm.D. from UCSF after a B.A. from UC Berkeley. The past 5 years have been with UC Health at the University of California in identifying policy, legislation , practice standards and opportunities for the statewide UC system. Patient safety has been her passion throughout her career and translating the complex regulations around sterile compounding into clear and concise guides so that California hospital pharmacies can provide the safest care in the country is her goal. She is moving to be closer to the 3(soon to be 4) grandsons but will be continuing to work in pharmacy is different capacities.

10

The Impact of Regulatory Changes on Sterile Compounding

Introduction and Background

Jeannette Hanni, Executive Director of Pharmacy, Sutter Health Bay Area

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Goals for the Program

- Become more familiar with the events that led to the increased federal and state oversight and regulation of sterile compounding
- Gain a better understanding of the changes that are being made to USP 797 and 800, and how those changes will directly affect your operations and processes
- Gain a better understanding of the changes that have been made to the California State Board of Pharmacy Sterile Compounding regulations, effective January 1, 2017
- Be introduced to the Board of Pharmacy waiver process that will be available to facilities who have determined that the time needed for local design and construction would not allow them to be compliant on January 1, 2017
- Be introduced to the newly-released crosswalks of the new regulations
- Gain familiarity with the newly-released sterile compounding matrix tools to aid in understanding each regulations at a granular level. These tools and the crosswalks are designed to give each facility a very nuts and bolts method of determining compliance for each major section of the regulations (e.g., facility design, testing, garbing, cleaning, temperature monitoring and documentation)

12

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Early Events

May, 2001, Doc's Pharmacy in Walnut Creek — Spinal injection of contaminated betamethasone causing acute bacterial meningitis, 13 people hospitalized, three deaths

October, 2001*, The Board of Pharmacy supports the introduction and passage of proposed legislation increasing the standards for pharmacies engaged in sterile compounding

January, 2002*, The Governor signed SB 293 (Torklakson)
1) Requires a separate sterile compounding license for pharmacies engaging in injectable sterile compounding
2) The bill also required that such sterile compounding be performed in a manner consistent with guidelines adopted by the Board
3) Exempted facilities with The Joint Commission accreditation

October, 2013 Governor Jerry Brown signs AB 294 (Emerson), following two incidents of out of state product shipped into California that caused significant harm in June and October, 2012

Hospital exemption for sterile compounding licensure is removed in July, 2014

13

* "The Script, October, 2001" and "The Script, January, 2002"

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The Response to the New England Compounding Center Tragedy 2012 - 2016

New England Compounding Center

- In September of 2012, NECC contaminated spinal preparations sold to hospitals and MD offices
- Greater than 800 patients were sickened and 64 people died
- The NECC tragedy has had profound impact on the practice of sterile compounding in the U.S.

National Response

- On November 27, 2013 President Obama signed the Drug Quality and Security Act (DQSA) into law
- The DQSA contains important provisions relating to the oversight of compounded products
- One provision of the DQSA is mandatory compliance with United States Pharmacopeia standards (USP 797 & 800) in ALL practice settings
- USP 797 and 800 regulations pertaining to sterile compounding are now legally enforceable in all 50 states

FDA Response

- In February 2016, a new chapter of USP was approved, USP 800. This chapter mandates specific requirements for facilities handling hazardous drugs (e.g., chemotherapy). This chapter is entirely focused on requirements to ensure employee safety
- USP 800 now limits hazardous compounding and storage of drug to negative pressure rooms that are externally vented, effective July 2018
- In September 2015, USP 797 was completely re-written and will most likely have a similar effective date of July 2018

California State Response

- AB 294 signed by Governor Jerry Brown in October, 2013
- In July of 2014, the California State Board of Pharmacy adopted a new licensing requirement for hospital pharmacies who compound sterile injectable products and inspects every licensed compounding facility annually
- In 2014, the State Board wrote a significant revision to their sterile compounding regulations, aligning more closely to the requirements of the Federal law with much stricter language. These regulations were adopted in February, 2016 and currently have an effective date of January, 2017

14

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Federal Changes

Doug O'Brien, PharmD

Kaiser Permanente

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The USP and Chapter 797

- The United States Pharmacopeia-National Formulary (USP-NF)
  - Recognized in the 1938 Federal Food, Drug, Cosmetic Act as the official compendia of drug standards in the United States
  - Chapters numbered 1-999 are official monographs and standards, and are enforceable by the FDA
- USP Chapter 797: Pharmaceutical Compounding – Sterile Preparations
  - Intended to protect patients by ensuring compounded sterile preparations (CSPs) are safe for use, including hazardous drugs
  - Applies to all persons who prepare CSPs and all places where CSPs are prepared
  - First published in 2004, subsequently revised in 2008 (current version)
  - New Draft version released in 2015 (comment period ended Jan 31, 2016)
  - Revised Chapter will most likely become effective July 1, 2018

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USP Chapter 800

- USP Chapter 800: Hazardous Drugs - Handling in Healthcare Settings
  - Describes practices and quality standards for handling and compounding hazardous drugs
  - Intended to promote patient safety, worker safety, and environmental protection
  - Released Feb 1, 2016 and will become effective July 1, 2018
  - Applies to all healthcare personnel who handle hazardous drugs, and all facilities that store, prepare, transport, or administer hazardous drugs
  - Hazardous drug standards will no longer be included in Chapter 797 when Chapter 800 becomes effective

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CMS Conditions of Participation for Hospitals

- CMS State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
  - Contains the tasks and interpretive guide for conducting surveys in hospitals to validate compliance with all CMS requirements
  - Compliance with USP Chapter 797 was added as a requirement on October 30, 2015
  - Language added to the Pharmaceutical Services section to require compliance with USP Chapter 797 when compounding sterile preparations
  - Language added to the Nursing Services section to require compliance with USP Chapter 797 when compounding sterile preparations outside the pharmacy (“immediate-use CSPs”)
  - Increases the regulatory scrutiny related to the compounding of sterile preparations throughout the hospital by surveyors from CMS and The Joint Commission

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2017 Compounding Regulations

Speaker: Michael Ignacio, PharmD

Slides by: Christine Acosta, PharmD

California State Board of Pharmacy

- 141,373 licensees
  - Drug rooms (38)
  - Hospital pharmacies (485)
  - Licensed correctional facilities (53)
  - Non-Resident pharmacies (453)
  - Non-Resident sterile compounding facilities (91)
  - Pharmacies (6,572)
  - Sterile compounding facilities (936)
  - Centralized Hospital Packaging Pharmacy (5)

Compounding Definitions

- "Potency" active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount.
  - Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.
- "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

Compounding Quality Assurance (1735.8)

- Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.
- The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

Compounding Quality Assurance

The quality assurance plan shall include:

- Written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing.
  - All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document.
- A schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.
- Written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.
- Written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Facility and Equipment Standards for Sterile Compounding

- Viable surface sampling shall be done at least:
  - Every six months for sterile-to-sterile compounding.
  - Quarterly for all non-sterile-to-sterile compounding.
- Viable air sampling by volumetric air sampling procedures under dynamic
  - At least once every six months.
- When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.
- 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.
- A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Sterile Compounding Consultation; Training of Sterile Compounding Staff

Pharmacies that compound sterile drug preparations must comply with the following training requirements:

- Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual.
  - Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations.
  - Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.
  - Each person's proficiency and continuing training needs must be reassessed at least every 12 months.
  - Results of these assessments must be documented and retained in the pharmacy for three years.

Sterile Compounding Quality Assurance and Process Validation (1751.7)

- Any pharmacy engaged in compounding sterile drug preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities.
- The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications.
- The quality assurance program shall include the following:
  - (1) Procedures for cleaning and sanitization of the sterile preparation area.
  - (2) Actions to be taken in the event of a drug recall.
  - (3) Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

Sterile Compounding Quality Assurance and Process Validation

- The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations.
  - The validation process shall be:
    - Carried out in the same manner as normal production,
    - Be representative of the types of manipulations, products and batch sizes.
    - Shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process.
    - The same personnel, procedures, equipment, and materials must be used in the testing.
  - Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations.
  - If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

Sterile Compounding Quality Assurance and Process Validation

- Each individual's competency must be revalidated every :
  - 12 months for compounding from sterile ingredients.
  - 6 months for compounding from non-sterile ingredients.
- The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:
  - Quality assurance program yields an unacceptable result,
  - There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment.
- The pharmacy must document the validation and revalidation process.

Sterile Compounding Quality Assurance and Process Validation

- All sterile compounding personnel must successfully complete an initial competency evaluation.
  - Immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.
- Re-evaluation of garbing and gloving competency shall occur every:
  - 12 months for compounding from sterile ingredients.
  - 6 months for compounding from non-sterile ingredients.

Compounding Requests for Construction Waiver

Virginia Herold
Executive Officer
CA State Board of Pharmacy

Title 16 California Code of Regulations section 1735.6(f);

Where compliance with the amendments to Article 4.5 or Article 7 require physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s).

More 1735.6

Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Under Construction

- The Enforcement and Compounding Committee of the board is working to develop the process for submittal and review of waivers
- At early stages of development – completion expected in fall.

Components

The board will seek the assistance of OSHPD in reviewing waivers.

OSHPD's recommendations include such components as:

- Purpose
- Scope of the project
- Project plan
- Definitive dates, including for project completion
- Structural modifications vs. non-structural modifications (remodel)
- Design professionals involved (including the architect of record and the inspector of record)

More to Come

- The next Enforcement and Compounding Committee meeting will further discuss the process for waivers more fully
- Meeting date: August 31

Using the CHA Sterile Compounding Tools

Lynn Paulsen, PharmD
Director, Pharmacy Practice Standards
UC Health, University of California

CALIFORNIA HOSPITAL ASSOCIATION

Why Were These Tools Developed?

- Pharmacists like to do things "right" but the last 10 years has been change by citation
- One goal is to provide everyone information in a more user-friendly format so that each facility does not have to do the difficult work of interpretation and translation
- The **BIG Goal** is to have patients in California experience the safest sterile compounding in the country/world

Does My Hazardous Compounding Space Meet the Requirements?

Step 1: Do you perform hazardous sterile compounding in your hospital pharmacy?

- Yes – Proceed to Step 2
- No – Stop here. You don't need to perform an assessment regarding *hazardous* sterile compounding. However, you will need to assess and compare changes that may be required for *non-hazardous* sterile compounding. Those changes can be found in the "CHA Sterile Compounding Matrices," included with this packet

More Questions

Step 2: What engineering controls and hazardous sterile compounding space do you have now? Check all that apply.

- ☐ A separate negative pressure room
- ☐ International Standard Classification Organization (ISO) class seven or cleaner air
- ☐ A negative pressure, unidirectional airflow hood vented to the outside, **and** at least 30 air exchanges per hour

If you have checked the previous three boxes above, you will meet the January 1, 2017 requirements for the full Beyond Use Days (BUDs) requirements. ***Stop here****. You have completed the assessment and will meet the regulatory requirements for hazardous compounding for full BUD requirements.*

Almost Done

Step 3: If you don't have all three of the above, do you have any of the following?

- ☐ A separate, negative pressure room
- ☐ Unclassified International Organization for Standardization (ISO) and air
- ☐ A negative pressure, unidirectional non-turbulent airflow hood, vented to the outside and at least ten air exchanges per hour

If all three are checked, you will meet the January 1, 2017 requirements for the short BUDs (12 hours) hazardous sterile compounding, without the need for a waiver. ***Stop here****. You have completed the assessment, unless you plan to extend your BUD capabilities, in which case you will need to skip to* ***"Next Steps"*** *(see below).*

More Difficult Situations

Any of the following:

- Negative pressure hood, not uni-directional
- No negative pressure room
- No negative pressure hood
- Hood not vented to the outside

Any of these will **not** meet the requirements and will require reconfiguration or other solution.

One Last Hope

If you have:

- Negative pressure, unidirectional hood
- Vented to the outside
- But, no negative pressure room

Consider a space that could be reconfigured to meet the minimum air exchanges and become negative pressure. This could be a relatively low cost solution for 12-hour BUD.

Next Steps

- Inform your senior management team of your initial assessment and potential changes needed to perform hazardous sterile compounding relative to BUD requirements. Also, inform them that the Board of Pharmacy will require a waiver for planned changes if the proposed facility changes will not meet the January 1, 2017 regulatory deadline
- Meet with appropriate staff and your facilities manager to determine a suitable location that can become a negative pressure room with venting to the outside (one vent per hood)
- If you have a recirculating hood, add a new hood to the budget and or contact the manufacturer for a possible upgrade

Next Steps (cont.)

- Engage an architect, if applicable, for construction plans/modifications
- Confer with your facilities manager to determine a tentative budget and timeline
- Prepare for OSHPD approval process if applicable
- Begin the process for capital budget and seek capital budget approval
- ***Submit a waiver to the Board of Pharmacy that includes:***
  - The assessment
  - The plan
  - The timeline

Non-Hazardous

- January 1, 2017 vs. July 1, 2018
- Scenario 1
  - ISO Class 7 clean room
  - ISO 8 or better ante-area

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
≥ISO Class 7 clean room with ISO 8 or better ante-area • No sink in clean room • Sink in ante • 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(e)(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. 1751.1(a)(8)

Non-Hazardous

- Scenario 2
  - **Segregated sterile compounding area**

SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)		PRIMARY ENGINEERING CONTROL (PEC=Sterile Compounding Hoods)	Beyond Use Dates	
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)	• Compounding Aseptic Isolators (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
	• Laminar Flow Hood • Biological Safety Cabinet with unidirectional flow CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	12 hours	• 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)
	• 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

How is USP 797 Changing?

Category 2

PEC in ISO 7 buffer room • **With ISO 8 or better ante, separated from surrounding unclassified area** • **Buffer and ante must be separate rooms with walls and doors, and controls to prevent low quality air into controlled areas** • **Sink in ante** • **Buffer and ante must have ACPH = or >30, at least 15 must be HEPA filtered fresh air vs. recirculated air** • **Positive pressure differential at least 0.02" wc to separate each ISO classified area and from ante to general pharmacy area**	ISO Class 5 PEC: • Laminar Air Flow System (LAFS) • Biological Safety Cabinet (BSC) • Restricted Access Barrier System (RABS), can be CAI or CACI	**Sterile to Sterile, No Preservatives, Aseptic Technique** Sterility Testing / Room Temp BUD / Refrigerated BUD / Freezer BUD NO / 6 days / 9 days / 45 days YES / 28 days / 42 days / 45 days BUD days start after the quarantine period for sterility testing For: Terminal sterilization, preservatives, non-sterile to sterile compounding BUDs, please see the USP <797> document	• Recertification every 6 months • No tacky mats in ISO classified areas • Document pressure differential or velocity daily or use continuous recording device • No shipping or external cartons allowed in buffer/ante • Endotoxin testing required for CSP compounded from non-sterile ingredient(s)
PEC in ISO 8 area • **Sink can be in ISO 8 area 1 meter from PEC** • **Must have ACPH = 15 ;must be HEPA-filtered fresh air vs. recirculated air** • **Positive pressure differential at least 0.02"wc to separate each ISO classified area and to general unclassified area**	• Isolator (must meet standards; see lines 505-511 in proposed USP <797>)		

And This

Category 1			Comments
Segregated compounding area (SCA) • **Not ISO classified** • **Buffer/ante not meeting ISO 7/8 respectively** • **Buffer/ante fails surface sampling** • **Away from significant traffic flow** • **Away from unsealed doors/windows that connect to outdoor** • **Perimeter must be defined** • **Sink must be 1 meter from PEC (greater than the 3 ft for the BOP requirements)** • **Not adjacent to construction, warehouse or food prep**	ISO Class 5 PEC: • Laminar Air Flow System (LAFS) • Biological Safety Cabinet (BSC) • Restricted Access Barrier System (RABS), can be CAI or CACI • Isolator	• Less than or equal to 12 hours at Room Temp* • Less than or equal to 24 hours at Cold Temp (Refrigerator)**	• Recertification every 6 months • Endotoxin and sterility testing not required for products • No shipping or external cartons allowed in SCA

Hazardous Drugs 1/1/2018

Hazardous Drugs - BOP

SECONDARY ENGINEERING CONTROL	PRIMARY ENGINEERING CONTROL	Beyond Use Dates		Comments
		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	
• 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 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 Isolators (CACI) with unidirectional flow. Air within the CACI shall not be recirculated or turbulent.	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 at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e); each hood must have a separate vent • All surfaces with the room shall be smooth, seamless, impervious and non-shedding 1735.6(e)(4) • No requirements for negative pressure drug storage
• Segregated Compounding Area • Sterile to sterile compounding only • Sink at least 3 ft from 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 Isolators (CACI) with unidirectional flow. CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	12 hours	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification at least 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces with 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) • No requirements for negative pressure drug storage

All the Other Grids are MUCH Easier Temperature

Temperature Description	Degrees Centigrade Min	Degrees Centigrade Max	Degrees Fahrenheit Min	Degrees Fahrenheit Max	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> proposed	Board of Pharmacy January 1, 2018
Controlled Freezer Temperature (USP and BOP)	-25º	-10º	-13º	14º	Check individual monographs for specific requirements outside this range	General Notices 10.20.10		No provision for excursions §1735.1 (i)
Freezer (CDC)	-50º	-15º	-58º	5º	Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Controlled Cold Temperature	2º	8º	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)
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 for July 1, 2018	
	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 Proposed
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)
Ambient Room	Includes all drug storage location rooms: no specific requirements for monitoring inside ADCs	Daily		

Laboratory Monitoring

Environmental Testing Under Dynamic Conditions	USP <797>	Board of Pharmacy (BOP)
Viable surface sampling	Every six months: Requires identification of every colony forming units (CFUs) to the genus level and action plan for CFUs exceeding USP thresholds 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]**	• Every six months for low and medium risk California Code of Regulations (CCR) §1751.4 (j) • Every 6months for high risk CCR §1751.4 (j) • Genus level identification of CFUs exceeding the threshold (facility determined) CCR §1751.4 (j)
Viable air sampling by volumetric impaction: (400-1,000 liters)		
Volumetric air sampling by impaction: non-viable particle counts	Every six months: requires action plan for particle counts exceeding ISO class as required	• Every six months as part of hood re-certification for low and medium risk • Weekly for high risk

Process validation: 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.

Personnel	When Required	What Tests Are Required (BOP and USP)
Moderate and low risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing, then 1x annually thereafter. CCR §1735.1(u)
Moderate and low risk compounding – ongoing competency	Annually as part of the competency testing process	
High risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing then semi-annually thereafter. CCR §1735.1(u)
High risk compounding – ongoing competency	Every 6 months as part of the competency testing process	

Lot Compounding (More than one of the identical product)	USP <797> July 1, 2018 Proposed	Board of Pharmacy: Additional Policies Required
Sterile to sterile compounding	N/A	Written policies and procedures including (1) master formulae and compounding logs, (2) appropriate documentation, (3) appropriate sterility and potency testing CCR §1751.3 (b)(1-3)
Non-sterile to sterile		Written policies and procedures including: (3)Process validation for chosen sterilization methods, and (2)end-product evaluation, quantitative and qualitative testing CCR §1751.3 (c)(1-2)

End Product Testing: Requirement for Sterility and Potency Testing for Lots of Low/Med Risk CSPs	Comments	USP <797> July 1, 2018	BOP January 1, 2017
Beyond Used Dating (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 • USP <797> revisions have different BUD	• As long as the shorter of the manufacturer insert stability and the USP <797> BUD is met, there is no batch sterility testing requirement.	• "appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CR §1751.3 (d)
Extended BUD (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. • USP <797> does not exempt extended BUDs from sterility testing.	• 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.	• "Appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1735.2(i)(3-4)
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 • Facility policy should describe processes as determined by the PIC to assure accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(3-4)

A Few Words to the Wise

- Remodel once — look ahead and remodel to the highest standards
- This is not a once-and-done. Requirements will continue to evolve

How Do I Use These Grids in Practice?

- One way for the SEC and PEC configurations
  - Identify the configuration of your pharmacy and edit the Grid to that configuration with requirements and BUDs
  - Laminate and post on the wall so there is no question regarding what can be done in your space
  - All staff should be able to identify what kind of sterile compounding space they are working in and what the limitations might be

How To Use The Other Tools

- Flow charts
- Check lists

These are easily turned into QA documents, should drive policy and can be laminated and posted for staff reference.

Will These Requirements Change?

- Oh, yes. Compounding continues to move towards cGMP, so might as well spend $35 for a copy on www.Smile.Amazon.com and ponder where this is going
- Are the cGMP standards changing? Of course!

Tools 2.0

- Will CHA update these tools?
  - If you find them useful, let us know

Adobe Connect - Q&A Pod Content from Meeting New Requirements for Sterile Compounding Webinar

Answered Questions (0)

Open Questions (66)
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1. Shari Lyons: Are there current requirements for sterile technique competencies for nursing staff?

2. denise.cummings@mchcares.com: Talk about nurse compounding on the unit, outside of the pharmacy

3. Shideh Ataii 2: regarding the BOP waiver process, should Pharmacies wait till the process is finalized before they submit the waiver?

4. Terry Lerma: If a site applies for a waiver for physical modification of a Clean Room Suite, is the expectation that the site uses 12 hour BUD until the physical space is compliant with new Regs?

5. Jerry Gonzales: For BUD dating, one slide mentioned using the shorter of the package insert or USP BUD. Many package inserts state for immediate use only. However, a 3rd party publciation such as TRissell'

6. Christine Low: If the Manufacturer's BUD is < USP 797, will sterility testing allow use of 797 BUD?

7. denise.cummings@mchcares.com: Please define "hazardous" drugs vs non-"hazardous'

8. Tommy Mai: Can you further clarify the requirements for the physician office sites?

9. Bob Shmaeff: What is hazardous sterrle compounding?

10. shahina shaikh: WE HAVE A SEGREGATED COMPOUNDING AREA WITH A CAI (ISO CLASS 5) - WHAT WILL OUR BUD 11. Linda Tran: For a temporary compounding space, is direct venting to the exterior required?

12. Cheryl Daniels: Is the NIOSH list what we should look to for identifying a hazzardous medication.

13. Carol Taketomo: Could you please comment on the humidity monitoring requirements for clean rooms. Children's Hospital Los Angeles

14. Ryan Stice: Page 22, references single vent per negative pressure hood. Does this mean that the venting needs to be seperate all the way outside of the building, or can two ents join to one exerior vent?

15. Nancy Zepeda 2: Will the exemption for HD sterile compounding go away in 1/2017? Will we beable to apply for a waiver?

16. Brandi Acevedo: The venting of the Chemotherapy hood does it need a ten foot stack? Also does the vent need a two hour fire wall?

17. Jerry Gonzales: Trissll's states longer BUD than pckg insert but shorter than USP. This would essentially mean we can't use anything but USP or pkg insert?

18. James Fung: Question for BOP. What is the CA BOP plan on inspecting for renewal of LSC (hospital)? If existing LSC expires prior to Jan 1, 2017, what type of inspections should be expect?

19. Sheetal Shah: need to know what definition of engaged from page 13 is?

20. Ramon Sanchez: With the increased use of TICE BCG, labeled a biohazardous substance but on the NIOSH group 1 list, what are your recommendations with reconstitution practices of the product? In a negative pressure room? In a separate designated hood for only that product? Or a cleaned hood that can be returned to service for other products?

21. Kwan Liou: We have an infusion clinic with negitive pressure buffer room, BSC and small Laminar FLow Hood (LFH) . We compound some antibotics and chemo premeds in the LFH. We were told that all products comming out of the LFH hood also has to have biohazardous warning lables. Is this true?

22. Kimberly Botwin: What is required for the designated area for immediate use sterile compounding outside of the pharmacy, such as a nurse preparing an IVPB in a critical situation?

23. Jose Lopez: what does CA BOP use as a reference for hazardous drugs? NISOH? what can be used as a guideline 24. shahina shaikh: THANKS - QUESTION HAS BEEN ANSWERED 25. Carol Taketomo: What is the current community standard of practice recommendations for the monitoring of mean kinetic tempertures (MKT)?

26. Grace Magedman: For non-hazardous compounding, if a satellite pharmacy is ISO-7 in the entire room, meets all the pressure/airflow requirements and has a demarcation between the buffer area where the ISO-5 PEC exists, will it still be eligible for Category 2 BUDs? Or does there need to be an additional/separate room with walls & door inside the ISO-7 satellite?

27. Gina Yam: we have a ISO-5 hood in a ISO-7 clean room in the new building. There is no buffer area. Should we target for Iso 7 or Iso 8 in the ante area?

28. Elizabeth DiGiacomo-Geffers: You mentioned compounding involves nursing. Can you delinieate expamples when a nurse compounds medication(s). Also what education and training is applicable.

29. Grace Magedman: It appears that the BOP BUD still overrides the USP 797/800, so even though the USP dating for cold temp is more restrictive than BOP's, the BOP dates will still override it? (9 vs 14 days) 30. Ross Domke: For clarification ..we currently have an isolator with segregated room ..what is the minimum we need to do to keep our current BUD's? Clean room with ante room?

31. Michael Sillman 4: What are the garbing requirements when using barrier isolators?

32. Thomas Jacobsen: USP 800 states that receiving and unpacking must occur in a negative or neutral pressure area. I believe Ca BOP requirements say that a pharmacy must be positive in pressure to the area outside of the pharmacy. So what are the recommendations of the presenters to deal with this issue?

33. Yoon Hee Kim: If we are undergoing construction, does the isolator hood need to be located the the pharmacy department, or can it be located in another area of the hospital?

34. Helen Kuo 2: Can you address NIOSH drugs in USP800?

35. Ranna Shamiya: A CAI in a segregated area can have 48h room temp/14 day refrigeration if the CAI meets criteria?

36. Kerry Rinato 2: Can you clarify for us when a waiver is required? What specific regulations must be met by the physical environment. Does this only apply to 797 or 800 as well?

37. Terry Lerma: Does a CACI that recirculates 70/30 prior to external exhaust meet the regulations?

38. Christine Low: thank you Lynn!

39. Gregory Prouty: During rescontruction period, we may need to rent a clean room trailer, can that waiver form be used to obtain a permit for trailer use or we need to apply for a seperate sterile compounding license for the trailer?

40. Ross Domke: never mind ...found the answer 41. Sheetal Shah: it said each person engaged in sterile compounding must complete competencies. what is the level of engagement required?

42. Thomas Jacobsen: Does the BOP support the use of mobile compounding facilities and will it license those for use?

43. denise.cummings@mchcares.com: Can nurses compound hazardous drugs on the unit, outside of the pharmacy?

44. Mark Minnie: Willl hazardous medication preparation have to cease pending waiver approval example being preparation of methotrexate for ectopic pregnancies 45. Shideh Ataii: Does BOP recommend any solid plan for moving infusion pharmcies to an interim area ? do we need to get licensure for the interim area?

46. Anup Patel: Is it required to have a dedicated HVAC?

47. Grace Magedman: Will recirculating BSCs no longer be allowed then, even though they vent to the outside? The hoods can contribute to the negative pressure differential and often times the CFM drawn from a BSC that vents 100% externally can cause problems with the pressure differential.

48. Shideh Ataii: the above was for during construction work in preparation of USP800 49. shahina shaikh: With the new prposed 797 - do we have to do humidity testing for a segregated compounding area and what will the BUD be with a CAI in a segregated area with the new proposed 797 50. Jane Hodding: Will pharmacies be held to the requirement for storing hazarduous substances in negative pressure rooms?

51. Shideh Ataii: we are due for IV recertification in November, do we need to have submitted our waiver before then?

52. Frank Cantelmi: We have a hazardus chem room and a iv prep room. Do we need a buffer room and a ante room? If so, what pressure differential do we need between the buffer and ante room?

53. Terry Lerma: Just an FYI we were recently surveyed regarding the definition of those engaged in sterile compounding and were informed that thks applies to all Pharmacy staff involved in checking or preparing CSP. In fact we just provided finger glove tip testing and media fills for 40+ Rx staff.. We could use some consistency with this survey point as we have a great number of staff involved and this requirement is 6-12 months 54. Shideh Ataii: To the BOP: what is the position of BOP when there is a conflict between 1735 and USP797 or USP800?

55. Gina Yam: question answered, thank you 56. Ross Domke: What specifically needs to be in place construction wise to be compliant with BOP by 1/1/17? I'm feeling a little confused :) 57. Chris Marking: The grid on Physical Plant Requirements - Hazardous states that a A2 and B2 cabinet are approved. Is this correct?

58. Fred Hom: Do we need to open chemo drugs from our wholesaler in a negative buffer room?

59. Shideh Ataii: for organizations without 24 hr pharmacy, is nursing allowed to compound and immediately use the med (within an hour)?

60. shahina shaikh: With the new prposed 797 - do we have to do humidity testing for a segregated compounding area and what will the BUD be with a CAI in a segregated area with the new proposed 797 61. Ramon Sanchez: With the increased use of TICE BCG,

labeled a biohazardous substance but on the NIOSH group 1 list, what are your recommendations with reconstitution practices of the product? In a negative pressure room? In a separate designated hood for only that product? Or a cleaned hood that can be returned to service for other products?

62. Kerry Rinato 2: Kerry Rinato 2: Can you clarify for us when a waiver is required? What specific regulations must be met by the physical environment. Does this only apply to 797 or 800 as well 63. Ramon Sanchez: what is the scientific/regulatory basis for the CA BOP regulation requiring separate external exhaust rather than co-mingled.

64. Dawn Rethmeier: what are the required training documentation for nursing when they perform compounding for immediate use
65. Joy Lai: Does prepackaged hazardous product need to be kept in hazardous compounding room?

66. Kethen So: What is the proper channel to submit questions about the compounding grid after the call? Kethen So, CSHP, UCSF Medical Center.

****Correction from Speaker Michael Ignacio (DCA)** During the Q&A, I spoke regarding recirculating or Class II Type A2 BSCs. I incorrectly stated the board would not permit the use of such BSCs. Provided the A2 BSCs are externally vented, the board will allow such BSCs. Sorry for the confusion.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

November 30, 2015

California State Board of Pharmacy
Attn: Lori Martinez
Lori.Martinez@dca.ca.gov
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

BY ELECTRONIC CORRESPONDENCE

RE: Reconciliation and Inventory Report of Controlled Substances, Notice of Proposed Regulations to Adopt Section 1715.65 of Article 2 of Division 17 of Title 16, California Code of Regulations

Dear Ms. Martinez:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments for consideration to the proposed regulations and adoption of Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR). The Board of Pharmacy (Board) has added these specific requirements for reconciliation and inventory reporting of controlled substances as part of their effort to combat drug loss and diversion from within pharmacies and prescription drug abuse within California.

The Board proposes to add specific requirements for periodic reconciliation and inventory at least every three months of all Schedule II controlled substances and at least one additional controlled substance as identified by the Board based on drug loss reports. According to the Board, by conducting a physical count inventory, pharmacists, pharmacies, and clinics will have more accountability and monitoring of controlled substances. The Board cites the availability of opioids is partly the cause of epidemic misuse of prescription medication. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. According to the Board, this will reduce the supply of controlled substances available for misuse and abuse without denying pain relief for those who need it.

CHA agrees with the underlying premise that comprehensive safeguards and highly reliable systems need to be in place to prevent controlled substance misuse, particularly with the high rate of opioid deaths across the nation and within the state. And while we agree with the need for comprehensive controls of opioid acquisition and distribution, we acknowledge the stringent hospital regulations and standards of practice presently in place, along with rigorous practices used by hospital pharmacists to secure all medications specifically to prevent misuse and

enhance appropriate use with patients. Presently, all hospital pharmacists undergo the "biennial inventory" of controlled substances required by federal law and agree that periodic inspection is necessary. In addition, each hospital, health system and clinic has a specific process in place for storage and security of controlled substances. The CHA Medication Safety Committee has developed the "Reducing Controlled Substances Diversion in Hospitals" tool to provide recommendations to hospitals on actions they could take to assess their resources and technology to develop an individualized diversion and prevention plan that protects organizations from substance diversion. The tool outlines recommendations utilizing present state and federal laws and regulations, as well as, stating best practice recommendations as goals for ongoing process improvement and high reliability performance. A section on storage and security of controlled substances identifies the numerous different ways controlled substances are securely stored within institutions, and therefore, how individualized plans for inventory and reconciliation must be utilized, especially as it pertains to narcotic storage outside of the main pharmacy, particularly in Administration Dispensing Cabinets (ADC's).

CHA and its members agree that physical inventory of the pharmacy vault every three months is reasonable, and most hospitals perform this activity monthly. The area of greatest concern with the proposed regulations revolve around the hospital's inventory of ADC's and the variable type and level of safety and security systems, necessitating a well-designed policy specific to that institution's resource capability. A periodic physical inventory every three months is not necessarily the best method to identify or limit diversion, depending on other technology and methods available to the organization. Systems in place and used by many organizations include biometric identification, blind counts, use of specific controlled substance software, etc. Hospitals need to provide the highest level of security within existing resources. Many of these alternative processes are far superior than a physical inventory, and the addition of labor intensive activity, as proposed in these regulations when other successful systems are in place, are wasteful and unnecessary.

CHA's specific comments are outlined in the attached grid. As mentioned in previous comments, our main concern is the fiscal impact incurred by hospitals across the state to comply with this regulation when there is no evidence to support its efficacy. One hospital system reports the need for additional $300,000 annually to provide ADC physical inventory. Extrapolated across 400 hospitals, this number would conservatively increase to over $3 million dollars for hospitals to deploy. While ADC physical inventory is one of several methods to identify and limit diversion, it is not the most effective method and should not be mandated.

In section 1715.65 (a), CHA agrees with the BOP that periodic reconciliation and inventory functions defined by hospital policy should prevail. We agree that periodic physical inventory of the pharmacy vault is appropriate, however, physical inventory of the ADC's should not be mandated due to the fiscal impact and availability of other equivalent, if not more successful methods such as biometric identification, blind counts, controlled substance software, etc.

In section 1715.65(b), CHA proposes to add designee status as all hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over

providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy.

In Section 1715.65(c) CHA specifically discusses our biggest concern with the proposed regulations on physical inventory count of ADC's. CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy vault is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do "blind counts" to verify they match the total in their software systems, if computerized software tracking software systems are in place.

If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue resource burden would occur. A California health care system with over 30 hospitals and 700 ADC's would need four hours of labor per machine to count all Schedule II controlled substances at an annual cost of $300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over $3 million annually. The physical inventory of ADC's should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion.

As discussed, this is an unnecessary financial burden, as other safeguards listed in the grid are examples of activities implemented in hospitals that utilize ADC's e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADC's by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation technology.

In section 1715.65(e) CHA offers the same perspective as per section 1715.65(c). CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC's or other mechanisms for narcotic administrative practice.

In section 1715.65(e)(3), CHA offers clarification language.

In section 1715.65(g), CHA would suggest that California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the Board within 30 days. ADC's located in hospitals or nursing homes would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggests changing the time frame to 30 days presently allowed for an actual irreconcilable loss of controlled drugs.

In section 1715.65(h), CHA agrees that additional measures should be implemented in response to unidentified controlled substance drug loss. However, we disagree that those measures should be specifically determined as presently proposed. Strike, “including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing”, and replace with “take additional steps to improve the security of the controlled substances to prevent losses”. Hospitals need to have flexibility in what resources are used to address narcotic loss.

In summary, hospitals and health systems are fully committed to combating drug loss and diversion from within hospital pharmacies. Each hospital has specific standardized policies and practices in place to mitigate diversion. We agree that robust systems need to be in place, however, we need to recognize the extreme resource variability, in particularly with ADC’s, and allow hospitals to develop plans and policies based on evidence and present resource capability. We are in full agreement that periodic, every three month physical inventory of the inpatient pharmacy vault is appropriate, and most hospitals are already performing this more often. Our main concerns, as discussed in depth, center around the physical inventory requirement for the ADC’s. This requirement is an unnecessary financial burden without appropriate evidence or rationale, particularly when other more stringent measures are present.

Once these regulations are finalized, the CHA Medication Safety Committee will update the medication safety tool, “Reducing Controlled Substances Diversion in Hospitals”, distribute, and continue to educate and foster improved narcotic administration practices that protect patients and lessens theft, diversion or other controlled substance untoward activities.

Respectfully Submitted:

BJ Bartleson, RN, MS, NEA-BS
Vice President, Nursing and Clinical Services

BJB:rf

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(a)	"Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances." This is added to ensure all Board licensees that dispense controlled substances are required to perform the inventory defined under this proposal.	"Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions, defined by policy, to prevent the loss of controlled substances."	California hospitals and health system pharmacies have stringent individualized standardized practices in place to prevent, detect, and mitigate controlled substance diversion. Because of the broad variability in types of facilities, and, medication administration resources, hospitals each define their individualized system in specific policies, as well as, perform periodic controlled substance inventory. All hospitals perform the required CMS biennial inventory of controlled substances and a monthly physical inventory of the respective pharmacy vault. While most hospitals have automated dispensing cabinets (ADC's), the types and utilization are variable, depending on available resources. Thus the most important aspect of this regulation should be the requirement for periodic reconciliation based on individualized hospital policy that defines the specific controlled substance procurement and administration process inventory and reconciliation process.
1715.65(b)	"The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section." This is added to ensure the licensee responsible for the pharmacy operations is reviewing the reconciliations and inventories. Additionally, the facility needs to develop policies and procedures to ensure that each reconciliation and inventory is completed following the same	"The pharmacist-in-charge or designee, or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled substances. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section."	All hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy,

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	methods to prevent inaccurate collection of data. Finally, the Board reviews policies and procedures while performing site inspections and will be able to confirm if the policies and procedures implemented by the pharmacy or clinic meet the regulatory requirements.		
1715.65(c)	"Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be **dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist."** This subdivision specifies the required time frame of at least every three months. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. While the Board is requiring the inventory to be completed quarterly, the term "at least" allows for the pharmacist-in-charge to use their professional judgment should they wish to perform the inventory more frequently. The additional requirement of at least one additional controlled substance based of drug loss reports allows the Board to utilize drug	"Perform a Periodic Inventory: An Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances *(within the inpatient pharmacy only if a licensed hospital) and at least one additional controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be **dated and signed (electronic signature acceptable) by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist."**	CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do "blind counts" to verify they match the total in their software systems, if computerized software tracking software systems are in place. If a physical inventory count was required of all dispensing cabinets throughout the hospital by the Inpatient Pharmacy, an undue burden of resources would be incurred. A California health care system with over 30 hospitals and 700 ADC's would need four hours of labor per machine to count all schedule II controlled substances at an annual cost of $300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over $3 million annually. The physical inventory of ADC's should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion. As discussed, this is an unnecessary financial burden, as other safeguards listed below are examples of activities implemented in hospitals that utilize ADC's e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADCs by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	loss reports and alert pharmacies and clinics of high theft controlled substances that may not be Schedule II. As regular inventory is being completed on Schedule II controlled substances, those wishing to divert controlled substances may change their focus to non-Schedule II in order to avoid detection, an example of this is Promethazine with Codeine cough syrup. Promethazine with Codeine has a high potential for abuse, but it is not Schedule II. By requiring an inventory of at least one non-schedule II, the Board will be able to reduce the theft and misuse of an additional controlled substance. Finally, as the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that those who performed the inventory sign and date the Inventory Report, and that it be countersigned by the pharmacist-in-change or consultant pharmacist to ensure they are aware and accountable for the inventory. By requiring the signing and countersigning of the Inventory Report, Board inspectors will know who completed the inventory during an inspection.		technology. Examples of automated dispensing cabinets (ADCs) inventory practices utilized in various facilities: • Use of biometric identification to access ADCs • Use of "blind counts" when removing controlled substances which eliminates the possibility of confirmation bias in the counting process and automatically records any discrepancies • Use of "blind counts" when restocking the ADCs • Required resolution of any controlled substance discrepancies on a daily basis by the nurses, and verification (oversight) by pharmacy that the process has been completed (including reviewing the rationale documented during the resolution process) • Physical inventory of controlled substances in the ADCs on a regular basis by the nurses utilizing "blind counts." • Daily monitoring ADC overrides to ensure there is a valid prescriber order for the medication that was removed • Regular review of oversight reports, e.g. ADC Users created; Cancelled transactions, to detect suspicious activity and prevent diversion • Use of specialized computer software (Pandora) to analyze patterns of controlled substances removal from ADCs and identify suspicious activity and/or users to prevent diversion • Perpetual inventory of all controlled substances in the pharmacy utilizing specialized computer software (C-II Safe). This software also tracks all controlled

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
			substances removed from the pharmacy and stocked in the ADCs and communicates with the ADCs to verify the controlled substances that left the pharmacy were subsequently stocked in the ADCs. • Review and approval of all Pharmacy orders for controlled substances from wholesalers/suppliers by a Pharmacy Manager • Verification by a Pharmacy Manager that all controlled substances received in the Pharmacy from a wholesaler/supplier are entered in to the specialized tracking software • Use of "blind counts" when adding and/or dispensing controlled substance from the Pharmacy inventory specialized computer tracking software As evidenced by the aforementioned numerous examples, each hospital, depending on size and resource availability must devise its individualized policy and plans for controlled substance reconciliation and inventory outside the inpatient pharmacy vault.
1715.65(c)(1)	"The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be **readily retrievable for three years**." This requirement is added so that the Inventory Report will be readily available for review by Board inspectors as defined in Business and Professions Code (B&P) section 4105(a). The three year time frame is defined in B&P section 4105(c) and is maintained in this proposal.	No Comment	
1715.65(c)(2)	"The biennial inventory of controlled substances required by federal law may	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:" This subdivision allows for the use of the federally required biennial inventory to be used as one of the proposals quarterly inventories. This specification will eliminate the need for repetitive inventories to meet state and federal Requirements.		
1715.65(c)(2)(A)	"A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container." This subdivision specifies that, in order to use the biennial inventory, it must have been a physical count inventory and not an estimate. The federally required biennial inventory does not specify a physical count as required in subdivision (c) of this proposal, so this specification is necessary to ensure a physical count Inventory is completed.	No Comment	
1715.65(c)(2)(B)	"The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section." This subdivision specifies that in order to utilize the federally required biennial inventory, it must be no older than 90 days from the last physical inventory completed. This subdivision ensures that an inventory is completed at least once every three months.	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(d)	"A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c)." This subdivision requires a new pharmacist-in-charge to complete an inventory. While this is currently recommended, it is not required. Requiring a new pharmacist-in-charge to complete an inventory within 30 days of becoming pharmacist-in-charge will familiarize the pharmacist with the pharmacies policies and procedures and will hold them accountable for the drug inventory and drug losses that may occur after they become pharmacist-in-charge. The Board selected the 30 day time frame to allow the new pharmacist-in-charge time to acclimate t o their new position and to allow time to address day to day operations. While not being mandated, the Board is also recommending that the outgoing pharmacist-in-charge should complete an inventory upon their departure. Completing an inventory upon departing will reduce or eliminate suspicion and possible disciplinary action against the departing Pharmacist-in-Charge should a drug loss be discovered by the new Pharmacist-in-Charge.	No Comment	
1715.65(e)	"Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand,	"Reconciliation with Inventory Report: The pharmacy or clinic shall review, based on policy, all acquisitions and dispositions of controlled substances as part of the inventory process (within	As per section 1715.65(c), CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC's or other mechanisms for

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form." This subdivision requires that the acquisition and disposition reports be reconciled with the inventory report. This reconciliation is necessary to ensure that controlled substances are not being ordered and diverted upon arrival without the knowledge of the pharmacist-in-charge. This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&P section 4105(a). The three year time frame is defined in B&P section 4105(c) and is maintained in this proposal.	other inpatient pharmacy only if a licensed hospital or clinic) as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form."	narcotic administrative practice. If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue burden of resources would be incurred. This is unnecessary as other individualized stringent safeguards are implemented, such as, blind counts; robust discrepancy resolution process, review of ADC overrides, periodic inventory of the ADCs by nurses, etc. (See more specific examples in section 1715.65(c).
1715.65(e)(1)	"Losses shall be identified in writing and reported to the Board and, when appropriate, to the Drug Enforcement Administration." This subdivision specifies what the licensee is required to do if a loss of controlled substances is discovered. If a drug loss is discovered, it is necessary for the Board to be informed from a regulatory stance to determine if there is an issue with security at the pharmacy or clinic.	No Comment	
1715.65(e)(2)	"Likely causes of overages shall be identified in writing and retained. This subdivision specifies what the licensee is required to do if an overage of controlled substances is discovered. The Board does not need to be informed of the overage; however, it is necessary to	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	educate and ensure that the pharmacy or clinic maintains better records of their controlled substances.		
1715.65(e)(3)	"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1." This subdivision specifies that a controlled substance is deemed to be a loss if it is unaccounted for after being in the inventory during the previous six-months. This subdivision will ensure that all controlled substances that are unaccounted for are deemed a loss and are reported as such. Reviewing the data for the prior six-month period will also catch counting and mathematical errors that may occur during the inventory process.	"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and, if the pharmacist-in-charge or consultant pharmacist d etermines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1."	Suggestions for language clarification
1715.65(f)	"Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages." This subdivision is added to balance the inventory. Once the overages and/or losses have been reported, adjustments are made to the inventory so there is a stock on hand starting point for the next inventory period. This will ensure that each inventory period is looking at three months of data at a time in an effort to quickly	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	determine when drug losses occur.		
1715.65(f)(1)	"Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date." This subdivision adds documentation requirements to the stock on hand adjustments. When reviewing the inventory reports, it is necessary to know who made the adjustment and when to hold staff accountable for the inventory.	No Comment	
1715.65(f)(2)	"The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report." As the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that they countersign the adjusted inventory report to ensure they are aware and accountable for the adjustments.	No Comment	
1715.65(f)(3)	"The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years." This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&P section 4105(a). The three year time frame is defined in B&P Section 4105(c) and is maintained in this proposal.	No Comment	
1715.65(g)		Language clarification and change of	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
		14 to 30 days per title 16, Division 17 section 1715.6, Reporting Drug Loss California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days. ADC's located in hospital or nursing home would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggest changing the time frame to 30 days as allowed for an actual irreconcilable loss of controlled drugs as presently in regulations.	
1715.65(h)		Strike," including installation of cameras, relocation of the controlled drugs to a more secure location within	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
		the pharmacy, or daily inventory counts of the drugs where shortages are continuing", and replace with "take additional steps to improve the security of the controlled substances to prevent losses". Hospitals need to have flexibility in what resources are used to address narcotic loss.	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(a)	"Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances." This is added to ensure all Board licensees that dispense controlled substances are required to perform the inventory defined under this proposal.	"Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions, defined by policy, to prevent the loss of controlled substances."	California hospitals and health system pharmacies have stringent individualized standardized practices in place to prevent, detect, and mitigate controlled substance diversion. Because of the broad variability in types of facilities, and, medication administration resources, hospitals each define their individualized system in specific policies, as well as, perform periodic controlled substance inventory. All hospitals perform the required CMS biennial inventory of controlled substances and a monthly physical inventory of the respective pharmacy vault. While most hospitals have automated dispensing cabinets (ADC's), the types and utilization are variable, depending on available resources. Thus the most important aspect of this regulation should be the requirement for periodic reconciliation based on individualized hospital policy that defines the specific controlled substance procurement and administration process inventory and reconciliation process.
1715.65(b)	"The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section." This is added to ensure the licensee responsible for the pharmacy operations is reviewing the reconciliations and inventories. Additionally, the facility needs to develop policies and procedures to ensure that each reconciliation and inventory is completed following the same	"The pharmacist-in-charge or designee, or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled substances. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section."	All hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy,

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	methods to prevent inaccurate collection of data. Finally, the Board reviews policies and procedures while performing site inspections and will be able to confirm if the policies and procedures implemented by the pharmacy or clinic meet the regulatory requirements.		
1715.65(c)	"Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be **dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist."** This subdivision specifies the required time frame of at least every three months. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. While the Board is requiring the inventory to be completed quarterly, the term "at least" allows for the pharmacist-in-charge to use their professional judgment should they wish to perform the inventory more frequently. The additional requirement of at least one additional controlled substance based of drug loss reports allows the Board to utilize drug	"Perform a Periodic Inventory: An Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances *(within the inpatient pharmacy only if a licensed hospital) and at least one additional controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be **dated and signed (electronic signature acceptable) by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist."**	CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do "blind counts" to verify they match the total in their software systems, if computerized software tracking software systems are in place. If a physical inventory count was required of all dispensing cabinets throughout the hospital by the Inpatient Pharmacy, an undue burden of resources would be incurred. A California health care system with over 30 hospitals and 700 ADC's would need four hours of labor per machine to count all schedule II controlled substances at an annual cost of $300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over $3 million annually. The physical inventory of ADC's should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion. As discussed, this is an unnecessary financial burden, as other safeguards listed below are examples of activities implemented in hospitals that utilize ADC's e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADCs by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	loss reports and alert pharmacies and clinics of high theft controlled substances that may not be Schedule II. As regular inventory is being completed on Schedule II controlled substances, those wishing to divert controlled substances may change their focus to non-Schedule II in order to avoid detection, an example of this is Promethazine with Codeine cough syrup. Promethazine with Codeine has a high potential for abuse, but it is not Schedule II. By requiring an inventory of at least one non-schedule II, the Board will be able to reduce the theft and misuse of an additional controlled substance. Finally, as the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that those who performed the inventory sign and date the Inventory Report, and that it be countersigned by the pharmacist-in-change or consultant pharmacist to ensure they are aware and accountable for the inventory. By requiring the signing and countersigning of the Inventory Report, Board inspectors will know who completed the inventory during an inspection.		technology. Examples of automated dispensing cabinets (ADCs) inventory practices utilized in various facilities: • Use of biometric identification to access ADCs • Use of "blind counts" when removing controlled substances which eliminates the possibility of confirmation bias in the counting process and automatically records any discrepancies • Use of "blind counts" when restocking the ADCs • Required resolution of any controlled substance discrepancies on a daily basis by the nurses, and verification (oversight) by pharmacy that the process has been completed (including reviewing the rationale documented during the resolution process) • Physical inventory of controlled substances in the ADCs on a regular basis by the nurses utilizing "blind counts." • Daily monitoring ADC overrides to ensure there is a valid prescriber order for the medication that was removed • Regular review of oversight reports, e.g. ADC Users created; Cancelled transactions, to detect suspicious activity and prevent diversion • Use of specialized computer software (Pandora) to analyze patterns of controlled substances removal from ADCs and identify suspicious activity and/or users to prevent diversion • Perpetual inventory of all controlled substances in the pharmacy utilizing specialized computer software (C-II Safe). This software also tracks all controlled

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
			substances removed from the pharmacy and stocked in the ADCs and communicates with the ADCs to verify the controlled substances that left the pharmacy were subsequently stocked in the ADCs. • Review and approval of all Pharmacy orders for controlled substances from wholesalers/suppliers by a Pharmacy Manager • Verification by a Pharmacy Manager that all controlled substances received in the Pharmacy from a wholesaler/supplier are entered in to the specialized tracking software • Use of "blind counts" when adding and/or dispensing controlled substance from the Pharmacy inventory specialized computer tracking software As evidenced by the aforementioned numerous examples, each hospital, depending on size and resource availability must devise its individualized policy and plans for controlled substance reconciliation and inventory outside the inpatient pharmacy vault.
1715.65(c)(1)	"The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be **readily retrievable for three years**." This requirement is added so that the Inventory Report will be readily available for review by Board inspectors as defined in Business and Professions Code (B&P) section 4105(a). The three year time frame is defined in B&P section 4105(c) and is maintained in this proposal.	No Comment	
1715.65(c)(2)	"The biennial inventory of controlled substances required by federal law may	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:" This subdivision allows for the use of the federally required biennial inventory to be used as one of the proposals quarterly inventories. This specification will eliminate the need for repetitive inventories to meet state and federal Requirements.		
1715.65(c)(2)(A)	"A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container." This subdivision specifies that, in order to use the biennial inventory, it must have been a physical count inventory and not an estimate. The federally required biennial inventory does not specify a physical count as required in subdivision (c) of this proposal, so this specification is necessary to ensure a physical count Inventory is completed.	No Comment	
1715.65(c)(2)(B)	"The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section." This subdivision specifies that in order to utilize the federally required biennial inventory, it must be no older than 90 days from the last physical inventory completed. This subdivision ensures that an inventory is completed at least once every three months.	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(d)	"A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c)." This subdivision requires a new pharmacist-in-charge to complete an inventory. While this is currently recommended, it is not required. Requiring a new pharmacist-in-charge to complete an inventory within 30 days of becoming pharmacist-in-charge will familiarize the pharmacist with the pharmacies policies and procedures and will hold them accountable for the drug inventory and drug losses that may occur after they become pharmacist-in-charge. The Board selected the 30 day time frame to allow the new pharmacist-in-charge time to acclimate t o their new position and to allow time to address day to day operations. While not being mandated, the Board is also recommending that the outgoing pharmacist-in-charge should complete an inventory upon their departure. Completing an inventory upon departing will reduce or eliminate suspicion and possible disciplinary action against the departing Pharmacist-in-Charge should a drug loss be discovered by the new Pharmacist-in-Charge.	No Comment	
1715.65(e)	"Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand,	"Reconciliation with Inventory Report: The pharmacy or clinic shall review, based on policy, all acquisitions and dispositions of controlled substances as part of the inventory process (within	As per section 1715.65(c), CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC's or other mechanisms for

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form." This subdivision requires that the acquisition and disposition reports be reconciled with the inventory report. This reconciliation is necessary to ensure that controlled substances are not being ordered and diverted upon arrival without the knowledge of the pharmacist-in-charge. This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&P section 4105(a). The three year time frame is defined in B&P section 4105(c) and is maintained in this proposal.	other inpatient pharmacy only if a licensed hospital or clinic) as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form."	narcotic administrative practice. If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue burden of resources would be incurred. This is unnecessary as other individualized stringent safeguards are implemented, such as, blind counts; robust discrepancy resolution process, review of ADC overrides, periodic inventory of the ADCs by nurses, etc. (See more specific examples in section 1715.65(c).
1715.65(e)(1)	"Losses shall be identified in writing and reported to the Board and, when appropriate, to the Drug Enforcement Administration." This subdivision specifies what the licensee is required to do if a loss of controlled substances is discovered. If a drug loss is discovered, it is necessary for the Board to be informed from a regulatory stance to determine if there is an issue with security at the pharmacy or clinic.	No Comment	
1715.65(e)(2)	"Likely causes of overages shall be identified in writing and retained. This subdivision specifies what the licensee is required to do if an overage of controlled substances is discovered. The Board does not need to be informed of the overage; however, it is necessary to	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	educate and ensure that the pharmacy or clinic maintains better records of their controlled substances.		
1715.65(e)(3)	"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1." This subdivision specifies that a controlled substance is deemed to be a loss if it is unaccounted for after being in the inventory during the previous six-months. This subdivision will ensure that all controlled substances that are unaccounted for are deemed a loss and are reported as such. Reviewing the data for the prior six-month period will also catch counting and mathematical errors that may occur during the inventory process.	"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and, if the pharmacist-in-charge or consultant pharmacist d etermines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1."	Suggestions for language clarification
1715.65(f)	"Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages." This subdivision is added to balance the inventory. Once the overages and/or losses have been reported, adjustments are made to the inventory so there is a stock on hand starting point for the next inventory period. This will ensure that each inventory period is looking at three months of data at a time in an effort to quickly	No Comment	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	determine when drug losses occur.		
1715.65(f)(1)	"Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date." This subdivision adds documentation requirements to the stock on hand adjustments. When reviewing the inventory reports, it is necessary to know who made the adjustment and when to hold staff accountable for the inventory.	No Comment	
1715.65(f)(2)	"The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report." As the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that they countersign the adjusted inventory report to ensure they are aware and accountable for the adjustments.	No Comment	
1715.65(f)(3)	"The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years." This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&P section 4105(a). The three year time frame is defined in B&P Section 4105(c) and is maintained in this proposal.	No Comment	
1715.65(g)		Language clarification and change of	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
		14 to 30 days per title 16, Division 17 section 1715.6, Reporting Drug Loss California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days. ADC's located in hospital or nursing home would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggest changing the time frame to 30 days as allowed for an actual irreconcilable loss of controlled drugs as presently in regulations.	
1715.65(h)		Strike," including installation of cameras, relocation of the controlled drugs to a more secure location within	

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
		the pharmacy, or daily inventory counts of the drugs where shortages are continuing", and replace with "take additional steps to improve the security of the controlled substances to prevent losses". Hospitals need to have flexibility in what resources are used to address narcotic loss.	

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XXI. Proposed Regulations to Add Title 16 California Code of Regulations (CCR) sections 1715.65, Related to Reconciliation and Inventory Report of Controlled Substances

At the July 2015 Board Meeting, the board approved proposed text to add Section 1715.65 of Title 16 CCR, related to Reconciliation and Inventory Report of Controlled Substances. The 45 day comment period began on October 16, 2015 and ended November 30, 2015. Additionally, a regulation hearing was held on February 2, 2016.

The Board received several comments during the comment period and at the regulation hearing.

At this Meeting

The board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the July 2015 Board meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

The Attachment immediately following this memo contains the proposed regulation text as noticed on October 16, 2015 and a compilation document of the comments received during the 45 day comment period and at the regulation hearing.

Reconciliation and Inventory of Controlled Substances - 1715.65

Reconciliation and Inventory of Controlled Substances - 45-Day/Hearing Comments

Comment Period Closed November 30, 2015

Code Section	Commenter	Comment
1715.65(a)	**BJ Bartleson** **CHA** **and** **Dignity Health**	"Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions, defined by policy, to prevent the loss of controlled substances." California hospitals and health system pharmacies have stringent individualized standardized practices in place to prevent, detect, and mitigate controlled substance diversion. Because of the broad variability in types of facilities, and, medication administration resources, hospitals each define their individualized system in specific policies, as well as, perform periodic controlled substance inventory. All hospitals perform the required CMS biennial inventory of controlled substances and a monthly physical inventory of the respective pharmacy vault. While most hospitals have automated dispensing cabinets (ADC's), the types and utilization are variable, depending on available resources. Thus the most important aspect of this regulation should be the requirement for periodic reconciliation based on individualized hospital policy that defines the specific controlled substance procurement and administration process inventory and reconciliation process.
1715.65(a)	**Kaiser**	Section 1715.65 (a} says "Every pharmacy...". This terminology is unclear as it does not differentiate between Community/Retail, Central Fill, Mail Order and other pharmacies licensed as "PHY" pharmacies and Hospital pharmacies that are licensed as "HSP" pharmacies. It does not reflect the discussion at the Board of Pharmacy meetings that the risk and history of diversion of large of amounts of controlled substances was substantially greater by many fold from Community ("PHY") pharmacies than it has been or is likely to be from Hospital ("HSP") licensed pharmacies. This section should be modified to indicate that the regulation only applies to "PHY" licensed pharmacies or to "PHY" pharmacies and controlled substances stored centrally in "HSP" pharmacies. In hospitals only small amounts of controlled substances are stored in each patient care areas away from the pharmacy, e.g. in nursing station,surgery related suites, "crash carts", etc. Storage in patient care areas are inside very secure equipment with sophisticated access and record keeping controls,e.g. "Pyxis" and similar dispensing equipment. Cost Impact: Without a regulatory language change reflecting the differentiation specified above regarding periodic physical inventory requirements in patient care areas vs. within the hospital's pharmacy the Board's predicted cost impact of the regulation on hospitals, including State,County and municipal hospitals,substantially under stated.
1715.65(a)	**Michael Tou** **Providence Health**	"Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions to prevent the loss of controlled substances."

Code Section	Commenter	Comment
1715.65(b)	**BJ Bartleson CHA** **and** **Dignity Health**	"The pharmacist-in-charge or designee, or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled substances. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section." All hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy.
1715.65(b)	**Michael Tou Providence Health**	"The pharmacist-in-charge or designee of a pharmacy or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section." Providence believes this section may also apply to unresolved orders for overrides of controlled substances. Pharmacists-in-charge are caught between end-users, such as nurses and physicians, of whom PICs do not have supervision over.
1715.65(b), (c), (e)	**Lauren Berton CVS** **Also provided at Hearing**	CVS Health maintains a perpetual inventory for all Schedule II controlled substances and also completes a physical count of these medications once a month. By maintaining the perpetual inventory, we are able to identify potential losses and investigate discrepancies on a regular basis. We strongly urge the board to consider adding language for pharmacies that maintain a perpetual inventory of Schedule II controlled substances to be deemed compliant with 1715.65(b), (c), and (e). Full reconciliations, as required by 1715.6(e) will take a substantial amount of time and focus for the pharmacist to complete by reviewing all acquisition invoices and dispensing records to determine the expected stock and then comparing to the balance on hand. Also, Pharmacists may not be able to perform cognitive services such as MTM or furnishing of hormonal contraceptives as well as experiencing difficulty to perform mandatory counseling as they will be focused on completing these reconciliations if maintaining a perpetual inventory is not deemed compliant.

Code Section	Commenter	Comment
1715.65(c)	**BJ Bartleson CHA** **and** **Dignity Health**	"Perform a Periodic Inventory: An Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances *(within the inpatient pharmacy only if a licensed hospital) and at least one additional controlled substance which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be dated and signed (electronic signature acceptable) by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist." CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do "blind counts" to verify they match the total in their software systems, if computerized software tracking software systems are in place. If a physical inventory count was required of all dispensing cabinets throughout the hospital by the Inpatient Pharmacy, an undue burden of resources would be incurred. A California health care system with over 30 hospitals and 700 ADC's would need four hours of labor per machine to count all schedule II controlled substances at an annual cost of $300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over $3 million annually. The physical inventory of ADC's should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion. As discussed, this is an unnecessary financial burden, as other safeguards listed below are examples of activities implemented in hospitals that utilize ADC's e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADCs by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation technology.

Code Section	Commenter	Comment
1715.65(c)	**BJ Bartleson CHA** **and** **Dignity Health** **(Also provided at Hearing)**	Examples of automated dispensing cabinets (ADCs) inventory practices utilized in various facilities: • Use of biometric identification to access ADCs • Use of "blind counts" when removing controlled substances which eliminates the possibility of confirmation bias in the counting process and automatically records any discrepancies • Use of "blind counts" when restocking the ADCs • Required resolution of any controlled substance discrepancies on a daily basis by the nurses, and verification (oversight) by pharmacy that the process has been completed (including reviewing the rationale documented during the resolution process) • Physical inventory of controlled substances in the ADCs on a regular basis by the nurses utilizing "blind counts." • Daily monitoring ADC overrides to ensure there is a valid prescriber order for the medication that was removed • Regular review of oversight reports, e.g. ADC Users created; Cancelled transactions, to detect suspicious activity and prevent diversion • Use of specialized computer software (Pandora) to analyze patterns of controlled substances removal from ADCs and identify suspicious activity and/or users to prevent diversion • Perpetual inventory of all controlled substances in the pharmacy utilizing specialized computer software (C-II Safe). This software also tracks all controlled substances removed from the pharmacy and stocked in the ADCs and communicates with the ADCs to verify the controlled substances that left the pharmacy were subsequently stocked in the ADCs. • Review and approval of all Pharmacy orders for controlled substances from wholesalers/suppliers by a Pharmacy Manager • Verification by a Pharmacy Manager that all controlled substances received in the Pharmacy from a wholesaler/supplier are entered in to the specialized tracking software • Use of "blind counts" when adding and/or dispensing controlled substance from the Pharmacy inventory specialized computer tracking software As evidenced by the aforementioned numerous examples, each hospital, depending on size and resource availability must devise its individualized policy and plans for controlled substance reconciliation and inventory outside the inpatient pharmacy vault.
1715.65(c)	**Grace Magedman**	In subsection (c), it states that a physical count must be done of all Schedule II controlled substances (CS) during this quarterly inventory. In our organization, the charge nurse and another nurse witness do a weekly physical count of the CS in their automated dispensing cabinets (Pyxis). This is a blind count, so it would force a physical count of the CS. Would this suffice as part of the required quarterly physical count for the Schedule IIs stored outside of the pharmacy department when compiling information? It would also be electronically "signed" and timed/dated, as access details are typically captured when this activity occurs and could then be countersigned by the PIC after review.

Code Section	Commenter	Comment
1715.65(c)	**John Gallegos**	As the pharmacy consultant, other than verification that the DEA schedule II count is done twice daily and that there is no shrinkage involved, am I responsible for more than documenting due diligence on the part of the surgery clinic staff as a result of my quarterly audits? I generate a multi-page report every quarter that covers my responsibilities listed under surgical clinic consultant pharmacist. My question was do I have any additional responsibilities under the proposed regulation as it applies to the quarterly controlled substances audit
1715.65(c)	**John Grubbs** **UC Davis**	As worded, Subdivision (c) would require my staff to complete an inventory of all Schedule II controlled substances plus one other Schedule III-V controlled substance every three months and for me as the Pharmacist-in-Charge to sign these inventories. At my hospital we have more than two thousand (2,000) locations where Schedule 11 controlled substances are stored, including all of the automated dispensing machines. Using a conservative estimate of two minutes per location, this inventory would take at least 1 33 hours to complete.
1715.65(c)	**Kaiser**	Section 1715.65 (c) again does not differentiate between hospital pharmacies,which have much stronger controlled substance inventory control procedures than other categories of pharmacies. Thus,this section's proposed requirement for physical inventories of Schedule II and other controlled substances specified by the Board, is unclear as it does not differentiate between controlled substances maintained in the pharmacy vs.controlled substances distributed throughout the patient care areas of a hospital,as specified above. The proposed regulation would place a disproportionate burden on hospitals in relation to the history and future risk of major controlled substance diversion from hospitals vs non-hospital licensed facilities. Hospital pharmacies are also governed by the California Department of Public Health {CDPH} and inspected by CDPH for compliance with CDPH regulations and all other California and federal law, including proper accounting for and security of,controlled substances. CDPH also inspects hospitals for compliance with federal CMS Conditions of Participation. Hospitals are also accredited by several deemed status organizations, such as The Joint Commission, on behalf of government and other payers for compliance,quality and safety. Because of these standards and the standards of practice for hospitals, much more strict procedures are employed by hospitals to secure controlled substances and usually include not only daily perpetual physical inventory counts of controlled substances in patient care areas, but the majority hospitals perform such counts several times per day upon nursing shift changes.

Code Section	Commenter	Comment
1715.65(c)	**Kaiser**	Section 1715.65(c) also does not reflect the difference in preponderance of use of different non- Schedule II controlled substances between Hospital (HSP) and Community (PHY) licensed pharmacies. Hospitals administer very few controlled substances intended for symptomatic relief, such as benzodiazepines and codeine containing cough preparations than do Community pharmacies. Therefore,the substantially diminished diversion risk for such "outpatient" controlled substances should be recognized in the regulation by language that indicates that the additional non-Schedule II inventory control requirements may not apply to Hospitals, as determined by the Board.
1715.65(c)	**Kaweah Delta**	Please consider the following revisions: Remove requirement that Inventory Reports be signed and dated by the individual performing the inventory and the PIC or consultant pharmacist. Instead allow for a report showing electronic access and remove requirement for countersignature of PIC or consultant pharmacist. At Kaweah Delta Health Care District, an inventory of all controlled substances is performed at each automated drug delivery machine weekly by two registered nurses using an inventory function. Each RN accesses the ADM using their sign on and password. The ADM records the access and this acts as an electronic signature. Change time frame requirement from every 3 months to quarterly.
1715.65(c)	**Lauren Berton CVS** **Also provided at Hearing**	We also request that the board limit the additional controlled substance identified in 1715.65(c) to be inventoried to one additional controlled substance. The current language leaves this open to the board adding on an infinite number of controlled substances to be inventoried, which can become very onerous for the pharmacies to complete. Current discussion includes Alprazolam and Promethazine with Codeine as the additional controlled substances. Alprazolam has multiple strengths and a pharmacy could possibly stock more than one manufacture, so this already requires at least 5 additional medications to be included in the count. Suggested Language: (c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of Schedule Ii controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year.

Code Section	Commenter	Comment
1715.65(c)	**Mary Staples** **NACDS**	In Section 1715.65, the Board seeks to require pharmacies to provide quarterly inventories of Schedule II drugs and “at least one additional controlled substance which may be specified by the board every year based upon loss reports.” While we have no objection to the Schedule II drug inventories, we have concerns regarding the scope of the latter provision. More specifically, our members will have difficulty meeting the inventory requirements for non-Schedule II drugs if the state does not provide enough notice of the specific “additional controlled substances” to be inventoried or does not effectively communicate which non-Schedule II drug or drugs will require quarterly inventories. In addition to this lack of specificity in the Proposed Rule, we are concerned that this provision could be used to overburden pharmacies and their inventory capabilities. While we understand the need to curb diversion and abuse of controlled substances, we believe that overly burdensome and time consuming quarterly inventories of non-Scheduled II controlled substances hinders the ability for pharmacists to focus on other needed patient care activities. We believe and have full confidence in other mechanisms that are currently in place to monitor and inventory these substances, which ultimately allows pharmacists to devote adequate time to patient care activities such as counseling patients, performing medication therapy management, providing disease management programs, engaging in other important pharmaceutical patient care services and conferring with other health care professionals, thus permitting a higher level of service to patients that ultimately improve patient outcomes. In light of the lack of specificity discussed above and the potential for a wide scope of non-Schedule II drugs subject to inventory, we ask the Board to adopt one of the following proposals. First, and our strongest preference, is for the Board to remove the provision for “at least one additional [non-Schedule II] controlled substance” to be inventoried. Second, as an alternative, in order to prevent undue inventory burdens on pharmacies, we ask the Board to limit how many non-Schedule II controlled substances can be identified each year. As a third alternative approach, we request that, with regard to non-Schedule II drugs, only pharmacies that have reported a theft or loss of the Board identified drug be required to do the quarterly audit and to do so for only one year following the reported loss. In conclusion, at a minimum, we are asking for more parameters regarding inventories of non-Schedule II drugs and we would prefer that such drugs not be subject to quarterly inventories.
1715.65(c)	**Rita Shane** **Cedars-Sinai**	Recommendation: Revise proposed regulations to: "Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist. Alternatively, a pharmacy or clinic may utilize automated drug delivery systems in lieu of performing a periodic inventory." As defined under 4186 (h), automated drug delivery systems (ADDs) collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. Since ADDs provide perpetual inventory of controlled substances, pharmacies should be allowed to utilize these systems to fulfill the requirements of the proposed regulation.

Code Section	Commenter	Comment
1715.65(c)(1)	**Grace Magedman**	In regards to subdivision (c)(1) and (e), will electronic copies of the signed CS inventory report as well as other records used in reconciliation be acceptable? It would be much more readily retrievable and it would cut down on the costs of increasing document storage requirements and retrieval.
1715.65(c)(1)	**Kaiser**	Section 1715.65 (c) (1) regarding record retention for "three years" "in the...pharmacy" without mention of the current ability for pharmacies to store records outside the pharmacy on the premises, and, with the Board's permission, offsite for the balance ofthe three years is vague and confusing. Historical storage of such records as allowed outside a hospital or community pharmacy space has not been discussed by the Board as being a significant problem or risk that would justify the additional space allocation and expense for storage inside the pharmacy.
1715.65(c)(1)	**Michael Tou Providence Health**	Providence requests clarification from the Board as to whether records can be stored off-site for licensed facilities that inventory more frequently than every 90 days.
1715.65(c)(2)(A)	**Lauren Berton CVS** **Also provided at Hearing**	Current proposed language in 1715.65(c)(2)(A) indicates that the biennial inventory of controlled substances required by federal law may serve as one of the periodic inventories, provided that a physical count of all controlled substances is performed. This is more stringent than DEA regulation 21 CFR 1304.11(e)(6)(i) and (ii) which allows for a registrant to estimate Schedule III to V, unless the container holds more than 1,000 tablets or capsules. We request that the board clarify this section that requires only an exact physical count for the additional controlled substance identified by the board as opposed to all controlled substances. Suggested Language: (A) A physical count of controlled substances in Schedule II and the additional controlled substance identified by the board to be inventoried periodically is performed, with an estimated count of all other Schedule III to V controlled substances as allowed by 21 CFR 1304.11.
1715.65(d)	**Kaiser**	Section 1715.65 (d) is vague as it does not reflect whether the requirement for a "new pharmacist-in-charge" to complete and inventory applies to an "interim pharmacist-in-charge", as specified in B&P Code section 4113(e). Further, for hospitals, is the required physical count limited to only what is stored inside the hospital pharmacy. Again, if the physical inventory is required for every patient care area storage unit,the burden is understated.

Code Section	Commenter	Comment
1715.65(e)	**BJ Bartleson CHA** **and** **Dignity Health**	"Reconciliation with Inventory Report: The pharmacy or clinic shall review, based on policy, all acquisitions and dispositions of controlled substances as part of the inventory process (within other inpatient pharmacy only if a licensed hospital or clinic) as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form." As per section 1715.65(c), CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC's or other mechanisms for narcotic administrative practice. If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue burden of resources would be incurred. This is unnecessary as other individualized stringent safeguards are implemented, such as, blind counts; robust discrepancy resolution process, review of ADC overrides, periodic inventory of the ADCs by nurses, etc. (See more specific examples in section 1715.65(c).
1715.65(e)	**John Grubbs UC Davis**	Subdivision (e) requires reconciliation between the on-hand inventory and all acquisitions and dispositions of controlled substances. At my hospital, we dispense approximately 50,000 CII doses per month. In addition, we perform approximately 5,000 refills. It would be difficult to estimate the time required to reconcile the acquisitions and dispenses against the inventory, but it's likely to be at least a full time job.
1715.65(e)	**Kaiser**	Section 1715.65 (e) is vague or incomplete because it does not reflect the discussion by staff and Board members of the problem found that reconciliation processes were not well understood by pharmacists. Further it does not reflect the Board's discussion that reconciliation should and be performed against Accounts Payable records rather than just relying on packing lists or invoices to determine what the actual total amounts of a controlled substances acquired by the pharmacy during the starting and ending physical count period. The Board's discussion indicated the entity (pharmacy or hospital) would be held responsible for what was "paid for" (or otherwise acquired) not just what was listed on packing lists or invoices that reached the pharmacist-in-charge.
1715.65(e)	**Michael Tou Providence Health**	Providence requests clarification from the Board on the following issues: Does this requirement take into account stock fluctuations based on demand, as well as facilities that ramp up purchases due to anticipated shortages? Does the language need to specify that this inventory report is meant to determine expected stock on hand? If the stock on hand has doubled for a legitimate reason, does it conflict with the proposed requirement?

Code Section	Commenter	Comment
1715.65(e)	**Rita Shane** **Cedars-Sinai**	Recommendation Revise proposed regulations to add: "Alternatively, organizations may use Automated Drug Delivery systems (ADDs) to perform ongoing perpetual inventory of all controlled medications that includes reconciliation of acquisitions and dispositions. Comments: As defined under 4186 (h),automated drug delivery (ADDs) systems collect,control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security,accuracy, and accountability. Organizations which utilize these systems perform reconciliation on an ongoing basis which meets the intent of this section and therefore should be included in the regulations as recommended above.
1715.65(e)(2)	**Michael Tou** **Providence Health**	Providence requests clarification from the Board on the following issues: Should overages be documented in the inventory report? Does this require dual- signature by the pharmacist- in-charge and another licensed pharmacist/technician?
1715.65(e)(3)	**BJ Bartleson** **CHA** **and** **Dignity Health**	"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and, if the pharmacist-in-charge or consultant pharmacist determines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1." Suggestions for language clarification
1715.65(e)(3)	**Kaweah Delta**	Please consider the following revision: Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and there is no matching disposition, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances.
1715.65(e)(3)	**Michael Tou** **Providence Health**	"Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and, if the pharmacist-in-charge or consultant pharmacist determines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1."

Code Section	Commenter	Comment
1715.65(g)	**BJ Bartleson** **CHA** **and** **Dignity Health**	Language clarification and change of 14 to 30 days per title 16, Division 17 section 1715.6, Reporting Drug Loss California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days. ADC's located in hospital or nursing home would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggest changing the time frame to 30 days as allowed for an actual irreconcilable loss of controlled drugs as presently in regulations.
1715.65(g)	**Candace Fong (Hearing)**	Allow the pharmacist-in-charge to delegate the reconciliation and inventory.
1715.65(g)	**Dale Costantino**	I would like to comment on the proposed changes to 1715.65. My comments are specific to paragraph "g' below. Hundreds and sometimes thousands of doses of controlled substances are removed from automated drug delivery systems daily at many California hospitals for patients administration. This obligation to review each record would be overwhelming if not impossible. One person, a PIC in this case, may be able to review approximately 50 records a day. (g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. I believe that oversight and audits are needed. However, please consider revising this proposed text.

Code Section	Commenter	Comment
1715.65(g)	**John Grubbs UC Davis**	Subd ivision (g) requires monthly reviews of all removals and additions of controlled substances to automated drug delivery systems and investigation and reporting of unusual accesses or discrepancies. Does this review supersede the inventory and reconciliation requirements of Subdivisions (c) and (e)? Also, what would constitute acceptable proof of this review? I suggest that the Board allow hospitals utilizing automated drug delivery systems to implement alternative processes to identify and prevent controlled substance diversion. Some examples of such processes would include monthly analysis of staff who are removing more controlled substances than their peers, daily investigation of all discrepancies in the inventories of controlled substances, and review of all removals of controlled substances that were made on "override" (ie emergent situation when physician 's order has not been verified by pharmacist) to ensure the remova l is appropriate. All inappropriate accesses or removals identified by these processes would be reported to the Board. Additionally, some hospitals have formed multi-disciplinary commi ttees charged with reviewing all audits of controlled substance use, for overseeing investigations into potentially inappropriate use, for ensuring appropriate reporting when theft or diversion has occurred and for implementing changes to prevent future occurrences. This would be another alternative process that hospitals could use instead of the requirements of Subdivisions (c) and (e). I feel that the alternative processes that I 've described above would be much more effective at preventing controlled substance diversion than the requirements of Subdivision (c) and (e). Hospitals that implement such alternative processes should not be subject to these new requ irements. The language in Subdivision (g) should be modified to allow for such alternative processes and should specify that hospitals that have these processes in place are exempt from the requirements of Subdivisions (c) and (e)
1715.65(g)	**Kaiser**	Section 1715.65 (g) is vague as it applies to hospital pharmacies in that it uses a term "review" for the duties of the pharmacist-in-charge regarding records of controlled substances "removed from or added into each automated drug delivery machine". It is unclear:1)because it is not clear whether this monthly task could serve as substitute for the tri-monthly physical inventory and reconciliation of such controlled substance in such secure storage devices as is implied by Sections 1715.65 (a)&(c) above,2) because it is not clear whether the reporting of "inappropriately accessed or removed" means would only be required if the removal resulted in a "loss" or diversion from the hospital,and 3) how this reporting responsibility corresponds to reporting a loss within 30 days in Regulation 1715.6. Allow the pharmacist to delegate to another staff person the inventory requirement.

Code Section	Commenter	Comment
1715.65(g)	**Kaweah Delta**	The text as proposed seems to imply that the pharmacist-in-charge would be required to review all transactions, including removal for a specific patient need, from every automated drug delivery machine. A more effective method to identify diversion would be the use of software to identify anomalous activity. Please consider softening the language to allow for the use of software to identify anomalous activity and change the requirement to state that the pharmacist-in-charge shall review any activity determined to be anomalous. Please consider clarifying if there is required documentation for the review that was performed. Additionally, please consider the following revision: Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the Board within 14 days of discovery. If the pharmacist-in charge is reviewing controlled substances removed from or added to each automated drug delivery machine monthly, it is possible that inappropriately accessed or removed medication would not be discovered within 14 days of access or removal. This would place the pharmacy immediately out of compliance.
1715.65(g)	**Lauren Berton CVS (Hearing)**	Allow some delegation of the inventory review and investigation of automated delivery systems. Is quarterly review mandatory of the machines.
1715.65(g)	**Michael Tou Providence Health**	"The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine system operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery drug system shall be reported to the Board within 14 30 days." California regulations currently require pharmacies to report losses associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days. Automated Dispensing Systems (ADS), which are located in a hospital or nursing home, would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. Nursing and medical personnel access the machines to remove doses of controlled substances on a more frequent basis than the pharmacy personnel, who access the inventory to restock or replenish the supply. Additionally as the actions of these non-pharmacy personnel are not under the direct supervision of the pharmacy or pharmacist-in-charge, it may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. Many occurrences may be resolved satisfactorily upon investigation. It may be discovered that the access or removal was not actually "inappropriate" after all.

Code Section	Commenter	Comment
1715.65(g)	**Michael Tou** **Providence Health**	The timeframe required by the Board should allow sufficient time for investigation first, and then, unresolved inappropriate access or removals should be reported. Pharmacies are being prompted to report every discrepancy to the Board prior to performing a diligent investigation in order to make that 14-day time period. This could create over-reporting and difficulty identifying actual events versus miscounts and typographical errors. The timeframe of 14 days for an inappropriate access or removal does not seem proportionate to the 30-day timeframe allowed for an actual irreconcilable loss of controlled drugs, as stated in Section 1715.65(h). Providence urges the Board to provide further clarification as to the definition of “inappropriately access or removed” in the proposed rule. Errors on the patient’s medication record may not be the result of an actual loss or diversion. Providence requests clarification from the Board as to how it plans to take action against non-pharmacy personnel associated with a reported loss or discrepancy. Has the Board engaged with the Medical Board of California and Board of Registered Nursing on the proposed rule to ensure effective compliance with the requirements across disciplines?
1715.65(g)	**Rita Shane** **Cedars-Sinai**	Recommendations: Revise proposed regulations as follows: "The pharmacist-incharge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where automated drug delivery systems (ADDs) are used shall ensure that: a) All controlled substances added to an automated drug delivery system are accounted for; b) Access to automated drug delivery systems is limited to authorized facility personnel; c) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and d) Confirmed losses of controlled substances are reported to the board." Comments: 1. The intent of the proposed regulations is to identify losses of controlled substances. Performing a monthly review of all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy will not meet this goal. Having policies in place to ensure effective use of ADDs and leveraging the capabilities of these systems to identify discrepancies/unusual access and investigating them in real time allow pharmacies to identify and follow up on discrepancies or unusual access. Of note, larger institutions such as Cedars Sinai Medical Center add and remove approximately 80,000 controlled substance doses each month. 2. Inappropriate access or removal of controlled substances does not always result in loss of controlled substances. A thorough investigation needs to be performed to confirm loss of controlled medications before reports are submitted to the board. This will minimize the number offalse positive reports submitted to the board and provide a more accurate estimate of the number of controlled substances lost due to employee pilferage.

Code Section	Commenter	Comment
1715.65(g)	**William Mcguire**	I am writing to ask for clarification on Ca. code of Regulations in section 1715.65(g) and also some comments. According to the proposed regulation, it states either the PIC or pharmacy consultant shall review at least once a month all controlled substances removed or added to the ADC. Questions; a. Can this function be delegated to another pharmacist or than the PIC or consultant pharmacist-like an assistant Mgr or lead pharmacist? Seems very onerous. b. Is this rule only for institutions with ADC's? It clearly states for those sites with ADC's so does that mean it is not mandatory for non-automated sites? If not mandated for non-automated sites-why? There are more chances of diversion without automation.
1715.65(h)	**BJ Bartleson CHA** **and** **Dignity Health**	Strike," including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing", and replace with "take additional steps to improve the security of the controlled substances to prevent losses". Hospitals need to have flexibility in what resources are used to address narcotic loss.
1715.65(h)	**Kaiser**	Section is vague as it does not indicate which action or actions have priority. The installation of cameras is mentioned first and seems to indicate that should be tried first before the "relocation of the controlled substance to a more secure location" or the implementation of "daily inventory counts". It is likely that the delay for the camera installation and the capture of good identification may result in further significant or substantial losses/diversions. Conversely, the implementation of a storage change or additional physical counts may alert the individual or individuals to the hospital's or pharmacy's awareness of the losses and thus prevent the identification of the individuals responsible for,or the methods employed, that resulted in the loss. The Board should provide guidance as to which is more important - apprehending the responsible individual{s) or protecting the public and patients immediately from further diversion. The Board's guidance has not been consistent on this point historically. Perhaps the Board's guidance on this point could be related to the US Drug Enforcement Administration's (DEA) multi-faceted guidance on when a loss is considered "significant" for reporting.
1715.65(h)	**Michael Tou Providence Health**	"A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing, until the cause is identified and resolved."

Code Section	Commenter	Comment
1715.65(h)	**Rita Shane Cedars-Sinai**	Recommendation: Revise proposed regulations to: "A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, which may include installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing. Comments: The pharmacist- in- charge should evaluate and determine which strategy will prevent further loss of controlled medications .
Overall	**Chad Signorelli**	Is there an allowance or exception allowed for those facilities that keep the entirety of their C-II inventory stock in perpetual inventory machines? In our facility, our C-II stock is in either the Pyxis C-II Safe or a Pyxis ADM with “Blind Count On” thereby allowing an inventory count to be completed every time the medication is removed. If counts are not correct there is an immediate discrepancy created that must be followed up on and acted upon. We therefore inventory our medications much more frequently than every 3 months and asking us to physically inventory the stock every 3 months would be unnecessary and unneeded. I can understand the importance of this process in non-perpetual inventory locations but do not see the need in a location such as ours.
Overall	**Hilary Ward**	Our humble opinion from Tahoe Forest is that increasing the frequency of narcotic inventory audits is not going to deter diversion effectively. Counts may be off for any number of reasons which are infrequently diversion, yet a diverter can operate in many ways that would never be detected by just looking at inventory counts. If the Board truly feels more frequent inventory audits will be beneficial, we believe doing every 6 month counts would be operationally feasible, but every 3 months is just excessive.

Code Section	Commenter	Comment
Overall	**Jeremish Joson**	This is another "reactive" action by the Board that does not solve the problem but further burdens already burdened pharmacists and their staff. This has happened with the New England Compounding Center debacle; the Board became overzealous with their regulations to the point that mixing three ingredients to make Magic Mouthwash was considered compounding. This level of bureaucratic insanity does nothing to protect the public (please, explain to me how preventing me from mixing 3 ingredients and letting the patient do it themselves is supposed to protect them) but only further complicates an already complicated and stressed profession. For one, opioids are just one class of abused prescription drugs (http://www.pdmpexcellence.org/drug-abuse-epidemic). According to the PDMP Center of Excellence, the "rise in the misuse and abuse of prescription drugs, opiates in particular, has been attributed to their increased availability over the last decade, a result of increased prescribing." Many deaths are due to heroin, due to its low cost, easy availability, and the fact that it can be smoked or snorted. Compounding the profession with excessive, ineffective regulations will only lead to increased robberies, threatening our livelihoods, as is also referenced by the PDMP. According to Okie, NEJM 2010, "more than 40% of opioid prescriptions are written by general or family practitioners, osteopaths or internists..." As studies by the State Departments of Health for Florida, Kentucky, and Ohio have shown, the vast majority of deaths were due to pain clinic over prescribing and oxycodone. When Kentucky and Florida decided to go after these "pill mills," their death rates were reduced drastically. They also increased drug abuse programs. Dr. Frieden of the CDC, published a report in 2014 stating that the drug abuse epidemic is caused largely by prescribers. His study, along with an LA Times investigation, showed that physician prescribing was a key contributor to the crisis of addiction (http://www.latimes.com/local/la-me-rx-source-20140304-story.html#axzz2v0MEW9Sh). Why are we asked to count all our Schedule II medications every three months when we are, by law, required to keep a perpetual inventory maintained daily? Furthermore, we are required to have policies & procedures in place addressing diversion. Furthermore, we are required to report theft or loss to the Board as well as the DEA via form 106. This is another attempt by the Board to "brown nose" the public, to put on a performance so as to assure them that it is doing everything in its power to protect the public from the drug epidemic, when in fact, it is just forcing its pharmacists to exercise futile maneuvers and to collect payment from them for "gotcha" non-compliance. Drug diversion within pharmacies is already well regulated and plays a minor part in the overall scheme of drug overdose deaths. As mentioned in many reports and studies (something the Board should undertake before jumping to conclusive actions), the greatest problem to the epidemic is PHYSICIAN PRESCRIBING.

Code Section	Commenter	Comment
Overall	**Jeremish Joson**	Thanks to the Board, and case law, State of California v. Thang Tran, pharmacists are already burdened with filling controlled substances, checking CURES, and acting as gate-keepers, fighting with patients and sometimes their prescribers. The burden of liability rests solely on pharmacists and nothing is being done to address the real problem, physician over-prescribing and/or inappropriate prescribing. This has opened up more paperwork, time spent filling prescriptions, hostility from patients toward pharmacists, and as has been already reported, increased gun-point robberies. Physicians should be required to staple a current CURES report with each opioid prescription they write before a patient leaves their office. It is my professional opinion that if the Board truly believes that the "protection of the public shall be the highest priority," it would work with the California Medical Association, CDPH, and the State DEA to conduct a study and set forth recommendations as did the states of Florida, Kentucky, Ohio, and Tennessee, all of whom were successful in reducing drug deaths. As a matter of fact, none of those states required their pharmacists to count their Schedule II prescriptions every 3 months. Also, counting every Schedule II (e.g., Adderall, Concerta, Vyvanse, Duragesic), a vast majority of which are not implicated in the epidemic, is another waste of time and energy. In addition, the Board should remove penalties of any kind for the self-reporting of controlled substance losses unless those losses were deemed intentional or have already been addressed in a previous infraction. Getting pharmacists and pharmacies to feel more comfortable with reporting diversion requires removing punishment the Board hands out to its pharmacists-in-charge. As has been known for a long time by the Institutes of Medicine, medication error reporting dramatically increases when employees know that no punitive action will be taken against them (https://www.ismp.org/Tools/whitepapers/concept.asp). It is ridiculous for the Board to make examples of its pharmacists and it does not help in the protection of the public, much like medication underreporting does not either. In summary: 1. No, do not require a Schedule II inventory every 3 months with more burdensome paperwork to fill out 2. Understand the true nature of the problem before creating a useless, ill-advised regulation that does not protect the public or address the problem. Create a taskforce with other key-institutions and come up with real solutions. 3. Physicians should be required to print a current CURES report and attach it to any controlled substance prescription they write 4. Codify that pharmacists-in-charge will not be punished by the Board for any reports of diversion or missing pills, within reason

Code Section	Commenter	Comment
Overall	**K. Scott Guess**	The need for a CS inventory monitoring system has been clearly demonstrated by the numbers of lost drug being reported. However, I feel this regulatory requirement will be too stringent, too time consuming, and too overly burdensome to the practice pharmacy, as well as for the Board. Surely the Board does not have the resources to account for every 'lost' tablet in the state? This level of accounting will require the documentation of every dropped pill, every broken tablet found in every bottle, and every over or under fill by a manufacturer. Diversion by internal theft in the retail or outpatient setting does not generally happen in counts of 1-10, but by the bottle, counts of 100, 500 or 1000. The institutional setting is quite different. That setting can and does loose full bottles as well as single doses to internal theft; setting tighter CS inventory controls may be necessary in the institutional setting. I will respectfully disagree with the Board's financial impact assessment. A full CS physical count using estimated values for C3-5 (as permitted by current rules) is roughly a 3-hour process at my stores. A full manual count of C-2 drugs is also a 3-hour project. Collating that data and comparing it to purchase data can take 10-15 hours. This is a sensitive job and should only be done by the PIC or owner, 13 hours of PIC labor will minimally cost the pharmacy $1200 in total payroll costs. In our current economic environment with ever-dwindling profit margins and third party reimbursements this is level of scrutiny and labor investment is not cost efficient. For general retail pharmacy a simple In-Out audit is all that is necessary. Compare monthly purchases to monthly dispensing; then look for the discrepancies that are greater than 1 package size (100, 500, 1000) for further research and documentation.
Overall	**K. Scott Guess**	A much more efficient mechanism, and just as capable of detecting diversion, if not more so would be: • Collect purchase data reports directly from the vendor either as a printed or downloaded report. Do not use invoices; the diverter can destroy invoices. • Collect sales data directly from the pharmacy software system. • Compare line items sorted by NDC number (more exacting than drug name). o If the difference is greater than 1 package size, documenting the on-hand inventory should balance the equation. o If not then a more exacting count and audit process is needed. • Mandating the use of a perpetual inventory for C-2 drugs is another tool that can be employed to catch inventory discrepancies in timely manner. It is well documented in the press, Board posted accusations and actions, and Law enforcement investigations the internal retail pharmacy diversion involves full bottles, not random hands full of drug. The full inventories for PIC change must remain as a hard data point for the staffing change. The Biennial inventory is mandated by Federal regulation and currently accepts count estimates for schedules C III-V for packages of 1000 or less. Retail and institutional pharmacy are vastly different, with different inventory management systems and needs. The above comments are directed towards the retail setting. As the practice of pharmacy becomes more and more specialized it is not unreasonable to develop separated inventory monitoring programs for retail (including institutional out patient) and institutional (inpatient) settings. Furthermore this regulation MUST apply to EVERY pharmacy licensed by the California Board of Pharmacy, hospital inpatient, retail (including institutional out-patient), LTC, central fill, and mail order (in or out of state). The Board can fulfill their mission of protecting the public without burdening the practice of pharmacy with down-to-the-tablet accounting.

Code Section	Commenter	Comment
Overall	**Kaiser Doug O'Brien (Hearing)**	Large losses unusual in California because of oversight by the Board and CDPH. Lots of controls in Hospitals with automated dispensing machines. Realtime discrepancy detection, blind counts, biometric ID access, and tracers. Hospitals have the tightest controls in California. Hospitals experience little loss of controlled substances. Target outpatient / community pharmacies as that is where most of the drug loss occurs. This regulation will not improve oversight in Hospitals. Do a Risk Based Approach.
Overall	**Robert Shmaeff Joyce E. Keefer Med Center**	I am the Director of Pharmacy Services of a hospital pharmacy providing services to 239 skilled nursing beds and 10 gero-psychiatric beds. The pharmacy employs two pharmacists, two technicians and a biller. During my tenure of over eight years we have not had a loss of any controlled substance. It is my belief that hospital pharmacies do not contribute significantly to the diversion problem. Mandating four controlled inventories annually would be over kill. The inventory process here is time consuming and would result in a waste of resources. It is my considered opinion that four controlled substance inventories per year is not necessary. Thank you for your consideration
Overall	**Terry Cater**	I am commenting on the proposed adoption of Section 1715.65 of Article 2 of Division 17 of Title 16 of the CCR (requirements for reconciliation and inventory of controlled substances) which, among other requirements, would require pharmacies to perform a physical inventory count of all Schedule II controlled substances every 3 months. This proposed regulation does not increase the protection of the public. It may actually take away from the public safety. This is one more non-patient centered activity that takes pharmacist's time and attention away from patient medication safety. The DEA currently requires a complete CS inventory every two years. The State of California regulations should either "mirror" the federal requirement or consider amending the current proposal from taking an inventory every three months to once a year.

Reconciliation and Inventory of Controlled Substances - Initial Proposed Text

Title 16. Board of Pharmacy
Proposed Text

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Reconciliation and Inventory Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
(c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
    (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
    (2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:
        (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
        (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
(d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
(e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
    (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
    (2) Likely causes of overages shall be identified in writing and retained.

(3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.

(1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.

(2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.

(3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

Reducing Controlled Substances Diversion in Hospitals

California Hospital Association Medication Safety Collaborative Committee
www.calhospital.org/medication-safety-committee

Introduction
The attached road map is intended for acute care settings as a plan to help navigate controlled substance diversion prevention goals. The document provides a recommended framework to coordinate the needed resources and technology for an optimal diversion prevention program. Actions taken pursuant to this framework should be reflected in a standardized set of processes within the organization to ensure that they are maintained.

Some actions are required by law or regulation (and marked with ►) while some may be good recommendations to have in place. Ultimately, each organization is responsible for developing a diversion prevention plan that protects patients from impaired care providers (i.e., to the extent it affects a provider's ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of controlled substances within the organization).

Credits
The committee thanks the Minnesota Department of Health and Minnesota Hospital Association and the Minnesota Drug Diversion Coalition[1] for developing the original document. With their permission, this document builds upon their work and includes California-specific guidance.

Committee Representation
The committee includes representatives from:

- Association of California Nurse Leaders
- California Association of Health Facilities
- California Board of Pharmacy
- California Department of Public Health
- California Hospital Association member hospitals
- California Hospital Patient Safety Organization
- California Medical Association
- California Society of Health System Pharmacists

[1] Minnesota Coalition members are listed at www.health.state.mn.us/patientsafety/drugdiversion/.

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, and others.

Component	Specific Action(s)	Self-Assessment Checklist
Safety Teams / Organizational Structure	1. Organization defines Controlled Substance (CS) Diversion Prevention Program.	1a. The organization has an interdisciplinary team involved in developing and overseeing the CS Diversion Prevention Program. 1b. The CS Diversion Prevention Program includes prevention, detection and investigation. 1c. The CS Diversion Prevention Program is reviewed by the team and updated at least annually. 1d. CS Diversion Prevention Program champions have been identified and have designated clear roles with expectations from the following areas: • Medical Staff • Pharmacy • Nursing • Security • Human Resources • Patient Safety/Risk Management/Compliance • Administration • Legal (as necessary) • Communications (as necessary)
	2. An organizational structure is in place that supports an effective CS Diversion Prevention Program.	2a. The organization has a designated coordinator(s) for the CS Diversion Prevention Program. 2b. The coordinator(s) has dedicated time to serve in this coordination function. 2c. The organization has a team prepared to respond to suspected CS diversion situations. 2d. The organization has and regularly reviews policies and procedures addressing all aspects of the CS use processes. 2e. The organization regularly reviews policies and procedures to assure compliance with state and federal laws.

	3. Organization proactively collaborates with local law enforcement.	3a. The organization (e.g. security) has engaged local law enforcement (e.g. county sheriff, chief of police) to discuss the CS Diversion Prevention Program and establish a communication strategy (including public) prior to CS diversion situations.
	4. Organization fulfills all reporting requirements for diversion or loss of CS.	4a. ►The owner reports to the California Board of Pharmacy within thirty days of discovery of any CS losses, including their amounts and strengths. 4b. ►The DEA registrant or their designee reports any CS theft or significant loss to the DEA within one business day of discovery. 4c. ►The organization follows other applicable requirements. For example, Medicare Conditions of Participation states: "Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate."
Access to Information / Accurate Reporting / Monitoring / Surveillance / Detection System	1. Organization reviews and audits relevant data that could indicate potential CS diversion.	1a. ►The organization has a process to generate controlled substance data on a minimum monthly basis such as controlled substance surveillance reports, high user report, CS use through reports/log-sheets and CS "Disposition and Inventory" sheets.
	2. Organization tracks and reviews measures recommended by Medication Safety Committee or other designated groups reporting directly to a Medical Staff Committee.	2a. ►The organization has a process in place to review and analyze CS data on a regular basis. 2b. ►The organization shares findings from the data analysis on a regular basis. 2c. ►There is a process in place to activate a response team that includes a patient care manager, pharmacy, Human Resources (HR) and security when diversion is suspected. 2d. ►The organization has a process in place to contact law enforcement when diversion or theft is suspected.
Facility Expectations	1. Organization communicates the expectation that staff "speak up" when they become aware of an issue related to CS diversion.	1a. ►Senior leadership has clearly communicated that all staff are to speak up and will be supported in speaking up when they become aware of possible diversion. 1b. ►The hospital treats such information as confidential and takes all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information.
	2. Organization establishes full disclosure policy.	2a. ►The organization has a clearly defined full disclosure policy and process to communicate to patients/families who are

		affected by CS prevention diversion.
	3. The organization's HR practices support an effective organization-wide CS Diversion Prevention Program.	3a. The organization has established and communicated ways for staff to speak up anonymously (e.g. hot line, paper or electronic submission). 3b. The organization has a process in place to remove an impaired caregiver from patient care. 3c. ►The organization conducts pre-employment background checks for Licensed Independent Practitioners (LIPs) and employees. 3d. A log of staff photographs and signatures are maintained as appropriate. 3e. The organization has a process to manage employee access to CS in a timely fashion when terminated or transferred. 3f. The organization has developed a "for cause" policy for drug testing.
	4. Organization does not allow sharing of pass codes.	4a. ►The organization establishes and enforces a policy of not sharing pass codes such as electronic medical record (EMR), Automated Distribution Machine[2] (ADM) and pharmacy door codes.
Education Staff (and Patients)	1. Organization has in place an effective and comprehensive training and education program for all staff on CS diversion prevention.	1a. The CS Diversion Prevention Program team has attended CS diversion prevention and statutory requirements training (e.g. National Association of Drug Diversion Investigators [NADDI], professional associations, licensing boards, state, local and federal law enforcement). 1b. Expectations and supporting education have been incorporated into training for all new staff and LIPs. 1c. Expectations and training include, at a minimum, providing awareness training to know the signs of diversion. 1d. Resources are available to support employees and LIPs, e.g. Employee Assistance Program (EAP) and Health Professional Services Program (HPSP). 1e. The facility requires training on CS policies and

[2] ADM is a robotic or computerized device in which the device components are designed to distribute drugs in a licensed health care facility. A pharmacist is responsible for the drug entry into the patient's profile, final review and distribution of the patient medications.

		procedures prior to authorizing staff to have CS access. 1f. The facility provides ongoing staff education at least annually to promote safe handling of CS and CS diversion awareness. 1g. The organization provides patient education on safe medication handling, including potential for diversion.
Storage and Security	1. Organization stores CS and other high-risk items securely, in all settings and circumstances.	1a. ►The organization has a process in place for securing CS (as described in section 2 below) for every setting and circumstance.
	2. Organization has a process in place for securing CS.	2a. Never leave CS unattended. 2b. CS are stored in a locked location (e.g., ADM, ℂ[3] vault or locked cabinet/drawer/box) at all times. 2c. ADM-managed CS are stored in a location with one CS-type access. For example, users cannot have access to a second type of CS when accessing the intended CS. 2d. Access to CS storage areas is limited to authorized staff. 2e. Non-ADM CS cabinets are secured with a locking device. 2f. ADM and non-ADM access is removed promptly for terminated employees. 2g. Patient-specific CS infusions (e.g., PCA[4], epidural, and continuous infusions) are enclosed in a locked box. 2h. Keys are controlled and accounted for. 2i. Prescription pads and paper are stored in ADM, locked location or under control of an LIP. 2j. Facility designates authorized individuals to order prescription pads/paper direct from the vendor for the operating unit or patient care area. 2k. Electronic and non-electronic prescriptions comply with state and federal requirements. 2l. CS brought in by a patient that cannot be returned home are inventoried by two authorized health care staff and stored in

[3] Schedule II controlled substance.
[4] Patient-controlled analgesia.

		a locked, limited access area. 2m. CS brought to the hospital for use by the patient (i.e., Patient's Own Medication) is securely stored and accounted for during the hospitalization as well as upon the patient's discharge. It is recommended to have a process in place where patients are contacted after discharge to pick up their CS in storage. CS remaining in the pharmacy and not picked up by the patient after discharge is to be destroyed per the hospital's policies. Preferably, the patient is contacted and asked to pick up their CS.
	3. Organization uses camera surveillance in high-risk areas as appropriate.	3a. Camera surveillance is used in primary CS pharmacy storage area (e.g. narcotics vault).
Procurement	1. Organization effectively and safely handles procurement in the hospital pharmacy.	The organization has a process in place for procuring CS that includes: 1a. ►If the hospital utilizes the controlled substance ordering system (CSOS)[5], then each user must have their own password. Passwords cannot be shared. 1b. ►Excluding radiopharmaceuticals[6], the hospital pharmacy procures all CS. 1c. ►Individuals authorized to order ©-© are limited to the DEA registrant and authorized individuals. DEA 222 forms are secured and accessible only to these individuals. 1d. ►Individuals other than the DEA registrant authorized to order CS must have a power of attorney on file to execute the DEA 222 forms as per 21CFR1305.05. 1e. The persons authorized to order CS are not the same persons who receive the CS. 1f. ►All invoices received are signed and have the date when the medications were received. 1g. ►Only a licensed pharmacist or authorized receiving person signs for the controlled substance delivery. 1h. ►If CS are delivered to hospital central receiving, an

[5] An electronic DEA 222 program. DEA's CSOS is an encrypted electronic controlled substance ordering system between a wholesaler and the DEA licensee's authorized user. The DEA's CSOS is the preferred method for © CS procurement.

[6] Currently, there is one © radiopharmaceutical: DaTscan™ (Iodine I-123 ioflupane), a cocaine analog indicated for striatal dopamine transporter visualization using SPECT brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes.

		authorized receiving person signs for the delivery, central receiving transfers CS to the pharmacy within one working day following receipt by the hospital, and then the pharmacist immediately inventories the CS. 1i. ►If CS are delivered to the pharmacy when the pharmacy is closed and pharmacist unavailable, then storage of this delivery must comply with the requirements of California Business and Professions Code 4059.5(f).[7] 1j. ►Any discrepancy between the receipt and the type or quantity of CS actually received is reported to the delivering wholesaler or manufacturer by the next business day after delivery.
Prescribing	1. The organization's ordering/ prescribing practices minimize the risk of CS diversion.	1a. ►CS are prescribed only by licensed authorized prescribers with a DEA registration or institutionally assigned DEA suffix. 1b. ►A valid order from an authorized prescriber exists for all CS administered. 1c. ►CS are not prescribed by an authorized prescriber for him/herself or immediate family members. 1d. Patient-specific CS orders are generated by electronic systems with controlled access except in emergencies in accordance with applicable federal and state laws and rules. 1e. Range orders for CS are minimized.
Preparation & Dispensing	1. The organization's preparation and dispensing practices minimize the risk of CS diversion.	1a. ►Tamper-evident packaging is utilized for CS prepared by pharmacy.[8] 1b. ►CS transported via pneumatic tube are sent via secured transaction. 1c. ►There must be a co-signature for delivery of CS to non-ADM areas. Document chain of custody. 1d. CS are dispensed in single-unit-dose packaging.[9] 1e. Secure, locked, non-transparent medication delivery

[7] See appendix for B&P 4059.5(f) text.
[8] Tamper-evident packaging means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.
[9] Single-unit-dose packaging means a single-unit container for articles intended for administration as a single dose, direct from the container.

		carts/containers are used to deliver CS and accessible only by authorized individuals. 1f. ADMs are utilized in patient care areas for the distribution of CS and are interfaced with the electronic patient profile to limit access only to medications ordered for a specific patient. 1g. Reconciliation is performed on ADM CS dispense transactions for temporary patients to ensure that the CS went to an actual patient.[10] 1h. Bar code scanning is utilized when replenishing ADMs. 1i. A blind count process is used for narcotic vault and ADM distributed CS.[11] 1j. The number of CS on override status in profile ADMs is minimized (e.g. one-time injectables for emergencies only). 1k. Biometric-ID technology is used instead of passwords. If passwords are used, passwords expire on a regular interval.[12] 1l. ADM downtime procedures must be defined to maintain the control, documentation and accountability of CS.
Administration	1. The organization's CS administration practices minimize the risk of CS diversion.	1a. There is a defined time between CS retrieval from storage areas and time of administration and documentation (e.g. within 30 minutes of ADM removal or within 30 minutes of the end of the procedure). 1b. The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered. 1c. ►Only health care providers operating within the scope of their practice may administer CS. 1d. ►CS are removed for one patient at a time from ADMs and/or locked storage areas.

[10] For example, a temporary patient ID may have been used when CS are needed in an emergency and the admission information is not yet transferred to the ADM.

[11] Blind count is a process utilized with ADM when refilling a controlled substance into the drug's individual pocket. The ADM requests the person replenishing the controlled substance to the ADM to count the quantity in the machine before adding the refill. The count in the pocket is not presented to the person replenishing the CS. If the count entered by the person replenishing the ADM is correct, the ADM will allow the refill of the controlled substance.

[12] For example, the ISMP recommends changing passwords every 90 days or less if biometric authentication is not also in use (http://www.ismp.org/selfassessments/ADC/Survey.pdf).

		1e. ►The individual retrieving CS from ADM/locked storage area/box is also the person that administers the medication. The organization defines exceptions (e.g. emergencies) and has a policy/process in place to assure chain of custody. 1f. ►All CS are drawn up into syringes that, if not immediately administered, are labeled per institutional policy.
Handling Waste	1. The organization's "waste" handling practices maintain chain of custody to minimize the risk for CS diversion.	Pharmacy: 1a. CS waste from Compounded sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed. Areas outside Pharmacy: 1b. ►Unusable product[13] (UP) CS are to be immediately wasted and witnessed by health care professionals per specific hospital procedures. 1c. All Potentially Reusable Product[14] (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue. 1d. The organization has identified the high-risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs. 1e. The organization has identified specific high-risk CS medications (e.g., fentanyl) that are randomly assayed. 1f. The organization has a process to randomly obtain and assay UP CS. For random assays, the UP CS would not be subject to immediate witnessed waste.
	2. The organization's practices for handling unused CS, empty CS containers or CS returned to pharmacy minimize the risk of diversion.	**Wasting of UP CS:** 2a. ►Approved methods for wasting a CS are defined per federal, state and county laws and regulations. 2b. ►The wasting of all CS requires an independent licensed witness and must be documented in the ADM or via proof of use form, except when UP CS are returned to pharmacy for assay. 2c. ►An individual witnessing CS wasting verifies the volume/amount being wasted matches the documentation and physically watches the medication being wasted per policy.

[13] UP: Any medication that may not be used for a patient due to either the integrity no longer being intact or the medication has exceed its expiration/ beyond use date.

[14] PRP: Medications that have been issued to a patient, which have not been used, the integrity of such packaging remains intact and expiration/beyond use date allow the medication to be re-issued to another patient.

		2d. ►Empty containers of CS (e.g., vials) are discarded in limited access waste containers. 2e. ►Waste containers with trace UP CS are secured to prevent tampering. 2f. ►The pharmacy accounts for manufacturer overfill in injectable containers. All overfill amounts are captured, verified, documented, and wasted accordingly. Controlled substance overfill should be considered unusable product (UP). **PRP Returns:** 2g. PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket. 2h. ►All PRP CS returns to pharmacy require chain of custody documentation in the patient care area and in pharmacy **Waste or Reverse Distribution:** 2i. ►DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company. 2j. Expired CS that are quarantined for reverse distribution are properly accounted by way of a log or inventory list. The items sent back via reverse distribution could be reconciled with the reverse distribution log of CS.
Monitoring of CS and Process if Diversion is Suspected	1. Organization removes access to CS if diversion is suspected.	1a. ►All personnel actions (e.g. suspension, terminations and resignations) are promptly communicated to pharmacy so access to CS can be removed. 1b. ►If the hospital becomes aware of an arrest of an employee for illicit use of CS, the hospital immediately conducts its own investigation. The organization assesses whether to suspend, transfer, terminate or take other action (e.g., remove access to CS) against the employee.
	2. Organization regularly monitors CS through inventory, reports and audits.	2a. CS purchase invoices are compared to CS orders and receipt into the pharmacy's perpetual inventory. Any CS purchases outside of the pharmacy department are tracked. Since the invoice-receipt pair may both be removed with CS diversion, invoices also are reconciled to statements or wholesale purchase history reports to detect missing invoices. 2b. Movement of CS throughout the hospital is tracked. For example, reports match narcotic vault transactions with receipt into ADM and/or paper inventory record with RN signature of

		receipt. 2c. ►CS within an ADM or narcotic vault are inventoried at least monthly. 2d. Non-automated CS storage areas are inventoried at each shift change. 2e. ADM reports are reviewed at least monthly by pharmacy or patient care managers as defined by the organization. Reports compare ADM activity with medication administration record. 2f. ADM CS activity is compared to peers with similar staffing responsibilities and FTE appointments. 2g. Transaction activity (e.g. inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns and waste) is compared to peers. 2h. Patient MAR: amount and quantity administered, is compared to what other caregivers administer on subsequent shifts (without patient change in condition). 2i. Non-ADM CS storage area record of use is compared with MAR (e.g. anesthesia record, sedation record, eMAR) to assure appropriate documentation of waste.
	3. A process is in place to resolve CS discrepancies.	3a. ►CS discrepancies are resolved upon discovery, no later than end of shift. Discrepancies that cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hours (e.g. metric: unresolved nursing unit CS discrepancies > 24 hours/total nursing unit CS discrepancies should be ≤8 percent). 3b. It is recommended that a pharmacist reconcile CS discrepancies in the ADMs. ►A pharmacist has responsibility for the discrepancy even when a technician performs these duties.
	4. Organization creates standard process to investigate potential diversion cases.	4a. ►There is a standard process in place to investigate potential diversion cases.

Selected Legal References[15]

Federal

21 Code of Federal Regulations Chapter II: Drug Enforcement Administration

Sec. 1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;
(2) The specific controlled substances lost;
(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
(5) Whether the specific controlled substances are likely candidates for diversion;
(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

Sec. 1301.90 Employee screening procedures.

It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:

Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission

[15] This is not a comprehensive listing of applicable laws and regulations.

of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

Sec. 1301.91 Employee responsibility to report drug diversion.

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

Sec. 1301.92 Illicit activities by employees.

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

Sec. 1301.93 Sources of information for employee checks.

DEA recommends that inquiries concerning employees' criminal records be made as follows:

Local inquiries. Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

DEA inquiries. Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

42 Code of Federal Regulations, State Operations Manual, Appendix A[16]

§482.25(a)(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs. A-0494

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.
- Facility policies and procedures should minimize scheduled drug diversion.

[16] Bulleted items are from the Interpretive Guidelines for that regulation.

§482.25(b) In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law. A-500

- Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals.
- The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

§482.25(b)(2)(i) All drugs and biologicals must be kept in a secure area and locked when appropriate. A-0502

- All controlled substances must be locked.

§482.25(b)(2)(ii) Drugs listed in Schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept within a secure area. A-0503

- All Schedule II, III, IV, and V drugs must be kept locked within a secure area. A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.

§482.25(b)(2)(iii) Only authorized personnel may have access to locked areas. A-504

- The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.
- The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored.

§482.25(b)(7) Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate. A-509

- Controlled drug losses are to be reported to appropriate authorities in accordance with State and Federal laws.

State of California

Business and Professions Code

4059.5

> (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.
>
> (b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
>
> (c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

4081(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept …

4332 Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

Health and Safety Code

11209. (a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.

Title 16, Division 17, California State Board of Pharmacy

§1714 Operational Standards and Security

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

§1715.6 Reporting Drug Loss

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

Title 22, Division 5, Licensing & Certification of Health Facilities…, Chapter 1, General Acute Care Hospitals

§70263 Pharmaceutical Services General Requirements

(c)(1) The [pharmacy and therapeutics] committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures.

(l) Medications shall not be left at the patient's bedside unless the prescriber so orders. Such bedside medications shall be kept in a cabinet, drawer or in possession of the patient. Drugs shall not be left at the bedside which are listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended. If the hospital permits bedside storage of medications, written policies and procedures shall be established for the dispensing, storage and records of use, of such medications.

(q)(10) Drugs maintained on the nursing unit shall be inspected at least monthly by a pharmacist. Any irregularities shall be reported to the director of nursing service and as required by hospital policy.

(q)(11)(A) Drugs listed in Schedules II, III, or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of two pharmacists or a pharmacist and a registered nurse employed by the hospital. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be in the patient's medical record or in a separate log. Such a log shall be retained for at least three years.

§ 70265 Pharmaceutical Service Staff

A pharmacist shall have overall responsibility for the pharmaceutical service. He shall be responsible for the procurement, storage and distribution of all drugs as well as the development, coordination, supervision and review of pharmaceutical services in the hospital.

§70269 Pharmaceutical Service Space

(b) All spaces and areas used for the storage of drugs shall be lockable and accessible to authorized personnel only.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 6, 2016

TO: Medication Safety Committee

FROM: Debby Rogers, VP Clinical Performance and Transformation

SUBJECT: Tubing Connectors

SUMMARY

Background

The law that prohibits hospitals from using tubing "connectors that would fit into a connector other than the type it was intended for" goes into effect in 2016. Hospitals are encouraged to create a careful and methodical transition to the new connectors once the evaluation of the market-place availability shows a stable supply. In addition, hospitals are encouraged to review patient safety plans to ensure that the prevention of misconnecting IV, enteral and epidural lines is adequately addressed.

Currently, all the tubing attached to one of three connector types (epidural, IV and enteral) can be interconnected. Until these connectors are reengineered, approved by the ISO and the FDA, and adequately distributed throughout the health care industry, there remains the possibility of human error.

Progress is being made to update the standards for manufacturing these connectors, but until all three tubing/connector types are reengineered and readily available, they can still be interconnected. Per the Advanced Medical Technology Association's annual report to the Legislature for 2015, ISO-compliant intravenous connectors became available January 1, 2016 and ISO-compliant epidural connectors will be available by January 1, 2017. ISO-compliant enteral connectors will be delayed beyond the July 1, 2016 deadline in the law**.** In addition, although ISO-compliant intravenous connectors are available now, they won't technically be "non-interconnectable" with epidural/enteral connectors until the epidural/enteral connectors are reengineered according to ISO requirements and fully available in 2017.

Hospitals have a risk of technical non-compliance with the law if the products are not available when the legal prohibition(s) take effect.

- **Hospitals are encouraged to review their Patient Safety Plans** to ensure that prevention of adverse events associated with misconnecting IV, enteral and epidural lines is adequately addressed. The plan may include an assessment of the sustained availability of connectors that meet the legal standard, staff training, etc.
- **Patient Safety Plans:** Hospitals are required to develop, implement, and comply with a patient safety plan for the purpose of improving the health and safety of patients and reducing preventable patient safety events (Health and Safety Code Section 1279.6 at: http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1279.6.&lawCode=HSC. A patient safety plan pursuant to Section 1279.6 must include measures to prevent adverse events associated with misconnecting intravenous, enteral feeding, and epidural lines (Health and Safety Code Section 1279.7 at: http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1279.7.&lawCode=HSC. (See chapter 21 of CHA's *Consent Manual* for more details about the requirements for Patient Safety Plans.).
- Hospitals are encouraged to perform a risk analysis, including the availability of the connectors and identify methods to mitigate the risks.

ACTION REQUESTED

Discuss and advise.

DBR:rf

Medication Safety Toolkit Manual

Section	Chapter Title	Author	Due Date	Rcv Docs	Review thru BJ	Review thru Pubs	Comments	Status	Final thru Pubs
Frontice		Emily							
	Title Page	Emily							
	Pubs Page	Emily							
	Intro	BJ/Mary					Build in contents of Jana's text and the Committee Memo		
	Acknowledgments	BJ/Emily							
	Quick Reference Guide	Emily							
1	Medication Guideline Activity Matrix	MS SubCmt		10/29			Revised May 2015		
2	Anticoagulants Guidelines	MS Cmte		10/29			"Anticoagulation Tool for Commonly Used Anticoagulants in the Inpatient Setting - Part 1" (BN)		
							"Anticoagulation Tool for Commonly Used Anticoagulants in the Inpatient Setting - Part 2"	Waiting on updates to Part 2 - may not receive by time of printing	
3	Reducing Controlled Substances Diversion in Hospitals	MS Cmte		10/29			Document dated May 2013		
4	Insulin Recommended Safe Practice Guidelines	MS Cmte		10/29			8/15 (BN)		
5	ED Medication Mgmt Safety Tool	MS Cmte		10/29			Current document dated 2014	Awaiting final updates	
6	Recommendations for Improving Safety of Opioid Use	MS Cmte		10/29			8/15 BN version		
7	Lab Testing Requirements for Medium and Low Risk Sterile Compounding	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
8	Temperature Monitoring Requirements	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
9	Sterile Compounding Frequency of Documentation	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
10	Physical Plant Requirements	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
11	SB 1039 Implementation	BJ					Pharm Tech Regulations	To Come from BJ	

Section	Chapter Title	Author	Due Date	Rcv Docs	Review thru BJ	Review thru Pubs	Comments	Status	Final thru Pubs
	Color Pieces								
	Cover, Back Cover								

MEDICATION GUIDELINE ACTIVITY MATRIX

ANTICOAGULANT GUIDELINES (Nasim Karmali: High Risk/High Alert Subcommittee)		
DATE	**ACTIVITY**	**STATUS**
November 2011	First Draft	
February 2012	Version 1.0	
June 2013	CHA pulled guidelines from website for update and revised format.	
October 2013	Edited and reformatted	Under review by Rory J. and BJ.
July 2014	Jeanette will send anticoag guidelines from Mills-Peninsula	
October 2014	Considered done except for Credit Section/agree to remove references and everyone will review	

CONTROLLED SUBSTANCE DIVERSION (Rory Jaffe)		
DATE	**ACTIVITY**	**STATUS**
May 16, 2013	Posted to CHPSO website	Complete.

FENTANYL TRANSDERMAL PATCH GUIDELINES (Various authors: High Risk/High Alert Subcommittee)		
DATE	**ACTIVITY**	**STATUS**
December 2010	First Draft	
April 2011	Version 1.0	
June 2013	CHA pulled guidelines from website for update and revised format.	
July 2013	Pam Richter volunteered to review/edit/update guidelines	
Nov 13, 2013	Guidelines template re-sent to Pam Richter	
February 2014	Pam Richter no longer at member hospital	Pending workgroup review
July 2014	Include Fentanyl with Safe Use of Opioids Guidelines	

INSULIN GUIDELINES (High Risk/High Alert Subcommittee)		
DATE	**ACTIVITY**	**STATUS**
July 2012	First Draft	
April 2013	Pending committee review and reformat.	
Aug 15, 2013	Jonathan asked for volunteers to help with review and revision, to which Nasim Karmali responded.	Pending review and reformat by Nasim Karmali
October 2013	Initial wordsmith review BJ/Rory	Forwarded to HR/HA for review
November 2013	Additional edits by E. Avedikian /J. Nelson	Edited.
December 2013	Back to BJ/Rory for final review	Pending final review
August 2014	Updates and revisions completed per Jillian Hacker	
October 2014	Need to add language regarding 2nd insulin check – page 4	

MED-ER (Jonathan Nelson, et al: High Risk/High Alert Subcommittee)		
DATE	**ACTIVITY**	**RESULT/STATUS**
11/20/13	Draft submission of Med-ER Tool	
1/3/14	Draft guidelines require addt'l review by committee prior to posting to CHA website.	Review at January 8 committee meeting.
1/8/14	Insufficient time for detailed review during committee meeting. Consensus was that additional review/edit still needed.	Defer review.
1/23/14	Hanni, Bartleson and Jaffe met re document title, med management elements, column titles (recommended/ideal).	Decision made to call the work group together for addt'l feedback.
1/29/14	Menet provided references for medication management elements.	
2/5/14	Workgroup meets to finalize edits to the grid.	
2/6/14	Nelson re-inserted descriptions names "small, medium and large" to the columns. Document name was also changed to "Emergency Department Medication Safety Tool" Jaffe's recommendations will be added to the tool guiding	

	principles: 1. For items coming from a hospital something like this: "This is example shows how YYY hospital addresses X, and is intended for hospital and health care providers for their consideration as they evaluate their approach." 2. Try to use objective third-party materials that are freely available whenever possible (e.g., IHI, Joint Commission, peer reviewed publications). 3. For internally developed documents, develop a review process and include information about the review process when distributing it.	
2/6/14	Edited document forwarded to CHA legal counsel for feedback and disclaimer verbiage	
2/7/14	Menet suggested tweaking the intro to emphasize medication management and safety as opposed to medication error reduction.	
2/11/14	CHA legal counsel suggested “Any disclaimer should be in terms of providing something to "assist" hospitals develop (or prepare, or evaluate, etc.) whatever it is that they are working on. It should also include a statement that this 'tool' or 'guideline' is informational only, any questions or issues of a legal nature should be reviewed by hospital counsel.”	
3/4/14	Emailed back to the workgroup for final review prior to committee vote on April 9	
3/15/14	Final revisions received; document updated.	
3/18/14	Document sent back to committee for final approval.	
3/27/14	All votes received: 8 “Yes” votes; 0 “no” votes	
4/9/14	Finalized document presented to committee at quarterly meeting.	Pending publications approval for posting to CHA website
April 2014	Posted to CHA MSC Webpage	

OPIOID SAFE USE GUIDELINES (Cleo Mutebi: High Risk/High Alert Subcommittee)		
DATE	**ACTIVITY**	**STATUS**
October 2012	First Draft	
January 2013	Posted to CHPSO Website	
April 2013	Version 1.0	
June 2013	Pulled from CHA website for revision and reformat.	
August 2013	Reformatted by Jonathan Nelson and Eddie Avedikian	
October 2013	Under re-review by BJ Bartleson and Rory Jaffe.	Pending addt’l word-smithing and final reformat by Rory and BJ.
July 2014	Added Fentanyl wording	Final review needed

SB 1036 IMPLEMENTATION		
DATE	**ACTIVITY**	**RESULT/STATUS**

STERILE COMPOUNDING		
DATE	**ACTIVITY**	**RESULT /STATUS**

Additional Comments made after draft guidelines were submitted by Jonathan Nelson.

Guideline	Date	Name	Comment/Recommendation	Result
Med-ER	1/21/14	BJ/Rory	Met for re-review of Med-ER Grid. Edits have been done. Will meet with Jeannette Hanni before submitting for final committee approval.	Discuss edits with Jeannette Hanni
All	1/8/14	BJ	Recommended to committee that guidelines be reviewed more closely and discussed at April's meeting before the committee cast a final vote to publish the guidelines.	
Insulin & Med-ER	12/16/13	BJ/Rory	Met and re-reviewed guidelines.	
Insulin	12/10/13	Jonathan N.	Bob's recommendations incorporated. Update emailed to Ingrid for Rory and BJ's review.	*12/10/13: Revisions forwarded to BJ and Rory.* *Also included in January's meeting packet. -ih*
Insulin	12/9/13	Bob Menet	Page 5, 3rd paragraph (Prescribing): Various entities may be charged with "policy and procedure" or "standardized procedures" review per Title 22, and there is no stipulation that they be done so "annually." For instance, nursing policy and procedures are to be reviewed every three years , or more often if necessary – see 70213(a)(4). Consider changing this entry to read: "Review and evaluate preprinted insulin order sets and insulin infusion protocols by the Pharmacy and Therapeutics (P&T) Committee minimally as established per hospital policy and more often if necessary." (It may be appropriate to include all committees involved in review of such order sets; e.g., "governing body," "medical exec," etc. as appropriate. *(from a follow-up email)*…Realized my response may not have been as clear as I originally thought. "Various entities may be charged with "policy and procedure" or "standardized procedures" review per Title 22…." By 'various entities" I was trying to get at various committees within the organization being charged with review of such documents as policies and procedures, pre-printed order sets, etc.	
Insulin	12/9/13	Bob Menet	Page 8, after last bullet (Other Considerations): Consider a fourth bullet addressing, "Establishment of demonstrated staff competencies to ensure safe and effective use of insulin therapies throughout the organization."	

Insulin	12/9/13	Dan Ross	Page 6: I just had one change, really a question or request for clarity – near the bottom of page 6 – shows in purple and I bolded it. Actual copy and paste is below so you can easily find it.	
Med-ER	11/20/13	Jonathan N.	Draft deliverable submitted with the following notes: Attached are the following: • Draft Med-ER deliverable which contains a cover sheet and the grid. • Draft cover sheet in word for ease in editing • Draft grid in excel for ease in editing. Our to-do was to finalize this and send to you to forward to the MSC committee for their vote. Perhaps BJ and Rory want to take a look first before sending it out? Let me know if anyone has any questions or edits that we could address.	*Revisions included in January's meeting packet. -ih*
Fentanyl	11/13/13	Pam R.	Requested guidelines template so she could convert from the old template and revise guidelines accordingly.	*Template sent -ih*
Opioid & Anticoag	11/10/13	Jonathan N.	Revised guidelines submitted with the following notes: • We utilized track changes and accepted most of your edits. We left a few edits as unaccepted where useful for explaining our edits. • At our last MSC meeting, there was discussion around the importance of indicating physician involvement in the development of the guidelines. The current guidelines include a list of the organizations which participated in the drafting process. Unfortunately, it looks like there were no physician groups represented. Perhaps a solution would be to simply state that the committee included "physician, pharmacist and nurse representatives" and leave it there without specifying the actual groups involved. • I spent some time trying to standardize the formatting for each specific document, but it would probably be advantageous for each guideline to get one final editorial/formatting pass before being republished.	*Revisions included in January's meeting packet. -ih*
Opioid & Anticoag	10/17/13	Rory J.	1. First round of edits submitted by Rory and BJ 2. Edits forwarded to Eddie A. and Jonathan N.	*Edits forwarded to JN and EA -ih*
All	10/14/13	Ingrid H.	Guidelines templates and instructions emailed to Med Safety Committee members	

Implementation of SB 1039 and Program Flex Requests

Enactment of SB 1039, on January 1, 2015, directly impacted pharmacy law (Business and Professions Code (B&PC)), and California Health and Safety Code (H&SC). As a result, several regulatory sections of California Code of Regulations (CCR), Title 22, primarily for general acute care hospitals (GACHs), are impacted as potential licensure requirement conflicts may arise. Before a licensed entity may implement those sections of SB 1039 conflicting with Title 22, program flex requests must be submitted and Departmental approval obtained. The following is provided as general guidance.

Implementation of …

Pharmacy Technician: B&PC Section 4115(a) through (h) requires no program flex. Modify policies and procedures as appropriate.

Pharmacy Technician: B&PC Section 4115(i)(1) through (3) affects CCR, Title 22 Section 70263(f)(2) **and** (3), as well as Section 70263(q)(10), and will require a program flex request at **each** affected section. As to performing “checks of drug supplies stored throughout the health care facility,” the new law reads "monthly." Section 70263(q)(10), which refers to drug storage area inspections in general, stipulates, “drugs maintained on the nursing unit” are to be “inspected at least **monthly**,” and by “a **pharmacist**.” However, Section 70263(f)(3), which is specific to nursing unit emergency drug supply inspections, stipulates these be done “**no less frequently than every 30 days**” (also by a **pharmacist**). So, along with your flex request to have a pharmacy technician package and seal emergency supplies and/or inspect drug storage areas, include a separate program flex request to permit inspection of emergency supplies “**monthly.**” This section is GACH specific.

Intern Pharmacist: B&PC Section 4119.6 requires no program flex. This bill does **not** change the scope of practice for an intern pharmacist (IP); i.e., IPs may continue to practice as they always have, under proper pharmacist supervision, in accordance with state law and regulation and facility policies and procedures. Policies and procedures are to address all intern pharmacist activities. This section is GACH specific.

Dangerous drugs, etc.: B&PC Section 4119.7(a) requires no program flex. This section does **not** change any regulatory expectation with regards to "standing orders," "order sets," and "protocols" established under the policies and procedures of the health care facility, etc. This section is GACH specific.

Drug storage: B&PC Section 4119.7(b) requires no program flex. The health care facility's policy and procedure **are** to specify medication storage parameters. While this section is GACH specific, all licensed health care facilities are otherwise expected to address medication storage requirements by regulation as reflected in their policy and procedure.

Intern Pharmacist: B&PC Section 4119.7(c) requires no program flex. This section is GACH specific.

Bulk cleaning agents, etc.: H&SC Section 1250.06 impacts CCR, Title 22, Section 70263(s) in a GACH and requires a program flex. Similarly, Section 71233(s) is so impacted in an acute psychiatric hospital (APH). Modify your policies and procedures and submit them with your program flex.

Write or issue a prescription: H&SC Section 11150 requires no program flex. Scope of practice modification – facility policy and procedure, etc., is to address any such activity as they would for any mid-level practitioner.

Prescribing, furnishing or administering controlled substances: H&SC Section 11210 requires no program flex. Scope of practice modification – facility policy and procedure, etc., is to address any such activity as they would for any mid-level practitioner.

Guidance for Submitting a "Program Flexibility" Request

Use of form *CDPH 5000 Program Flexibility* is not required, but recommended. Use of facility letterhead is acceptable, as long as the same information as requested on form *CDPH 5000* is provided.

The following assumes use of form *CDPH 5000.*

Under "Subject" simply enter "see below" as space is otherwise limited.

In the box, under "proposed alternate method(s) for meeting the intent of the regulations is," enter the following:

1. The regulation and subparagraph you desire to flex; e.g., "Section 70263(f)(2)." Do not simply enter "Section 70263" as this implies **all** of 70263 *Pharmaceutical Services and General Requirements;* i.e., subparagraphs (a) through (t).
2. Straight forward language for **each** flex request is suggested. For example:

> B&PC Section 4115(i)(1) and (2) conflicts with CCR, Title 22 Section 70263(f)(2). ***Name of your hospital*** requests program flexibility to allow a pharmacy technician to restock and seal emergency medication supplies used throughout the facility.
>
> B&PC Section 4115(i)(3) conflicts with CCR, Title 22 Sections 70263(f)(3) and 70263(q)(10). ***Name of your hospital*** requests program flexibility to allow a pharmacy technician to: (1) Perform monthly inspections of emergency medication supplies instead of no less frequently than 30 days; and, (2) Perform monthly inspections of the drug supplies in nursing units and areas. Any identified irregularities are to be reported within 24-

hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with facility policy and procedure.

H&SC Section 1250.06 conflicts with CCR, Title 22, Section 70263(s). ***Name of your hospital*** requests program flexibility to adopt policies and procedures whereby a pharmacist is not required to consult on the proper methods of repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital, except for areas where sterile compounding is performed.

Note: For an acute psychiatric hospital, reference CCR, Title 22, 71233(s) to request a program flex at H&SC Section 1250.06.

3. Repeat the process as outlined in 1 and 2 for **each** regulatory section a program flex is desired.
4. Be sure to include the policy and procedure for **each** program flex request as it serves as your supporting documentation.

Please include a contact person's name and their contact information (email and phone number) should questions arise.

Submit the request form(s) and all pertinent policies and procedures to your assigned CDPH L&C District Office. You can expect a response within 60 days.

Medication Safety Committee

Anticoagulants Guidelines

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

TABLE OF CONTENTS

REVISION LOG

VERSION	REVIEW DATE	REVISIONS/CHANGES
2.0	2/12	Final draft approved by committee
3.0	8/13	Revised to CHA Med Safety guideline specifications
4.0		
5.0		
6.0		

INTRODUCTION

The tools contained herein have been reviewed by the California Hospital Association's Medication Safety Committee, and are intended for hospital and health care providers for consideration as they evaluate current practices and develop specific programs**. These tools are not fixed protocols that must be followed, nor are they entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results.** The CHA Medication Safety Committee is a voluntary collaborative supported by the California Hospital Association (CHA)~~, and is comprised of CHA member hospitals and non-hospital representatives, which include the Association of California Nurse Leaders (ACNL), California Association of Health Facilities (CAHF), California Board of Pharmacy, California Correctional Health Care Services (CDCR), California Department of Public Health (CDPH), California Hospital Patient Safety Organization (CHPSO), California Society of Health-System Pharmacists (CSHP), Collaborative Alliance for Nursing Outcomes (CALNOC).~~

Information contained in this tool should not be construed as legal advice or used to resolve legal problems by health care facilities or practitioners without first consulting legal counsel.

COMMITTEE REPRESENTATION

The committee includes nurse, physician, and pharmacist representatives from:

- Association of California Nurse Leaders (ACNL)
- California Association of Health Facilities (CAHF)
- California Board of Pharmacy
- California Correctional Health Care Services (CDCR)
- California Department of Public Health (CDPH)
- California Hospital Patient Safety Organization (CHPSO)
- California Society of Health-System Pharmacists (CSHP)
- Collaborative Alliance for Nursing Outcomes (CALNOC)

Anticoagulation is a high risk therapy involving complex dosing, monitoring, and ensuring patient adherence with outpatient therapy. Reports of adverse events related to the improper use of anticoagulant drugs have received significant attention[1-9]. The following guidelines focus on safety strategies for **unfractionated heparin, warfarin and enoxaparin**. A number of tools are listed in the 'Resource Tools' section to assist with an organizational self-assessment of practices relating to anticoagulant use[RJ1].

The following tool is intended to guide acute care facilities in the safe use of anticoagulation agents. Medication safety includes all aspects of medication use from the acquisition stage to ongoing monitoring.

Step	Actions to Consider ~~to Increase Medication Safety~~		
	Heparin	**Warfarin**	**Low Molecular Weight Heparin**
Pharmacy Purchasing, Storage and Product Labeling	• Purchase commercially available, standard concentrations of IV heparin infusions for use throughout the facility. • Restrict purchases and storage of premixed IV solutions to the pharmacy if feasible • Limit the variety of concentrations and sizes purchased both for large volume parenterals and vials of heparin. Consider eliminating 10,000 units/ml vials • Store away from other drugs in the pharmacy with look alike names or packaging. Use TALLman lettering on labels and bins to differentiate between HeSpan and hEParin • Clearly differentiate heparin products used for treatment from low concentration products such as flushes. • Purchase patient population specific strengths of prefilled heparin flush syringes (e.g. Peds) • Use Tallman lettering on labels, order screens, MARs and other documents when feasible	• Purchase from a single manufacturer to promote consistent bioavailability for this narrow therapeutic index drug	• Purchase commercially available doses in prefilled syringes
Patient Care	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**

Common considerations:

- If providing unit stock, do so in automated dispensing cabinets (ADCs)
- stock in automated dispensing cabinets that are interfaced with the pharmacy system to enable pharmacy review prior to removal (not available via override feature).
- Employ additional verification measures in procedure areas if ADCs are not interfaced with the pharmacy system
- Segregate vials of different concentrations in single access pockets ('cubies') in automated dispensing cabinets

Prescribing

Heparin	Warfarin	Low Molecular Weight Heparin
• Ensure patients are screened for known history of HIT and/or allergy to heparin prior to initiation of therapy. Positive responses are entered in the perpetual medical record • Approved order sets are readily available and used for prescribing • Baseline labs are ordered for monitoring therapy - aPTT or factor Xa if available. • Institute a protocol for rounding of doses (e.g. to closest 500 units) for weight based dosing. Consider maximum dosing for obese patients • Use standard concentrations of heparin in a standardized base solution.	• Require a baseline INR result be available prior to initiation of warfarin therapy and that baseline liver function tests and albumin are ordered • Consider adoption of protocols to allow pharmacists to monitor and order labs and adjust therapy • Intiate therapy at doses of 2.5 to 5 mg for patients 65 years and older, or younger patients with co morbid conditions that may affect their response to warfarin (e.g. thyroid disease)	• Screen patients for known history of HIT and/or allergy to heparin prior to initiation of therapy. Positive responses are entered in the record • Institute a protocol for rounding of doses for weight based dosing

Common considerations for heparin, warfarin, LMWH.

- Obtain a baseline serum creatinine and a complete blood count that includes hemoglobin, hematocrit and platelet count, prior to initiating therapy.
- Include ongoing lab monitoring in preformatted orders and policies/protocols
- Usemetric units for weight-based dosing and specify use of ideal or actual body weight in orders and guidelines.
- Consider approved protocols to treat patients with known or suspected HIT with direct thrombin inhibitors if antithrombotic therapy is required
- Include reminders on protocols, order forms and CPOE system to avoid concomitant use of heparin products or to discontinue other anticoagulants as appropriate
- Maintain a list of error-prone abbreviations that are not permitted.. Commas should be used when expressing large doses (e.g. 10,000 units)
- Establish a procedure for 'hold' orders
- Reconcile anticoagulants upon admission, transfer and discharge
- Update guidelines/order sets to reflect current evidence based practice e.g. CHEST, ACC, AHA, etc.

Pharmacist Order Entry

Heparin	Warfarin	Low Molecular Weight Heparin
	• Implement a process to screen for drug/food/nutritional product interactions	• Implement a process to screen for the presence of an epidural catheter

		• Consider standard administration time such as 17:00 or 18:00	
	Common considerations: • Use height and weight in metric units in pharmacy computer systems • Create pharmacy system alerts for duplicate orders from the same drug class. Provide dose range alerts for over/under dosing as applicable • One time doses administered in the ED or procedure settings should be entered in the pharmacy system to prevent dose duplication • Pharmacist should validate baseline labs		
Pharmacy Dispensing	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Heparin orders are verified by pharmacy prior to dispensing	• Doses are provided in unit dose packaging. • Consider elimination of pill splitting on nursing units	
	Common considerations • If available, use machine readable bar coding for verification prior to dispensing from the pharmacy for refill of automated dispensing cabinets or for single patient use		
Administration	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Conduct an independent verification of 5 "rights", drug concentration, rate of infusion, pump channel selection, IV line labeling and attachment is conducted prior to administration and at change in therapy • Use infusion pumps, preferably smart pumps with error reduction software, for IV infusions • Use smart pumps to deliver bolus and continuous doses from the same container only when a bolus dose can be safely programmed (with hard limits on total dose and minimum infusion time), and the pump automatically converts to continuous infusion after bolus is delivered. Be mindful of the volume required for bolus doses delivered through the pump versus IV push dosing. • Use initial weight for weight based dosing. Do not adjust weight each day unless there is a significant weight change as determined by organizational policy	• Consider MAR documentation of pertinent lab values used to monitor therapy (e.g. INR) • Schedule warfarin administration for the same time each day after INR results are available (afternoon or early evening)	• Conduct an independent verification of 5 "Rights" and correct indication prior to administration • Rotate and document injection sites • Monitor injection sites for hematomas • Use initial weight for weight based dosing. Do not adjust weight each day • To avoid the loss of drug when using the 30 and 40 mg prefilled syringes, do not expel the air bubble from the syringe before the injection.

	• Label lines of IV heparin infusions to help prevent line mix ups • Routinely ensure IV heparin infusions are connected to the right lines. This includes at initiation, change-in-rate, new bag being hung and at shift handoff. ~~Trace back~~ and reconcile IV lines upon initiation, change in orders and at shift handoff[RJ2] • Do not administer IM		
	Common considerations • Make clearly labeled and approved protocols, pathways, nomograms, flow sheets and/or checklists readily accessible in print or electronic form • Consider requiring MAR documentation of pertinent lab values used to monitor therapy (e.g. aPTT,factor Xa levels, INR) when doses are administered • Incorporate screening questions in automated dispensing cabinets to identify adverse drug reactions when reversal agents (e.g. protamine, Vitamin K) are dispensed List specific interventions or treatments that are to be avoided (e.g. IM injections) on pharmacy and medication administration records		
Education	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Instruct patients diagnosed with HIT to communicate this to all healthcare providers	• Give patients and caregivers verbal and written information at 8th grade reading level or below, preferably in their language: o on proper dietary methods and their effect on therapy goals o how their therapy is monitored with changes in dose based on lab results and adherence to prescribed treatment o instructions on how to manage dose changes safely at home when existing tablet strength differs from a new dose o signs and symptoms of bleeding (e.g. bleeding gums) or thromboembolic complications o drug and herbal interactions. Ensure patients/caregivers understand that warfarin and Coumadin are the same drug o Ensure the patient	• Have patients/caregivers demonstrate proficiency if they are to self administer at home • Use videos, pamphlets, and other facility approved tools to complement one on one education • Instruct patients diagnosed with HIT to communicate this to all healthcare providers

		understands importance of adherence with anticoagulation dosing • Prior to discharge, stress the importance of follow up appointments. Facilitate a confirmed appointment with the lab, physician or anticoagulation clinic	
	Common considerations • Consider initial training and baseline competency evaluation for all practitioners who prescribe, dispense and/or monitor therapy (including physicians, nursing, pharmacy and dieticians) • Include anticoagulants on list of High Alert meds and educate staff on risk reduction strategies that are employed to improve safety • Share information about error-prone situations and errors within and outside the facility with practitioners on an ongoing basis • For inpatients, provide education about antithrombotics at initiation of therapy; aim to provide most of the information about after discharge therapy well before discharge		
Monitoring	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Monitor complete blood counts at routine intervals • Obtain an aPTT or factor Xa level between 6-8 hrs after initiation of heparin therapy (unless bleeding) • Modify dosing protocols and nomograms if lab changes are made that impact test values (e.g. reagents, testing methods). • Check and recalibrate point of care and monitoring devices when new lots of reagent are received	• Draw blood specimens at the same time each morning so results are available before warfarin doses are prescribed • If the patient is placed on NPO status, contact the prescriber for new anticoagulation orders as appropriate • Use a protocol to guide the reversal of supra therapeutic INR when indicated. **Oral** phytonadione preferred unless rapid reduction is required. • Ensure a process is in place to notify the food and nutrition department when patients are on warfarin therapy • If IV Vitamin K is required, dilute in at least 50 ml of solution, and administer over 30-60 min. Avoid IM administration of Vitamin K	• Obtain baseline serum creatinine, hemoglobin, hematocrit and platelet count are available prior to initiating therapy • Monitor platelet counts at routine intervals (e.g. every 3 days) for the first 2 weeks of therapy • Adjust dose for renal impairment and extremes of body weight as specified by approved protocols
	Common Considerations • Implement a protocol or guideline for monitoring and/or discontinuing therapy prior to invasive procedures • Include alerts on pharmacy order entry screens, automated dispensing cabinets, protocols/pathways to review medications the patient has received in the last 24hrs (including in ED) to ensure that an adequate time has lapsed between doses • Ensure that practitioners have easy access to inpatient (and preferably applicable outpatient) lab results to guide therapy		

	• Report critical values to the responsible caregiver within the facility identified time frame • If platelet counts decline to less than 100,000/mm3 or less than 50% of baseline, ensure there is a mechanism in place for heparin-induced thrombocytopenia (HIT) evaluation, and discontinue of all sources of heparin including flushes and heparin coated instruments • Enhance detection of potential adverse events by interfacing pharmacy and lab systems and incorporating alerts to the pharmacy system for selected values of lab tests (e.g. aPTT greater than 100 sec, platelet count less than 100,000/mm^3, facility defined value of elevated INR) • Monitor patients for fall risk and notify physician immediately post fall

Other	Heparin	Warfarin	Low Molecular Weight Heparin
	• Consider inpatient pharmacy managed anticoagulation services • Use saline flushes (not heparin flushes) for peripheral venous access catheters • When appropriate, discontinue heparin 4 hours before surgery	• Consider inpatient and outpatient pharmacy managed anticoagulation services • When appropriate 5 days prior to surgery or procedures. For patients at high risk for VTE, consider bridge therapy with low molecular weight ~~LMWH [RJ3] or~~ heparin (LMWH).	• Consider inpatient pharmacy managed anticoagulation services • Implement a protocol or guideline for safely managing the care and removal of epidural catheters placed during regional anesthesia when LMW heparin has been administered for surgical prophylaxis • When appropriate, administer last dose 24 hours prior to surgery and give ½ total daily dose for last pre-operative dose.

Transitional Care: Discharge Planning	Heparin	Warfarin	Low Molecular Weight Heparin
	Common Considerations 1. Provide education on the importance of vigilant adherence with anticoagulation therapy 2. Educate patients to be mindful of brand to brand variation resulting in differences in bioavailability when refilling prescriptions for warfarin 3. Facilitate a confirmed appointment with the lab, physician and/or anticoagulation clinic prior to discharge from the hospital. Stress the importance of making and keeping follow up appointments. 4. Prior to discharge, collaborate with case managers and social workers to identify and address barriers for adherence to medication therapy e.g. insurance coverage, prescription affordability, access and transportation for physician appointments, support in post discharge setting 5. Collaborate with long term care providers and community based organizations who can provide follow up visits or phone calls to encourage medication adherence 6. See Resource Tools section for **WARFARIN DOSE REMINDER CHART**		

References	1. The Joint Commission Accreditation Program: Hospital National Patient Safety Goals. http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals 2. Fanikos J, et. al. Medication errors associated with anticoagulant therapy in the hospital. *Am J Cardiol* Aug 15 2004;94(4):532-5. 3. Winterstein AG, et. al. Identifying clinically significant preventable adverse drug events through a hospital's database of adverse drug reaction reports. *Am J Health Syst Pharm* Sep 15 2002;59(18):1742-9. 4. Errors Involving Drug Products Used to Treat Cardiovascular Diseases: Part III. USP *CAPSLink Newsletter*. May 2005. http://www.usp.org/pdf/EN/patientSafety/capsLink2005-05-01.pdf. 5. Hicks RW, Becker SC, Cousins DD. MEDMARXR data report. A report on the relationship of drug names and medication errors in response to the Institute of Medicine's call for action. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia;2008. 6. Hicks RW, Becker SC, Cousins DD. MEDMARXR data report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998-2005. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia; 2006. 7. Santell JP, Hicks RW, Cousins DD. MEDMARXR data report: A Chartbook of 2000-2004 Findings from Intensive Care Units and Radiological Services.Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia; 2005. 8. Adverse events in Hospitals OIG report http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf
Resource tools	1. **ISMP Medication Safety Self Assessment for Antithrombotic Therapy in** Hospitals http://www.ismp.org/selfassessments/asa2006/Intro.asp 2. **ISMP - Failure Mode and Effects Analysis for Anticoagulants** http://www.ismp.org/Tools/FMEAofAnticoagulants.pdf 3. **The Joint Commission Sentinel Event Alert**, **Issue 41: Preventing errors relating to commonly used anticoagulants** http://www.jointcommission.org/ 4. **ASHP Anticoagulation Resource Center http://www.ashp.org/anticoagulation** 5. **Anticoagulant Toolkit Developed by Purdue University PharmaTAP in collaboration with the Indiana Patient Safety Center (IPSC), Indiana Hospital Association (IHA) and VHA Central, this toolkit aims to reduce adverse drug events associated with high-alert medications.** 6**. LA County - Best Practice Recommendations Guidelines for the Use of Concentrated Heparin** 7. **Warfarin Dose Reminder Chart** http://www.aafp.org/fpm/2005/0500/p77.html 8. **AHRQ Guide to Using Warfarin Safely**: http://www.ahrq.gov/consumer/btpills.htm#booklet

Reducing Controlled Substances Diversion in Hospitals

California Hospital Association Medication Safety Collaborative Committee
www.calhospital.org/medication-safety-committee

Introduction
The attached road map is intended for acute care settings as a plan to help navigate controlled substance diversion prevention goals. The document provides a recommended framework to coordinate the needed resources and technology for an optimal diversion prevention program. Actions taken pursuant to this framework should be reflected in a standardized set of processes within the organization to ensure that they are maintained.

Some actions are required by law or regulation (and marked with ►) while some may be good recommendations to have in place. Ultimately, each organization is responsible for developing a diversion prevention plan that protects patients from impaired care providers (i.e., to the extent it affects a provider's ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of controlled substances within the organization).

Credits
The committee thanks the Minnesota Department of Health and Minnesota Hospital Association and the Minnesota Drug Diversion Coalition[1] for developing the original document. With their permission, this document builds upon their work and includes California-specific guidance.

Committee Representation
The committee includes representatives from:

- Association of California Nurse Leaders
- California Association of Health Facilities
- California Board of Pharmacy
- California Department of Public Health
- California Hospital Association member hospitals
- California Hospital Patient Safety Organization
- California Medical Association
- California Society of Health System Pharmacists

[1] Minnesota Coalition members are listed at www.health.state.mn.us/patientsafety/drugdiversion/.

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, and others.

Component	Specific Action(s)	Self-Assessment Checklist
Safety Teams / Organizational Structure	1. Organization defines Controlled Substance (CS) Diversion Prevention Program.	1a. The organization has an interdisciplinary team involved in developing and overseeing the CS Diversion Prevention Program. 1b. The CS Diversion Prevention Program includes prevention, detection and investigation. 1c. The CS Diversion Prevention Program is reviewed by the team and updated at least annually. 1d. CS Diversion Prevention Program champions have been identified and have designated clear roles with expectations from the following areas: • Medical Staff • Pharmacy • Nursing • Security • Human Resources • Patient Safety/Risk Management/Compliance • Administration • Legal (as necessary) • Communications (as necessary)
	2. An organizational structure is in place that supports an effective CS Diversion Prevention Program.	2a. The organization has a designated coordinator(s) for the CS Diversion Prevention Program. 2b. The coordinator(s) has dedicated time to serve in this coordination function. 2c. The organization has a team prepared to respond to suspected CS diversion situations. 2d. The organization has and regularly reviews policies and procedures addressing all aspects of the CS use processes. 2e. The organization regularly reviews policies and procedures to assure compliance with state and federal laws.

	3. Organization proactively collaborates with local law enforcement.	3a. The organization (e.g. security) has engaged local law enforcement (e.g. county sheriff, chief of police) to discuss the CS Diversion Prevention Program and establish a communication strategy (including public) prior to CS diversion situations.
	4. Organization fulfills all reporting requirements for diversion or loss of CS.	4a. ►The owner reports to the California Board of Pharmacy within thirty days of discovery of any CS losses, including their amounts and strengths. 4b. ►The DEA registrant or their designee reports any CS theft or significant loss to the DEA within one business day of discovery. 4c. ►The organization follows other applicable requirements. For example, Medicare Conditions of Participation states: "Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate."
Access to Information / Accurate Reporting / Monitoring / Surveillance / Detection System	1. Organization reviews and audits relevant data that could indicate potential CS diversion.	1a. ►The organization has a process to generate controlled substance data on a minimum monthly basis such as controlled substance surveillance reports, high user report, CS use through reports/log-sheets and CS "Disposition and Inventory" sheets.
	2. Organization tracks and reviews measures recommended by Medication Safety Committee or other designated groups reporting directly to a Medical Staff Committee.	2a. ►The organization has a process in place to review and analyze CS data on a regular basis. 2b. ►The organization shares findings from the data analysis on a regular basis. 2c. ►There is a process in place to activate a response team that includes a patient care manager, pharmacy, Human Resources (HR) and security when diversion is suspected. 2d. ►The organization has a process in place to contact law enforcement when diversion or theft is suspected.
Facility Expectations	1. Organization communicates the expectation that staff "speak up" when they become aware of an issue related to CS diversion.	1a. ►Senior leadership has clearly communicated that all staff are to speak up and will be supported in speaking up when they become aware of possible diversion. 1b. ►The hospital treats such information as confidential and takes all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information.
	2. Organization establishes full disclosure policy.	2a. ►The organization has a clearly defined full disclosure policy and process to communicate to patients/families who are

		affected by CS prevention diversion.
	3. The organization's HR practices support an effective organization-wide CS Diversion Prevention Program.	3a. The organization has established and communicated ways for staff to speak up anonymously (e.g. hot line, paper or electronic submission). 3b. The organization has a process in place to remove an impaired caregiver from patient care. 3c. ►The organization conducts pre-employment background checks for Licensed Independent Practitioners (LIPs) and employees. 3d. A log of staff photographs and signatures are maintained as appropriate. 3e. The organization has a process to manage employee access to CS in a timely fashion when terminated or transferred. 3f. The organization has developed a "for cause" policy for drug testing.
	4. Organization does not allow sharing of pass codes.	4a. ►The organization establishes and enforces a policy of not sharing pass codes such as electronic medical record (EMR), Automated Distribution Machine[2] (ADM) and pharmacy door codes.
Education Staff (and Patients)	1. Organization has in place an effective and comprehensive training and education program for all staff on CS diversion prevention.	1a. The CS Diversion Prevention Program team has attended CS diversion prevention and statutory requirements training (e.g. National Association of Drug Diversion Investigators [NADDI], professional associations, licensing boards, state, local and federal law enforcement). 1b. Expectations and supporting education have been incorporated into training for all new staff and LIPs. 1c. Expectations and training include, at a minimum, providing awareness training to know the signs of diversion. 1d. Resources are available to support employees and LIPs, e.g. Employee Assistance Program (EAP) and Health Professional Services Program (HPSP). 1e. The facility requires training on CS policies and

[2] ADM is a robotic or computerized device in which the device components are designed to distribute drugs in a licensed health care facility. A pharmacist is responsible for the drug entry into the patient's profile, final review and distribution of the patient medications.

		procedures prior to authorizing staff to have CS access. 1f. The facility provides ongoing staff education at least annually to promote safe handling of CS and CS diversion awareness. 1g. The organization provides patient education on safe medication handling, including potential for diversion.
Storage and Security	1. Organization stores CS and other high-risk items securely, in all settings and circumstances.	1a. ►The organization has a process in place for securing CS (as described in section 2 below) for every setting and circumstance.
	2. Organization has a process in place for securing CS.	2a. Never leave CS unattended. 2b. CS are stored in a locked location (e.g., ADM, ℂ[3] vault or locked cabinet/drawer/box) at all times. 2c. ADM-managed CS are stored in a location with one CS-type access. For example, users cannot have access to a second type of CS when accessing the intended CS. 2d. Access to CS storage areas is limited to authorized staff. 2e. Non-ADM CS cabinets are secured with a locking device. 2f. ADM and non-ADM access is removed promptly for terminated employees. 2g. Patient-specific CS infusions (e.g., PCA[4], epidural, and continuous infusions) are enclosed in a locked box. 2h. Keys are controlled and accounted for. 2i. Prescription pads and paper are stored in ADM, locked location or under control of an LIP. 2j. Facility designates authorized individuals to order prescription pads/paper direct from the vendor for the operating unit or patient care area. 2k. Electronic and non-electronic prescriptions comply with state and federal requirements. 2l. CS brought in by a patient that cannot be returned home are inventoried by two authorized health care staff and stored in

[3] Schedule II controlled substance.
[4] Patient-controlled analgesia.

		a locked, limited access area. 2m. CS brought to the hospital for use by the patient (i.e., Patient's Own Medication) is securely stored and accounted for during the hospitalization as well as upon the patient's discharge. It is recommended to have a process in place where patients are contacted after discharge to pick up their CS in storage. CS remaining in the pharmacy and not picked up by the patient after discharge is to be destroyed per the hospital's policies. Preferably, the patient is contacted and asked to pick up their CS.
	3. Organization uses camera surveillance in high-risk areas as appropriate.	3a. Camera surveillance is used in primary CS pharmacy storage area (e.g. narcotics vault).
Procurement	1. Organization effectively and safely handles procurement in the hospital pharmacy.	The organization has a process in place for procuring CS that includes: 1a. ►If the hospital utilizes the controlled substance ordering system (CSOS)[5], then each user must have their own password. Passwords cannot be shared. 1b. ►Excluding radiopharmaceuticals[6], the hospital pharmacy procures all CS. 1c. ►Individuals authorized to order ©-© are limited to the DEA registrant and authorized individuals. DEA 222 forms are secured and accessible only to these individuals. 1d. ►Individuals other than the DEA registrant authorized to order CS must have a power of attorney on file to execute the DEA 222 forms as per 21CFR1305.05. 1e. The persons authorized to order CS are not the same persons who receive the CS. 1f. ►All invoices received are signed and have the date when the medications were received. 1g. ►Only a licensed pharmacist or authorized receiving person signs for the controlled substance delivery. 1h. ►If CS are delivered to hospital central receiving, an

[5] An electronic DEA 222 program. DEA's CSOS is an encrypted electronic controlled substance ordering system between a wholesaler and the DEA licensee's authorized user. The DEA's CSOS is the preferred method for © CS procurement.

[6] Currently, there is one © radiopharmaceutical: DaTscan™ (Iodine I-123 ioflupane), a cocaine analog indicated for striatal dopamine transporter visualization using SPECT brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes.

		authorized receiving person signs for the delivery, central receiving transfers CS to the pharmacy within one working day following receipt by the hospital, and then the pharmacist immediately inventories the CS. 1i. ►If CS are delivered to the pharmacy when the pharmacy is closed and pharmacist unavailable, then storage of this delivery must comply with the requirements of California Business and Professions Code 4059.5(f).[7] 1j. ►Any discrepancy between the receipt and the type or quantity of CS actually received is reported to the delivering wholesaler or manufacturer by the next business day after delivery.
Prescribing	1. The organization's ordering/ prescribing practices minimize the risk of CS diversion.	1a. ►CS are prescribed only by licensed authorized prescribers with a DEA registration or institutionally assigned DEA suffix. 1b. ►A valid order from an authorized prescriber exists for all CS administered. 1c. ►CS are not prescribed by an authorized prescriber for him/herself or immediate family members. 1d. Patient-specific CS orders are generated by electronic systems with controlled access except in emergencies in accordance with applicable federal and state laws and rules. 1e. Range orders for CS are minimized.
Preparation & Dispensing	1. The organization's preparation and dispensing practices minimize the risk of CS diversion.	1a. ►Tamper-evident packaging is utilized for CS prepared by pharmacy.[8] 1b. ►CS transported via pneumatic tube are sent via secured transaction. 1c. ►There must be a co-signature for delivery of CS to non-ADM areas. Document chain of custody. 1d. CS are dispensed in single-unit-dose packaging.[9] 1e. Secure, locked, non-transparent medication delivery

[7] See appendix for B&P 4059.5(f) text.
[8] Tamper-evident packaging means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.
[9] Single-unit-dose packaging means a single-unit container for articles intended for administration as a single dose, direct from the container.

		carts/containers are used to deliver CS and accessible only by authorized individuals. 1f. ADMs are utilized in patient care areas for the distribution of CS and are interfaced with the electronic patient profile to limit access only to medications ordered for a specific patient. 1g. Reconciliation is performed on ADM CS dispense transactions for temporary patients to ensure that the CS went to an actual patient.[10] 1h. Bar code scanning is utilized when replenishing ADMs. 1i. A blind count process is used for narcotic vault and ADM distributed CS.[11] 1j. The number of CS on override status in profile ADMs is minimized (e.g. one-time injectables for emergencies only). 1k. Biometric-ID technology is used instead of passwords. If passwords are used, passwords expire on a regular interval.[12] 1l. ADM downtime procedures must be defined to maintain the control, documentation and accountability of CS.
Administration	1. The organization's CS administration practices minimize the risk of CS diversion.	1a. There is a defined time between CS retrieval from storage areas and time of administration and documentation (e.g. within 30 minutes of ADM removal or within 30 minutes of the end of the procedure). 1b. The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered. 1c. ►Only health care providers operating within the scope of their practice may administer CS. 1d. ►CS are removed for one patient at a time from ADMs and/or locked storage areas.

[10] For example, a temporary patient ID may have been used when CS are needed in an emergency and the admission information is not yet transferred to the ADM.

[11] Blind count is a process utilized with ADM when refilling a controlled substance into the drug's individual pocket. The ADM requests the person replenishing the controlled substance to the ADM to count the quantity in the machine before adding the refill. The count in the pocket is not presented to the person replenishing the CS. If the count entered by the person replenishing the ADM is correct, the ADM will allow the refill of the controlled substance.

[12] For example, the ISMP recommends changing passwords every 90 days or less if biometric authentication is not also in use (http://www.ismp.org/selfassessments/ADC/Survey.pdf).

		1e. ►The individual retrieving CS from ADM/locked storage area/box is also the person that administers the medication. The organization defines exceptions (e.g. emergencies) and has a policy/process in place to assure chain of custody. 1f. ►All CS are drawn up into syringes that, if not immediately administered, are labeled per institutional policy.
Handling Waste	1. The organization's "waste" handling practices maintain chain of custody to minimize the risk for CS diversion.	Pharmacy: 1a. CS waste from Compounded sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed. Areas outside Pharmacy: 1b. ►Unusable product[13] (UP) CS are to be immediately wasted and witnessed by health care professionals per specific hospital procedures. 1c. All Potentially Reusable Product[14] (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue. 1d. The organization has identified the high-risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs. 1e. The organization has identified specific high-risk CS medications (e.g., fentanyl) that are randomly assayed. 1f. The organization has a process to randomly obtain and assay UP CS. For random assays, the UP CS would not be subject to immediate witnessed waste.
	2. The organization's practices for handling unused CS, empty CS containers or CS returned to pharmacy minimize the risk of diversion.	**Wasting of UP CS:** 2a. ►Approved methods for wasting a CS are defined per federal, state and county laws and regulations. 2b. ►The wasting of all CS requires an independent licensed witness and must be documented in the ADM or via proof of use form, except when UP CS are returned to pharmacy for assay. 2c. ►An individual witnessing CS wasting verifies the volume/amount being wasted matches the documentation and physically watches the medication being wasted per policy.

[13] UP: Any medication that may not be used for a patient due to either the integrity no longer being intact or the medication has exceed its expiration/ beyond use date.

[14] PRP: Medications that have been issued to a patient, which have not been used, the integrity of such packaging remains intact and expiration/beyond use date allow the medication to be re-issued to another patient.

		2d. ►Empty containers of CS (e.g., vials) are discarded in limited access waste containers. 2e. ►Waste containers with trace UP CS are secured to prevent tampering. 2f. ►The pharmacy accounts for manufacturer overfill in injectable containers. All overfill amounts are captured, verified, documented, and wasted accordingly. Controlled substance overfill should be considered unusable product (UP). **PRP Returns:** 2g. PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket. 2h. ►All PRP CS returns to pharmacy require chain of custody documentation in the patient care area and in pharmacy **Waste or Reverse Distribution:** 2i. ►DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company. 2j. Expired CS that are quarantined for reverse distribution are properly accounted by way of a log or inventory list. The items sent back via reverse distribution could be reconciled with the reverse distribution log of CS.
Monitoring of CS and Process if Diversion is Suspected	1. Organization removes access to CS if diversion is suspected.	1a. ►All personnel actions (e.g. suspension, terminations and resignations) are promptly communicated to pharmacy so access to CS can be removed. 1b. ►If the hospital becomes aware of an arrest of an employee for illicit use of CS, the hospital immediately conducts its own investigation. The organization assesses whether to suspend, transfer, terminate or take other action (e.g., remove access to CS) against the employee.
	2. Organization regularly monitors CS through inventory, reports and audits.	2a. CS purchase invoices are compared to CS orders and receipt into the pharmacy's perpetual inventory. Any CS purchases outside of the pharmacy department are tracked. Since the invoice-receipt pair may both be removed with CS diversion, invoices also are reconciled to statements or wholesale purchase history reports to detect missing invoices. 2b. Movement of CS throughout the hospital is tracked. For example, reports match narcotic vault transactions with receipt into ADM and/or paper inventory record with RN signature of

		receipt. 2c. ►CS within an ADM or narcotic vault are inventoried at least monthly. 2d. Non-automated CS storage areas are inventoried at each shift change. 2e. ADM reports are reviewed at least monthly by pharmacy or patient care managers as defined by the organization. Reports compare ADM activity with medication administration record. 2f. ADM CS activity is compared to peers with similar staffing responsibilities and FTE appointments. 2g. Transaction activity (e.g. inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns and waste) is compared to peers. 2h. Patient MAR: amount and quantity administered, is compared to what other caregivers administer on subsequent shifts (without patient change in condition). 2i. Non-ADM CS storage area record of use is compared with MAR (e.g. anesthesia record, sedation record, eMAR) to assure appropriate documentation of waste.
	3. A process is in place to resolve CS discrepancies.	3a. ►CS discrepancies are resolved upon discovery, no later than end of shift. Discrepancies that cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hours (e.g. metric: unresolved nursing unit CS discrepancies > 24 hours/total nursing unit CS discrepancies should be ≤8 percent). 3b. It is recommended that a pharmacist reconcile CS discrepancies in the ADMs. ►A pharmacist has responsibility for the discrepancy even when a technician performs these duties.
	4. Organization creates standard process to investigate potential diversion cases.	4a. ►There is a standard process in place to investigate potential diversion cases.

Selected Legal References[15]

Federal

21 Code of Federal Regulations Chapter II: Drug Enforcement Administration

Sec. 1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;
(2) The specific controlled substances lost;
(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
(5) Whether the specific controlled substances are likely candidates for diversion;
(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

Sec. 1301.90 Employee screening procedures.

It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:

Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission

[15] This is not a comprehensive listing of applicable laws and regulations.

of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

Sec. 1301.91 Employee responsibility to report drug diversion.

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

Sec. 1301.92 Illicit activities by employees.

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

Sec. 1301.93 Sources of information for employee checks.

DEA recommends that inquiries concerning employees' criminal records be made as follows:

Local inquiries. Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

DEA inquiries. Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

42 Code of Federal Regulations, State Operations Manual, Appendix A[16]

§482.25(a)(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs. A-0494

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.
- Facility policies and procedures should minimize scheduled drug diversion.

[16] Bulleted items are from the Interpretive Guidelines for that regulation.

§482.25(b) In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law. A-500

- Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals.
- The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

§482.25(b)(2)(i) All drugs and biologicals must be kept in a secure area and locked when appropriate. A-0502

- All controlled substances must be locked.

§482.25(b)(2)(ii) Drugs listed in Schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept within a secure area. A-0503

- All Schedule II, III, IV, and V drugs must be kept locked within a secure area. A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.

§482.25(b)(2)(iii) Only authorized personnel may have access to locked areas. A-504

- The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.
- The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored.

§482.25(b)(7) Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate. A-509

- Controlled drug losses are to be reported to appropriate authorities in accordance with State and Federal laws.

State of California

Business and Professions Code

4059.5

> (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.
>
> (b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
>
> (c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

4081(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept …

4332 Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

Health and Safety Code

11209. (a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.

Title 16, Division 17, California State Board of Pharmacy

§1714 Operational Standards and Security

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

§1715.6 Reporting Drug Loss

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

Title 22, Division 5, Licensing & Certification of Health Facilities…, Chapter 1, General Acute Care Hospitals

§70263 Pharmaceutical Services General Requirements

(c)(1) The [pharmacy and therapeutics] committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures.

(l) Medications shall not be left at the patient's bedside unless the prescriber so orders. Such bedside medications shall be kept in a cabinet, drawer or in possession of the patient. Drugs shall not be left at the bedside which are listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended. If the hospital permits bedside storage of medications, written policies and procedures shall be established for the dispensing, storage and records of use, of such medications.

(q)(10) Drugs maintained on the nursing unit shall be inspected at least monthly by a pharmacist. Any irregularities shall be reported to the director of nursing service and as required by hospital policy.

(q)(11)(A) Drugs listed in Schedules II, III, or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of two pharmacists or a pharmacist and a registered nurse employed by the hospital. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be in the patient's medical record or in a separate log. Such a log shall be retained for at least three years.

§ 70265 Pharmaceutical Service Staff

A pharmacist shall have overall responsibility for the pharmaceutical service. He shall be responsible for the procurement, storage and distribution of all drugs as well as the development, coordination, supervision and review of pharmaceutical services in the hospital.

§70269 Pharmaceutical Service Space

(b) All spaces and areas used for the storage of drugs shall be lockable and accessible to authorized personnel only.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee Guidelines

Insulin Recommended Safe Practice Guidelines

1215 K Street, Suite 800, Sacramento, CA 95814 • *Telephone:* 916.443.7401 • *Facsimile:* 916.552.7596 • www.calhospital.org

Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

TABLE OF CONTENTS

DRAFT DOCUMENT CHANGE LOG

VERSION	DATE	AUTHOR	CHANGES
0.1	8/20/14	Jillian Hacker	Updates and Revisions
1.0		Jillian Hacker	Final draft approved by committee

ANNUAL REVISION LOG

VERSION	REVIEW DATE	REVISIONS/CHANGES
2.0		
3.0		
4.0		
5.0		
6.0		

INTRODUCTION

Insulin therapy is required in a substantial percentage of hospitalized patients. Insulin (all forms) is a high-alert medication that is commonly associated with adverse drug events in hospitalized patients.

The intent of these guidelines is to summarize the insulin safe practices that have been shown to reduce the risk of preventable harm when insulin is used to treat hospitalized patients. Hospitals should use these guidelines to perform a gap analysis to evaluate their current practices and then use the results to develop a plan to improve insulin safety in their organization. These guidelines are not fixed protocols that must be followed, nor are they entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results. Working through the Pharmacy and Therapeutics Committee, each hospital should carefully review the guidelines and adopt and implement the safe practices in a manner that is appropriate for their institution.

Information contained in this tool should not be construed as legal advice or used to resolve legal problems by health care facilities or practitioners without first consulting legal counsel.

COMMITTEE REPRESENTATION

The committee includes nurse, physician, and pharmacist representatives from:

- Association of California Nurse Leaders (ACNL)
- California Association of Health Facilities (CAHF)
- California Board of Pharmacy
- California Department of Public Health (CDPH)
- California Hospital Association member hospitals
- California Hospital Patient Safety Organization (CHPSO)
- California Medical Association
- California Society of Health-System Pharmacists (CSHP)

Actions to Consider to Increase Medication Safety

Pharmacy Purchasing 1.1

- Consider using visual clues, such as affixing a photo to the bin of the insulin that should be stored there, to help ensure the correct vial is returned to the correct bin.
- Do not store different insulin types, such as U-500 Insulin products, and brands in the same bin with a divider; instead, store different insulin types and brands in separate bins labeled accordingly.
- Use both brand and generic names on pharmacy bin labels.
- Use ISMP recommended Tall Man lettering on pharmacy bin labels – for example, HumaLOG, HumuLIN, NovoLIN, NovoLOG.

Unit Storage of Medications

In Pharmacy 2.1

- Consider using visual clues, such as affixing a photo to the bin of the insulin that should be stored there, to help ensure the correct vial is returned to the correct bin.
- Store different insulin types, strengths and brands in separate bins labeled accordingly.
- Do not keep insulin vials on top of counters or within pharmacy compounding hoods, as insulin could be confused with heparin, which is also measured in units. Put all insulin vials back in the appropriate storage area immediately after use2.
- Insulin syringes should be stored separately from tuberculin syringes.
- If U-500 insulin is used in a facility, then store in a locked box labeled U-500 CONCENTRATED Insulin to prevent mix-up.

Inpatient Care Area 2.2

- Consider If possible, inpatient pharmacy prepares patient-specific syringes.
- DO NOT use multi-dose vials for more than one patient as according to Center for Disease Control and Prevention (CDC) guidelines.
- All multi-dose insulin products should have proper patient labeling and corresponding expiration dates.
- If insulin products are stored in automatic dispensing cabinets (ADCs), they should be placed in individual pockets (single-medication access) to prevent errors in retrieval. All insulin types should be segregated (both ADC and medication room storage).
- Insulin should not be stored at the patient's bedside. When insulin is needed, the insulin should be obtained by a nurse and provided to the patient for observed administration, then returned to a secure area for proper storage.
- Insulin syringes should be stored separately from tuberculin syringes.

- Insulin used to refill insulin pumps should not be stored in the medication room or ADC. Instead, pharmacy should deliver directly to nurse any insulin used for the refilling of cartridges in an insulin pump.
- Pharmacy personnel should store all insulin medications in patient care areas without the original carton (remove packaging container from actual pen/vial).
- Utilize physical and/or electronic alerts to care providers that insulin pens should not be used for multiple patients. Utilize reminders that multiple dose vials are not to be used for multiple patients.

Prescribing

- Avoid complicated and error-prone insulin infusion protocols and limit the number of insulin protocols to minimize confusion.
- Ensure an alternate source of glucose is ordered when NPO/reduction or discontinuation of enteral/parenteral feeding is ordered, especially for patients on an insulin drip or a long-acting insulin to prevent hypoglycemia.
- Always review and evaluate preprinted insulin order sets and insulin infusion protocols by the Pharmacy and Therapeutics (P&T) committee at least annually.
- Nursing staff should provide feedback to ensure uniform understanding and accurate execution of orders/protocols.
- Set criteria for blood glucose levels with upper and lower limits upon which the physician should be notified.
- Ensure protocol for managing hypoglycemia is available which includes criteria for notifying physician.
- Encourage the use of scheduled subcutaneous insulin order sets with basal, nutritional, and correction components; this glycemic management is the preferred method for achieving and maintaining glucose control in non-critically ill patients3.
- Bedside capillary point of care (POC) testing should be ordered for patients receiving insulin. Schedules should be based on patient's nutritional status:
    - Before meals and at bedtime (AC&HS) for patients who are eating or receiving bolus enteral nutrition,
    - Every 4 to 6 hours for patients who are NPO or receiving continuous enteral/parenteral nutrition.
    - Consider periodic late night blood glucose (BG) testing (e.g. 0200) to monitor for nocturnal hypoglycemia.

Pharmacy Order Entry & Dispensing

- DO NOT use multi-dose vials for more than one patient as according to CDC guidelines.
- Ensure U-500 unit vials remain in the inpatient pharmacy.
- Pharmacy should dispense patient-specific individual doses of U-500, one dose at a time. As there are no U-500 insulin syringes, to avoid confusion, each dose should be dispensed in a tuberculin syringe with the total dose being expressed in both units and volume (i.e. , 200 units [0.4 ml]).4
- All insulin infusions should be standardized and prepared within the inpatient pharmacy when possible.
- Ensure pharmacist competency on differentiating between different insulin types and duration of action.
- If doses of insulin are included on the label, they should be listed as “units” or “units = ml”, but not “ml” alone.
- If patient’s own insulin is allowed, independent verification of the product by a pharmacist or prescriber must be performed and documented.
- Pharmacy information system should include appropriate alerts and decision support to reduce risk of input errors. This means the pharmacist should have real-time access to the laboratory information system.
- Pharmacy technicians involved in distribution and preparation of insulin products should be educated regarding the high-alert status of insulin, appropriate safety practices and consequences of error. Double checks will be utilized when possible.
- Pharmacy should establish standard safety-focused practice for pharmacist review of insulin orders, which includes all preparations of IV products for injection.
- Pharmacy-generated medical administration records (MARs) should include appropriate warnings and alerts related to insulin therapy. When a patient is prescribed more than one type of insulin, pharmacy-generated MARs should clearly discriminate between insulin types.
- Pharmacy-generated MARs should include specific administration times or time prior to or after meals

Nursing Administration

- **DO** Require a second independent check for all insulin administration, second independent check includes verification of blood glucose result upon which dosing is based.
- Single-use, auto-disabling fingerstick devices must be utilized in the hospital setting when obtaining blood sample. The glucometer should be cleaned and disinfected after every use, per manufacturer’s instructions, to prevent carry-over of blood and infectious agents3.
- Ensure an alternate source of glucose is ordered when NPO/reduction or discontinuation of enteral/parenteral feeding is ordered, especially for patients on an insulin drip or a long-acting insulin, to prevent hypoglycemia.

Monitoring

Blood Glucose Monitoring While on Non-Infusion Insulin 6:1

- All patients with diabetes should have an order for blood glucose monitoring, with the results available to all members of the healthcare team.
- Patients with known diabetes should have a hemoglobin A1c level drawn if a recent level is unavailable.
- All patients with high blood sugar values on admission, receiving enteral/parenteral nutrition, or receiving therapies associated with hyperglycemia (e.g. corticosteroids), should have their blood glucose monitored independent of diabetes history.
- Establish blood glucose goals for critically ill and non-critically ill patients using current recommended guidelines (e.g., American Association of Clinical Endocrinologists)
- Bedside capillary point of care (POC) testing schedules should be based on patient's nutritional status:
- Before meals and at bedtime (AC&HS) for patients who are eating or receiving bolus enteral nutrition.
- Every 4 to 6 hours for patients who are NPO or receiving continuous enteral/parenteral nutrition.
- Consider periodic late night BG testing (e.g. 0200) to monitor for nocturnal hypoglycemia.
- POC results should be documented in the medical record with corresponding insulin administration times.
- Monitor the patient's nutritional intake. If less than 100% of the meal is consumed, you may need to adjust the prandial insulin dose per institution's protocol.

Blood Glucose Monitoring Before Starting Insulin Infusion 6:2

- Ensure blood glucose assessment is done immediately prior to beginning insulin infusion.
- If the glucose measurement is above a predefined level, initiate the insulin protocol as ordered.

Prior to Initiation of Continuous Infusion Insulin 6:3

- Discontinue all previous insulin and any other oral hypoglycemics.
- Optimal glucose control should be achieved in patients who are NPO and receiving a continuous glucose source (continuous tube feeding, parenteral nutrition, or dextrose containing IV Fluids).
- Use with caution in patients receiving oral feedings or bolus tube feedings.
- Use with caution in patients who are pregnant. Consider an Endocrinology or Perinatology consult before instituting this protocol in pregnancy.

Monitoring Considerations While on Insulin Infusion 6:4

Call the physician when:

- Per hospital infusion protocols, patients blood glucose to be monitored routinely and as needed.
- Other orders for insulin (SubQ, IV or in parenteral nutrition) are received without discontinuing this order set.

- Tube feedings, dextrose containing IV Fluids, or parenteral nutrition are started, stopped, interrupted or changed.
- Notify physician when blood glucose levels fall outside predefined upper and lower limits.

Patients with diabetes or hyperglycemia who are eating should be on a consistent-carbohydrate diet, and glucose monitoring should be ordered before each meal and at bedtime. Typically, oral agents should be discontinued during acute illness unless it is a very brief hospitalization. Oral agents can be restarted as patients approach discharge or transfer to a non-acute setting[5].

It should be emphasized that using a correction scale insulin regimen, also known as "sliding scale insulin," alone is not appropriate to treat sustained hyperglycemia (> 140 mg/dl)[6].

Other Considerations

- Develop policies and procedures on safe and appropriate use of patient's own insulin pump (allow/disallow) and insulin and ensure they include risk assessment, proper communication and documentation on MAR of self-administered insulin doses.
- Ensure insulin protocol compliance by conducting periodic retrospective record review to assess adherence to insulin protocol and blood sugar monitoring requirements.
- QA program to track and trend hypoglycemic incidents (e.g. D50, glucagon, or oral glucose use) in patients receiving insulin to drive performance improvement efforts.

REFERENCES

1) Reports of insulin pen sharing between patients have continued despite numerous warnings by the ISMP, CDC, and FDA. ISMP has stated that the safe use of insulin pens in the inpatient setting can "only be assured through timely education and ongoing monitoring" (ISMP Medication Safety Alert Newsletter 2012; 17 (1): 1-4).
2) ISMP Med Safety Alert 2002 May 1, 2002
3) CDC Safe Injection Practice Guidelines http://oneandonlycampaign.org/content/what-are-they-why-follow-them Accessed July 2, 2014.
4) ISMP Medication Safety Alert Newsletter 2013; 18 (22): 1-2.
5) American Association of Clinical Endocrinologists' Comprehensive Diabetes Management Algorithm 2013 Consensus Statement. 2013; 19 (supp 2): 1-48
6) http://clinical.diabetesjournals.org/content/29/1/3.full / http://clinical.diabetesjournals.org/content/29/1/3.full#sec-7

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee

Emergency Department Medication Management Safety Tool

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Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

TABLE OF CONTENTS

REVISION LOG

VERSION	DATE	AUTHOR	CHANGES
0.1	November 2013	Med-ER Workgroup	Initial Draft
1.0	April 2014	Med-ER Workgroup	Final draft approved by committee

INTRODUCTION

More and more, healthcare professionals and regulators are turning their focus to mitigating risk for medication management in the emergency department. Reducing opportunities for medication error and increasing the opportunities for a safe medication management environment represents a prime opportunity to improve the healthcare delivery system – and helping your organization do so is the goal of this tool.

When using this tool, consider using it as a gap analysis tool that sets out two benchmarks:

- **Recommended** which is considered a minimal level of care which all institutions should strive to meet as a baseline level of care, and

- **Ideal** which is an optimal level of care to strive toward, recognizing that it may or may not be fully attainable at a given hospital.

If your institution does not meet the "recommended" level, consider conducting analysis to determine pathways for meeting this benchmark. However, once the **recommended** level is obtained, consider ways to then move toward the **ideal** benchmark level of care. The **Medication Management Elements** are intended to assist with development of a formal plan to minimize medication related events described in Health and Safety Code Section 1339.63, and address elements routinely used in CDPH MERP surveys.

This tool has been reviewed by the California Hospital Association's Medication Safety Committee, and is intended for hospital and health care providers for consideration as they evaluate current practices and develop specific programs. **This tool is not to be viewed as fixed protocol that must be followed, nor is it entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results.** The CHA's Medication Safety Committee is a voluntary collaborative supported by the CHA, and is comprised of CHA member hospitals and non-hospital representatives.

Information contained in this tool should not be construed as legal advice or used to resolve legal problems by health care facilities or practitioners without first consulting legal counsel. It is important to note that facilities must adhere to all relevant state and federal regulations and statutes governing operations and practice.

COMMITTEE REPRESENTATION

The Medication Safety Committee includes nurse, physician, and pharmacist representatives.

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
PRESCRIBING	**Utilize:** • Order sets • Protocols • Guidelines **Verify:** • Allergy info	**CPOE:** • Allergy verification hard stop • Weight-based dosing for pediatric populations *(Includes clinical decision support tools)*	**CPOE:** • Allergy verification hard stop • Weight-based dosing for pediatric populations *(Includes clinical decision support tools)*	**CPOE - Includes, But Not Limited To:** • Allergy verification hard stop • Weight-based dosing for pediatric populations • Standardized order sets, best practice drug information hyperlinks and best practice physician alerts *(Includes clinical decision support tools)*	**CPOE - Includes, But Not Limited To:** • Allergy verification hard stop • Weight-based dosing for pediatric populations • Standardized order sets, best practice drug information hyperlinks and best practice physician alerts	**CPOE - Includes, But Not Limited To:** • Allergy verification hard stop • Weight-based dosing for pediatric populations • Standardized order sets, best practice drug information hyperlinks and best practice physician alerts *(Includes clinical decision support tools)*
RX ORDER COMMUNICATION	**Utilize:** • Order sets • Protocols • Guidelines **Verify:** • Allergy info	**CPOE:** • Allergy verification hard stop • Weight-based dosing for pediatric populations *(Includes clinical decision support tools)*	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE
LABELING	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings
PACKAGING	**Liquids (or Oral IV):** • Smallest Size Possible • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded	**Liquids (or Oral IV) :** • Unit Dose • Barcoded • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded	**Liquids (or Oral IV):** • Smallest Size Possible • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded	**Liquids (or Oral IV):** • Unit Dose • Barcoded **Oral Solids:** • Unit Dose • Barcoded **Injectables:** -Unit Dose -Barcoded -• Minimize # of IV Product Concentrations (utilize manufacturer pre-made IV products when possible)	**Liquids (or Oral IV):** • Smallest Size Possible • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded **Injectables:** -Unit Dose -Barcoded -• Minimize # of IV Product Concentrations (utilize manufacturer pre-made IV products when possible)	**Liquids (or Oral IV):** • Unit Dose • Barcoded • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded **Injectables:** -Unit Dose -Barcoded -• Minimize # of IV Product Concentrations (utilize manufacturer pre-made IV products when possible)

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
COMPOUNDING	**During Pharmacy Operating Hours:** • Utilize laminar flow hood • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours *(24 hours)*:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours *(24 hours)*:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present
Dispensing	**Utilize** automated dispensing machine **Prevent** after-hours use of pharmacy by stocking ADM with sufficient quantities of medications and enabling "non-profile" feature **Enable** ADM "profile" feature, and allow for either concurrent or retrospective review of medication overrides if resources and manpower allow for it and in consideration of HR-HA population needs **Enable** available alert features on ADM **Review** ADM content monthly for appropriateness *NOTE: See administration section for additional safeguards to use with these strategies*	**Utilize** automated dispensing machine **Enable** ADM "profile" feature, and allow for review of medication overrides **Enable** ADM "profile" feature, and allow for either concurrent or retrospective review of medication overrides if resources and manpower allow for it and in consideration of HR-HA population needs . **Review** ADM content monthly for appropriateness **Ensure** "on-call" pharmacist is available for emergency dispensing	**Utilize** automated dispensing machine **Enable** ADM "profile" feature, and allow for review of medication overrides **Enable** ADM "profile" feature, and allow for either concurrent or retrospective review of medication overrides if resources and manpower allow for it and in consideration of HR-HA population needs **Review** ADM content monthly for appropriateness **Ensure** "on-call" pharmacist is available for emergency dispensing **Enable** ADM "profile" feature if facility has ability to provide 24-hour order verification	**Utilize** automated dispensing machine **Review** ADM content monthly for appropriateness **Enable** ADM "profile" feature, and allow for review of medication overrides *NOTE: see monitoring section for concurrent order* *NOTE: See monitoring section for pharmacist review guidelines*	**Utilize** automated dispensing machine **Review** ADM content monthly for appropriateness **Enable** ADM "profile" feature, and allow for review of medication overrides *NOTE: See monitoring section for concurrent order verification*	**Utilize** automated dispensing machine **Review** ADM content monthly for appropriateness **Enable** ADM "profile" feature, and allow for review of medication overrides *NOTE: See monitoring section for concurrent order verification*

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
Distribution	**Pharmacy:** • Controls or directs medication distribution (to the extent possible allowed for by operating hours) • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution (to the extent possible allowed for by operating hours) • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution (to the extent possible allowed for by operating hours) • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution • Distributes ER medications in most ready to use formulation available • Delivers specialty items • Utilizes advanced technology with features for secure medication delivery	**Pharmacy:** • Controls or directs medication distribution • Distributes ER medications in most ready to use formulation available • Delivers specialty items • Utilizes advanced technology with features for secure medication delivery
Administration	**Implement** independent double checks for caregivers administering High Risk-High Alert medications	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system
Education	**Current drug information resources** are available to practitioners in a form that is readily available **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education
Monitoring	**Retrospective Review:** • Review sample cohort representative of patient population (for example, at-risk patient populations such as pediatrics and/or geriatrics)	**Concurrent Review:** • Review orders	**Concurrent Review:** • ER patients being held for admission to an inpatient bed **Retrospective Review:** • Review sample cohort representative of patient population (for example, at-risk patient populations such as pediatrics and/or geriatrics)	**Concurrent Review:** • Review orders	**Concurrent Review:** • ER patients being held for admission to an inpatient bed **Retrospective Review:** • Review sample cohort representative of patient population (for example, at-risk patient populations such as pediatrics and/or geriatrics)	**Concurrent Review:** • Review orders

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
Use	**Regularly evaluate medication use processes** and identify system vulnerabilities - e.g., including but not limited to, chart review, direct observations, etc.	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval **Regularly evaluate medication use processes** and identify system vulnerabilities - e.g., including but not limited to, chart review, direct observations, etc.	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval Consider utilizing an ER pharmacist for at least 8 hours a day, 7 days a week *Note: Entities which do not utilize pharmacists in the ER should consider increasing the frequency of MUE's*	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval Consider adding additional pharmacy resources beyond the 8 hour per-day minimum	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval Consider utilizing an ER pharmacist for at least 16 hours a day, 7 days a week	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval For large-sized hospitals, consider utilizing an ER pharmacist 24/7

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee Guidelines

Recommendations for Improving Safety of Opioid use

1215 K Street, Suite 800, Sacramento, CA 95814 • *Telephone:* 916.443.7401 • *Facsimile:* 916.552.7596 • www.calhospital.org

Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

TABLE OF CONTENTS

DRAFT DOCUMENT CHANGE LOG

VERSION	DATE	AUTHOR	CHANGES
0.1	01/2013	Cleo Mutebi	Draft
1.0	04/2013	Cleo Mutebi	Final draft approved by committee
1.1	11/2013	Multiple	Edits: Hanni/Aveikian/Jaffe/Bartleson

ANNUAL REVISION LOG

VERSION	REVIEW DATE	REVISIONS/CHANGES
2.0	10/2013	Revised to CHA Med Safety guideline specifications
3.0	07/2014	Added Fentanyl guidelines
4.0		

INTRODUCTION

Opioid use is generally safe but is associated with serious adverse effects such as over sedation (0.5% incidence). The purpose of these recommendations is to reduce the risk of adverse drug events associated with use of opioids in perioperative settings. These recommendations focus on narcotic over-sedation in adult patients being treated for acute pain.

The tools contained herein have been reviewed by the California Hospital Association's Medication Safety Committee, and are intended for hospital and health care providers for consideration as they evaluate current practices and develop specific programs**. These tools are not fixed protocols that must be followed, nor are they entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results**. The CHA Medication Safety Committee is a voluntary collaborative supported by the California Hospital Association (CHA), and is comprised of CHA member hospitals and non-hospital representatives~~, which include the Association of California Nurse Leaders (ACNL), California Association of Health Facilities (CAHF), California Board of Pharmacy, California Correctional Health Care Services (CDCR), California Department of Public Health (CDPH), California Hospital Patient Safety Organization (CHPSO), California Society of Health-System Pharmacists (CSHP), Collaborative Alliance for Nursing Outcomes (CALNOC).~~

The attached recommendations/~~guide~~ is intended for acute care settings as a plan to help assess the safe use of opioids.

Information contained in this tool should not be construed as legal advice or used to resolve legal problems by health care facilities or practitioners without first consulting legal counsel.

COMMITTEE REPRESENTATION

The committee includes nurse, physician, and pharmacist representatives. ~~from:~~

- Association of California Nurse Leaders (ACNL)
- California Association of Health Facilities (CAHF)
- California Board of Pharmacy
- California Correctional Health Care Services (CDCR)
- California Department of Public Health (CDPH)
- California Hospital Patient Safety Organization (CHPSO)
- California Society of Health-System Pharmacists (CSHP)
- Collaborative Alliance for Nursing Outcomes (CALNOC)

The following tool is intended to guide acute care facilities in the safe use of opioid agents. Medication safety includes all aspects of medication use, from the prescribing stage to ongoing monitoring.

Medication Use Step	Recommendation(s)
Prescribing	1) Consider using an acute pain management order set. *Rationale* i. A standardized order set will promote national best practices ii. Encourages multimodal techniques for pain management (e.g., including round the clock non-opioid therapy if not contraindicated). iii. Minimize opioid side effects a. Naloxone orders b. Bowel regimen orders c. Antiemetic orders d. Reduce variation from best practices 2) Improve provider awareness of patient's history of opioid use and other risk factors for over sedation. *Rationale* i. Opioid naïve patients are at the highest risk for experiencing over sedation. ii. Screening information (for patients at high risk for over sedation) should be available prescribers and other clinicians. iii. Design information support systems to identify patients who are at high risk (Sleep apnea, Morbid obesity, elderly >60 years old). 3) Improve use of patient controlled analgesia (PCA) *Rationale* i. Patient centered treatment ii. Minimizes adverse drug events such as over sedation 4) Consider development and implementation of an acute pain management service *Rationale* i. Prospective assessment of patients at high risk for respiratory depression/ over-sedation ii. Actively manages pain therapy iii. Addresses patient satisfaction

Dispensing / Distribution	Assess need for stocking multiple concentrations of narcotics *Rationale* i. High concentrations can be mistakenly administered resulting in over-sedation
Administration	1) Consider establishing standardized procedure for naloxone administration to ensure availability and consistency in the emergent management of over-sedation. *Rationale* i. Naloxone is not consistently ordered on patients that are on ~~opioid~~s, including naloxone orders during opioid prescribing provides healthcare professionals an approved order to act on in the event of an emergency. Each organization to develop policies and procedures that define parameters for when naxolone orders should begin being initiated. 2) Consider lower and upper limits for 'smart' infusion pumps by utilizing drug libraries intended to prompt users when settings reach above or below these pre-determined settings. For opioids, these limits should take into consideration all routes of administration. Furthermore, the drug library can delineate acuity and patient populations; including, but not limited to, neonatal, pediatric, adult, and geriatric patients *Rationale* i. Use of infusion pump drug libraries can help minimize and prevent errors with opioid overdose.
Clinical Education	1) Train staff to identify the patients at high risk for over-sedation and respiratory depression. a) No previous use of opioid history b) Sleep apnea c) Morbid obesity d) Elderly >60 years old *Rationale:* i. Clear guidance to staff in identifying risk areas.

Medication Use Step	Recommendation(s)
Clinical Education	2) Improve documentation and communication of risk factors for over-sedation to all care givers across the continuum of care a) Pain scale scores b) Sedation scale assessment c) Pain goals *Rationale:* i. Complete information should be readily available to prescribers for timely pain treatment care plan adjustments in response to an adverse drug event 3) Staff should be educated on equianalgesic potency (physician & nurse). a) Potency reference cards b) Talks on pain management therapies and alternatives c) Incorporate into order set *Rationale:* i. Staff competence on dose equivalencies. 4) Advise prescribers in the use of multimodal therapies a) Benefits of multimodal therapy alternatives based on best practices (Tylenol, Motrin, Neurontin®) b) Around the clock use of non-opioid analgesics therapy unless contraindicated *Rationale:* i. Medical staff education. 5) Educate clinicians on the recognition of advancing sedation a) Utilization of sedation scale assessment tools *Rationale:* i. Medical staff education.

Clinical Education	6) Nursing education, pain management a) Standardized process of pain goal setting b) Define frequency of patient/family pain management education *Rationale:* i. Medical staff education.
Patient Education	7) Standardized patient orientation/education to pain scale tool and use a) Educate patients on realistic pain goals and use of pain scale b) Educate patients/families on responding to adverse effects *Rationale:* ~~➢~~i. Medical staff and patient education.
Monitoring	~~1) Improve documentation and communication of risk factors for oversedation to all care givers across the continuum of care~~ ~~a) Pain scale scores~~ ~~b) Sedation scale assessment~~ ~~c) Pain goals~~ ~~*Rationale*~~ ~~i. Complete information should be readily available to prescribers for timely pain treatment care plan adjustments in response to an adverse drug event~~ 2) Implement appropriate physiologic monitoring practices a) Consider use of capnograpy to monitor ventilation in identified high risk patients b) Consider continuous pulse oximetry in identified high risk patients ~~b)~~ *Rationale* ii. Enables earlier recognition and intervention in advancing oversedation. ~~1)~~ 3) Consider implementing~~Implement~~ a stop (i.e., either a hard and/or soft stop) that engages prescribers to routinely review the use of opioids. a) Utilize an alert system to trigger an opioid therapy evaluation. This process to include a communication tool to notify the prescriber when the desired number of days has passed from the original order date. b) Consider using pharmacists ~~Pharmacists~~ to oversee these stops as it relates to disease management and ensure the prompt re-evaluation by the prescriber whether or not the opioid is continued or discontinued.

Policy and Procedure Documentation Tools	1) Revision of pain assessment and reassessment policy to include a) Sedation measurement and documentation
Quality Measures: Examples	1) Naloxone administration for the purposes of reversing Opioid therapy 2) Reported over-sedation events 3) Rapid Response Team calls related to over-sedation

*Note: Despite warnings from the FDA, manufacturers, and various patient safety agencies, transdermal fentaNYL patches continue to be prescribed inappropriately to treat patients with acute pain and patients who are not opioid tolerant. FentaNYL patches are only for patients who are **opioid-tolerant** for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time AND cannot be managed by other means.*
*The patches are **NOT** to be used to treat sudden, occasional or mild pain, or pain after surgery.*

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Instructions for Using the CHA/CSHP Compounding Grids 2016

WHAT

The California Hospital Association (CHA)/California Society of Health-System Pharmacists (CSHP) Compounding Grids identify the proposed Board of Pharmacy requirements that will take effect Jan. 1, 2017, as well as describe the upcoming USP 797 and USP 800 requirements that will likely be effective July 1, 2018. There are six compounding grids: Physical Plant Requirements for Non-Hazardous Compounding, Physical Plant Requirements for Hazardous Compounding, Compounding Frequency of Documentation, Temperature Requirements and Monitoring, Required Laboratory Testing, and Non-Hazardous and Hazardous Garbing.

These tools are intended for hospital and health care pharmacists in charge (PICs) and other hospital staff as they evaluate their current sterile compounding practices. The grids are based on the Board of Pharmacy's Feb. 24, 2016, "Order of Adoption- Sterile Compounding Regulations" and interpreted by CHA's and CSHP's Medication Safety senior pharmacy leaders. The grids are not a fixed compliance assessment that must be followed, and they should not be construed as legal advice or used to resolve legal problems.

WHEN

The Board of Pharmacy regulations take effect Jan. 1, 2017. If a facility is not able to meet the physical plant requirements, a waiver will be required prior to Jan. 1, 2017. The waiver requires a plan and a proposed timeline. *Note: There is no waiver for training, testing and cleaning requirements.*

USP 800 is in its final form with an effective date of July 1, 2018. USP 797 is undergoing review and is expected to be finalized for an effective date of July 1, 2018, but there may be some changes to the proposed language.

HOW

To use the grids:

1. The Compounding Frequency of Documentation, Temperature Requirements and Monitoring, Required Laboratory Testing, and Non-Hazardous/Hazardous Garbing grids are self-explanatory.

2. The physical plant grids for non-hazardous and hazardous sterile compounding should be used as follows:

Which room	Date requirements take effect	
	January 1, 2017	**July 1, 2018**
Hazardous	Board of Pharmacy	USP <800> (CDPH requirement)
Non-hazardous	Board of Pharmacy	USP <797> still draft (CDPH requirement)

1. Look at the negative pressure, Hazardous Compounding Grid, space, equipment and the Board of Pharmacy requirements.

   a. Find the type of room in the current space (the SEC = secondary engineering control).
   b. Second, determine if you can meet the minimum requirements.
      - If yes, congratulations. Next, be sure to review the USP 800 requirements.
      - The USP requirements go into effect in two years — July 2018.
   c. If the current set up does **not** meet the Board of Pharmacy requirements, a waiver will be required prior to Jan. 1, 2017. This will require a plan and a timeline.
   d. If structural changes are necessary, be sure to review the USP 800 planned requirements and proposed changes simultaneously, especially refrigeration and storage in negative pressure spaces.

2. Repeat the same process with the positive pressure, non-hazardous space compounding grid.

WHO

CHA and CSHP created a task force in the fall of 2014 to develop a series of grids to assist health system pharmacists understand the requirements as delineated by the California State Board of Pharmacy and the current and proposed USP chapters 797 and 800. The Sterile Compounding Task Force members are:

Christine Acosta, Board of Pharmacy
Elaine Beals, CSHP Southern California Chapter, Kaiser
Corbin Bennett, CSHP Sierra Chapter, Kaiser
Darrell R. Chan, CSHP Orange County Chapter, Prime Health Care
Lucinda Chan, CSHP Diablo Chapter, Touro University
Helen Chun, CSHP Southern California Chapter, Kaiser
Candace Fong, Past Chair, CHA Medication Safety Committee, Dignity Health
Ken Fukushima, CSHP Orange County Chapter, CPS Pharmacy
Jeannette Hanni, CSHP QuatraCounty Chapter, Sutter, CHA Medication Safety Committee Chair
Stephanie Holcomb, CSHP Sierra Chapter, Community Medical
Martin Iyoya, Diablo, CSHP Board Liaison, John Muir Health
Mervyn Kalman, CSHP San Fernando Valley Chapter, Consultant
Doug. C. O'Brien, CHA Medication Safety Committee, Kaiser
Lynn Paulsen, University of California, CHA Medication Safety Committee, Chair SCTF
Maria Serpa, CSHP Sacramento Valley Chapter, Sutter
Art Woo, California Department of Public Health, CHA Medication Safety Committee
Betty Yee, CSHP Diablo Chapter, Retired

TEMPERATURE REQUIREMENTS AND MONITORING

(CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797>(7/1/18) 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> proposed	Board of Pharmacy January 1, 2018
	Min	Max	Min	Max				
Controlled Freezer Temperature (USP and BOP)	-25º	-10º	-13º	14º	Check individual monographs for specific requirements outside this range	General Notices 10.20.10		No provision for excursions §1735.1 (i)
Freezer (CDC)	-50º	-15º	-58º	5º	Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Controlled Cold Temperature	2º	8º	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)
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 for July 1, 2018	
	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 Proposed
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)
Ambient Room	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. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption Sterile Compounding Regulations" and designed by CHA's and CSHP's Medication Safety Senior Pharmacy Leaders. 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.

PHYSICAL PLANT REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) 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 • **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**	**APPLIES TO ALL**
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**			
>ISO Class 7 clean room with ISO 8 or better ante-area • No sink in clean room • Sink in ante • 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(e)(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. 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
	• Laminar Flow Hood • Biological Safety Cabinet with unidirectional flow • CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	12 hours	• 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)
	• 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
PROPOSED USP 797 - NON-HAZARDOUS DRUGS Effective July 1,2018				

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption Sterile Compounding Regulations" and designed by CHA's and CSHP's Medication Safety senior pharmacy leaders. 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.

PHYSICAL PLANT REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

<table>
<tr><th>SECONDARY ENGINEERING CONTROL
• Temp = or < 20 C
• Humidity < 60%
• Controlled through HVAC
• Air enters HEPA filter in the ceiling of buffer room and returns low on the wall</th><th>PRIMARY ENGINEERING CONTROL (PEC)
ISO 5 with unidirectional flow</th><th>BEYOND USE DATES</th><th></th></tr>
<tr><td colspan="3">Category 1</td><td>Comments</td></tr>
<tr><td>Segregated compounding area (SCA)
• Not ISO classified
• Buffer/ante not meeting ISO 7/8 respectively
• Buffer/ante fails surface sampling
• Away from significant traffic flow
• Away from unsealed doors/windows that connect to outdoor
• Perimeter must be defined
• Sink must be 1 meter from PEC (greater than the 3 ft. for the BOP requirements)
• Not adjacent to construction, warehouse or food prep</td><td>ISO Class 5 PEC:
• Laminar Air Flow System (LAFS)
• Biological Safety Cabinet (BSC)
• Restricted Access Barrier System (RABS), can be CAI or CACI
• Isolator</td><td>• Less than or equal to 12 hours at Room Temp*
• Less than or equal to 24 hours at Cold Temp (Refrigerator)**</td><td>• Recertification every six months
• Endotoxin and sterility testing not required for products
• No shipping or external cartons allowed in SCA</td></tr>
<tr><td colspan="3">Category 2</td><td>Comments</td></tr>
<tr><td>PEC in ISO 7 buffer room
• With ISO 8 or better ante, separated from surrounding unclassified area
• Buffer and ante must be separate rooms with walls and doors, and controls to prevent low quality air into controlled areas
• Sink in ante
• Buffer and ante must have ACPH = or >30, at least 15 must be HEPA filtered fresh air vs. recirculated air
• Positive pressure differential at least 0.02” wc to separate each ISO classified area and from ante to general pharmacy area</td><td>ISO Class 5 PEC:
• Laminar Air Flow System (LAFS)
• Biological Safety Cabinet (BSC)
• Restricted Access Barrier System (RABS), can be CAI or CACI</td><td rowspan="2">Sterile to Sterile, No Preservatives, Aseptic Technique
<table><tr><th>Sterility Testing</th><th>Room Temp BUD</th><th>Refrigerated BUD</th><th>Freezer BUD</th></tr><tr><td>NO</td><td>6 days</td><td>9 days</td><td>45 days</td></tr><tr><td>YES</td><td>28 days</td><td>42 days</td><td>45 days</td></tr></table>BUD days start after the quarantine period for sterility testing

For: Terminal sterilization, preservatives, non-sterile to sterile compounding BUDs, please see the USP <797> document</td><td rowspan="2">• Recertification every six months
• No tacky mats in ISO classified areas
• Document pressure differential or velocity daily or use continuous recording device
• No shipping or external cartons allowed in buffer/ante
• Endotoxin testing required for CSP compounded from non-sterile ingredient(s)</td></tr>
<tr><td>PEC in ISO 8 area
• Sink can be in ISO 8 area 1 meter from PEC
• Must have ACPH = 15 ;must be HEPA-filtered fresh air vs. recirculated air
• Positive pressure differential at least 0.02”wc to separate each ISO classified area and to general unclassified area</td><td>• Isolator (must meet standards; see lines 505-511 in proposed USP <797>)</td></tr>
</table>

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NON-HAZARDOUS GARBING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

Compounding attire	Order of garbing in the anteroom	Specifications
Shoe covers	1	May be eliminated IF written documentation by CAI manufacturer
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)	May be eliminated IF written documentation by CAI mfr.
Non-shedding gown	4	
Sterile gloves Must wear sterile gloves over any CAI gauntlet gloves	5	Tested for compatibility with sterile 70% isopropyl alcohol (SIPA)
PROHIBITED ITEMS AND INDIVIDUALS		
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing with jewelry • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails • False eyelashes		Eyelash extensions are permitted
Excluded from ISO 7 and ISO 5 spaces until resolved		
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases		

HAZARDOUS GARBING: In addition to the above requirements (USP<800>)

Compounding attire	Specifications	Information
Double shoe covers		Don the second pair upon entering the buffer area. Remove upon leaving.
Sterile chemo gloves	Chemo gloves must meet ASTM standard 6978 (or its successor). NO powder.	Change every 30 minutes or when torn, punctured or contaminated.
Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	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.
Face shields	Required when working outside a C-PEC	Surgeons, spill cleanup, etc.

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REQUIRED LABORATORY TESTING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

<table>
<tr><th>Environmental Testing
Under Dynamic Conditions</th><th>USP <797></th><th>Board of Pharmacy (BOP)</th></tr>
<tr><td>Viable surface sampling

Viable air sampling by volumetric impaction: (400-1,000 liters)</td><td>Every six months: Requires identification of every colony forming units (CFUs) to the genus level and action plan for CFUs exceeding USP thresholds
<table>
<tr><th>Location</th><th>Viable airborne</th><th>Viable surface</th></tr>
<tr><td>ISO-5 (PEC)</td><td>>1</td><td>>3</td></tr>
<tr><td>ISO-7 (Buffer)</td><td>>10</td><td>>5</td></tr>
<tr><td>ISO-8 (Anteroom)</td><td>>100</td><td>>100</td></tr>
</table>
(highly pathogenic microorganisms [e.g., G(-) rods, coag (+) Staph, molds and yeasts] must be immediately remedied, regardless of CFU count)</td><td>• Every six months for low and medium risk California Code of Regulations (CCR) §1751.4 (j)
• Every six months for high risk CCR §1751.4 (j)
• Genus level identification of CFUs exceeding the threshold (facility determined) CCR §1751.4 (j)</td></tr>
<tr><td>Volumetric air sampling by impaction: non-viable particle counts</td><td>Every six months: requires action plan for particle counts exceeding ISO class as required</td><td>• Every six months as part of hood re-certification for low and medium risk
• Weekly for high risk</td></tr>
<tr><td colspan="3">Process validation: 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.</td></tr>
</table>

Personnel	When Required	What Tests Are Required (BOP and USP)
Moderate and low risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing, then 1x annually thereafter. CCR §1735.1(u)
Moderate and low risk compounding – ongoing competency	Annually as part of the competency testing process	
High risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing then semi-annually thereafter. CCR §1735.1(u)
High risk compounding – ongoing competency	Every six months as part of the competency testing process	

Lot Compounding (More than one of the identical product)	USP <797> July 1, 2018 Proposed	Board of Pharmacy: Additional Policies Required
Sterile to sterile compounding	N/A	Written policies and procedures including (1) master formulae and compounding logs, (2) appropriate documentation and (3) appropriate sterility and potency testing CCR §1751.3 (b)(1-3)
Non-sterile to sterile		Written policies and procedures including: (1) process validation for chosen sterilization methods and (2) end-product evaluation, quantitative and qualitative testing CCR §1751.3 (c)(1-2)

End Product Testing: Requirement for Sterility and Potency Testing for Lots of Low/Med Risk CSPs	Comments	USP <797> July 1, 2018	BOP January 1, 2017
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 • USP <797> revisions have different BUD	• As long as the shorter of the manufacturer insert stability and the USP <797> BUD is met, there is no batch sterility testing requirement.	• "Appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CR §1751.3 (d)
Extended BUD (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. • USP <797> does not exempt extended BUDs from sterility testing.	• 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.	• "Appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1735.2(i)(3-4)
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 • Facility policy should describe processes as determined by the PIC to assure accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(3-4)

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PHYSICAL PLANT REQUIREMENTS - HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

Hazardous Drugs - BOP				
		Beyond Use Dates		
SECONDARY ENGINEERING CONTROL • **Temp 20-24C (68-75F)** • **Externally vented** • **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 dedicated to 1 BSC or Compounding Aseptic Isolators (CACI)**	**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 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 • CACI with unidirectional flow. Air within the CACI shall not be recirculated or turbulent.	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 at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e); each hood must have a separate vent • All surfaces with the room shall be smooth, seamless, impervious and non-shedding 1735.6(e)(4) • No requirements for negative pressure drug storage
• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft. from 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 • CACI with unidirectional flow. CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	12 hours	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification at least 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces with 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) • No requirements for negative pressure drug storage
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				

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PHYSICAL PLANT REQUIREMENTS - HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

HAZARDOUS DRUGS - USP 797				
SECONDARY ENGINEERING CONTROL **Externally vented through HEPA filtration**	**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 (greater than the 3 feet required by BoP)**	• 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	*USP <800> and <797> BUDs* *6 days at Room Temp** *9 days at Cold Temp*** *45 days Freezer Temp **** ***BUT will be overridden by the BOP BUDs unless there is a regulatory change*** **BOP BUDs** **48 hours Room Temp** **14 days Cold Temp** **45 days Solid Frozen State**	*USP <800> and <797> BUDs* *6 days at Room Temp** *9 days at Cold Temp*** *45 days Freezer Temp **** ***BUT will be overridden by the BOP BUDs unless there is a regulatory change*** **BOP BUDs** **30 hours Room Temp** **9 days 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.
• **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 HEPA filtered air** • **Sink at least 1 meter from C-PEC (greater than the 3 feet required by the BOP)**	• 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	

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

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

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

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COMPOUNDING FREQUENCY OF DOCUMENTATION

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and Proposed USP<797> (7/1/18) 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 (Twice a day for vaccines)	X	X
Freezer (Twice a day for vaccines)	X	X
Air pressure differentials or air velocity between adjoining ISO rooms	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
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
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	X
Volumetric air sampling Particle count CFUs, identified to genus. ALL CFUs identified to genus per USP <797>, only facility-determined limits for BOP	X	NA
Hood certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Media fill for employees	NA	X
ANNUAL	LOW AND MEDIUM RISK	HIGH RISK
Media fill for employees	X	NA
Competency testing Observation Written	X	X

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CA AB 1069

AUTHOR: Gordon [D]
TITLE: Prescription Drugs: Collection and Distribution
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/26/2015
LAST AMEND: 07/01/2015
DISPOSITION: Pending - Carryover
LOCATION: Senate Appropriations Committee
SUMMARY:

Authorizes an entity participating in the medication repository and distribution program to transfer eligible donated medication to a participating entity in any other county. Prohibits such entity from transferring more than a specified percentage of its donated medications annually. Authorizes medication donated to the program to be maintained in new, properly labeled containers. Prohibits donated medication from being repackaged more than twice. Makes a technical, nonsubstantive change.

STATUS:

07/06/2015 From SENATE Committee on BUSINESS, PROFESSIONS AND ECON. DEVELOPMENT: Do pass to Committee on APPROPRIATIONS. (7-0)

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

CA AB 1668

AUTHOR: Calderon I [D]
TITLE: Investigational Drugs,Biological Products and Devices
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 01/15/2016
LAST AMEND: 03/07/2016
DISPOSITION: Pending
COMMITTEE: Senate Appropriations Committee
HEARING: 08/01/2016 10:00 am
SUMMARY:

Permits a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with life-threatening conditions. Authorizes a health benefit plan to provide coverage for any investigational drug, biological product, or device. Prohibits disciplinary action against any physician for a related recommendation. Prohibits using such recommendation as the basis for excluding a physician from Medicaid or Medicare certification.

STATUS:

06/27/2016 From SENATE Committee on BUSINESS, PROFESSIONS AND ECON. DEVELOPMENT: Do pass to Committee on APPROPRIATIONS. (9-0)

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

CA AB 1831

AUTHOR: Low [D]

TITLE:	Health Care Coverage: Prescription Drugs: Refills
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/09/2016
LAST AMEND:	06/09/2016
DISPOSITION:	Pending
COMMITTEE:	Senate Appropriations Committee
HEARING:	08/01/2016 10:00 am

SUMMARY:

Requires a health care service plan contract or health insurance policy that provides coverage for prescription drug benefits to allow for early refills of covered topical opthalmic products according to specified standards.

STATUS:

06/22/2016	From SENATE Committee on HEALTH: Do pass to Committee on APPROPRIATIONS. (9-0)
INDEX:	39, 89
ISSUES:	BJ, DG, DJP*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1977

AUTHOR:	Wood [D]
TITLE:	Opioid Abuse Task Force
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2016
LAST AMEND:	04/13/2016
DISPOSITION:	Pending
LOCATION:	Senate Second Reading File

SUMMARY:

Requires health care service plans and health insurers to convene an Opioid Abuse Task Force for the purpose of developing recommendations regarding the abuse and misuse of opioids. Requires the task force to submit a report detailing its findings and recommendations to specified government entities.

STATUS:

06/29/2016	From SENATE Committee on HEALTH: Do pass. (8-0)
INDEX:	39, 89
ISSUES:	BJ, DG, DJP*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 2050

AUTHOR:	Steinorth [R]
TITLE:	Health Care Coverage: Prescription Drugs: Refills
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/17/2016
LAST AMEND:	06/06/2016
DISPOSITION:	Pending
LOCATION:	Senate Health Committee

SUMMARY:

Requires a health care service plan or health insurance policy that provides coverage for prescription drug benefits to implement a medication synchronization program for the dispensing of prescription drugs by a single retail network pharmacy so that prescriptions that are refilled at the same

frequency may be filled concurrently for the purpose of improving medication adherence or it it is in the best interest of the enrollee or insured.

STATUS:

06/06/2016	From SENATE Committee on HEALTH with author's amendments.
06/06/2016	In SENATE. Read second time and amended. Re-referred to Committee on HEALTH.

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

CA AB 2095

AUTHOR: Allen T [R]
TITLE: Medi-Cal: Prescriptions
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/17/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
LOCATION: Assembly Health Committee
SUMMARY:

Requires the Legislative Analyst's Office to conduct or cause to be conducted a study comparing the purchase or administration of brand name prescription medications through the Medi-Cal program to the purchase or administration of biosimilars through the Medi-Cal program. Requires the study to cover specified fiscal years.

STATUS:

03/18/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

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

CA AB 2144

AUTHOR: Rodriguez [D]
TITLE: Pharmacy: Prescriptions
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/17/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
LOCATION: Assembly Health Committee
SUMMARY:

Revises specified patient information provisions of existing law to require that a health facility require each patient to acknowledge in writing that the patient has received information regarding drugs given to the patient at the time of discharge including the use and storage of each drug, the precautions, and relevant warnings, and the importance of compliance with directions. Makes a nonsubstantive change to a provisions of existing law regarding substitution of an alternative biological product.

STATUS:

	03/18/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
	03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.
	INDEX:	89
	ISSUES:	BJ*, DP
	LOBBYIST:	AH
	POSITION:	F

CA AB 2400

AUTHOR:	Nazarian [D]
TITLE:	Prescription Drug Coverage: Prior Authorization
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
LAST AMEND:	04/06/2016
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Specifies that an external exception request may be file in lieu of a grievance with a health care service plan or health insurer regarding nonformulary drugs, following an adverse benefit determination. Requires any plan or insurer grievance system process or a plan or insurer internal process to require the resolution of grievances or complaints that involve the disapproval of a request for a formulary drug within a specified time period for both nonurgent and exigent circumstances.

STATUS:

05/27/2016	In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.
INDEX:	39, 89
ISSUES:	BJ, DG, DJP*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 2436

AUTHOR:	Hernandez R [D]
TITLE:	Health Care Coverage: Disclosures: Drug Pricing
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/19/2016
LAST AMEND:	04/27/2016
DISPOSITION:	Pending
LOCATION:	Assembly Unfinished Business - Reconsideration

SUMMARY:

Requires a health care service plan contract or a policy of health insurance that provides coverage for prescription drug benefits to notify the enrollee or insured of information related to the cost of a prescription drug at the time that the drug is purchased or delivered. Requires the Department of Managed Health Care to adopt regulations relating to these requirements.

STATUS:

05/31/2016	In ASSEMBLY. Read third time. Failed to pass ASSEMBLY. (25-38)
05/31/2016	In ASSEMBLY. Motion to reconsider.
INDEX:	39, 89
ISSUES:	BJ, DG, DJP*

	LOBBYIST:	AH
	POSITION:	F

CA AB 2592

AUTHOR:	Cooper [D]
TITLE:	Controlled Substances: Medicine Packages: Grants
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/19/2016
LAST AMEND:	04/25/2016
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Authorizes the State Department of Public Health to establish a pilot program to award grants to combat opioid abuse through the safe prescribing of opioids. Requires the Department to award grants to individual pharmacies that choose to participate in the program. Requires such pharmacies to offer all patients prescribed an opioid a medicine locking closure package. Requires the Department of evaluate the program and reports its findings.

STATUS:

05/27/2016	In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 2712

AUTHOR:	Chiu [D]
TITLE:	Pharmacies: Medi-Cal Program Participation
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/19/2016
LAST AMEND:	03/28/2016
DISPOSITION:	Pending
LOCATION:	Assembly Health Committee

SUMMARY:

Relates to pharmacies and Medi-Cal program participation. Relates to any patient upon presentation of a valid prescription for the patient and evidence of residency in California. Provide that the term covered by insurance does not apply to a prescription for a specific medication prescribed for a patient that is not included on the drug formulary maintained by that patient's health care service plan or health insurer, and for which the patient is prepared to pay cash.

STATUS:

03/28/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/28/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.
INDEX:	65, 89
ISSUES:	AK, AO*, BJ, DP
LOBBYIST:	AH, BG*
POSITION:	F

CA SB 149

AUTHOR:	Stone [R]
TITLE:	Investigational Drugs: Biological Products or Devices

FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/29/2015
LAST AMEND:	07/13/2015
DISPOSITION:	Pending - Carryover
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Permits a manufacturer of an investigational drug, biological product, or device to make the product available to certain patients with an immediately life-threatening disease or condition. Provides the Medical Practice Act does not require a health benefit plan or governmental agency to provide coverage for the cost of such products made available under these provisions. Authorizes a health benefit plan to provide coverage for such products. Prohibits action against a physician for making a recommendation.

STATUS:

08/27/2015	In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F, X

CA SB 447

AUTHOR:	Allen [D]
TITLE:	Medi-Cal: Clinics: Enrollment Applications
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/25/2015
LAST AMEND:	08/24/2015
DISPOSITION:	Pending - Carryover
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Eliminates the requirement that the State Department of Health Care Services approve an application for enrollment in the PACT Program. Requires specified health facilities to submit an application to the State Department of Public Health. Requires a clinic not enrolled in the Medi-Cal program to submit an application for enrollment in both programs. Requires a clinic already under Medi-Cal to apply for the PACT Program. Provides the time period for application review. Requires development of related forms.

STATUS:

08/26/2015	In ASSEMBLY Committee on APPROPRIATIONS: Not heard.
INDEX:	65, 89
ISSUES:	AK, AO*, BJ, DP
LOBBYIST:	AH, BG*
POSITION:	F

CA SB 482

AUTHOR:	Lara [D]
TITLE:	Controlled Substances: CURES Database
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/26/2015
LAST AMEND:	06/21/2016
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Requires a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a controlled substance to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance for the first time and on a specified basis, if the substance remains part of the patient's treatment. Exempts a veterinarian. Provides for waivers. Relates to actions for failure to consult the database.

STATUS:

06/29/2016	In ASSEMBLY Committee on APPROPRIATIONS: To Suspense File.
INDEX:	89
ISSUES:	BJ, DP*
LOBBYIST:	AH
POSITION:	F, X

CA SB 992

AUTHOR:	Fuller [R]
TITLE:	Pharmacy Practice
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/10/2016
DISPOSITION:	Pending
LOCATION:	Senate Rules Committee

SUMMARY:

Makes a technical, no nonsubstantive changes to a provision declaring that pharmacists are health care providers.

STATUS:

02/18/2016	To SENATE Committee on RULES.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA SB 1193

AUTHOR:	Hill [D]
TITLE:	Healing Arts
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
LAST AMEND:	06/21/2016
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Relates to pharmacy law to include a pharmaceutical outsourcing facility license and related fee, temporary pharmacy permits, registering automated drug delivery systems, pharmacy license investigations, sterile compounding pharmacy licenses, the purchase of drugs at wholesale by clinics, the fee for an outsourcing license, electronic data transmission prescriptions, ownership of professional organizations, and veterinary practice license requirements.

STATUS:

06/28/2016	From ASSEMBLY Committee on BUSINESS AND PROFESSIONS: Do pass to Committee on APPROPRIATIONS. (13-0)
INDEX:	89

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

CA SB 1229

AUTHOR:	Jackson [D]
TITLE:	Home-Generated Pharmaceutical Waste
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
LAST AMEND:	06/27/2016
DISPOSITION:	Pending
LOCATION:	Assembly Third Reading File

SUMMARY:

Provides that a collector is not liable for civil damages, or subject to criminal prosecution, for any injury or harm resulting from the collector maintaining a secure drug take-back bin on its premises if the collector acts in good faith to take specified steps, including that the collector regularly inspects the area surrounding the bin for potential tampering or diversion, to ensure the health and safety of consumers and employees and disposal in the waste stream of home-generated pharmaceutical waste.

STATUS:

06/28/2016	In ASSEMBLY. Read second time. To third reading.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA SB 1230

AUTHOR:	Stone [R]
TITLE:	Pharmacies: Compounding
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
DISPOSITION:	Pending
LOCATION:	Senate Business, Professions & Economic Development Committee

SUMMARY:

Authorizes a pharmacy that provides compounding services to provide to a clinic commercial products that are unique and otherwise unavailable to the clinic, if the compounding pharmacy and the clinic have entered into a professional compounding services agreement to provide nonpatient-specific compounded medications that cannot be planned for prospectively.

STATUS:

03/03/2016	To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA SB 1346

AUTHOR:	Allen [D]
TITLE:	Pharmacists: Drug Labeling
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no

INTRODUCED:	02/19/2016
DISPOSITION:	Pending
LOCATION:	Senate Business, Professions & Economic Development Committee

SUMMARY:

Relates to drug labeling. Authorizes a pharmacist to offer a patient, as an alternative to a printer paper medication guide for a prescription drug, the electronic delivery of the medication guide. Authorizes a pharmacist to deliver the medication guide by electronic means if the patient chooses electronic delivery. Authorizes the board to exempt a drug from that authorization by regulation.

STATUS:

03/03/2016	To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA SB 1454

AUTHOR:	Stone [R]
TITLE:	Pharmacy
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/19/2016
LAST AMEND:	03/31/2016
DISPOSITION:	Pending
LOCATION:	Senate Business, Professions & Economic Development Committee

SUMMARY:

Prohibits a pharmacy benefits manager from requiring that a pharmacist or pharmacy provide reimbursement to the pharmacy benefit manager for the costs of any drug dispensed to a patient that was property adjudicated, except upon a showing of fraud or malfeasance. Requires any improper reimbursement during a specified time period, to be refunded to the pharmacist or pharmacy.

STATUS:

04/18/2016	In SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT: Heard, remains in Committee.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F