CALIFORNIA HOSPITAL ASSOCIATION

Medication Safety Committee

Jan 07, 2015 at 10:00 AM - 02:00 PM

California Hospital Association

1215 K Street, Suite 800

Sacramento, California 95814

Conference Call Option: 800-882-3610

Passcode: 5968133#

Meeting Book - Medication Safety Committee Meeting

AGENDA

Meeting Facilitator: BJ Bartleson

10:00	**I. CALL TO ORDER/INTRODUCTIONS**		Hanni
	A. Roster - Page 5		
	B. Membership Updates		
	a. Memo - Members Update - Page 9		
	b. Map of Member Locations		
	a. MSC Map 2015 - Page 10		
	c. Member Attendance		
	a. MSC Attendance 2012-2014 - Page 11		
10:15	**II. MINUTES OF THE OCTOBER 8, 2014 MEETING**	*Recommend: Approval*	Hanni
	A. MSC Draft Minutes 100814 - Page 13		
10:20	**III. OLD BUSINESS**		
	A. Sterile Compounding Regulations Update		Hanni/Herold
	a. BOP Letter Oct 2014 - Page 18		
	B. Sterile Compounding Matrixes		Paulsen
	a. CHA and CSHP Sterile Compounding Testing Required for Low-Medium Risk with USP BUDs 12232014 - Page 50		
	b. CHA and CSHP Sterile Compounding Physical Plant Requirements 12232014 - Page 51		
	c. CHA and CSHP Sterile Compounding Pharmacy Temperature Requirements Grid 12222014 - Page 52		
	d. CHA and CSHP Sterile Compounding Documentation Frequency Grid 12222014 - Page 53		
	C. PharMEDium		Bartleson/Herold
	a. Update on out-of-state licensing		
	b. Bartleson Memo - Page 54		
	c. PhaMEDium letter - Page 55		
11:30	**IV. NEW BUSINESS**		
	A. CDPH AFL 14-34		

a. LNC-AFL-14-34 - Page 63

B. Controlled Substances

a. Safe Medicine Prescribing in the ED — Munoz/Morath

a. Munoz/Morath Safe Prescribing Practices - Page 66

b. Generic Drug Prices — Perrott

a. Perrott memo - Page 67

b. Generic Prices Take Flight.pdf - Page 69

c. California Medical Board - Controlled Substances Guidelines — Hanni

a. Hanni memo - Page 71

12:00 **V. LUNCH**

12:30 **VI. STANDING REPORTS**

A. Board of Pharmacy — Herold

B. CDPH Update — Lee/Woo

12:45 **VII. WORK GROUP REPORTS**

A. High Risk/High Alert (HR/HA) Drugs — Hacker/Benton

a. Anticoagulant Guidelines

a. MSC Guidelines for Anticoag - Page 72

b. Opioid Guidelines

a. Gap analysis tool - CMS Memorandum - Page 80

b. MSC Improving Safety of Opioid Use Guidelines - Page 88

c. Insulin Guidelines

a. Insulin Guidelines - Page 99

B. ED Management Medication Safety — Bartleson

a. ED Medication Management Safety Tool - Page 105

C. Drug Shortage — Jaffe

D. Medication Technology — Jaffe

1:45 **VIII. LEGISLATIVE UPDATES** — Bartleson

1:50 **IX. OTHER BUSINESS** — Bartleson

A. 2015 Committee Goals and Objectives

1:55	**X. NEXT MEETING**	ALL
	A. Wednesday, April 8, 2015 - CHA Board Room, Sacramento	
2:00	**XI. ADJOURNMENT**	Hanni

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2015

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: January 7, 2015

TO: Medication Safety Committee Members

FROM: Marla Bartle, CHA Staff

SUBJECT: Member Updates

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1. **NEW MEMBERS:**

   The following nominees have been approved for membership by a vote of the Medication Safety Committee:

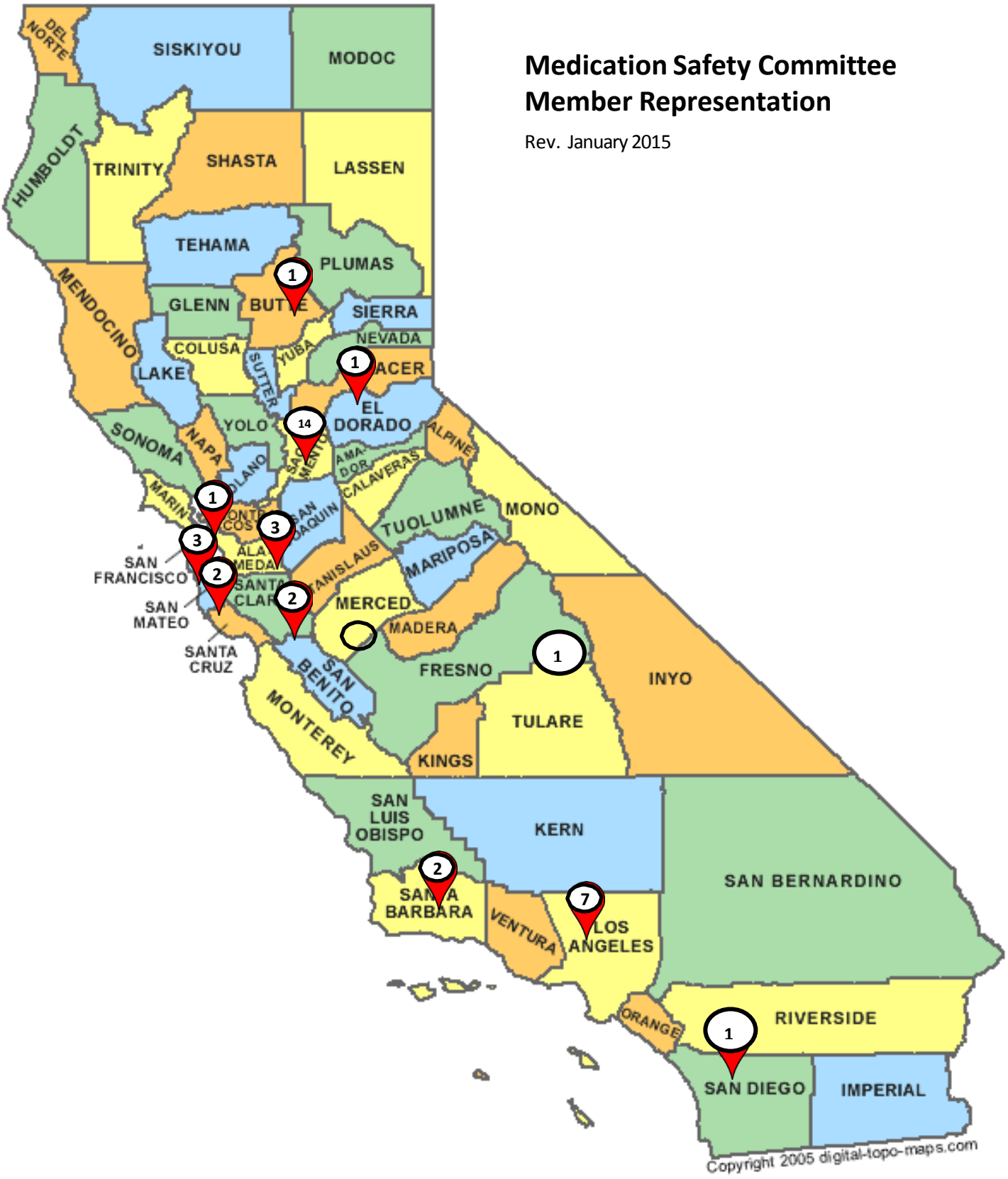
   Sarah Stephens, Medication Safety Coordinator, Kaweah Delta Health Care District

2. **MEMBER RESIGNATIONS:**

   Sandra Perkins – No longer with organization

Medication Safety Committee Member Representation

Rev. January 2015



MEMBER NAME					Total 2012					Total 2013					Total 2014	
	12-Jan	18-Apr	25-Jul	10-Oct		9-Jan	10-Apr	10-Jul	9-Oct		8-Jan	9-Apr	9-Jul	8-Oct		
Eddie Avedikian	Y	Y	Y	Y	4	N	N	Y	Y	2	Y	Y	N	Y	3	
Dawn Benton	Y	Y	Y	Y	4	N	Y	Y	Y	3	Y	Y	Y	N	3	
Nancy Blake	Y	Y	N	N	2	Y	Y	N	Y	3	Y	N	Y	Y	3	
Jacalynn Blankenship	--	--	--	--	--	--	--	--	--	0	--	--	Y	Y	2	New
Carolyn Brown	Y	Y	Y	Y	4	Y	Y	Y	N	3	Y	N	Y	N	2	
Katie Choy (2013)	--	--	--	--	--	--	N	Y	Y	2	Y	N	N	N	1	
Edna DeLeon	Y	Y	Y	N	3	Y	N	N	N	1	N	N	N	Y	1	
Kevin Dorsey-Tyler	--	--	--	--	--	--	--	--	Y	1	N	N	Y	N	1	
Mary Foley	Y	N	Y	N	2	N	Y	Y	Y	3	N	N	Y	Y	2	
Candace Fong (2013)	--	--	--	--	--	--	Y	Y	Y	3	Y	Y	Y	Y	4	
Terri Gately	Y	Y	N	Y	3	N	Y	N	N	1	N	N	N	N	0	
Amy Gutierrez	Y	Y	Y	Y	4	Y	N	Y	Y	3	N	Y	Y	Y	3	
Jillian Hacker	--	--	--	--	--	--	--	--	--	0	--	Y	Y	Y	3	
Jeannette Hanni	Y	N	Y	Y	3	Y	Y	Y	Y	4	Y	Y	Y	Y	4	
Virginia Herold	Y	Y	Y	Y	4	Y	Y	Y	N	3	N	Y	Y	N	2	
Rory Jaffe	Y	Y	Y	Y	4	Y	Y	Y	Y	4	Y	Y	Y	Y	4	
Randy Kajioka	Y	Y	N	N	2	N	N	N	N	0	N	N	Y	Y	2	
Nasim Karmali	Y	Y	Y	N	3	Y	N	N	Y	2	Y	N	Y	Y	3	
Jerry Kim (2013)	--	--	--	--	--	--	Y	N	N	1	N	N	N	N	0	
Cari Lee (2012)	--	Y	Y	Y	3	Y	Y	Y	N	3	Y	Y	N	N	2	
Christine Low (2014)																New
Patricia McFarland	Y	N	N	N	1	N	Y	Y	Y	3	N	N	N	N	0	
Robert Menet	Y	Y	Y	Y	4	Y	N	N	N	1	Y	N	Y	N	2	
Jocelyn Montgomery	--	--	--	--	--	--	--	--	--	0	--	--	Y	Y	2	New
Lori Nolan-Mullenhour (2014)	--	--	--	--	--	--	--	--	--	0	--	--	N	Y	1	
Doug O'Brien (2014)	--	--	--	--	0	--	--	--	--	0	--	--	N	Y	1	New
Lynn Mulchay Paulsen (2014)	--	--	--	--	0	--	--	--	--	0	--	--	N	Y	1	New
Richard Rabens	N	Y	N	N	1	N	N	Y	N	1	N	N	Y	Y	2	

Dana Radman	N	N	**Y**	N	*1*	**Y**	N	N	N	*1*	N	N	N	**Y**	*1*	
Sue Reed (2013)	--	--	--	--	--	--	**Y**	N	N	*1*	**Y**	**Y**	**Y**	N	*3*	
Dan Ross (2012)	--	--	**Y**	**Y**	*2*	**Y**	**Y**	**Y**	N	*3*	N	**Y**	**Y**	**Y**	*3*	
Sarah Stephens (2015)	--	--	--	--	*0*	--	--	--	--	*0*	--	--	--	--	*0*	New
Art Woo (2012)	--	--	--	**Y**	*1*	N	N	N	**Y**	*1*	**Y**	N	N	**Y**	*2*	

Regional Reps

Jenna Fischer (HCNCC)	N	**Y**	**Y**	**Y**	*3*	**Y**	N	**Y**	N	*2*	**Y**	N	N	N	*1*	
Alicia Munoz (HASDIC)	--	--	**Y**	**Y**	*2*	**Y**	**Y**	**Y**	**Y**	*4*	**Y**	N	**Y**	N	*2*	
Julia Slininger (HASC)	N	**Y**	**Y**	**Y**	*3*	N	**Y**	N	**Y**	*2*	**Y**	N	N	N	*1*	

CHA Staff

BJ Bartleson	--	--	--	--	*0*	**Y**	**Y**	**Y**	**Y**	*4*	**Y**	**Y**	**Y**	**Y**	*4*	
David Perrott	--	--	--	--	*0*	**Y**	**Y**	N	N	*2*	N	N	N	N	*0*	
Rhonda Filipp	--	--	--	--	*0*	--	--	--	--	*0*	**Y**	**Y**	**Y**	**Y**	*4*	
Bonnie Zell	--	--	--	--	*0*	--	--	--	--	*0*	--	--	--	--	*0*	

Deleted

Andrew Lowe	N	N	N	N	*0*	N				*0*					*0*	
Diane Brown	N	**Y**	**Y**	N	*2*	N	**Y**	**Y**	N	*2*					*0*	
Mary Ann Cone	N	N	N	N	*0*	N				*0*					*0*	
Loriann DeMartini	**Y**	**Y**	**Y**	**Y**	*4*	N	N	N	N	*0*					*0*	
Steve Gold	N	N	N	N	*0*	N				*0*					*0*	
Mary Jann	--	N	N	N	*0*	N	N	N	N	*0*					*0*	
Jan Kiely	N	N	**Y**	N	*1*	N	N	N	N	*0*					*0*	
Jocelyn Montgomery	--	N	N	N	*0*	N				*0*					*0*	
Cleo Mutebi (2012)	--	--	--	**Y**	*1*	**Y**	**Y**			*2*		**Y**			*1*	
Elizabeth Oyekan	**Y**	N	N	N	*1*	N				*0*					*0*	
Allen Schaad	**Y**	N	N	N	*1*	N				*0*					*0*	
Jeffrey Uppington	N	N	N	N	*0*	N				*0*					*0*	
Frank Maas	N	N	N	N	*0*	N				*0*					*0*	
Jonathan Nelson (2012)	--	--	**Y**	**Y**	*2*	N	**Y**	**Y**	**Y**	*3*	**Y**		N	N	*1*	
Pamela Richter	**Y**	**Y**	**Y**	N	*3*	**Y**	**Y**	**Y**	N	*3*	N	N	N	N	*0*	
Lynne Whaley Welty	**Y**	**Y**	**Y**	N	*3*	**Y**	N	**Y**	N	*2*	**Y**	N	N	N	*1*	retired

MEDICATION SAFETY COMMITTEE
MEETING MINUTES

October 8, 2014 / 10:00 a.m. – 2:00 p.m.

California Hospital Association
Sacramento, CA

Members Present: Nancy Blake (phone), Jacalyn Blankenship, Carolyn Brown (phone), Kevin Dorsey-Tyler (phone), Mary Foley, Candace Fong, Terri Gately (phone), Any Gutierrez, Jillian Hacker, Jeannette Hanni, Virginia Herold, Rory Jaffe, Randy Kajioka (phone), Nasim Karmali (phone), Patricia McFarland (phone), Rob Menet, Jocelyn Montgomery, Susan Reed (phone), Dan Ross

Members Absent: Eddie Avedikian, Katie Choy, Jerry Kim, Cari Lee, Farid Nasr, Richard Rabens, Art Woo

Regional Advisors: Alicia Muňoz (via phone)

CHA Staff: BJ Bartleson, Rhonda Filipp, Sandra Perkins, Ingrid Hamel

I. CALL TO ORDER/INTRODUCTIONS

Introduction of the new members: Lori Nolan-Mullenhour, Lynn Paulsen, and Doug O'Brien

II. MINUTES OF PREVIOUS MEETING

IT WAS MOVED, SECONDED AND CARRIED:

- *To approve the minutes of the April 9, 2014, Medication Safety Committee meeting.*

III. OLD BUSINESS

A. Sterile Compounding Regulation (Hanni/BJ)

Sterile compounding regulatory response draft shared with the group. Amy Guiterrez commented that the regulations were to be discussed at the November 4th meeting.

Action: BJ requested all comments be sent to her.

B. Sterile Compounding Matrixes

Lynn Paulsen was congratulated by the committee on her significant contributions on the matrixes.

It was explained that the physical plant matrix described issues so that staff could pick up the different requirements and appropriate responses.

Questions included when is nurse preparation of IV or other medication considered compounding? It was noted that that if you use a specific attachment, this is not compounding. It was also stated that USP 797 applies to all people within the hour of the drawn up medication. Most issues occur in the ER. This would need to be noted if this is a profound practice change. Questions were asked about Title 22 requirements. Does the temperature meet temperature requirements?

Action: Finalized matrix will be sent out

IV. SPEAKER

A. Rita Shane, Pharm. D., FASHP, FCSHP - Chief Pharmacy Officer for Cedars-Sinai Medical Center, Los Angeles and Assistant Dean, Clinical Pharmacy UCSF School of Pharmacy, gave a presentation regarding: *Recommendations to Improve Medication Safety: Risks Associated with Medication Reconciliation and Transitions of Care with the State Board Med Rec & Transitions of Care.*

V. NEW BUSINESS

A. DEA: Secure & Responsible Drug Disposal was discussed. AHA had concerns about appropriate waste management of drugs. CHA announced there may be specific California implications.

Action: Continue to monitor and work with AHA to keep informed

VI. LUNCH

VII. NEW BUSINESS (CONTINUED)

B. US Office of Disease Prevention & Health Promotion: National Action Plan for Adverse Drug Event Prevention

Action: It was suggested that the committee members review on their own. Pull what is needed for their sub-committees.

C. Pharmedium

Sterile compounding vendors: Lynn Candice, BJ & Dawn met with CDPH in reference to FDA warning letter - is it a recall/not a recall? The vendors were treated as pharmacies but they were bulk compounders. So FDA created 503B to

cover this group. The language is not perfect, but is workable. CDPH agrees with the news blast language and that there was a need to communicate this information to hospital administration.

Action: CHA will continue to monitor

D. Schedule II Controlled Substances FAQ

Issues discussed:

- No grace period from DEA. Only one kind of paper; log is locked
- Are patients controlling pain better?
- Logistics: Some pharmacies are not setup to receive the drugs.
- Noted: Some doctors have been breaking the printer locks out of frustration
- The need to gear up the ER with the prescriptions that run out quickly. Part of the law states if patient received prescription before October 6th then they get 6 months refill.

Action: None

VIII. STANDING REPORTS

A. Board of Pharmacy - none

B. CDPH – Art Woo gave an update on survey activity

IX. WORKGROUP REPORTS

A. Adverse Drug Events – none

B. High Risk/High Alert Drugs – Dawn Benton/Jillian Hacker

1. On Opioid use – Yellow highlighted items - please review and agree.
   It was recommended to add in CMS guidelines, but green highlight refers people instead. Will take recommendations. Identify information you want added and bring to us. Agreed to reference and not add.
   Action – Eddie, Jillian and Amy to meet. Jillian will organize.

2. Anti-Coag- We consider it done, except for credit section. Agreed to remove references and everyone to review
   Action – Amber to send to group one week from today

3. Insulin - Internal formatting. Discussion included regarding second check on insulin, many hospitals have gone away from it, so hesitant to put on our listings. Might have to divide it out. It was asked "Who will articulate it?" When done, they will be put on the website with ED med tool kit. All public. Add version and date.

Action - Add language to page 4- Define when a second insulin check is required. One week to reply.

Action: Disband high risk/high account work group

C. Medication Technology – Rory Jaffe

Issues:
Can we come up with information?.
Could we make a list of risk analysis based on safe guides

Action – Group to convene

D. Medication Administration – Amy Gutierrez

Action: Move to make Lori Mullenhour new chair. Ms. Mullenhour accepted. Ms. Gutierrez will send Ms. Mullenhour past meeting minutes.

X. LEGISLATIVE UPDATE

A. SB 1039 passed. In effect, it updated Title 22. Goes into effect on first of the year. Conversation ensued about the pending interpretations of impacts of SB 1039 and how to communicate the information?

B. New bill AB 2757 – reintroducing

Existing law requires that inpatient medications be barcoded to be readable at the inpatient's bedside in order to retrieve certain information, including the date that the medication was prepared and the components used in the drug product. This bill would instead require that this information be displayed on a human-readable label or be retrievable using the lot number or control number of the medication, rather than by reading the barcode.

XI. NEXT MEETING

January 7, 2014 | CHA Board Room, Sacramento.

New meeting schedule for 2015

Action – change meeting time to 10:00 am; correct day of the week for October date 14th and send update

XII. ADJOURNMENT

Having no further business, the committee adjourned at 1:35 p.m.

Revised 12/22/14 mb

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 20, 2014

California Board of Pharmacy
Attn: Carolyn Klein
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

BY ELECTRONIC AND WRITTEN CORRESPONDENCE

RE: Compounding Regulations, Notice of Proposed Action, Articles 4.5 and 7 of Division 17 of Title 16 of the California Code of Regulations Section 1735 et seq. and 1751 et seq. Add Article 7.5, 45-Day Comment Period: September 5, 2014 to October 20, 2014.

Dear Ms. Klein:

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 changes to compounding regulations for hospital pharmacies set forth in Articles 4.5 and 7 of Division 17 of Title 16 California Code of Regulations Section 1735 et seq. and 1751 et seq.

CHA and its member hospitals agree that, in light of the recent national events with sterile compounding pharmacies, public protection along with efficient, effective delivery of pharmaceutical care is of utmost importance. We agree that updating the state compounding regulations to improve overall patient safety is paramount. We applaud the board of pharmacy's willingness to pursue a fair and equitable process in which to make these critical changes, keeping in mind the complexities of the regulations, the enormity of hospital and other pharmaceutical operations, and the pursuit of the highest safety measures for the public we serve.

CHA, CSHP and CHA's Medication Safety Committee, and member hospitals, have been actively engaged in detailed conversations over the last ten months to address the proposed regulations and their continuous modifications over this time period. We have activated a special sub-committee of elite hospital pharmacy leaders to help inform and address issues to enable all hospitals within the state, large and small, to collectively agree on reasonable recommendations for the latest proposal. We have held numerous stakeholder calls with hospital members from rural and urban areas. The varied stakeholders in the CHA Medication Safety Committee enhance problem solving and rapid resolution to complex issues, reflective in this regulatory package. We believe over this ten month period, with all stakeholders involved, (the board, hospitals, and CDPH, etc.) that we have educated, negotiated and improved interpretation of the intent of the present recommendations to address both hospital nuances and public safety intentions. Our recommendations reflect a comprehensive refined synthesis concluding with sixteen reasonable suggestions to enhance the accuracy and clarity of the regulations.

In review of our participation in the ten month regulatory process, CHA gave extensive comments in January, 2014 to address the board of pharmacy's initial notice of proposed changes in the California's compounding regulations. The board reviewed these extensive comments given by CHA and other stakeholders and made a motion to allow the BOP sterile compounding workgroup to make changes and submit a second version of the proposed text based on the numerous comments. CHA appreciates the consideration of several of its concerns across the body of those proposed regulations. In April, 2014, the board withdrew the current rulemaking file to continue to provide guidance and negotiate new updated language based on all the substantive comments received by the board and notice the revised language as new rulemaking. New proposed regulations were released and CHA submitted comments in July, 2014. CHA appreciates the board's recognition of the potential implication of these regulatory changes and welcomed both the manner in which the board moved through this process and their intense focus on negotiating with all stakeholders in a fair and equitable manner.

Due to the extraordinary collaboration and review amongst all stakeholders, CHA, CSHP and our special subcommittee for sterile compounding regulatory review, developed and distributed four interpretive matrixes to assist hospital pharmacists in understanding the proposed sterile compounding regulations, prompt them for a thorough gap analysis and review, and provide a conversational forum in which to acknowledge the present needs, and anticipate future strategic pharmaceutical changes. The matrixes are dated 9/5/2014 and represent the knowledge lifted from the board of pharmacy's latest sterile compounding regulatory draft and are composed of: (1) Physical Plant Requirements, (2) Laboratory Testing Requirements for Medium and Low Risk Sterile Compounding, 3) Temperature Monitoring Requirements, and 4) Sterile Compounding Frequency of Documentation, (See Attachments). We recognize the matrixes are based on draft guidelines and will review and revise any issues, if necessary, once the regulations are finalized.

Another nuance noted in this process is the pending USP 800 guideline changes that are not yet finalized. While we appreciate the board's desire to meet those proposed guidelines and key provisions, the present USP Chapter 797 guidelines must be adhered to and recognized as imperative for hospitals to align with at this time. The emphasis on preparing for the upcoming guidelines has been appreciated and precipitated the development of the hospital gap analysis matrixes to stress the need for hospitals to fully review their present pharmaceutical operations and prepare for future transformation, being mindful of the express needs of the present sterile compounding regulations which should not supersede draft guidelines.

We offer sixteen reasonable recommendations to the proposed regulatory changes. These recommendations are made after many initial significant issues identified in both our January 10, 2014 and July 15, 2014 letters have been mitigated, clarified or realigned as reasonable processes from a majority of our members. The following issues represent our combined thinking to date and our most reasonable suggestions to strengthen the intent of the regulatory language. All of these comments reflect clarifications or acknowledgements of present regulations or statues to be considered.

A summary of Recommendations is listed below in section I. Detailed recommendations and rationale are noted in applicable sections of the, "CHA Recommended Comments "grid, Section II. The grid lists the Title 16 sections in the first column, present regulatory proposed language in the second column, and our recommendations and rationale in the third column.

I. Summary of Recommendations:

1) **1735.1 (a.) Compounding Definitions** – Six changes have been requested for the section on compounding definitions to improve clarity and understanding of the regulations. They are:

a) **Add four new terms**, “adjacent”, “warehouse”, “single dose container” and “humidity”. Ongoing hospital construction supports defining “adjacent” to address hospital pharmacies in transition. Adjacent may have different meaning under differing physical environments or environments under temporary change. Warehouse should be defined to differentiate it from a pharmacy that may be built in a building constructed as a warehouse. “Single dose container” should be defined for clarification.

b) **Ante-Area** – recommend removal of ante- room presently included in parenthesis as the area will not always be a room but a space. A room is not presently required under regulations. The present requirements include a designated buffer area and ante area, no room is required.

c) **1735.1(b)** – recommend modifying the present definition of “batch” to, “compounding at any risk level, of two or more finished drug preparation units produced during the same continuous cycle of compounding and prepared in advance for patients yet to be identified”, to differentiate between patient specific and patient non-specific pre-prepared batches.

d) **1735.1.(g) -** recommend current USP temperatures already in use under USP37-NF32.

e) **1735.1.(q) -** recommend eliminating potency testing requirements and potency + or - 10% range requirements for three scenarios, add: (1) a compounded drug product where the full prepared quantity will be delivered in the original diluents contained in manufacturer produced overfill, (2) Manufacturer written communication, (PI, letter, email) stating that a particular prep has been tested, and (3) scientific article from refereed journal identifying stability.

f) **1735.(y) –** recommend removal of smoke test definition as it is not a term used or referenced to throughout this regulation.

2) **1735.3.(a).(10).** – recommend removing the documentation for storage of the drug preparation from 1735.3(a)(10) and adding this to section 1735.2(e) to be included as a requirement for the master formula record for the drug preparation. Storage requirements for the compounding drug preparation should be consistent each time it is compounded or batch prepared and included in the master formula record.

3) **1735.4(c).** - recommend adding, “if the container is too small to add the facility label, the facility label may be placed on the overwrap”.

4) **1735.5.(c)** - recommend additional language at end after “pharmacist-in-charge” or other evidence that each policy and procedure has been reviewed annually”.

5) **1751.3.(d).(4).B.(iii).** - This currently states “appropriate sterility and bacterial endotoxin testing” when in fact no endotoxin testing is required for sterile to sterile compounding. Recommend reversing B.iii with C.ii low risk and medium risk preparation that would only require testing if extended beyond use dating was being used.

6) **1751.4(e).** - recommend replacing with the following language to increase clarification, "Counters, tables and cleanable work surfaces shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g. sterile isopropyl alcohol) daily. Floors shall be cleaned with a germicidal detergent and water daily. Walls, ceilings, storage shelving, and stools shall be cleaned with a germicidal detergent and water monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination".

7) **1751.4(j) -** recommend deleting "which includes a room temperature of" since this applies to personal comfort and not directly to medication or consumer safety, and add humidity to the definitions.

8) **1751.5.(a)** - recommend improving clarity by adding "severe" before rashes and omitting "sunburn".

9) **1751.8. (e). -** Low volume is not defined in any current national guidelines therefore we recommend deleting the low volume definition since (1) moderate and high volume would no longer be addressed in the regulations, and, 2) there is no existing official definition of low volume chemo preparation, and , 3) new guidelines are pending from USP.

10) **1753.(b) -** Drugs such as urokinase are outdated, and safety issues around droperidol suggest review and revision of medications listed in this section.

CHA appreciates the opportunity to comment to these proposed regulations and looks forward to ongoing work with all stakeholders to improve patient quality and safety in the most efficient and effective way.

Sincerely,

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

Enclosures (5)

BJB: AM

CHA Recommended Comments

Title 16 Board of Pharmacy Proposed Language, 10/20/2014

Title 16	Proposed Language	Recommendation/ Comments
1735. Compounding in Licensed Pharmacies Page 1, line 4-9	"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription: (1) Altering the dosage form or delivery system of a drug (2) Altering the strength of a drug (3) Combining components or active ingredients (4) Preparing a compounded drug ~~product~~ preparation from chemicals or bulk drug substances	
1735 (b) Compounding in Licensed Pharmacies Page 1, line 10-13	"Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.	
1735 (c) Compounding in Licensed Pharmacies Page 1, line 14-17	"Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug ~~product~~ preparation that is commercially available in the marketplace.	
1735 (d) Compounding in Licensed Pharmacies Page 1, line 18-20	The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).	
1735.1. (a) Compounding Definitions Page 2, line 4-9	"Ante-area"(also called anti-room) means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate- generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the buffer area and maintains air flows from clean to dirty areas.	*1735.1 Compounding Definitions* *Where appropriate in the definitions section add the following terms:* 1. Add a definition of "adjacent" to allow for hospital construction. 2. Add a definition of "warehouse" to differentiate it from a pharmacy that may be built in a building constructed as a warehouse. 3. Add a definition for single dose container. 4. Add a definition for humidity 1735.1 (a) Ante-Area Recommend removing "(also called ante room)" as this is different than what is currently required under regulation. There is a designated buffer area and ante area, and no room requirement.
1735.1. (b) Compounding Definitions Page 2, line 10-12	"Batch" means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient.	1735.1.(b) "Batch" Recommend modifying definition to: "batch means compounding, at any risk level, of two or more finished drug preparation units produced

		during the same continuous cycle of compounding and prepared in advance for patients yet to be identified"
1735.1. (c) Compounding Definitions Page 2, line 13-14	"Beyond use date" means the date or date and time after which a compounded drug preparation shall not be stored or transported, or administration begun.	-
1735.1. (d) Compounding Definitions Page 2, line 15-16	"Buffer area" means an area providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located.	
1735.1. (e) Compounding Definitions Page 2, line 17-20	"Bulk drug" means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.	
1735.1. (f) Compounding Definitions Page 2, line 21-28 & Page 3, line 1-4	"Cleanroom" (which may also be referred to as a buffer area) means a physically separate room with walls and doors providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located. This room maintains segregation from the adjacent ante-area (ante-room) by means of specific pressure differentials. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding.	
1735.1. (g) Compounding Definitions Page 3, line 5-6	"Controlled cold temperature" means 2.2 degrees to 7.7 degrees C (36 degrees to 46 degrees F).	1735.1.(g) Recommend use of current USP temperatures Of 2-8 degrees C. referencing USPN.F 37-NF-32
1735.1. (h) Compounding Definitions Page 3, line 7-8	"Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).	
1735.1. (i) Compounding Definitions Page 3, line 9-10	"Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).	
1735.1. (j) Compounding Definitions Page 3, line 11	"Equipment" means items that must be calibrated, maintained or periodically certified.	
1735.1. (k) Compounding Definitions Page 3, line 12-13	"First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.	
1735.1. (l) Compounding	"Gloved fingertip sampling" means a process where, compounding personnel lightly press each fingertip and thumb onto appropriate	

Definitions Page 3, line 14-17	growth media, that are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.	
1735.1. (m) Compounding Definitions Page 3, line 18-21	"Integrity" means ~~retention of potency~~ that all aspects of quality including sterility, packaging, chemical stability and potency, handling, and transport and storage are maintained throughout the drug preparation process, and until the ~~expiration~~ beyond use date ~~noted~~ provided on the label.	
1735.1. (n) Compounding Definitions Page 3, line 19-22	"Media-fill test" means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. Media fill tests are conducted on the most challenging and routine compounding procedures performed.	
1735.1. (o) Compounding Definitions Page 3, line 23-24	"Parenteral" means a sterile preparation of drugs for injection or implantation through one or more layers of skin.	
1735.1. (p) Compounding Definitions Page 4, line 1-3	"Personal protective equipment" means clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.	
1735.1. (q) Compounding Definitions Page 4, line 4-6	"Potency" means 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.	1735.1.(q) Recommend eliminating potency testing requirements for the following three scenarios: 1. A compounded drug product where the full prepared quantity will be delivered in the original diluent contained in Manufacturer produced overfill 2. Manufacturer written communication (PI, Letter, email) stating that a particular prep has been tested 3. Scientific article from refereed journal identifying stability
Ng for 1735.1. (r) Compounding Definitions Page 4, line 7-9	"Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not contain sterile products.	
1735.1. (s) Compounding Definitions Page 4, line 10-11	'"Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment.	
1735.1. (t) Compounding Definitions Page 4, line 12-13	"Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air.	
1735.1. (u) Compounding Definitions Page 4, line 14-17	"Process validation" means demonstrating that when a process is operated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.	
1735.1. (v) Compounding Definitions	"Product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.	

Page 4, line 18-19		
1735.1. (w) Compounding Definitions Page 4, line 20-22	"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active and inactive ingredients other than those noted on the label.	
1735.1. (x) Compounding Definitions Page 4, line 23-29 Page 5, line 1-2	"Segregated compounding area" means a designated space where a device that provides unidirectional airflow of ISO Class 5 air quality, including compounding aseptic isolators, is located within either a demarcated area (at least three foot perimeter) or room. Such area shall contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation, and shall not have a sink located within at least three feet of the ISO Class 5 PEC. This sterile compounding area will be restricted to preparing sterile-to-sterile compounded preparations.	
1735.1. (y) Compounding Definitions Page 5, line 3-4	"Smoke test" means an analysis of the airflow in the ISO Class 5 PEC using a smoke generating device.	1735.1(y) Recommend removal of the smoke test definition as it is not used or referenced throughout the regulation.
1735.1. (z) Compounding Definitions Page 5, line 5-6	"Strength" means amount of active ingredient per unit of a compounded drug ~~product~~ preparation.	
1735.2. (a) Compounding Limitations and Requirements; Self-Assessment. Page 5, line 11-14	Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.	
1735.2. (b) Compounding Limitations and Requirements; Self-Assessment. Page 5, line 15-18	A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.	
1735.2. (c) Compounding Limitations and Requirements; Self-Assessment. Page 5, line 19-25 Page 6, line 1-13	A "reasonable quantity" ~~as used in~~ furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052 subdivision (a)(1) means that amount of compounded drug ~~product~~ preparation that: (1) is ordered and paid for by the prescriber, using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for either office administration ~~or application to patients in the prescriber's office, or for distribution of not more than or furnishing of a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and~~ ~~(2) is delivered to the prescriber office and signed for by the prescriber; and~~ ~~(3) is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 72-hour~~	

	~~supply solely to the prescriber's own patients seen as part of regular treatment in the prescriber's office, as estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy; and (4) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and~~ ~~(3) (5) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product preparation; and (6) does not exceed an amount the pharmacy can reasonably and safely compound.~~	
1735.2. (d) Compounding Limitations and Requirements; Self-Assessment. Page 6, line 14-24	No pharmacy or pharmacist shall compound a drug preparation that: (1) is classified by the FDA as demonstrably difficult to compound; (2) appears on a FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or (3) is a copy or essentially a copy of one or more drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense. The pharmacy shall retain a copy of the documentation of the shortage in the pharmacy records for three years.	
1735.2. (e) Compounding Limitations and Requirements; Self-Assessment. Page 6, line 25-30 Page 7, line 1-4	A drug ~~product~~ preparation shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements: (1) Active ingredients to be used. (2) Equipment to be used. (3) ~~Expiration dating requirements.~~ The rationale or reference source for determining the maximum allowable beyond use date for this preparation. (4) Inactive ingredients to be used. (5) ~~Process and/or procedure~~ Specific compounding steps used to prepare the drug. (6) Quality reviews required at each step in preparation of the drug. (7) Post-compounding process or procedures required, if any.	
1735.2. (f) Compounding Limitations and Requirements; Self-Assessment. Page 7, line 5-7	Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.	
1735.2. (g) Compounding Limitations and Requirements; Self-Assessment. Page 7, line 8-10	The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until it is dispensed.	
1735.2. (h) Compounding Limitations and Requirements; Self-Assessment. Page 7, line 11-13	All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.	
1735.2. (i) Compounding	Every compounded drug ~~product~~ preparation shall be given a~~n expiration~~ beyond use date representing the date beyond which, in	

Limitations and Requirements; Self-Assessment. Page 7, line 14-22	the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun. This "beyond use date" of the compounded drug ~~product~~ preparation shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug ~~product~~ preparation, unless a longer date is supported by stability studies of finished drugs or compounded drug ~~products~~ preparations using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.	
1735.2. (j) Compounding Limitations and Requirements; Self-Assessment. Page 7, line 23-24	The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.	
1735.2. (k) Compounding Limitations and Requirements; Self-Assessment. Page 7, line 23-28 Page 8, line 1-9	Prior to allowing any drug ~~product~~ preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board ~~(Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.)~~ as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile ~~injectable~~ compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile ~~injectable~~ compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.	
1735.2. (l) Compounding Limitations and Requirements; Self-Assessment. Page 8, line 10-19	Packages of ingredients that lack a supplier's expiration date are subject to the following limitations: (1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy unless either appropriate documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and (2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity.	
1735.3. (a) ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.. Page 8, line 20 Page 9, line 1-20	For each compounded drug ~~product~~ preparation, ~~the~~ pharmacy records shall include: (1) The master formula record. (2) The date the drug ~~product~~ preparation was compounded. (3) The identity of ~~the~~ any pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product~~ preparation. (4) The identity of the pharmacist reviewing the final drug ~~product~~	1735.3(a)(10) Recommend removing the documentation for storage of the drug preparation from 1735.3(a)(10) and adding this to section 1735.2(e) to be included as a requirement for the master formula record for the drug preparation. Storage requirements for the compounded drug preparation should be consistent each time it is

	preparation. (5) The quantity of each component used in compounding the drug ~~product~~ preparation. (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile ~~products~~ preparations compounded on a one- time basis for administration within seventy-two (72) hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (~~35~~ 37th Revision, Effective ~~May~~ December 1, ~~2012~~ 2014), hereby incorporated by reference~~, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code~~. (7) A pharmacy-assigned reference or lot number for the compounded drug ~~product~~ preparation. (8) The ~~expiration~~ beyond use date of the final compounded drug ~~product~~ preparation. (9) The final quantity or amount of drug ~~product~~ preparation compounded for dispensing. (10) Storage for the drug preparation.	compounded or batch prepared and included in the master formula record.
1735.3. (b) ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.. Page 9, line 21-22	Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.	
1735.3. (c) ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.. Page 9, line 23-28 Page 10, line 1-2	Active pharmaceutical ingredients shall be obtained from a FDA registered supplier. All other ~~C~~chemicals, bulk drug substances, and drug products~~, and components~~ used to compound drug ~~products~~ preparations shall be obtained, whenever possible, from ~~reliable~~ FDA-registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis for chemicals, and bulk drug substances~~, drug products, and components~~ used in compounding. ~~Certificate s of purity or analysis are not required for drug products that are approved by the Food and Drug Administration. Certificates of purity or analysis are to be matched to the product received.~~	
1735.3. (d) ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.. Page 10, line 3-7	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).	
1735.4. (a) Labeling of Compounded Drug ~~Products~~ Preparations. Page 10, line 13-15	In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug ~~product~~ preparation shall contain the generic name(s) of the principal active ingredient(s).	
1735.4. (b) Labeling of	A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.	

Compounded Drug ~~Products~~ Preparations. Page 10, line 16-17		
1735.4. (c) Labeling of Compounded Drug ~~Products~~ Preparations. Page 10, line 18-22	Drug ~~products~~ preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and ~~expiration~~ beyond use date.	1735.4 (c) Recommend adding", if the container is too small to add the facility label, the facility label may be placed on the overwrap"
1735.5. (a) Compounding Policies and Procedures. Page 11, line 4-9	Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The pharmacy shall follow its policies and procedures. Failure to follow these policies and procedures shall constitute grounds for disciplinary action.	
1735.5. (b) Compounding Policies and Procedures. Page 11, line 10-12	The policy and procedure manual shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.	
1735.5. (c) Compounding Policies and Procedures. Page 11, line 13-26 Page 12, line 1-14	The policy and procedure manual shall include the following: (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual. (2) Evidence that staff have been educated and trained on all policies and procedures. (~~2~~ 3) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent verification demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. All affected doses can be accounted for as part of the recall. (~~3~~ 4) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process. (5) The procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process. (~~4~~ 6) Documentation of the methodology appropriate to compounded drug preparations used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. (~~5~~ 7) Documentation of the methodology used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations. (8) Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge. (9) Dates of any revisions to the policy and procedure manual approved by the pharmacist-in- charge, signed and dated by the pharmacist-in-charge. (10) Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures. (11) Policies and procedures regarding ensuring appropriate	1735.5.(c) (8) Recommend additional language at end after "pharmacist-in-charge" "or other evidence that each policy and procedure has been reviewed annually."

	functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations.	
1735.6. (a) Compounding Facilities and Equipment. Page 12, line 21-25	Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug ~~products~~ preparations. Where applicable, this shall include records of certification(s) of facilities or equipment.	
1735.6. (b) Compounding Facilities and Equipment. Page 12, line 26-27	Any equipment used to compound drug ~~products~~ preparations shall be stored, used, and maintained in accordance with manufacturers' specifications.	
1735.6. (c) Compounding Facilities and Equipment. Page 13, line 1-5	Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, per manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.	
1735.7. (a) Training of Compounding Staff. Page 13, line 11-15	Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.	
1735.7. (b) Training of Compounding Staff. Page 13, line 16-18	The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.	
1735.7. (c) Training of Compounding Staff. Page 13, line 19-21	Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.	
1735.8. (a) Compounding Quality Assurance. Page 14, line 2-4	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 ~~products~~ preparations.	
1735.8. (b) Compounding Quality Assurance. Page 14, line 5-8	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.	
1735.8. (c) Compounding Quality Assurance. Page 14, line 9-13	The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug ~~products~~ preparations. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and collated with the compounding record and master formula.	
1735.8. (d) Compounding Quality Assurance. Page 14, line 14-16	The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug ~~product~~ preparation is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.	
1735.8. (e) Compounding Quality Assurance. Page 14, line 17-18	The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations, including for preparations furnished to patient care areas.	
1751. (a) Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.	Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~	

Page 15, line 2-6	compounding.	
1751. (b) Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment. Page 15, line 7-28 Page 16, line 1-10	Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug ~~products~~ preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The buffer area, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards: (1) ~~Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ ~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ ~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~ ~~(4) Be~~ Each ISO environment shall be certified ~~annually~~ at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4 of Title 16, Division 17, of the California Code of Regulations. Certification records must be retained for at least 3 years. ~~(5)~~ (2) ~~The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable~~ drug ~~products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment. ~~(6)~~ (3) A sink shall be included in accordance with Section 1250 of Title 24, Part 2, of the California Code of Regulations. Sinks and drains shall not be present in an ISO Class 7 or better buffer area, nor within three feet of an ISO Class 5 PEC or better located in segregated compounding areas. A sink may be located in an ante-area. ~~(7)~~ (4)There shall be a refrigerator and,~~/or~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing. (c) Any pharmacy compounding a sterile ~~injectable~~ drug ~~product~~ preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.	
1751.1. (a) Sterile ~~Injectable~~ Compounding Recordkeeping Requirements. Page 16, line 17-23 Page 17, line 1-20	~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~ In addition to the records required by section 1735.3 ~~and subdivision (a)~~, for sterile compounded drug ~~products~~ preparation ~~compounded from one or more non-sterile ingredients~~, the following records must be made and kept by the pharmacy: (1) The training and competency evaluation of employees in sterile ~~product~~ preparation procedures. (2) Results of hand hygiene and garbing assessment with integrated gloved fingertip testing. (3) Results of assessments of personnel for aseptic techniques including results of media fill tests and gloved	

	fingertip testing performed in association with media fill testing. (4) Results of viable volumetric air and surface sampling. ~~(2)~~ (5) Daily documentation of room, ~~R~~ refrigerator, and freezer temperatures appropriate for drug preparations consistent with the temperatures listed in section 1735.1 for:. (A) Controlled room temperature. (B) Controlled cold temperature. (C) Controlled freezer temperature. ~~(3)~~ (6) Certification(s) of the sterile compounding environment. (7) Daily documentation of air pressure differentials or air velocity between adjoining all ISO rooms or areas and measurement between all ISO rooms or areas, including those associated with compounding aseptic (containment) isolators. ~~(4)~~ (8) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment). ~~(5)~~ (9) Logs or other documentation of inspections for expired or recalled pharmaceutical products or raw ingredients. ~~(6)~~ (10) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.	
1751.1. (b) Sterile ~~Injectable~~ Compounding Recordkeeping Requirements. Page 17, line 21-24	Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name of the compounded drug preparation, lot number, amount, and date on which the preparation was provided to a prescriber.	
1751.1. (c) Sterile ~~Injectable~~ Compounding Recordkeeping Requirements. Page 17, line 25-27 Page 18, line 1-2	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).	
1751.2. (a) Sterile ~~Injectable~~ Compounding Labeling Requirements. Page 18, line 12-13	Telephone number of the pharmacy, except for sterile ~~injectable~~ drug ~~products~~ preparations dispensed ~~for~~ to inpatients ~~of~~ by a hospital pharmacy.	
1751.2. (b) Sterile ~~Injectable~~ Compounding Labeling Requirements. Page 18, line 14-15	Name and concentration~~s~~ of ingredients contained in the sterile ~~injectable~~ drug ~~product~~ preparation.	
1751.2. (c) Sterile ~~Injectable~~ Compounding Labeling Requirements. Page 18, line 16	Instructions for storage and handling.	
1751.2. (d) Sterile ~~Injectable~~ Compounding Labeling Requirements. Page 18, line 17-19	All ~~cytotoxic~~ hazardous agents shall bear a special label which states ~~"Chemotherapy - Dispose of Properly" or~~ "~~Cytotoxic~~ Hazardous – Dispose of Properly." or "Chemotherapy - Dispose of Properly," if applicable.	
1751.2. (d) Sterile ~~Injectable~~ Compounding Labeling	All ~~cytotoxic~~ hazardous agents shall bear a special label which states ~~"Chemotherapy - Dispose of Properly" or~~ "~~Cytotoxic~~ Hazardous – Dispose of Properly." or "Chemotherapy - Dispose of Properly," if	

Requirements. Page 18, line 20-23	applicable.	
1751.3. (a) **Sterile ~~Injectable~~ Compounding Policies and Procedures.** Page 19, line 4-27	Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following: (1) Compounding, filling, and labeling of sterile ~~injectable compounds~~ drug preparations. (2) Labeling of the sterile ~~injectable~~ drug ~~product~~ preparations based on the intended route of administration and recommended rate of administration. (3) Proper use of ~~E~~equipment and supplies. (4) Training of staff in all aspects of the preparation of sterile ~~injectable~~ drug ~~products~~ preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; cleaning and disinfection of controlled compounding areas and proper aseptic technique. (5) Hand hygiene and garbing. (6) Cleaning and maintenance of ISO environments and segregated compounding areas. (7) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling. (8) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time. (9) Media fill testing procedure. (10) Compounded sterile drug preparation stability and beyond use dating. (11) Visual inspection and other final quality checks of sterile drug preparations. ~~(5)~~ (12) Procedures for handling, compounding and disposal of ~~cytotoxic~~ hazardous agents. ~~(6)~~ (13) Quality assurance program. ~~(7)~~ (14) Record keeping requirements.	
1751.3. (b) **Sterile ~~Injectable~~ Compounding Policies and Procedures.** Page 20, line 1-2	The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.	
1751.3. (c) **Sterile ~~Injectable~~ Compounding Policies and Procedures.** Page 20, line 3-6	Pharmacies compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing ~~cytotoxic~~ hazardous residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.	
1751.3. (d) **Sterile ~~Injectable~~ Compounding Policies and Procedures.** Page 20, line 7-29 Page 21, all Page 22, line 1-8	Pharmacies compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ must have written policies and procedures that comply with the following: (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors. (2) All personnel involved must read the policies and procedures before compounding sterile ~~injectable~~ drug ~~products~~ preparations, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.	1751.3.d.4.B.iii Currently states, "Appropriate sterility and bacterial endotoxin testing", no endotoxin testing required for sterile to sterile compounding. Recommend reverse B.iii with C.ii. Low risk and medium risk preparation would only require testing if extended beyond use dating was being used.

	(3) Policies and procedures must address at least the following: (A) Orientation, training, and ~~C~~competency evaluation of compounding personnel. (B) Storage and handling of products and supplies. (C) Storage and delivery of final products. (D) Media fill testing and ~~P~~process validation. (E) ~~Personnel access and movement of materials into and near the controlled area~~ Conduct of personnel in controlled areas and aseptic technique overview. (F) Use and maintenance of ~~environmental control devices~~ PECs used to create the ~~critical~~ direct compounding area for ~~manipulation of sterile products~~ compounding of sterile drug preparations ~~(e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations)~~. (G) ~~Regular~~ Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area ~~and the alternation of disinfectants~~ as specified in California Code of Regulations section 1751.4. ~~Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~ (H) ~~Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~ Non-viable particle testing. (I) ~~For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.~~ Viable air sampling. (J) ~~Sterilization.~~ Surface sampling. (K) ~~End-product evaluation and testing.~~ Airflow considerations and pressure differential monitoring. (L) Temperature and humidity monitoring in compounding and controlled storage areas. (M) Facility management including certification and prevention maintenance of controlled environments and related equipment. (N) Gloved fingertip sampling. (O) Compounded sterile product stability and assignment of beyond use dating. (P) Use of automated compounding devices (if applicable). (Q) Hazardous drug compounding (if applicable). (i) Hazardous drug employee training and safety program. (ii) Hazardous drug handling, storage, labeling and transport. (iii) Hazardous drug compounding techniques. (iv) Hazardous drug spill, deactivation and waste management. (R) Preparing sterile solutions from nonsterile components (if applicable). (S) Hand hygiene and garbing. (4) Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subparagraph. (A) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area. (B) For sterile batch compounding:, (i) use of master formulas and compounding work sheets; (ii) appropriate documentation; and (iii) appropriate sterility and bacterial endotoxin testing. (C) For non-sterile to sterile compounding: (i) Sterilization methods (ii) End-product evaluation and testing. (D) Action levels for colony-forming units (CFUs) detected during	

	viable surface testing, glove fingertip and volumetric air sampling.	
1751.4. (a) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 22, line 13-16	No sterile ~~injectable~~ drug ~~product~~ preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable~~ drug ~~products~~ preparations.	
1751.4. (b) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 22, line 17-19	During the compounding of ~~preparation of~~ sterile ~~injectable~~ drug ~~products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.	
1751.4. (c) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 22, line 20-21	All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.	
1751.4. (d) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 22, line 22-24 Page 23, line 1	Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including: (1) at the beginning of each shift; (2) before and after each batch; (3) after each spill; and (4) when surface contamination is known or suspected.	
1751.4. (e) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 23, line 2-9	~~Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.~~ Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.	1751.4(e) Recommend the following language for increased clarification: "Counters, tables, and cleanable work surfaces shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Floors shall be cleaned with a germicidal detergent and water daily. Walls, ceilings, storage shelving, and stools shall be cleaned with a germicidal detergent and water monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination."
1751.4. (f) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 23, line 10-29 Page 24, line 1-3	Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). Certification records must be retained for at least 3 years. Compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 buffer area if the isolator meets the following criteria: (1) particle counts sampled approximately 6-12 inches upstream of the critical exposure site	

	shall maintain ISO Class 5 levels during compounding operations. (2) not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer. (3) recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators or compounding aseptic containment isolators that do not meet the requirements as outlined in this subdivision and are not located within an ISO Class 7 buffer area may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.	
1751.4. (g) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 24, line 4-21	Pharmacies preparing ~~parenteral cytotoxic~~ sterile hazardous agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769- 8010) or manufacturer's specifications.~~ CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). ~~Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a hazardous drug PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur, complete with hair cover, facemask, beard cover (if applicable), polyprophylen or low shedding gown that closes in the back, shoe covers, and two layers of gloves that have been tested to meet ASTM 6978-05 with the outermost glove that contacts the sterile drug preparation.	
1751.4. (h) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 24, line 22-28	If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.	
1751.4. (i) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.	(i) Viable surface sampling shall be done at least monthly for low and medium risk-level compounding and weekly for high-risk compounding. Volumetric air sampling by impaction shall be done at least once every six months for low and medium risk-level compounding and weekly for high-risk compounding. Viable surface	

Page 25, line 1-11	and volumetric air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Surface sampling is to be performed under dynamic conditions of actual compounding. 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. Remediation shall include an immediate investigation of cleaning and compounding operations and facility management.	
1751.4. (j) Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding. Page 25, line 12-15	(j) The pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. Humidity levels should be consistent ASHRAE Standard 55 (30-65% RH).	1751.4(j) Recommend deleting "which includes a room temperature of" since this applies to personal comfort and not directly to medication or consumer safety
1751.5. (a) **Sterile ~~Injectable~~ Compounding Attire.** Page 25, line 22-24 Page 26, line all	~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~ ~~(b)~~ (a) When compounding sterile drug ~~products~~ preparations ~~from one or more non-sterile~~ ~~ingredients~~ the following standards must be met: (1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low~~ non-shedding ~~coverall~~ gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times, unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing are not required. (2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or immediately outside the segregated compounding area. (3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown. ~~(3)~~ (4) Compounding personnel shall not wear ~~H~~hand, finger, ~~and~~ or wrist jewelry ~~must be eliminated~~. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove. ~~(4) Head and facial hair must be kept out of the critical area or be covered.~~ (5) ~~Gloves made of low-shedding materials are required.~~ Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or buffer area. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected. (6) Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics	1751.5.(a) Recommend in (a). (6) adding "Severe" to rashes and omitting "sunburn".

	shall be excluded from the compounding areas until their conditions are remedied.	
1751.5. (b) **Sterile ~~Injectable~~** **Compounding Attire.** Page 27, line 1-5	~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~ (b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).	
1751.6 (a) ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ Sterile Compounding Consultation; Training of Sterile Compounding Staff. Page 27, line 12-14	Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile ~~injectable~~ drug ~~products~~ preparations and related supplies furnished by the pharmacy.	
1751.6 (b) ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ Sterile Compounding Consultation; Training of Sterile Compounding Staff. Page 27, line 15-19	The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~shall~~ have training and demonstrated competence in the safe handling and compounding of sterile ~~injectable~~ drug ~~products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.	
1751.6 (c) ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ Sterile Compounding Consultation; Training of Sterile Compounding Staff. Page 27, line 20-21	Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.	
1751.6 (d) ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ Sterile Compounding Consultation; Training of Sterile Compounding Staff. Page 27, line 22-23	The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations.	
1751.6 (e) ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ Sterile Compounding Consultation; Training of Sterile Compounding Staff.	Pharmacies that compound sterile ~~products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements: (1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:	

Page 27, line 24-25 Page 28, line 1-23	(A) Aseptic technique. (B) Pharmaceutical calculations and terminology. (C) Sterile ~~product~~ preparation compounding documentation. (D) Quality assurance procedures. (E) Aseptic preparation procedures using media fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the selected manipulations. (F) Proper hand hygiene, gowning and gloving technique. (G) General conduct in the controlled area. (H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area. (I) Sterilization techniques for compounding sterile drug preparations from one or more non- sterile ingredients. (J) Container, equipment, and closure system selection. (2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices. 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.	
1751.7. (a) Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation. Page 29, line 4-17	Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ 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 ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following: (1) Procedures for ~~C~~cleaning and sanitization of the ~~parenteral medication~~ sterile preparation area. ~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~ ~~(3)~~ (2) Actions to be taken in the event of a drug recall. ~~(4)~~ (3) ~~Written justification of~~ Documentation justifying the chosen ~~expiration~~ beyond use dates for compounded sterile ~~injectable~~ drug ~~products~~ preparations.	
1751.7. (b) Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation. Page 29, line 18-28 Page 30, line 1-10	Each individual involved in the preparation of sterile ~~injectable~~ drug ~~products~~ preparations must first successfully demonstrate competency by successfully performing aseptic media fill tests ~~complete a validation process on technique~~ before being allowed to prepare sterile ~~injectable~~ drug ~~products~~ preparations. ~~The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare.~~ The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promoted growth. Completed ~~medium~~ media samples must be incubated in a manner consistent with the manufacturer's	

	recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the ~~validation process~~ media fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile ~~injectable~~ drug ~~products~~ preparations ~~is~~ are repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.	
1751.7. (c) Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation. Page 30, line 11-15	All compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.	
1751.7. (d) Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation. Page 30, line 16-18	Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.	
1751.7. (e) Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation. Page 30, line 19-29 Page 31, line 1-19	Batch-produced sterile ~~injectable~~ drug ~~products~~ preparations compounded from one or more non-sterile ingredients ~~shall be subject to documented end product testing for sterility~~ that are exposed longer than 12 hours at 2 to 8 degrees C and longer than 6 hours at warmer than 8 degrees C before they are sterilized shall meet the sterility test in accordance with methodologies and processes found in Chapter 71 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), and testing for pyrogens in accordance with the methods of Chapters 85 and 151 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. In a circumstance where a batch-produced sterile drug preparation compounded from one or more non-sterile ingredients is necessary for immediate dispensing where failure to dispense could result in loss of life or intense suffering, the drug preparation may be dispensed before receipt of test results so long as the pharmacy complies with a written procedure included in the pharmacy's policies and procedures that includes: (1) Prior to dispensing: (A) Notifying the prescriber of the inability to conduct testing; (B) Suggesting an available alternative product to the prescriber; and (C) Securing the prescriber's written consent to dispense. (2) And subsequent to dispensing: (A) Daily observation of the incubating test specimens; and	

	(B) Immediate recall of the dispensed compounded sterile preparation's when there is any evidence of microbial or pyrogen growth in the test specimens. Any such dispensing shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.	
1751.7. (d) **Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.** Page 31, line 20-22	~~Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.~~	
1751.8. (a) **Beyond Use Dating for Sterile Compounded Drug Preparations.** Page 32, line 6-23	Where the sterile compounded drug preparation was compounded solely with aseptic manipulations (1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using only sterile ingredients, products, components, and devices; and (2) the compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and (3) compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 48 hours at controlled room temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature.	
1751.8. (b) **Beyond Use Dating for Sterile Compounded Drug Preparations.** Page 32, line 24-25 Page 33, line 1-16	Where the sterile compounded drug preparation was compounded solely with aseptic Manipulations (1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and (2) the compounding process involves complex aseptic manipulations other than the single- volume transfer; and (3) the compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at	

	controlled freezer temperature.	
1751.8. (c) **Beyond Use Dating for Sterile Compounded Drug Preparations.** Page 33, line 17-30 Page 34, line 1-2	Where the sterile compounded drug preparation was compounded solely with aseptic manipulations entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using non-sterile ingredients, including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature. For the purposes of this paragraph, "non-sterile" includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation, transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.	
1751.8. (d) **Beyond Use Dating for Sterile Compounded Drug Preparations.** Page 34, line 3-18	Where the sterile compounded drug preparation was compounded solely with aseptic manipulations (1) entirely within an ISO Class 5 PEC that is located in a segregated compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and (2) the compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and (3) the compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet.	
1751.8. (e) **Beyond Use Dating for Sterile Compounded Drug Preparations.** Page 34, line 19-25	Where the sterile compounded drug preparation was compounded (1) using or containing hazardous drugs or components; and (2) in facilities that prepare a low volume of hazardous drugs, where low volume is defined as five or less per a week, the use of two tiers of containment (e.g., closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non-negative pressure room) the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours.	1751.8.(e) Low volume is not defined in any current national guidelines. Recommend deleting the low volume definition since (1) Moderate and high volume would no longer be addressed in the regulations, 2) There is no existing official definition of low volume chemo preparation and (3) new guidelines are pending from USP. delete

1751.8. (f) **Beyond Use Dating for Sterile Compounded Drug Preparations.** Page 34, line 26-29 Page 35, line 1-15	Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.	delete
1751.9 (a) **Single-Dose and Multi-Dose Containers; Limitations on Use** Page 35, line 20-21	Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.	delete
1751.9 (b) **Single-Dose and Multi-Dose Containers; Limitations on Use** Page 35, line 22-23 Page 36, line 1-6	Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents discarded within the following time limit, depending on the environment: (1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour; (2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours.	delete
1751.9 (c) **Single-Dose and Multi-Dose Containers; Limitations on Use** Page 36, line 7-11	Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such condition.	
~~**1751.8.**~~ **1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.** Page 36, line 17-19	In any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable~~ drug ~~products~~ preparations located in or immediately available to the pharmacy.	
~~**1751.10.**~~ **1752. Furnishing to Parenteral**	Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than	

Patient at Home. Page 37, line 7-9	controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.	
1753. (a) Furnishing to Home Health Agencies and Licensed Hospices. Page 38, line 1-11	The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is: (1) furnished by a registered pharmacist; (2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs; (3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy; (4) labeled on the outside of the container with a list of the contents; (5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.	
1753. (b) Furnishing to Home Health Agencies and Licensed Hospices. Page 38, line 12-29 Page 39, line 1-12	The portable container may contain up to: (1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy; (2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy; (3) two vials of urokinase 5000 units; (4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container: (A) heparin sodium lock flush 100 units/mL; (B) heparin sodium lock flush 10 units/mL; (C) epinephrine HCl solution 1:1000; (D) epinephrine HCl solution 1:10,000; (E) diphenhydramine HCl 50mg/mL; (F) methylprednisolone 125mg/2mL; (G) normal saline, preserved, up to 30 mL vials; (H) naloxone 1mg/mL 2 mL; (I) droperidol 5mg/2mL; (J) prochlorperazine 10mg/2mL; (K) promethazine 25mg/mL; (L) dextrose 25gms/50mL; (M) glucagon 1mg/mL; (N) insulin (human) 100 units/mL; (O) bumetamide 0.5mg/2mL; (P) furosemide 10mg/mL; (Q) EMLA Cream 5 gm tube; (R) Lidocaine 1 percent 30mL vials. (5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policy and procedures.	1753.(b) Recommend review and revision of medication listed in this section.
1753. © Furnishing to Home Health Agencies and Licensed Hospices. Page 39, line 23-33	The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not: (1) implement and maintain policies and procedures for: (A) the storage, temperature stability and transportation of the portable container; (B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and © a specific treatment protocol for the administration of each medication contained in the portable container. (2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.	
1753. (d)	A copy of these policies, procedures and protocols shall be maintained	

Furnishing to Home Health Agencies and Licensed Hospices. Page 39, line 34-36	by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.	
1753. (e) Furnishing to Home Health Agencies and Licensed Hospices. Page 39, line 37-39 Page 40, line 1-2	In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.	
1753. (f) Furnishing to Home Health Agencies and Licensed Hospices. Page 40, line 3-8	The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.	
1753. (g) Furnishing to Home Health Agencies and Licensed Hospices. Page 40, line 9-10	The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.	
1753. (h) Furnishing to Home Health Agencies and Licensed Hospices. Page 40, line 11-14	The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.	
1753. (i) Furnishing to Home Health Agencies and Licensed Hospices. Page 40, line 15-16	The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.	
~~**1751.12**~~ **1754. (a) Obligations of a Pharmacy Furnishing Portable Containers.** Page 40, line 22-24	A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section 1751.11.	
~~**1751.12**~~ **1754. (b) Obligations of a Pharmacy Furnishing Portable Containers.** Page 41, line 1-3	A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 1751.11.	

Lab Testing Requirements for Medium and Low Risk Sterile Compounding in 9/5/2014 Proposed Board of Pharmacy Compounding Regulations Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists *

<table>
<tr><th>Facility Testing</th><th>USP <797></th><th>Board of Pharmacy (BOP) Proposed</th></tr>
<tr><td>Viable surface sampling</td><td rowspan="2">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></td><td>• Monthly for low and medium risk California Code of Regulations (CCR) §1751.4 (i)
• Weekly for high risk
• Genus level identification of CFUs exceeding the threshold (facility determined)</td></tr>
<tr><td>Volumetric Air sampling by impaction: viable</td><td>• Every six months for low and medium risk
• Weekly for high risk
• Genus level identification of CFUs exceeding the threshold (facility determined)</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	Where Is The Requirement (BOP and USP)
Moderate 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 CCR §1735.1(n)	CCR §1751.6 (e) (1) (E) and §1751.7 (b)
Moderate 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		
High risk compounding – ongoing competency	Every 6 months as part of the competency testing process		
Product Batching (More than one of the identical product)			
Following manufacturer written communication (package insert or letter)	No requirement; facility policy should describe processes as determined by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) to assure sterility and accuracy of sterile compounding processes within the facility		CCR §1751.7(b)

End Product Testing: The Requirement For Sterility And Potency Testing Per Batch	Comments	USP<797>	BOP proposed July 30,2014
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	• 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 CCR §1751.3 (d)(3)(I)
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	• "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 §1751.3 (d)(3)(I)
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 • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(I)
Low/Med Risk Batch: "Batch" means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient. "Batch" does not refer to the process of preparing multiple, disparate sterile compounds for an upcoming time period – frequent cause of misunderstanding, as in the "morning batch."			

Temperature Monitoring Requirements in 9/5/2014 Proposed Board of Pharmacy Sterile Compounding Regulations Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists *

TEMPERATURE REQUIREMENTS								
Temperature Description	**Degrees Centigrade**		**Degrees Fahrenheit**		**Comments/Explanations** (Requires NIST certified temperature monitoring devices (USP <1118>))	**USP 37 NF 32 (2014)** (Used as a reference by the FDA for all Package Inserts)	**CDC Vaccine Storage** (May 2014)	**Board of Pharmacy (BOP) 9/5/2014 Proposed** (references 1995 USP)
	Min	Max	Min	Max				
Freezer (USP)	-25º	-10º	-13º	14º	• Check individual monographs for specific requirements outside this range	General Notices 10.20.10		CA Code of Regulations (CCR) §1731.1 (h)
Freezer (CDC)	-50º	-15º	-58º	5º	• Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Cold	NA	8º	NA	46º		General Notices 10.30.20		
Refrigerated	2º	8º	36º	46º			See CDC Vaccine Storage and Handling Toolkit	BOP defines CCT as 2.2º C to 7.7º C vs. USP and CDC range of 2º C to 8º C CCR §1731.1 (g)
Controlled Cold Temperature	2º	8º	36º	46º	• Transient excursions (0º to 15º C) but the calculated MKT must be ≤ 8º C (46º F) • Transient spikes to 25º C (77º F) (not to exceed 24 hours) if supported by manufacturer's stability in writing	General Notices 10.30.40		
Cool	8º	15º	46º	59º		General Notices 10.30.30		
Room Temperature	Prevailing room temperature					General Notices 10.30.50		CCR §1731.1 (i)
Controlled Room Temperature	20º	25º	68º	77º	• Excursions allowed between 15º to 30º C (59º to 86º F) as long as the MKT is ≤ 25º C (77º F) • Spikes to 40º C (104º F) are permitted for less than 24 hours as long as the MKT is ≤ 25º C (77º F) • Check for specific drugs with narrow ranges	General Notices 10.30.60		
Cleanroom Temperature		≤ 20º		≤ 68º	• In order to compensate for the additional layers of protective garb, this is the general recommendation.			Only appears in BOP 9/5/2014 proposed CCR §1751.4 (j)
Warm	30º	40º	86º	104º		General Notices 10.30.70		
Excessive Heat		>40º		>104º		General Notices 10.30.80		

Mean Kinetic Temperature (MKT) approximates the effects of temperature on drug degradation. Higher temperatures result in faster degradation; lower temperatures result in less degradation. MKT calculations weigh the various temperatures by 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 calculated by hand, by the temperature monitoring software vendor or by the manufacturer using software to determine the MKT for every product.
Note: 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. In this case, 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	**Comments**	**USP 37 NF 33**	**CDC Vaccines** (May 2014)	**BOP Proposed**
Freezers	• Daily lapse time monitoring or continuous monitoring • See CDC Vaccine Storage and Handling Toolkit (CDC website)	Daily	Twice daily	Daily CCR §1735.5 (c) (10) & §1751.5 (b) (5) (A, B, C)
Refrigerators		Daily	Twice daily	Daily CCR §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		

*** Check with legal counsel before relying on this document (Last updated 9/12/2014)**

Sterile Compounding Frequency of Documentation in 9/5/2014 Proposed Board of Pharmacy Regulations
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists*

Frequency	Low and Medium Risk	High Risk
Daily		
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 isolation rooms	X	X
MiniHelix differentials for Containment Aseptic Isolator (CAI) and Compounding Aseptic Containment Isolators (CACIs)	X	X
Clean the following with germicidal cleaners and disinfected with suitable agent (sterile isopropyl alcohol): - Counters - Cleanable surfaces - Floors	X	X
Cleaning within the ISO 5 environment (before each shift and before and after each batch)	X-> no alternative for closed system automation	X-> no alternative for closed system automation
Weekly		
Cleaning the following with germicidal cleaners and disinfected with suitable agents (sterile IPA): - Exterior workbench - Walls - Ceiling - Shelves - Tables - Stools	N/A	X (USP 797-> every 1 mo.)
Viable surface sampling (Colony Forming Units (CFUs) identified to genus)	N/A	X (USP 797-> every 6 mos.)
Volumetric air sampling (Particle count; CFUs, identified to genus)	N/A	X (USP 797-> every 6 mos.)
Monthly		
Cleaning the following with germicidal cleaners and disinfected with suitable agents (sterile IPA): - Exterior workbench - Walls - Ceiling - Shelves - Tables - Stools	X (USP 797-> every mo.)	N/A
Viable surface sampling (CFUs identified to genus)	X (USP 797-> every 6 mos.)	N/A
Bi-Annual		
Volumetric air sampling (Particle count; CFUs, identified to genus)	X	N/A
Hood certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Fingertip testing (initially x3)	N/A	x
Media Fill testing for employees	N/A	X
Annual		
Fingertip testing (initially x3)	x	N/A
Media Fill testing for employees	X	N/A
Competency testing (Observation/Written)	X	X

*** Check with legal counsel before relying on this document (Last updated 10/13/2014)**

Physical Plant Requirements in 9/5/2014 Proposed Board of Pharmacy Compounding Regulations
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists *

Location	Primary Engineering Control (PEC)	Beyond Use Dates		Comments
		Low Risk	Medium Risk	
Non-Hazardous Drugs (Low and Medium Risk)				
ISO Class 7 environment with physical separation (0.02-0.05" w.c. positive pressure differential) OR **Segregated Compounding Area without physical separation** (requires air velocity of ≥40 feet per minute from the cleanroom to the anteroom) CCR §1751.4 (f) & §1250.4 (1-4)	Any ISO Class 5 PEC: • ISO Class 5 Laminar Flow Hood • Biological Safety Cabinet with unidirectional flow • ISO Class 5 Compounding Aseptic Isolators (CAI) with unidirectional flow	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14°F CCR §1751.8 (a)	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F CCR §1751.8 (b)	• Requires ISO 5 PEC • ISO Class 7 Cleanroom CA Code of Regulations (CCR) §1735.51 & 1250
Any preparation area that is not ISO classed, >ISO 7, or does not meet pressure or air flow differentials CCR §1751.4 (f) & §1250.4 (1-4)	• ISO Class 5 Compounding Aseptic Isolators (CAI) with unidirectional flow	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14° CCR §1751.8 (h)	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F CCR §1751.8 (h)	• Requires ISO 5 PEC • Requires PEC manufacturer documentation CCR §1250.4 (5.3)
	• ISO Class 5 Laminar Flow Hood with unidirectional flow • Biological Safety Cabinet with unidirectional flow	12 hours CCR §1751.8 (d)		
	• No PEC • PEC that does not meet ISO Class 5 and/or unidirectional flow • Lack of gowning	1 hour from time of mixing CCR §1751.8 (f)	N/A	• Immediate use only for low risk non-hazardous agents • Does not require gowning
Hazardous Drugs				
Location	**Primary Engineering Control (All PEC's ISO class 5 negative pressure unidirectional flow)**	**Beyond Use Dates**		**Comments**
		Low Risk	**Medium Risk**	
Negative Pressure Room 0.01" w.c. negative (12 air exchanges per hour) CCR §1751.4 (g)	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B2 • Containment Aseptic Compounding Isolators (CACI)	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14°F	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F	• Requires certification every six months CCR §1751.4 (g)
Positive Pressure Room Low use defined as not more than 5 preps per week CCR §1751.8 (e) (2)	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B2	12 hours CCR §1751.8 (e) (1-3)		• Requires certification every six months CCR §1751.4 (g) • Requires use of Closed System Transfer Devices (CSTDs) CCR §1751.8 (e) (2)
	• Containment Aseptic Compounding Isolators (CACI)	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14°F	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F	• Requires certification every six months CCR §1751.4 (g) • Requires manufacturer documentation CCR §1751.4 (h) • Requires use of CSTDs CCR §1751.8 (e) (2)
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				
Transfer Devices				
The use of transfer devices (minibag plus, AddVantage, etc.) are not considered compounding and therefore a PEC is not required; however, the use of proper aseptic technique is required.				

* Check with legal counsel before relying on this document (Last updated 9/12/2014)

<table>
<tr><th>Environmental Testing</th><th>USP <797></th><th>Board of Pharmacy (BOP) Proposed</th></tr>
<tr><td>Viable surface sampling</td><td rowspan="2">Every six months: requires identification of every Colony Forming Unit (CFU) 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>• Monthly for low and medium risk California Code of Regulations (CCR) §1751.4 (i)
• Weekly for high risk
• Genus level identification of CFUs exceeding the threshold (facility determined)</td></tr>
<tr><td>Volumetric Air sampling by impaction: viable</td><td>• Every six months for low and medium risk
• Weekly for high risk
• Genus level identification of CFUs exceeding the threshold (facility determined)</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: Validation process shall be done in the same manner as normal production, except when appropriate microbiological growth medium is used in place of actual product used during sterile prep.</td></tr>
<tr><th>Personnel</th><th>When required</th><th>What Tests Are Required</th><th>Where Is The Requirement (BOP and USP)</th></tr>
<tr><td>Moderate risk compounding – initial competency</td><td>Prior to the first compound prepared for a patient</td><td rowspan="2">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(n)</td><td rowspan="3">CCR §1751.6 (e) (1) (E) and §1751.7 (b)</td></tr>
<tr><td>Moderate risk compounding – ongoing competency</td><td>Annually as part of the competency testing process</td></tr>
<tr><td>High risk compounding – initial competency</td><td>Prior to the first compound prepared for a patient</td><td rowspan="2">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(n</td></tr>
<tr><td>High risk compounding – ongoing competency</td><td>Every 6 months as part of the competency testing process</td><td></td></tr>
<tr><td colspan="4">Product Batching (More than one of the identical product)</td></tr>
<tr><td>Following manufacturer written communication (package insert or letter)</td><td>No requirement; facility policy should describe processes as determined by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) to assure sterility and accuracy of sterile compounding processes within the facility</td><td></td><td>CCR §1751.7(b)</td></tr>
<tr><th>End Product Testing: The Requirement For Sterility And Potency Testing Per Low/Med Risk Batch</th><th>Comments</th><th>USP<797></th><th>BOP proposed July 30,2014</th></tr>
<tr><td>Beyond Used Dating (BUD) is the lesser of the USP<797> or the manufacturer package insert/written communication</td><td>• Meets all PEC ISO 5 Requirements
• Low risk: 48 hour RT, 14 days refrigeration
• Medium risk: 30 hour RT, 9 days refrigeration</td><td>• As long as the shorter of the manufacturer insert stability and the USP<797> BUD is met, there is no batch sterility testing requirement</td><td>• “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 §1751.3 (d)(3)(I)</td></tr>
<tr><td>Extended BUD (USP<797>)</td><td>• 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</td><td>• No exemption for sterility testing for extended BUD
• Every batch of extended BUD requires sterility testing and sequestering</td><td>• “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 §1751.3 (d)(3)(I)</td></tr>
<tr><td>Potency testing is the USP monograph described testing of potency</td><td>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</td><td>• No requirements in USP<797></td><td>• Will require potency testing
• Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility
CCR §1751.3 (d)(3)(I)</td></tr>
<tr><td colspan="4">Low/Med Risk Batch: “Batch” means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient (non-patient specific). “Batch” does not refer to the process of preparing multiple, disparate sterile compounds for an upcoming time period – frequent cause of misunderstanding, as in the “morning batch.”</td></tr>
</table>

Non-Hazardous Drugs (Low and Medium Risk)				
Location	Primary Engineering Control (PEC)	Beyond Use Dates		Comments
		Low Risk	Medium Risk	
ISO Class 7 environment with physical separation (0.02-0.05" w.c. positive pressure differential) OR **without physical separation** (requires air velocity of ≥40 feet per minute from the cleanroom to the anteroom) CCR §1751.4 (f) & §1250.4 (1-4)	Any ISO Class 5 PEC: • ISO Class 5 Laminar Flow Hood • Biological Safety Cabinet with unidirectional flow • ISO Class 5 Compounding Aseptic Isolators (CAI) with unidirectional flow	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14°F CCR §1751.8 (a)	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F CCR §1751.8 (b)	• Requires ISO 5 PEC • ISO Class 7 Cleanroom CA Code of Regulations (CCR) §1735.1 & 1250
Segregated Compounding Area, Any preparation area that is not ISO classed, >ISO 7, or does not meet pressure or air flow differentials CCR §1751.4 (f) & §1250.4 (1-4)	• ISO Class 5 Compounding Aseptic Isolators (CAI) with unidirectional flow	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14° CCR §1751.4 (h)	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F CCR §1751.4 (h)	• Requires ISO 5 PEC • Requires PEC manufacturer documentation CCR §1250.4 (5.3) • Requires use of sterile gloves over isolator gloves
	• ISO Class 5 Laminar Flow Hood with unidirectional flow • Biological Safety Cabinet with unidirectional flow	12 hours CCR §1751.8 (d)	N/A	• 12 hours BUD for low risk non-hazardous preparations only
	• No PEC • PEC that does not meet ISO Class 5 and/or unidirectional flow • Lack of gowning	1 hour from time of mixing CCR §1751.8 (f)	N/A	• Immediate use only for low risk non-hazardous agents • Does not require gowning

Hazardous Drugs				
Location	Primary Engineering Control (All PEC's ISO class 5 negative pressure unidirectional flow)	Beyond Use Dates		Comments
		Low Risk	Medium Risk	
Negative Pressure Room and ISO Class 7 environment 0.01" w.c. negative (12 air exchanges per hour) CCR §1751.4 (g)	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B2 • Containment Aseptic Compounding Isolators (CACI)	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14°F	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F	• Requires negative pressure ISO 5 PEC • Requires certification every six months CCR §1751.4 (g)
Segregated Compounding Area, Any preparation area that is not ISO classed, >ISO 7, or Non-negative Pressure Room Low Volume defined as not more than 5 preps per week CCR §1751.8 (e) (2)	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B2	12 hours CCR §1751.8 (e) (1-3)		• Allowed only for Low Volume hazardous compounding • Requires certification every six months CCR §1751.4 (g) • Requires use of Closed System Transfer Devices (CSTDs) CCR §1751.8 (e) (2)
	• Containment Aseptic Compounding Isolators (CACI)	48 hours at 68-77°F 14 days at 36-46°F 45 days at -13-14°F	30 hours at 68-77°F 9 days at 36-46°F 45 days at -13-14°F	• Requires certification every six months CCR §1751.4 (g) • Requires manufacturer documentation CCR §1751.4 (h) • Requires use of CSTDs CCR §1751.8 (e) (2)

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
Transfer Devices
The use of transfer devices (minibag plus, AddVantage, etc.) are not considered compounding and therefore a PEC is not required; however, the use of proper aseptic technique is required.

Temperature Monitoring Requirements in 9/5/2014 Proposed Board of Pharmacy Sterile Compounding Regulations
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists *

TEMPERATURE REQUIREMENTS

Temperature Description	Degrees Centigrade		Degrees Fahrenheit		Comments/Explanations (Requires NIST certified temperature monitoring devices (USP <1118>))	USP 37 NF 32 (2014) (Used as a reference by the FDA for all Package Inserts)	CDC Vaccine Storage (May 2014)	Board of Pharmacy (BOP) 9/5/2014 Proposed (references 1995 USP)
	Min	Max	Min	Max				
Freezer (USP)	-25º	-10º	-13º	14º	• Check individual monographs for specific requirements outside this range	General Notices 10.20.10		CA Code of Regulations (CCR) §1731.1 (h)
Freezer (CDC)	-50º	-15º	-58º	5º	• Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Refrigerated	2º	8º	36º	46º	Exceptions for Transportation, Refrigerator Failure, Etc. • Transient excursions (0º to 15º C) but the calculated MKT must be ≤ 8º C (46º F) • Transient spikes to 25º C (77º F) (not to exceed 24 hours) if supported by manufacturer's stability in writing • See individual monographs or manufacturer information for specific acceptable excursions		See CDC Vaccine Storage and Handling Toolkit	BOP defines CCT as 2.2º C to 7.7º C vs. USP and CDC range of 2º C to 8º C CCR §1731.1 (g) (Note: Title 22 requires 2.2º-7.7º C)
Room Temperature	20º	25º	68º	77º	• Excursions allowed between 15º to 30º C (59º to 86º F) as long as the MKT is ≤ 25º C (77º F) • Spikes to 40º C (104º F) are permitted for less than 24 hours as long as the MKT is ≤ 25º C (77º F) • Check for specific drugs with narrow ranges	General Notices 10.30.60		
Cleanroom Temperature		≤ 20º		≤ 68º	• In order to compensate for the additional layers of protective garb, this is the general recommendation.			Only appears in BOP 9/5/2014 proposed CCR §1751.4 (j)

Mean Kinetic Temperature (MKT) approximates the effects of temperature on drug degradation. Higher temperatures result in faster degradation; lower temperatures result in less degradation. MKT calculations weigh the various temperatures by 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 calculated by hand, by the temperature monitoring software vendor or by the manufacturer using software to determine the MKT for every product.
Note: 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. In this case, 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	Comments	USP 37 NF 33	CDC Vaccines (May 2014)	BOP Proposed
Freezers	• Daily lapse time monitoring or continuous monitoring • See CDC Vaccine Storage and Handling Toolkit (CDC website)	Daily	Twice daily	Daily CCR §1735.5 (c) (10) & §1751.5 (b) (5) (A, B, C)
Refrigerators		Daily	Twice daily	Daily CCR §1735.5 (c) (10) & §1751.5 (b) (5) (A, B, C)
Room Temperature	• Includes all drug storage location rooms: no specific requirements for monitoring inside Automated Dispensing Cabinets	Daily		

*** Check with legal counsel before relying on this document (Last updated 12/22/2014)**

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Sterile Compounding Frequency of Documentation in 9/5/2014 Proposed Board of Pharmacy Regulations
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists*

Frequency	Low and Medium Risk	High Risk
Daily		
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 isolation rooms	X	X
MiniHelix differentials for Containment Aseptic Isolator (CAI) and Compounding Aseptic Containment Isolators (CACIs)	X	X
Cleaning of the following: - Counters - Cleanable surfaces - Floors	X	X
Cleaning within the ISO 5 environment (before each shift and before and after each batch)	X-> no alternative for closed system automation	X-> no alternative for closed system automation
Weekly		
Cleaning of the following: - Exterior workbench - Walls - Ceiling - Shelves - Tables - Stools	N/A	X (USP 797-> every 1 mo.)
Viable surface sampling (Colony Forming Units (CFUs) identified to genus)	N/A	X (USP 797-> every 6 mos.)
Volumetric air sampling (Particle count; CFUs, identified to genus)	N/A	X (USP 797-> every 6 mos.)
Monthly		
Cleaning of the following: - Exterior workbench - Walls - Ceiling - Shelves - Tables - Stools	X (USP 797-> every mo.)	N/A
Viable surface sampling (CFUs identified to genus)	X (USP 797->"periodic basis")	N/A
Semi-Annual		
Volumetric air sampling (particle count; CFUs, identified to genus)	X	N/A
Hood certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Fingertip testing (initially x3)	N/A	X
Media Fill testing for employees	N/A	X
Competency testing (observation/written)	N/A	X
Annual		
Fingertip testing (initially x3)	X	N/A
Media Fill testing for employees	X	N/A
Policy and procedure review	X	X
Competency testing (Observation/Written)	X	N/A

*** Check with legal counsel before relying on this document (Last updated 12/22/2014)**

*** USP 797 recommendations in parenthesis**

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

January 5, 2015

TO: CHA Membership Safety Committee Members

FROM: BJ Bartleson

SUBJECT: PharMEDium

PharMEDium has issued a letter of concern to BOP over its licensure statute within the state (see attached letter). California requirements and PharMEDium FDA status conflict and CA hospitals are at risk of losing access to PharMEDium sterile compounding products.

PharMEDium Services, LLC

Two Conway Park
150 North Field Drive
Suite 350
Lake Forest, IL 60045

T 847-457-2300
F 847-234-1363

www.pharmedium.com

December 23, 2014

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834

RE Proposed California Compounding Regulations Threaten Supply of Compounded Medications to Hospital Pharmacies

Dear Ms. Herold:

Thank you for meeting with representatives of PharMEDium during the American Society of Health-System Pharmacists' recent conference in Anaheim. I know your schedule is demanding and appreciate your efforts to make time for our meeting.

PharMEDium understands your desire to be vigilant in the oversight of compounding, and supports your goal of raising the bar on quality. At PharMEDium, we share the Board of Pharmacy's commitment to ensuring the safe supply of compounded sterile preparations (CSPs). To that end, we have grave concerns about the Board's plans to finalize proposed revisions to several sections of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations ("proposed regulations"). Alongside hospital industry professionals and organizations, PharMEDium has provided written comments on several occasions and supporting verbal comments at the recent open Board hearing to relay our concerns.

If the proposed regulations are finalized without significant revisions, we believe they would directly conflict with federal law and inadvertently reduce the supply of high-quality CSPs. In particular, they could prevent PharMEDium and other federally registered Outsourcing Facilities from continuing to supply California hospitals and health care providers. This outcome could have far-reaching implications for the delivery of health care in California, further exacerbate current drug shortages and supply interruptions in the region, and quickly lead to a public health crisis.

We recognize that the California State Board of Pharmacy's highest priority is the protection of the public health.[1] Unfortunately, we believe that these proposed regulations would inadvertently jeopardize the safety and quality of the drug supply. There are a number of alternatives available to the Board under federal and state law that would ensure that public health interests are advanced. Because FDA-registered Outsourcing Facilities, not operating as 503A Pharmacies, do not

[1] CAL. BUS. & PROF. CODE § 4001.1.

meet the statutory definition of "pharmacy" and their activities do not constitute "compounding" as defined in California statute, the Board should avoid imposing requirements that conflict with federal law and should not require these facilities to maintain a Nonresident Pharmacy Permit or a Nonresident Sterile Compounding License.

In the remainder of this letter we:

- Describe the need for outsourced preparation of CSPs;
- Identify central objectives of the Drug Quality and Security Act of 2013 (DQSA);
- Explain how the Board's proposed regulations would unintentionally undermine those objectives; and
- Propose several alternatives that would advance the public health without running afoul of or undermining federal law.

I. California Hospitals Have a Legitimate Need to Outsource The Preparation of Sterile Compounds

The legitimate need for CSPs is undeniable. For example, essentially all epidural pain management products used routinely in settings such as labor and delivery are compounded products. A recent report by the U.S. Department of Health and Human Services Office of the Inspector General (OIG) found that 92 percent of hospitals used CSPs in 2012 for products ranging from antibiotics to opioids, epidurals, oxytocics, total parenteral nutrition, and cardioplegic solutions.[2] The vast majority of these hospitals outsourced the preparation of some or all CSPs.

Over time, hospitals have increasingly turned to outsourcers that are able to prepare CSPs, customized to their medical faculty's specifications, and prepared under controlled conditions. Unlike hospital settings—which are not held to manufacturing standards (and roughly half of which do not have on-site facilities that meet minimum USP standards for sterile compounding)—Outsourcing Facilities compound these preparations in tightly regulated environments.[3] Unlike hospital pharmacies, Outsourcing Facilities conduct extensive testing to ensure the identity, potency, stability and sterility of CSPs.

If hospitals are unable to use FDA-registered and inspected Outsourcing Facilities to supply their CSPs, they will have to turn to alternative suppliers or to "insource" compounding back into the hospital. Shifting production to "traditional" compounding pharmacies that fall under section 503A of the FDCA could be even more detrimental to public health than insourcing. All of these

[2] Department of Health and Human Services Office of Inspector General, *Memorandum Report: High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them*, OEI-01-13-00150 (Apr. 10, 2013).

[3] *See* Roy Guharoy et al., *Compounding Pharmacy Conundrum: We Cannot Live Without Them but We Cannot Live With Them According to the Present Paradigm*, 143(4) CHEST 896 (2013). The study also found that far less than half of smaller hospitals had USP-compliant facilities.

pharmacies do not follow applicable current Good Manufacturing Practices (CGMPs), many do not even meet the minimum USP <797> standards and are not prepared to process hospital required volumes, either from a physical or personnel capacity.

PharMEDium alone supplies 249 hospitals and health systems throughout the State of California. The volumes of these products, on average, range from a few dozen to several hundred units per hospital per day. The solutions range from simple admixtures to very complicated epidural formulas, many of which have been purchased by the accounts from us for years. There are over 50 therapies that are covered by our services. We are aware of several other Outsourcing Facilities that provide large-scale production of CSPs to California hospitals. If the entire supply from Outsourcing Facilities were to cease, hospitals would be left scrambling to replace critical preparations and would surely overburden ill-equipped smaller pharmacies and hospital-based facilities, thus jeopardizing patient health.

II. Congress Established Section 503B to Ensure the Supply of High-Quality Sterile Compounds Subject to Robust Federal Oversight

In late 2012, the deadly fungal meningitis outbreak drew the attention of the U.S. Congress and revealed the need for clearer lines of state and federal oversight of large-scale, anticipatory drug compounding, and clarification of the confines of state-licensed and inspected pharmacy compounders. The DQSA was born out of congressional desire to eliminate the patchwork of federal and state regulations, which allowed the deadly outbreak to occur, by placing one responsible regulator on the "flagpole" for each facility.[4]

Title I of the DQSA clarified the Food and Drug Administration's (FDA's) oversight of traditional pharmacy compounding under section 503A of the federal Food, Drug, and Cosmetic Act (FDCA), and created a pathway for Outsourcing Facilities to engage in larger-scale compounding of CSPs for use in health care settings without employing a pharmacy model or obtaining individual patient prescriptions. Instead, Outsourcing Facilities must register with FDA under section 503B of the FDCA, pay annual and inspection fees, submit to routine FDA inspections, and meet manufacturing standards and other requirements.

Outsourcing Facilities are now firmly under FDA oversight. The DQSA characterizes Outsourcing Facilities as "electing" to register with FDA. This has been misconstrued by some to suggest that an entity engaging in outsourcing activities may also opt *not* to be FDA-regulated. Registration is only optional in

[4] *See* H.E.L.P. Committee Chairman Tom Harkin, 159;160 CONG. REC. S7941 (Nov. 12, 2013), responding to Senator Alexander's comments that the DQSA is designed "to find a way to clarify who is accountable for large-scale drug compounding facilities, who is on the flagpole for overseeing the safety of drugs made in these facilities." Adding "To be in this category, [Outsourcing Facilities] follow one nationwide quality standard, and the FDA is responsible for all the drugs made in that facility. FDA is on the flagpole."

the sense that no company is obligated to engage in a particular line of business. As the DQSA provides, "Upon electing *and in order to become* an outsourcing facility," an entity "shall register" with FDA.[5] Thus, any entity wishing to engage in sterile compounding must either: (1) meet all of the requirements of section 503B; (2) abide by the parameters of section 503A, including receipt of a patient-specific prescription;[6] or (3) meet all of the requirements of the FDCA applicable to conventional drug manufacturers, including filing new drug applications and obtaining premarket approval. The only option for an entity distributing CSPs without a prescription is to be registered with the FDA and regulated as an Outsourcing Facility.

A second concern raised by various stakeholders concerns the degree of actual FDA oversight during this initial phase of the DQSA implementation. There is a misperception that FDA has not been actively scrutinizing new 503B registrants or compounding operations generally. That is not the case. FDA has been actively implementing the DQSA, promulgating new regulations, issuing numerous draft, interim, and final guidance documents, and establishing a new advisory committee to advise the Agency on sections 503A and 503B of the FDCA. FDA inspectors have conducted more than 175 inspections of compounding facilities in the past two years, issued Form-483 observations in most cases, sent dozens of warning letters to compounders, and taken further corrective actions as necessary.[7] As of December 19, 2014, FDA had conducted 46 inspections of Outsourcing Facilities—conducting 13 of those inspections in the second half of 2014, including a number of re-inspections—and neared completion of its objective to inspect all registered facilities.[8] In fact, the Agency has issued new Form-483s and warning letters within the past several weeks. FDA has followed through with enforcement as well, overseeing more than 20 product recalls and seizing product and pursuing charges in extreme cases. Notably, the vast majority of warning letters, recalls and additional enforcement actions have been directed at section 503A compounding pharmacies that operate primarily under state jurisdiction.

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[5] FDCA § 503B(b)(1)(A)(i) (*codified at* 21 U.S.C. § 353b) (emphasis added).

[6] 21 U.S.C. § 353a(a) (exempting from FDCA requirements a "drug product [that] is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation . . . [or] by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient").

[7] *See* FDA Commissioner Margaret Hamburg, *Protecting the Public from Unsafe Compounded Drug Products*, FDA VOICE, Dec. 17, 2014, *available at*: http://blogs.fda.gov/fdavoice/index.php/2014/12/protecting-the-public-from-unsafe-compounded-drug-products/?source=govdelivery&utm_medium=email&utm_source=govdelivery. *See also* FDA, *Compounding: Inspections, Recalls, and other Actions*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm.

[8] *See* FDA, *Registered Outsourcing Facilities*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm (*updated* Dec. 5, 2014).

preparation of a "written master formula," and limits on the volume that can reasonably be compounded. Section 1751 establishes detailed criteria for many aspects of compounding operations that cover the same topics as, but are inconsistent with, significant elements of section 503B CGMPs—relating to buffer areas, ISO environments, compounding attire, storage protocols, and release testing.

The DQSA section on "Labeling of drugs" establishes a comprehensive set of labeling requirements for drugs prepared in Outsourcing Facilities—fifteen separate items in total, which FDA can supplement via rulemaking.[13] The Board's proposed section 1735.4 includes labeling requirements that would expand upon the federal statutory requirements, by requiring the name of the dispensing entity and the beyond use date. In contrast, the DQSA requires the expiration date. Having two different dates and conflicting terminology on the labeling adds little value and is potentially confusing for health care providers and patients. Moreover, because an Outsourcing Facility's batch production must employ uniform labeling to satisfy FDA requirements, including additional items on the labels of only those products shipped into California would vastly complicate production, and undermine batch uniformity.

Beyond labeling and compounding standards, many of the Board's other proposed requirements deviate substantially from the federal regulatory framework. The limitation of a 72-hour anticipatory supply is inconsistent with section 503B and the DQSA's pronouncement that Outsourcing Facilities are not required to obtain prescriptions for the drug products they distribute.[14] In implementing the DQSA, FDA established a robust protocol for reporting serious adverse events that differs from the scope, process, and timeframes included in the Board's proposed regulations. Under section 503B CGMPs, Outsourcing Facilities are required to keep extensive records; but these record-keeping requirements differ in many respects from those proposed by the Board.

It does not serve the public health to preclude Outsourcing Facilities from fulfilling a role that the DQSA explicitly allows—namely, supplying needed compounded medications in quantities that support higher quality, GMP-level, development. That role cannot be effectively fulfilled if states then require them also to operate within the confines of traditional pharmacy practice. The purpose of the DQSA is thwarted by requiring section 503B registrants to take and maintain individual prescriptions, provide patient counseling services, and maintain patient-specific records, as pharmacies must do. It would simply not be feasible for PharMEDium to comply with all applicable federal requirements under the FDCA and all of the proposed regulatory requirements for a Nonresident Pharmacy Permit in California. And it surely would be impossible if more states sought to overlay their own unique and conflicting standards on the mandatory federal scheme. Not only would this make interstate shipment

[13] 21 U.S.C. § 353b(a)(10).
[14] 21 U.S.C. § 353b(d)(4)(C).

impracticable for Outsourcing Facilities, it would immensely complicate FDA's job and undermine the central objective of the DQSA – regulatory certainty and clear lines of authority.

We urge the Board not to finalize the draft regulations as currently written or, alternatively, to exempt federally registered Outsourcing Facilities from the Nonresident Pharmacy Permit and Nonresident Sterile Compounding License requirements.

IV. Constructive Approaches that Do Not Conflict with Federal Law Are Available to the Board

In our public comments, PharMEDium identified alternative approaches that would comport with California statutes without violating federal law or undermining the promising public health benefits of the DQSA.

The most straightforward solution would be to expressly exempt FDA-registered Outsourcing Facilities from the obligation to hold a Pharmacy Permit and a Sterile Compounding License. This approach is consistent with exemptions for other entities subject to lesser oversight by private accreditation entities. Not only would including such an exemption fall within the Board's legal authority, but it appears to be the more faithful reading of California SB 294 and other provisions of the California Business and Professional Code. Nothing in California law requires an Outsourcing Facility to hold a sterile compounding license. SB 294 only prohibits "a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state" without a sterile compounding license.[15] Outsourcing Facilities are *not* pharmacies (unless they elect to also operate as one) just as conventional drug manufacturers are not. Presumably, other classes of FDA-regulated manufacturers, such as conventional drug manufacturers, may ship product into the State without obtaining this license.

According to California statute, a "pharmacy" includes any "premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded."[16] Most Outsourcing Facilities are not practicing the profession of pharmacy and are not compounding per *prescriptions*, but rather customer orders. In the proposed regulations, "compounding" is defined as a series of activities "occurring in a licensed pharmacy . . . pursuant to a prescription." This is fundamentally different than the function for which the Outsourcing Facility category was created. To the extent that the Board feels compelled to license federally regulated Outsourcing Facilities, the Board should issue a new license specifically designated for Outsourcing Facilities, which is subject to federal requirements incorporated by reference.

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[15] SB 294 Legislative Counsel's Digest (Oct. 4, 2013). *See also* CAL. BUS. & PROF. CODE § 4127.2(a).

[16] CAL. BUS. & PROF. CODE § 4037(a).

Alternatively, the Board could consider licensing Outsourcing Facilities as manufacturers or wholesalers (or at least incorporate them in the general category); as they are licensed in most other states, and apply the applicable regulatory requirements to the extent they are consistent with the FDCA. California's statutory definition of "manufacturer" "includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."[17] The subsequent exception for a pharmacy that compounds "pursuant to a prescription" would not appear to extend to Outsourcing Facilities or other entities that compound "prior to receipt of the prescription."[18] Moreover, the Board could choose to continue to perform inspections of California licensed 503B Outsourcing Facilities, under federal standards, until such time as the Board gains confidence in FDA's oversight of those entities.

As noted, we do not read SB 294 or other California statute to be in conflict with the DQSA, FDCA or other federal law, because California laws do not categorize Outsourcing Facilities or otherwise impose any regulatory requirements on them. To the contrary, SB 294 seeks to align the Board's "activities related to the inspection and licensure of nonresident pharmacies" with changing federal laws that govern compounding.[19] SB 294 certainly does not dictate promulgation of these regulations as proposed, which would create a conflict with, rather than alignment with, federal standards. Nevertheless, if further clarity from the legislature would help guide a positive legal framework for Outsourcing Facilities that aligns with federal law, PharMEDium and other members of the health care sector are eager to work with the Board in that endeavor.

We hope that the Board will use this opportunity to make further refinements to the proposed regulations to avoid undermining the potential public health benefits of the DQSA by disrupting the supply of high-quality and safe outsourced CSPs. PharMEDium desires to continue to serve our California hospital clients and their patients. We encourage the Board to work in partnership with FDA to facilitate the implementation of DQSA at the state level, and to use PharMEDium as a resource if we can be helpful in any way.

* * *

[17] *Id.* § 4033(a)(1).
[18] *Id.* § 4033(a)(2).
[19] SB 294 § 7 (*codified at* CAL. BUS. & PROF. CODE § 4127.2(g)).

Once again, I thank you for your time in meeting with PharMEDium, thoughtfully reviewing our comments and others, and continuing to find solutions that will advance the public health. Please do not hesitate to contact me at [(847-457-2323/ BSpalding@pharmedium.com] if you have any questions or comments.

Sincerely,

for William Spalding

William Spalding
Chief Executive Officer
PharMEDium Services, LLC

cc: Members, California State Board of Pharmacy
Secretary Anna Caballero

bcc: California Hospital Association
[redacted]

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

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN, JR.
Governor

December 16, 2014 AFL 14-34

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

SUBJECT: Pharmaceutical Service Changes Made by Senate Bill (SB) 1039

AUTHORITY: Health and Safety Code (HSC) Sections 1250.06, 11150, 11210;
Business & Professions Code (BPC) Sections 4115, 4119.6, 4119.7

This All Facilities Letter (AFL) provides notice of the enactment of SB 1039 (Chapter 319, Statutes of 2014), effective January 1, 2015.

SB 1039 makes the following changes regarding the provision of pharmaceutical services in GACHs:

- *Pharmacy Technicians.* A pharmacy technician, working under the direct supervision and control of a pharmacist in a GACH, may perform any of the following duties:
  - packaging emergency supplies for use in the GACH and the hospital's emergency medical system, or as authorized by BPC section 4119 regarding the furnishing of dangerous drugs/devices for emergency pharmaceutical supply containers;
  - sealing emergency containers for use in the GACH; and
  - performing monthly checks of the drug supplies stored throughout the GACH, with irregularities being reported within 24 hours to the pharmacist in charge and the director or the chief executive officer of the facility in accordance with the facility's policies and procedures (P&Ps).

- *Intern Pharmacists*. Intern pharmacists under the direct supervision and control of a pharmacist may:
  - stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a GACH;
  - inspect the drugs maintained in the GACH at least once per month, with the facility being required to establish specific written P&Ps for such inspections.

- *Furnishing Dangerous Drugs or Dangerous Devices*. A hospital pharmacy servicing a GACH may furnish a dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocols established under the facility's P&Ps as approved according to the policies of the facility's governing board, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or device will be provided.

- *Storage and Maintenance of Drugs*. A GACH shall store and maintain drugs in accordance with national standards regarding the storage areas and refrigerator and freezer temperatures, and otherwise pursuant to the manufacturer's guidelines. Nationally recognized standards would include:

    - *U.S. Pharmacopeial Convention* (USP 34), General Notices and Requirements (link: http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/USP34-NF29General%20Notices.pdf), Section 10: Preservation, Packaging, Storage and Labeling.

    - Centers for Disease Control and Prevention: *Vaccines and Immunizations* (link: http://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html), the best practice guidance for the storage and handling of vaccines.

The facility's P&Ps must specify the above storage parameters.

SB 1039 makes the following change regarding the provision of pharmaceutical services in both GACHs and APHs:

- Facilities must adopt P&Ps regarding the responsibility for ensuring proper methods of repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital. Contrary to Sections 70263(s) and 71233(s) of Title 22 of the California Code of Regulations (CCR), GACHs and APHs will no longer be required to consult a pharmacist regarding the repackaging and labeling of these substances, except for areas where sterile compounding is performed.

Several sections of SB 1039 address topics already covered by Title 22. In some instances, the statutory change conflicts with those regulations. Until the department can promulgate revisions to Title 22 that reflect the changes made by SB 1039, facilities seeking to follow the BPC provisions must request and receive program flexibility from their local district office. In order to help facilities identify those conflicts, a comparison table is attached to this AFL. Facilities must submit all program flexibility requests in writing and include supporting documentation such as proposed policies and procedures. The program flexibility request form can be found at the link below.

http://www.cdph.ca.gov/pubsforms/forms/CtrldForms/cdph5000.pdf

Please note that facilities are responsible for following all applicable laws. Any failure of the California Department of Public Health to expressly notify facilities of statutory or regulatory requirements does not relieve facilities of their responsibility for following all laws and regulations. Facilities should refer to the full text of all applicable sections of the HSC, the BPC, and Title 22 of the CCR to ensure compliance.

If you have questions regarding any of the matters discussed in this AFL, please contact your local district office.

Sincerely,

Original signed by Jean Iacino

Jean Iacino
Interim Deputy Director

Attachment

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

January 5, 2015

TO: CHA Medical Safety Committee Members
FROM: Alicia Munoz and Julie Morath
SUBJECT: Safe Prescribing Practices and Hospital ED Satisfaction

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Physicians are reporting concerns with deploying the safe pain prescription guidelines that may result in patient dissatisfaction affecting HCAP scores.

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

January 5, 2015

TO: CHA Medical Safety Committee Members

FROM: David Perrott, MD

SUBJECT: Generic Drug Prices

Please see the attached article describing generic drug price increases and the problem the FDA is having in controlling costs.

How is this affecting California hospitals?

http://www.nxtbook.com/nxtbooks/medimedia/pt_201412/#/26

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

Generic Prices Take Flight

The FDA Is Struggling to Ground Them

Stephen Barlas

Over the past few years, safety and effectiveness have been the issues plaguing generic pharmaceuticals. But concern has largely faded about the quality of active pharmaceutical ingredients manufactured in places such as India or China, or the bioequivalence of products such as Budeprion XL 300 mg. Now a new series of question marks hovers over generic drugs.

The price of generics looms largest. Still prized for their low cost, some generics have lifted off into the dollar stratosphere—though admittedly they haven't reached the moon like some new brand-name drugs, such as Gilead's Sovaldi. That said, the number of generics posting higher prices, and the height of those leaps, worry consumers, payers, and some members of Congress.

Stephen Barlas

A variety of reasons account for the increases. Loss of momentary competition in a category because one manufacturer stops producing, for any number of reasons, comes into play. So does the dropping of product lines. New products in existing generic markets find the door to entry barred, sometimes by competitors already selling into that market, sometimes by a Food and Drug Administration (FDA) besieged by applications and understaffed to handle them.

The FDA must approve abbreviated new drug applications (ANDAs) filed by generic drug companies, and the agency was thought to be making big strides in light of $300 million a year in new user fees from generic companies thanks to the 2012 Generic Drug User Fee Amendments (GDUFA). The fees were supposed to guarantee faster approval, leading to lower costs to companies and lower prices for new drugs that would be introduced more quickly.[1] But some industry experts think that GDUFA has failed to deliver, and that the FDA has gone backward on approval speed.

Walter Jump, President of Cornerstone Regulatory (a consulting firm that works with both generic and brand-name companies), says that costs for industry have increased since the passage of GDUFA. "Nothing provided for in GDUFA will decrease costs to industry. Although the Generic Drug User Fee Amendments propose to reduce the current delays in the drug approval process, currently there is no proof that the delays in the current approval process are being addressed," Jump says. In fact, the FDA's ANDA backlog has increased. Currently, Mylan Inc. has 288 ANDAs awaiting FDA approval that represent $111.5 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing $28.7 billion in annual brand sales for the 12 months ending June 30, 2014, IMS Health adds.

During a meeting at the FDA on September 17, 2014, called to air a number of GDUFA issues, David R. Gaugh, RPh, Senior Vice President for Sciences and Regulatory Affairs of the Generic Pharmaceutical Association (GPhA), said that in 2013, the median time for generic drug approvals jumped to 36 months and is projected to reach 43 months in 2014 once the final numbers are in.

Jump hypothesizes that the slowdown in approval times may be related in part to the need for more-experienced FDA drug reviewers to spend part of their time training new drug reviewers who have been hired thanks to the $300 million infusion. Such training will take time to ensure that all these new employees are consistent in their reviews.

"The generic supply chain has become very fragile. For many generic drugs, there are only a few suppliers," says Adam J. Fein, PhD, of Pembroke Consulting, Inc. "Any supply shock to the system, such as a manufacturing problem or FDA action, can rapidly create a shortage because alternative capacity isn't ramping up to meet demand."

Tetracycline shortages, for instance, have resulted in much higher generic prices. Watson Pharmaceuticals stopped producing tetracycline tablets in December 2013 and was acquired by Activis PLC in 2014. Activis has not restarted production. As of October 2014, Teva Pharmaceutical Industries Ltd., a one-time producer of tetracycline, was no longer selling the product because of a raw material shortage. Heritage Pharmaceuticals Inc. markets the brand-name version of tetracycline, called Achromycin V. In October 2013, Heritage announced it was making available generic tetracycline HCl capsules in 250- and 500-mg strengths. Not surprisingly, then, with only one manufacturer in the game, the price of tetracycline 500-mg and 250-mg tablets increased from $0.05 and $0.06 per capsule in July 2013 to $8.59 and $4.26 in July 2014. Those are increases of 17,714% and 7,340%, based on pricing data from Drug Channels, a website written by Dr. Fein.[2]

The Importance of Generics

The importance of generics to slowing the growth of health care costs is obvious. The FDA has approved more than 8,000 generic equivalents to brand-name drugs; as a result, generics represent more than 85% of all U.S. prescriptions and have saved U.S. consumers and the health care system $1.5 trillion in the past decade alone, according to the GPhA.

For years, the discounted price of generics was the glittering jewel in their crown. Not any more. Escalating prices have hit hospital pharmacies, drug stores, and consumers alike. This year, Walgreens fired its chief financial officer and the president of its pharmacy, health, and wellness division because they underestimated the cost of generic drugs and overestimated pharmacy unit earnings for the fiscal year ending in 2016.

Insurance plans are responding in order to mitigate the price pressures. Dr. Fein states, "Some payers are already establishing a 'nonpreferred' or 'more costly' generic tier for products that

continued on page 843

Mr. Barlas, a freelance writer based in Washington, D.C., covers topics inside the Beltway.

continued from page 833

have experienced significant inflation. If generic inflation continues, I expect to see more plans with multiple generic tiers."

Hospitals are suffering from generic drug price increases, too, since drug costs for any inpatient "event" are bundled into the cost of reimbursement for that patient, whether Medicare, Medicaid, or a private insurer is paying. Any generic drug price increase will not be reflected in the global payment from private or public insurers, paid on the basis of a diagnosis-related group (DRG)—at least not any time soon. True, generic costs make up a tiny percentage of any DRG reimbursement. But over the course of a year, they may add up. Hospitals also face potential cost implications on the outpatient pharmacy side. "The average selling price for the generic will not be updated for up to six months after the actual price increase, meaning hospitals will have to pay the difference for that six-month period," explains Bill Woodward, MS, RPh, Senior Director of Pharmacy Contracting for Novation, a contracting and information company that serves 100,000 members and affiliates of VHA Inc. and UHC, two national health care alliances; Children's Hospital Association, an alliance of the nation's leading pediatric facilities; and Provista, LLC.

Generic price increases have caught the attention of some in Congress. On October 2, Representative Elijah Cummings, ranking member of the House Committee on Oversight and Government Reform, and Senator Bernard Sanders, Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor, and Pensions, sent letters to 14 generic drug manufacturers requesting information about the escalating prices they have been charging for generic drugs.[3] "When you see how much the prices of these drugs have increased just over the past year, it's staggering, and we want to know why," says Cummings.

Huge Generic Price Increases

In their letters, Cummings and Sanders cited data from the Healthcare Supply Chain Association on purchases of 10 generic drugs by group purchasing organizations for which prices have skyrocketed in the past year. Among the citations:

- Albuterol sulfate, used to treat asthma and other lung conditions, increased 4,014% in price, from $11 to $434 for a bottle of 100 2-mg tablets.
- Doxycycline hyclate, an antibiotic used to treat a variety of infections, increased 8,281% in price for a bottle of 500 100-mg tablets (from $20 to $1,849).
- Glycopyrrolate, used to prevent irregular heartbeats during surgery, increased 2,728% in price for a box of 10 0.2-mg/mL, 20-mL vials (from $65 to $1,277).

It doesn't appear that any of the 10 drugs cited in the letters are marketed by only one company, so competition should keep prices from breaking through the roof. But in some instances, that competition is limited. Albuterol sulfate is sold by Mylan and Mutual Pharmaceuticals. Doxycycline hyclate is sold by 10 companies, with three representing most of the market share. West-Ward, Inc., dominates the market for glycopyrrolate.

Mylan, Teva, and Lannett Company, Inc., are among the companies that received the Cummings/Sanders letter. The first two did not respond to a query asking for a response. In its 2013 annual report, Lannett said: "Gross profit improved considerably to $57 million from $39 million. As a percent of net sales, gross margin rose to 38% from 32%, with the increase primarily due to favorable sales mix, price increases, and enhanced manufacturing efficiencies." Asked about the extent of product price increases, spokesman Robert Jaffe says, "Lannett's management respectfully declines to be interviewed."

Why the Price Hikes?

A number of factors can cause a spike in a generic price, justifiable or perhaps not. There are also reasons why drug prices won't drop. A number of mega-consolidations have taken place in the industry over the past few years. One by one, generic companies are disappearing. Competition in each category is diminishing. Earlier this year, Mylan acquired Agila Specialties Private Ltd., giving Mylan a strong hold on the generic injectables market. In that instance, the FDA forced Mylan to divest drugs in a number of categories before it approved the acquisition. For example, Mylan divested etomidate injection, ganciclovir injection, and some other injectables to JHP Pharmaceuticals. Earlier this year, Par Pharmaceutical Companies, Inc., acquired JHP. Valeant Pharmaceuticals International, Inc., is trying to acquire Allergan, Inc., and promises, if successful, to put a plug in its research pipeline. Teva acquired Cephalon, Inc., in 2012. Also in 2012, Valeant bought Ortho Dermatologics, Inc., from Johnson & Johnson and Dermik Laboratories, Inc., from Sanofi.

New products are not entering the market as quickly as had been hoped in the wake of GDUFA passage. And when they do enter the market, it is after the manufacturer has spent more in development and regulatory costs than might otherwise have been necessary. The GDUFA was supposed to pave the way for eliminating ANDA approval backlogs by mandating, for the first time, that generic suppliers pay "user fees" to the FDA. In return, the agency committed to approving ANDAs—submitted when a generic company wants to sell a copy of a patented pharmaceutical—according to specified time frames. The fees amount to about $300 million a year. The GDUFA required the FDA to publish five guidance documents that lay out how the agency planned to meet the approval deadlines in its GDUFA "commitment letter." For example, the FDA has committed to review and act on 90% of original ANDA submissions within 10 months from the date of submission in year 5 of the program, which begins on October 1, 2016.

Of course, generic companies themselves are responsible for many delays. They fight like Hatfields and McCoys over whether one or the other should have its ANDA approved, whether as the "first-time" generic in a category or as a new competitor to an existing generic. One example is Apotex Corporation's filing of a citizen petition with the FDA in January 2014 to block Forest Laboratories' generic version of Apotex's Namenda XR (memantine hydrochloride extended release capsules). The Apotex drug was approved in June 2010 and first became available in June 2013. Apotex argued that since its drug only became available in June 2013, it would have been impossible, time-wise, for Forest to conduct the required bioequivalence studies. The FDA rejected the petition on June 12, 2014. Ross Maclean, PhD, Senior Vice President for Scientific and Regulatory Affairs at Apotex, did not return a call asking for comment.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

January 5, 2015

TO: CHA Medical Safety Committee Members

FROM: Jeanette Hanni

SUBJECT: California Medical Board Safe Prescibing Guidelines

The California Medical Board has published the attached guidelines that your pharmacists will be held to under this doctrine of "corresponding responsibility" (Health and Safety Code §11153).

http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf

Anticoagulants Guidelines

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

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).

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.

Credits

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)

CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

Road Map to Anticoagulation Guidelines

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.

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			
Pharmacy Purchasing, Storage and Product Labeling	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**	**New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto**
	• 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.	• Purchase indication specific strengths of medications.
Patient Care Unit Storage	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**	**New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto**
	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.			

	Heparin	Warfarin	Low Molecular Weight Heparin	New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto
Prescribing	• 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 – a PTT 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. • Initiate 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.	• Recommend baseline renal function prior to initiation, when clinically indicated and at least annually: o Eliquis does not require renally adjustment for treatment of DVT/PE and post-operatively DVT/PE prophylaxis. • Do not require routine monitoring of coagulation tests. • Consider risks vs. benefits before neuraxial intervention for patients who are anticoagulated due to risks of spinal/epidural hematoma that can lead to paralysis. • Specify indications for each order: o Pradaxa is only indicated for non-valcular Atrial Fibrillation (NVAF), treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with parenteral anticoagulants for 5-10 days, and prevention of recurrent DVT and PE.
	Common considerations: • 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. • Use metric units for weight-based dosing and specify use of ideal or actual body weight in orders and guidelines.			

<table>
<tr><td></td><td colspan="4">

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.

</td></tr>
<tr><td rowspan="3">Pharmacist Order Entry Process</td><td>Heparin</td><td>Warfarin</td><td>Low Molecular Weight Heparin</td><td>New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto</td></tr>
<tr><td></td><td>Implement a process to screen for drug/food/nutritional product interactions.
Consider standard administration time such as 17:00 or 18:00.</td><td>Implement a process to screen for the presence of an epidural catheter.</td><td>Implement a process to screen for prior admission of heparin, low molecular weigh heparin or warfarin to ensure appropriate conversion to new oral anticoagulants.
Implement a process to screen for drug interaction and adjust dosage as appropriate.</td></tr>
<tr><td colspan="4">Common considerations:
Use height and weight in metric units in pharmacy computer systems.
Create pharmacy system alerts for duplicated 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</td></tr>
<tr><td rowspan="3">Pharmacy Dispensing</td><td>Heparin</td><td>Warfarin</td><td>Low Molecular Weight Heparin</td><td>New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto</td></tr>
<tr><td>Heparin orders are verified by pharmacy prior to dispensing.</td><td>Doses are provided in unit dose packaging.
Consider elimination of pill splitting on nursing units.</td><td></td><td>Doses are provided in unit dose packaging.</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td rowspan="2">Administration</td><td>Heparin</td><td>Warfarin</td><td>Low Molecular Weight Heparin</td><td>New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto</td></tr>
<tr><td>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</td><td>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).</td><td>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</td><td>Conduct an independent verification of 5 "Rights" and correct indication prior to administration.
Administer Xarelto 15 mg and 20 mg with meals.</td></tr>
</table>

	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. • 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 and reconcile, IV lines upon initiation, change in orders and at shift handoff. • Do not administer IM.		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.	
	Common considerations • Make clearly labeled and approved protocols, pathways, monograms, 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**	**New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto**
	• 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,	• Have patients/caregivers demonstrate proficiency if they	• Give patients and caregivers verbal and written information at 8th grade reading level

		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 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.	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.	or below, preferably in their language: o Signs and symptoms of bleeding (e.g. bleeding gums) or thromboembolic complications o Drug interactions: ensure patients/caregivers understand the generic and brand names of medications o Ensure the patient understands importance of adherence with anticoagulation dosing o Ensure the patient understand the dose and duration of therapy • Prior to discharge, stress the importance of follow up appointments.
	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 before discharge.			
Monitoring	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**	**New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto**
	• Monitor complete blood counts at routine intervals. • Obtain an aPTT or factor Xa level between 6-8 hrs after initiation of heparin therapy (unless	• 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	• Obtain baseline serum creatinine, hemoglobin, hematocrit and platelet count are available prior to initiating therapy.	• Obtain baseline serum creatinine, hemoglobin, hematocrit and platelet count prior to initiating therapy, when clinically indicated and at least annually.

	bleeding). • Modify dosing protocols and monograms 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.	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.	• 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.	• Monitor for sign and symptoms of bleeding. • Adjust dose for renal impairment (and body weight for Eliquis). • Do not require routine monitoring of coagulation tests.
	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. a PTT 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**	**New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto**
	• 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 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	• Review recommendations on package insert or institution's protocol for timing of holding anticoagulants for surgery.

			dose.	
Transitional Care: Discharge Planning	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**	**New Oral Anticoagulants: Pradaxa, Eliquis, Xarelto**
	Common Considerations • Provide education on the importance of vigilant adherence with anticoagulation therapy • Educate patients to be mindful of brand to brand variation resulting in differences in bioavailability when refilling prescriptions for warfarin • 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. • 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 • Collaborate with long term care providers and community based organizations who can provide follow up visits or phone calls to encourage medication adherence • 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 HealthSyst Pharm* Sep 15 2002;59(18):1742-9. 4. Errors Involving Drug Products Used to Treat Cardiovascular Diseases: Part III. USP *CAPSLinkNewsletter*. 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 9. Xarelto [Package Insert]. Titusville, NJ. Janssen Pharmaceticals, Inc.; 09 2014. 10. Eliquis [Package Insert]. Princeton, NJ Bristol-Myers Squibb Company; 08 2014. 11. Pradaxa [Package Insert]. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc.; 09 2014.			
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 anticoagulantshttp://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			

Medication Safety Committee
June 23, 2014
Gap analysis tool for
CMS MEMORANDUM MARCH 14, 2014
Requirements for Hospital Medication Administration, Particularly Intravenous (IV)
Medications and Post-Operative Care of Patients Receiving IV Opioids

NUMBER	INTERPRETIVE GUIDELINE	COMPLIANCE Y/N/NA	ACTIONS (IF NEEDED) AND RESPONSIBLE PARTY	DUE DATE
Tag A-0405 §482.23(c) Standard: Preparation and Administration of Drugs	**Orders of an authorized practitioner** All practitioner orders must include the age and weight of the patient when applicable. Policies and procedures must address weight-based dosing for pediatric patients and the use of metric weight for dosing calculations in all patients is required. (*The CoPs permit hospitals to record weight in pounds and have electronic system convert to metric, but this practice is NOT recommended)* All practitioner orders must include dose calculation requirements, when applicable. **Basic safe practices for medication administration** The hospitals P&P's must reflect that the five rights be confirmed prior to each administration of medication (*a hospital can choose to have more than the basic five if they so choose, but the five listed below are required)* Right patient Right medication (including that the patient does not have a documented allergy to it) Right dose Right route Right time **Timing of Medication Administration** (*Just minor changes in wording here – your policies should be modified accordingly. We will add that we have seen many hospitals that still have not incorporated these changes that were effective 12/22/11into policy/practice. Now would be a good time to double-check compliance with this whole section of this standard)*			

NUMBER	INTERPRETIVE GUIDELINE	COMPLIANCE Y/N/NA	ACTIONS (IF NEEDED) AND RESPONSIBLE PARTY	DUE DATE
	Medications or categories of medication not eligible for scheduled dosing times **Time-critical scheduled medications** Examples of time-critical scheduled medications/medication types may include, but are not limited to: Pain medication *(non-IV)* **Assessment / Monitoring of Patients Receiving Medications** Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital's requirements for the method(s) of communication. Depending on the medication and route/delivery mode, monitoring may need to include assessment of: Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, oxygenation and carbon dioxide levels. Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc. High risk (*interchangeably called "High-alert" both in COPs and in the literature*) medications (see 482.25(b) for further discussion) pose a higher risk for adverse drug events and therefore requiring a higher level of monitoring. Considerations of patient risk factors as well as the risks			

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	inherent in a medication must be taken into account when determining the type and frequency of monitoring. Risk factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight, asthma, history of smoking, drug-drug interactions, and first-time medication use may increase risk All relevant information regarding patients' medication risk factors and monitoring requirements must be communicated during patient care handoffs such as change of shift, patients are transferred from one unit to another, etc. This applies not only to nursing staff but to other types of staff who administer medications (e.g. respiratory therapists) as well. As part of the monitoring process, staff are expected to include patient's reports of his/her experience of the medication's effects. If monitoring requires awakening the patient in order to assess the effects of medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. The patient and his/her representative should also be educated about notifying nursing staff promptly when there is difficulty breather or other changes that might be a reaction to a medication. Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established hospital protocols, and must also be reported immediately to the practitioner responsible for the care of the patient.			
Tag A-0409 §482.23(c)(4) Blood transfusions and intravenous medications must be administered	Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice, and must address at least the following: **Vascular Access Route** Hospital policies and procedures must address which medications can be given intravenously via what type of access. IV medications, such as fluids, antibiotics, and			

NUMBER	INTERPRETIVE GUIDELINE	COMPLIANCE Y/N/NA	ACTIONS (IF NEEDED) AND RESPONSIBLE PARTY	DUE DATE
in accordance with State law and approved medical staff procedures.	chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medications chemical properties or safety concerns. **Other Patient Safety Practices** Tracing invasive lines and tubes prior to administration to ensure the medication is being administered via the proper route (for example, peripheral catheter versus epidural catheter connections); Avoiding forcing connections when the equipment offers clear resistance; Verifying proper programming of infusion devices (concentrations, flow rate, dose rate). **Patient Monitoring** **Monitoring for Fluid & Electrolyte Balance** Hospital policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications. **Monitoring Patients Receiving High-alert Medications, Including IV Opioids** Policies and procedures related to IV medication administration must address those medications the hospital has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously. Hospitals must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients. Policies and procedures must address, at a minimum, the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what			

NUMBER	INTERPRETIVE GUIDELINE	COMPLIANCE Y/N/NA	ACTIONS (IF NEEDED) AND RESPONSIBLE PARTY	DUE DATE
	is to be monitored, and monitoring methods. Hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients. The frequency and duration of monitoring post-operative patients receiving IV opioids must be determined on at least the following considerations: Patient risk for adverse events Opioid dosing frequency and IV delivery method (push or PCA) Duration of IV opioid therapy Monitoring must include at a minimum: Vital signs (BP, HR, RR, temp) Pain level Respiratory status Sedation level **Blood Components and Blood Administration Procedures** Policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to: Confirming the following prior to each blood transfusion: the patient's identity			

NUMBER	INTERPRETIVE GUIDELINE	COMPLIANCE Y/N/NA	ACTIONS (IF NEEDED) AND RESPONSIBLE PARTY	DUE DATE
	verification of the right blood product for the right patient (standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation) Requirements for patient monitoring, including frequency and documentation of monitoring How to identify, treat and report any adverse reactions the patient may experience during or related to the transfusion **Staff training and Competencies** Intravenous (IV) medications and blood transfusions must be administered by qualified personnel, regardless of whether they are practitioners or non-practitioners. Generally IV medications and blood transfusions are administered to patients by registered nurses (RNs), consistent with State law governing scope of practice, and approved medical staff policies and procedures. Among other things, personnel must be able to demonstrate competency in venipuncture, in accordance with State law and hospital policy. If other types of vascular access are utilized, staff must have demonstrated competency in appropriate usage, care, and maintenance. Staff must also be trained in early detection of and timely intervention for IV opioid-induced over-sedation and respiratory depression.			
Tag A-0412 §482.23(c)(6) The hospital may	PCA pumps allow for the self-administration of intravenous (IV) medications to patients. See the interpretive guidelines for §482.23(c)(4) concerning assessment and monitoring requirements for post-surgical patients receiving IV opioids,			

NUMBER	INTERPRETIVE GUIDELINE	COMPLIANCE Y/N/NA	ACTIONS (IF NEEDED) AND RESPONSIBLE PARTY	DUE DATE
allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medication brought into the hospital, as defined and specified in the hospital's policies and procedures	including via patient-controlled analgesia (PCA) pumps, in and out of the post-anesthesia care and intensive care units. (*this topic is already covered earlier in this gap analysis tool. Just make sure that your PCA policy covers the risk assessment and monitoring frequency requirements or references the policy that does)*			
Tag A-0957 §482.51(b)(4) There must be adequate provisions for immediate post-operative care	Adequate provision for immediate post-operative care means: Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the *PACU* includes*, but is not limited to*: • Level of activity; • Respirations; • Blood pressure; • Level of consciousness; • <u>Level of pain;</u> (*this is the only new item here)*			

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	Hospitals are expected to develop and implement policies and procedures addressing the minimum scope and frequency of patient monitoring in post-PACU care settings, consistent with accepted standards of practice. When post-surgical patients are transferred out of the PACU to another area of the hospital but continued on IV opioid medications, they need vigilant monitoring, even if post-PACU care is not typically referred to as "immediate" post-operative care. Does the hospital have a system for identifying and addressing the monitoring needs of post-operative patients transferred from the PACU to other areas of the hospital?			

Recommendations for Improving Safety of Opioid Use

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

Introduction

This guideline document is intended to summarize safe use practices to reduce the risk of adverse drug events associated with the use of opioids in perioperative settings and reduce preventable harm to patients in acute care settings. These recommendations focus on narcotic over-sedation in adult patients being treated for acute pain and are designed to help assess the safe use of opioids.

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. Opioid use is generally safe but is associated with serious adverse effects such as over sedation (0.5% incidence). 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.

The tools contained herein have been reviewed by the California Hospital Association's (CHA) 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 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.

Committee Representation

The committee includes nurse, physician, and pharmacist representatives.

- 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)

Road Map to Improving Safety of Opioid Use

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	Specific Action(s)
Administration	➢ Consider establishing standardized procedure for naloxone administration to ensure availability and consistency in the emergent management of oversedation. *Rationale: Naloxone is not consistently ordered for patients that are on opioids. 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 naloxone orders should be implemented.*
	➢ 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: Use of infusion pump drug libraries can help minimize and/or prevent adverse outcomes with opioid overdose.*
	➢ Refer to CMS Guidelines on appropriate administration practices.
Clinical Education	➢ Train staff to identify the patients at high risk for oversedation and respiratory depression: • No previous use of opioid history • Sleep apnea • Morbid obesity • Elderly >60 years old *Rationale: Clear guidance to staff in identifying risk areas.*
	➢ Improve documentation and communication of risk factors for oversedation to all care givers across the continuum of care: • Pain scale scores • Sedation scale assessment • Pain goals *Rationale: Complete information should be readily available to prescribers for timely pain treatment care plan adjustments in response to an adverse drug event.*

Medication Use Step	Specific Action(s)
	➢ Staff should be educated on equianalgesic potency (physician & nurse): • Potency reference cards • Talks on pain management therapies and alternatives • Incorporate into order set *Rationale: Staff competence on dose equivalencies.*
	➢ Advise prescribers in the use of multimodal therapies: • Benefits of multimodal therapy alternatives based on best practices (Tylenol, Motrin, Neurontin®) • Around the clock use of non-opioid analgesics therapy unless contraindicated. *Rationale: Medical staff education.*
	➢ Educate clinicians on the recognition of advancing sedation: • Utilization of sedation scale assessment tools. *Rationale: Medical staff education.*
	➢ Nursing education, pain management: • Standardized process of pain goal setting • Define frequency of patient/family pain management education *Rationale: Medical staff education.*
	➢ Define and educate staff on opioid tolerance i.e. taking opioids for a week or longer and the equivalent of oral morphine 60 mg/day or oral hydromorphone 8 mg/day or oral oxycodone 30 mg/day.
	➢ Refer to CMS Guidelines on appropriate staff training practices.
Definitions	• *ADC*- Automated Dispensing Cabinets • *Profiled ADC*- an automated dispensing cabinet that requires a pharmacist to review and approve a medication <u>before</u> they are available for selection and administration by clinical staff, unless the medication is available on an override medication list • *Override medication* - a pre-approved list of medications that may be removed from a specific patient care area ADC for selection and administration without a prospective pharmacist review • *MAR* - medication administration record • Opioid-tolerant - those who have been taking opioids for a week or longer and the equivalent of oral morphine 60 mg/day or oral

Medication Use Step	Specific Action(s)
	hydromorphone 8 mg/day or oral oxycodone 30 mg/day.
Dispensing / Distribution	➢ Assess need for stocking multiple concentrations of narcotics. *Rationale: High concentrations can be mistakenly administered resulting in over-sedation.*
	➢ Require pharmacist review for dispensing of all fentaNYL patches.
	➢ When a prospective pharmacist review is not conducted, a retrospective review to occur on all patients to assess for appropriateness of use.
Monitoring	➢ Implement appropriate physiologic monitoring practices: • Consider use of capnograpy to monitor ventilation in identified high risk patients • Consider continuous pulse oximetry in identified high risk patients *Rationale: Enables earlier recognition and intervention in advancing oversedation.*
	➢ Consider implementing an alert (i.e., either a hard and/or soft stop) that engages prescribers to routinely review the use of opioids: • 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. • Utilize 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.
	➢ Implement a monitoring policy that includes assessment of alertness, respiratory and cardiovascular systems throughout use of the fentaNYL patch, with special emphasis on the initial 24 hours after patch placement or after dose increases.
	➢ Conduct periodic audits to monitor if healthcare staff are following policies and monitoring parameters at all steps in the medication use process.
	➢ Refer to CMS Guidelines on appropriate monitoring practices.
Nursing	➢ Never cut the fentaNYL patch.

Medication Use Step	Specific Action(s)
Administration	➢ Apply patch to non-irritated skin such as the chest, back, flank or upper arm.
	➢ Do not shave skin; hair at application site may be clipped.
	➢ Add MAR warning note that includes monitoring parameters and appropriate administration technique.
	➢ Avoid external heating sources (e.g. heating blankets, hot baths). Monitor patients for core body temperature above 102, as heat may result in increased release of drug from transdermal system, leading to potential toxicity.
	➢ Monitor all patients for toxicity (e.g. alertness, respiratory drive, vital signs).
	➢ Verify patch placement upon admission and transfer.
	➢ Caregiver should use gloves when handling the patch and wash hands immediately after handling the patch (for placement or disposal).
	➢ Consider additional documentation requirements for: • Documentation of patch placement. • Daily check for presence of a patch. • Removal of old patch BEFORE placement of a new patch.
Patient Education	➢ Standardized patient orientation/education to pain scale tool and use: • Educate patients on realistic pain goals and use of pain scale • Educate patients/families on responding to adverse effects *Rationale: Medical staff and patient education.*
	➢ Consider discharge planning responsibilities to ensure patient will not suffer adverse health consequences upon discharge and that those given the fentaNYL patch upon discharge are given discharge teaching and instructions related to the medication.
	➢ Ensure patients upon discharge understand how to properly and securely dispose of used fentaNYL patches so children can't find them.
Pharmacist Order Entry Process	➢ Have references and tools for pharmacist assessment of appropriateness.

Medication Use Step	Specific Action(s)
	➢ Establish requirements for minimum pharmacist review with the goal of identifying the potential for adverse consequences. To include pharmacist assessment of: • Appropriate indication (severe chronic pain) • Meet opioid-tolerance criteria • Appropriate starting dose based on dosing history and indication • Potential drug interactions • Validation of home dosing - last refill information • Change in patch strength – pharmacist to ensure that strength is not changed prior to 3 days after initiation or 6 days after dose increase.
	➢ Consider Black Box Warning (BBW) pop-up reminder for pharmacist within the electronic health record.
Pharmacy Purchasing, Storage and Product Labeling	➢ Ensure manufacturer provides clear identification of fentaNYL patch contents once it is removed from the packaging. Be sure your product clearly identifies the ingredient fentaNYL and strength.
	➢ Electronic health record and ADC descriptions along with storage bin labels shall utilize TALLman lettering.
	➢ Consider eliminating storage in Emergency rooms, PACU, Operating rooms, and short day surgery, which are considered problem-prone areas for fentaNYL patch use.
	- Unit Storage of fentaNYL patches (for example, ADCs): - ADC configuration for hospitals **<u>with</u>** 24/7 pharmacy coverage is: - <u>Never place on an override medication list.</u> - Consider bar code verification upon refill or a pharmacist check post load/refill. - Stock in a single access pocket and not in a communal (matrix) pocket. - Load only in ADC cabinets that are profiled and releases medication only after the pharmacist order verification has occurred. - In non-profiled areas, have pharmacy send stock patient specific once pharmacist order verification has occurred. - ADC configuration for hospitals **<u>without</u>** 24/7 pharmacy coverage

Medication Use Step	Specific Action(s)
	- Limit quantities and strengths stocked. Include two independent double checks where appropriate. - Recommend that ADCs alert nurse with the following type of question: Review of patient opioid history confirms opioid tolerance? YES = proceed with removal, NO = contact prescriber for alternative medications. - Hospitals without ADCs: - Require second verification as to medication appropriateness - Promote patient-specific pharmacy dispensing of doses on demand - Segregate strengths in separate locations - Label doses with warnings against cutting patches - Storage bin labels shall utilize TALLman lettering.
Policy and Procedure Documentation Tools	➢ Revision of pain assessment and reassessment policy to include: • Sedation measurement and documentation
	➢ Refer to CMS Guidelines on appropriate documentation practices.
Prescribing	➢ Consider using an acute pain management order set. *Rationale:* - *A standardized order set will promote national best practices.* - *Encourages multimodal techniques for pain management (e.g., including round the clock non-opioid therapy if not contraindicated).* - *Minimize opioid side effects:* o *Naloxone orders* o *Bowel regimen orders* o *Antiemetic orders* o *Reduce variation from best practices*
	➢ Improve provider awareness of patient's history of opioid use and other risk factors for over sedation. *Rationale:* - *Opioid naïve patients are at the highest risk for experiencing over sedation.* - *Screening information (for patients at high risk for over sedation) should be available prescribers and other clinicians.* - *Design information support systems to identify patients who are at high risk (Sleep apnea, Morbid obesity, elderly >60 years old).*
	➢ Improve use of patient controlled analgesia (PCA). *Rationale:*

Medication Use Step	Specific Action(s)
	- *Patient centered treatment.* - *Minimizes adverse drug events such as over sedation.*
	➢ Consider development and implementation of an acute pain management service. *Rationale:* - *Prospective assessment of patients at high risk for respiratory depression/ oversedation.* - *Actively manages pain therapy.* - *Addresses patient satisfaction.*
	➢ FentaNYL patches should ONLY be prescribed to manage persistent, moderate-to-severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, particularly when the pain cannot be managed by other means such as non-steroidal analgesics, opiate combination products, or immediate-release opioids.
	➢ Consider use of pre-formatted order form that requires the prescriber to identify appropriate indications for use prior to dispensing.
	➢ Consider requiring the prescriber to document in the medical record that the patient meets criteria for using the fentaNYL patch. Ideally this documentation would list previous drug dosing history.
	➢ Provide guidance on appropriate starting dose and opioid dosing equivalence.
	➢ Consider prescriber limitations for use (specific trained prescribers or maximum dosing of 25 mcg/hr patch for general practitioners).
	➢ Consider pharmacist-driven protocol for use of fentaNYL patch.
	➢ Dosage modifications should not be made prior to 72 hours after initiation of therapy, and not prior to 6 days after dose changes (per package insert).
Quality Measures: Examples	➢ Naloxone administration for the purposes of reversing Opioid therapy.
	➢ Reported oversedation events.
	➢ Rapid Response Team calls related to over-sedation.
Other Considerations	➢ Disposal: Do NOT flush fentaNYL patches. Dispose in secured pharmaceutical waste container per appropriate medical waste

Medication Use Step	Specific Action(s)
	management regulations.
	➢ Implement hospital policy to identify appropriate actions for patients who undergo MRI, with detailed in place policy identifying who is responsible for identifying the presence of a fentaNYL patch with metal backing, who can remove it, how it is replaced after procedure and where this process is documented.
	➢ Define opioid tolerance and dose equivalencies. Consider use of reference cards for opioid equivalencies.
	➢ Develop policy on escalation of medication orders (when pharmacist and prescriber do not agree) if the patient does not meet dosing criteria, or if initial dosing exceeds recommended criteria.
	➢ Determine when appropriate for the fentaNYL patch to be utilized in patients treated in non-profiled areas.
	➢ Develop competencies for all clinical staff involved with fentaNYL patch use.
	➢ Consider adding naloxone to order sets or have emergency guidelines for when naloxone is appropriate.
	➢ Consider the potential for suicidal tendency of a patient when prescribing fentaNYL patch for ambulatory care use.
	➢ Refer to CMS Guidelines on appropriate survey procedures.

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Recommended Safe Insulin Practice Guidelines

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

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 Leader
- 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

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Medication Use Step	Actions to Consider to Increase Medication Safety
Pharmacy Purchasing, Storage and Product Labeling	**Pharmacy Purchasing:** ➢ Consider removing insulin pens from the hospital formulary for inpatient use[1]. If pens are used, seal with a tamper-evident fastener. ➢ Limit insulin types available on the hospital formulary. ➢ Procure the smallest product size available for inpatient use (i.e., 3 mL vials versus 10 mL vials). ➢ Purchase a single "brand" source for each insulin type. ➢ Stock only those insulin products approved for addition to the hospital formulary by the Pharmacy and Therapeutics Committee. **Storage & Product Labeling:** ➢ 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, Huma**LOG**, Humu**LIN**, Novo**LIN**, Novo**LOG.**
Unit Storage of Medications	**In Pharmacy:** ➢ 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 use[2]. ➢ 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:** ➢ 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 patients[3]. ➢ 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 for all standing insulin doses.
Nursing Administration	➢ 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 agents[3]. ➢ 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:**

	➢ 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:** ➢ 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:** ➢ 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:** 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* *Image License: http://www.flickr.com/photos/jill_a_brown/2629206800/sizes/l/in/photostream/*

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee Guidelines

Emergency Department Medication Management Safety Tool

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