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

ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT
July 12, 2017

Amy Gutierrez, PharmD, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Enforcement Matters

a. Discussion and Consideration of Reporting Drug Losses Under State and Federal Laws.

Attachment 1

Background

At prior meetings, the committee has discussed the federal and state requirements for the reporting of lost controlled substances under federal and state law.
California Code of Regulations, Title 16, section 1715.6, Reporting Drug Loss, states;

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

Federal regulations require that registrants notify the Drug Enforcement Agency (DEA) Field Division Office in their area, in writing, of the theft or "significant" loss of any controlled substance within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in their area, DEA Form 106, "*Report of Theft or Loss of Controlled Substances*" regarding the theft or loss. Below is Title 21, Chapter II, Code of Federal Regulations, 1301.76 (b).

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

among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

The DEA requirements specify immediate reporting of "*significan*t" controlled substances losses to the DEA. The board's regulation uses the broader standard of reporting "*any"* controlled substances loss to the board, in part to remove the ambiguity of a pharmacy's ability to determine the meaning of a "significant" loss. For example, a large pharmacy could lose several thousand controlled substances and still not consider it a "significant" loss. Whereas in a small pharmacy, several thousand pills lost, especially of a Schedule II drug, would be a significant loss.

The board's regulation requiring the reporting of any controlled substance loss in section 1715.6 has been a requirement since before 1990, and it likely reflects the actions the board took in the early to mid-1980s to address pill mill pharmacies in Los Angeles.

During a prior discussion of this matter, DCA Legal Counsel Laura Freedman, has indicated that removal of the word "significant" would create lack of clarity in what licensees are required to do under regulations.

Currently pending before the board for action at the July board meeting is a proposed regulation requirement for quarterly inventory reconciliation counts of all federal Schedule II drugs.

During this meeting, the committee will discuss whether it wishes to make any changes to section 1715.6. The committee may also consider whether to direct staff to continue to provide the board with drug losses reported under section 1715.6 and monitor what impact the quarterly reconciliation regulation has on drug losses.

Drug Loss Statistics are provided in **Attachment 1**.

b. Discussion and Consideration on Drug Diversion by Employees and Proposal to Mandate Reporting to Law Enforcement.

Attachment 2

Relevant Law

Article 6, Business and Professions Code (BPC) 4104 et seq., Licensed Employee, Theft or Impairment: Pharmacy Procedures.

Background

During the May Board Meeting, Board Member Albert Wong asked that the board agendize a discussion on the mandatory reporting of drug diversion and/or theft to the appropriate law enforcement agency.

There is currently no requirement to report drug diversion and/or theft to law enforcement agencies although the board has encouraged pharmacies to contact law enforcement agencies when employees admit drug thefts or work under the influence. Based on reports to the board under section 4104, the board has opened 112 case investigations.

Discussion on adding mandatory reporting language regarding drug diversion and/or theft to the regulations.

The following is staff recommended language to amend BPC, Section 4104.

(f) Every pharmacy shall contact local law enforcement within 24 hours when an employee admits to drug theft or being chemically, mentally, or physically impaired as provided in this section. A copy of the report shall be retained for three years.

A copy BPC, Section 4104 is provided in **Attachment 2**.

c. Update on the Development of the Joint Training from the Board and the DEA on CURES and Prescription Drug Abuse.

Attachment 3

Background

In March the board, DEA and the University of California, San Diego (UCSD) provided a day-long conference on prescription drug abuse, corresponding responsibility and preventing drug losses from a pharmacy. There were 200 attendees who earned 6 hours of continuing education (CE) credits, and another 132 attendees earned one additional hour of continuing education to secure the training needed to provide naloxone under California's protocol. Since March, Executive Officer Virginia Herold and Enforcement Chief Tom Lenox have been working on additional joint training sessions on opioid abuse for 2017. The tentative training schedule is below. Staff requests board approval to award CE for the following training presentations. **Attachment 3** includes the draft agendas for the training.

- August 26 - One full day training session at Cal Northstate University, College of Pharmacy in Elk Grove (7 units).
- October 21 - One full day training session at Keck Graduate Institute in Claremont (7 units).
- November 7 - One 3-hour training session from 6-9pm at the Catamaran Hotel in San Diego, this session will be a part of the California Opioid Summit hosted by a variety of organizations including the California Department of Public Health (3 units).

d. Safe Medication Transitions for Patients Being Discharged.

Attachment 4

A significant number of errors are found on patients' computer hosted medication lists which results in errors during hospital admissions and adverse outcomes post-discharge, including emergency department visits and readmissions. Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

During this portion of the meeting, Rita Shane, Pharm D, will provide a presentation on this subject.

The *Safe Medication Transitions: Evidence-Based Solutions Infographic* is provided in **Attachment 4**.

e. Discussion and Consideration of Recalls of Drug Manufacturers at the Patient Level.

Attachment 5

At the board's request, staff reviewed all subscriber alerts involving recalls that were sent from the board from May 2014 through May 2017 at the patient or pharmacy level. The list of drug manufacturer recalls is provided in **Attachment 5.**

There were 785 recalls issued and the greatest number of recalls from any manufacturer was 67. The data lists the top 20 manufacturers that had recalls. It should be noted that some of the manufacturers could be subsidiaries to other manufacturers but are listed according to how the recall and manufacturer's name was submitted.

f. Discussion and Consideration on Request for Wholesalers to Report Suspicious Drug Sales.

Attachments 6 and 7

Relevant Laws

Current California law on wholesalers furnishing controlled substances states that no wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer in California shall furnish controlled substances for other than legitimate medical purposes. Violations shall be punishable by imprisonment or fine, or both, fine and imprisonment. California Health and Safety Code, Section 11153.5 is provided in **Attachment 6**.

Federal law is in **Attachment 7** under the Code of Federal Regulations, Title 21, Part 1301, section 1301.74 (a) (b). In summary this section provides the following:

Before distributing a controlled substance the registrant shall make a good faith inquiry either with the Administration or with the appropriate state controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance. If the registrant is suspicious that they are not registered, they shall inform the Field Division Office of the Administration. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Background

Earlier this year two large drug wholesale distributers agreed to pay millions of dollars in civil penalties for alleged violations of the Controlled Substance Act (CSA). The distributors allegedly failed to notify the DEA of suspicious orders for controlled substances. McKesson Corporation agreed to pay a record penalty of $150 million and suspended their sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida for multiple years. McKesson also agreed to compliance terms for the next five years that includes specific, rigorous staffing and organizational improvements. Cardinal Health has agreed to pay $44 million in fines for allegations that it failed to alert the DEA of suspicious orders of powerful narcotics by pharmacies in Florida, Maryland and New York.

Recently, Oregon Board of Pharmacy adopted a new rule for wholesale distributors to report "suspicious orders" to the board for review. The rule went into effect on July 1, 2017. The new rule follows several recent settlements by wholesale distributors around the country who have received huge fines for failing to report suspicious orders of controlled substances to the DEA.

Oregon's new regulation provides: *"A wholesale distributor must notify the Board in writing of suspicious orders of controlled substances to be distributed in Oregon upon discovery. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." OAR 855-065-0010. (This notification must be in writing, which means a written letter, email or fax copy of what is submitted to the DEA)*

At the request of Board President Gutierrez, this item has been added to this agenda for consideration. Executive Officer Herold states that while there are no requirements for wholesalers to report excessive or suspicious orders to the board, there have been several such reports made in the last few years. Staff recommends securing similar mandatory reporting requirements. In the event the committee recommends pursuing such a regulation in California, staff has provided the following possible language for consideration

Upon discovery, a wholesale distributor must notify the board in writing by letter, email

or fax of suspicious orders of controlled substances to be distributed in California upon discovery. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

g. Discussion and Consideration of the California State Auditor Report on Home-Generated Sharps and Pharmaceutical Waste.

Attachment 8

Background

Over a year ago, the Legislature requested that an audit of home-generated sharps and pharmaceutical waste services be conducted by the State Auditor Agency. The audit report was recently released; below is a summary of the report's recommendations as well as comments made by the State Auditor Agency. This report is provided for information to the community.

As a reminder, on June 6, 2017, the board's take-back regulations took effect.

Summary of Recommendations

The conclusion of the report is that the Legislature should provide CalRecycle statutory oversight responsibility for home-generated sharps and pharmaceutical waste disposal, and provide CalRecycle additional resources to the extent it can justify the need. This responsibility should include:

- Developing and implementing a public education campaign about home-generated sharps and pharmaceutical waste. CalRecycle should coordinate this campaign with local, state, and, to the extent possible, federal agencies to ensure consumers receive consistent guidance regarding proper disposal methods.
- Maintaining an up-to-date, well-publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites.
- Increasing consumer access to proper disposal sites in underserved areas.

To increase in-state options for processing California's home-generated pharmaceutical waste, the Legislature should consider expressly authorizing municipal solid waste incinerators to burn limited quantities of home-generated pharmaceutical waste, but only after considering environmental impacts.

To ensure consistency throughout the state, the Legislature should adopt standard requirements for counties to follow when implementing Extended Producer Responsibility (EPR) programs. These requirements should limit any additional costs the programs may impose on consumers.

The State Auditor Agency commented that although it recommended that CalRecycle be the lead state agency over the disposal of sharps and pharmaceutical waste, CalRecycle took issue with certain information in its report and expressed significant reluctance in taking on this leadership role.

California State Auditor Summary of Report Number 2016-127 is provided in **Attachment 8**. The full report may be found at the link below.

http://www.auditor.ca.gov/pdfs/reports/2016-127.pdf

IV. Compounding Matters

a. Review and Discussion of the Board's Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq., and Relevant Chapters of US Pharmacopeia Relating to Compounding.

Attachment 9

Relevant Law

CCR Section 1735 et seq., and CCR section 1751 et seq., establishes the requirements for compounding drug preparation.

Business and Professions Code section 4127.1 requires the board to adopt regulations to establish policies, guidelines and procedures to implement Article 7.5, Sterile Drug Products, and further requires the board to review any formal revisions to General Chapter 797 of the United States Pharmacopeia and the National Formulary (USP-NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official.

Background

In April 2015, the board formally initiated a rulemaking to promulgate the board's compounding regulations. The final version of the regulation language was adopted by the board on January 19, 2016, and approved by the Office of Administrative Law on September 13, 2016. The effective date of the regulations was January 1, 2017.

Since adoption, both the committee and board have received public comment regarding the impact of the regulations on patient populations principally for oral compounded preparations, including animals.

In response to the public comments, the committee held a special meeting on June 2, 2017 that focused solely on the board's compounding regulations. As part of the meeting, the committee reviewed written comments and recommendations from board staff and members of the regulated public as well as heard public comments during the meeting. At its conclusion, the committee approved the recommendations offered by staff. The committee also requested that members of the public provide examples of compounded preparations that would provide additional context to support requested changes. Further the committee requested that staff evaluate comments received from the public and provide recommendations.

Since that time board staff have reviewed the comments provided, reviewed the examples submitted and conferred with internal and external experts.

For Committee Discussion

Attachment 9 includes a chart detailing the requested amendments to various sections of the board's compounding regulations, staff's recommendation, and a brief statement supporting the recommendation.

Attachment 9 also includes supplemental information submitted by stakeholders and the draft minutes from the June 2, 2017 meeting.

b. Discussion and Consideration of Possible Recommended Changes to Board Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq.

Attachment 10

Attachment 10 includes draft proposed language that could be used to implement the recommended changes. Below is a list of each of the sections where amendments are being suggested.

- CCR 1735 (b)
- CCR 1735.1 (c) & (f)
  Note: This change was approved by the board during the January 2017 Board meeting.
- CCR 1735.1 (r)
- CCR 1735.2 (i)(1)(A-G)
- CCR 1735.6 (e)(3)
  Note: This change was approved by the board during the January 2017 Board meeting.
- CCR 1751.1 (a)(5)
- CCR 1751.4 (d) & (d)(1-2)
- CCR 1751.4 (k)
- CCR 1751.7 (e)(1)
- CCR 1751.7 (e)(2)(C)

Proposed amendments to CCR Section 1735.2 (i)(2)-(4) will be provided during the meeting.

c. Discussion and Consideration of Waiver Requests for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6. and 1751.4.

Background

Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states that where compliance with California's compounding regulations requires physical construction or

alteration to a facility or physical environment, the board may grant a waiver for a period of time to permit the required physical changes. There is a related provision in CCR section 1751.4 which provides the same allowances for sterile compounding facilities.

An application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board is able to grant the waiver for a specified period when, in its discretion, good cause is demonstrated for the waiver. Initial review of the waiver is performed by staff led by the executive officer, who approves or denies the waiver request. Approval or denial of a waiver has been provided to facilities in writing. If a waiver is denied by the executive officer, there is an appeal process which will be reviewed by two board members, currently Board Members Schaad and Law. The goal of the construction waiver process is to secure full compliance at the earliest possible time and no latter that implementation date of USP <800> on July 1, 2018.

Update

The waiver review process is ongoing, as board staff continues to work with facilities that have applied for a waiver. There have been instances where the Executive Officer has approved extensions to waivers due to construction delays. The Executive Officer has provided specific timelines to facilities requesting a waiver with respect to the Office of Statewide Health Planning and Development (OSHPD) approval, status reports of construction and final completion dates. Facilities which have been denied a waiver have been made aware that there is an appeal process to the compliance waiver process. Such waiver appeals go to the subcommittee of Mr. Schaad and Mr. Law.

Status of Waiver Requests Received as of 6/27/17:

- Total Waivers Received: 609
- Total Waivers Processed: 607
    - Denied: 40 - 6.5%
    - Withdrawn: 100 - 16.5%
    - Approved: 380 - 62.6%
    - Non-responsive letters sent: 21 - 3.5%
    - In process: 66 - 10.8%
- Total Waivers Pending Review: 2
- Total Waiver Extensions Granted: 60

The committee previously discussed the denied applications for waivers were provided an opportunity to re-apply or appeal.

V. Enforcement Statistics

a. Medication Error Trends

Data on medication errors will be provided at the committee meeting.

b. Compounding Cite and Fines

Attachment 11

Attachment 11 contains two pages on data for the top 10 compounding case citation and fines and compounding inspection data. Also included is the number of compounding pharmacies with licenses and top corrections and violations.

c. Other Enforcement Statistics

Attachment 12

Attachment 12 contains end of fiscal year enforcement statistics including quarterly citation and fine stats and top ten violations by license type.

VI. Review and Discussion of News or Journal Articles

Attachment 13

Attachment 13 includes a report from the California Department of Public Health (CDPH) on the End of Life Option Act (Act).

On June 27, 2017, CDPH released the first annual report on the Act, which became law on June 9, 2016 and allows terminally ill adults to obtain and self-administer aid-in-dying drugs. This first reporting covers the time period of June 9, 2016 thru December 31, 2016. Subsequent reports will be for full calendar years.

Attachment 13 also includes an article from the *American Society of Health-System Pharmacists (ASHP)*, titled *"Attention Turns to Nonpharmacy Sterile Compounding Activities."*

The ASHP article describes the potential dangers of compounding in healthcare facilities without a pharmacy professional. Below is also a link to the article on ASHP's website.

https://www.ashp.org/news/2017/06/12/20/24/attention-turns-to-nonpharmacy-sterile-compounding-activities

VII. Future Meeting Dates

Currently there is a committee meeting scheduled for October 4, 2017. This committee meeting will be rescheduled. Once the new date is selected the board's website will be updated and a subscriber alert will be sent out.

Below are the committee dates for 2018.

- March 28, 2018
- June 7, 2018
- September 5, 2018
- December 13, 2018

Attachment 1

Top 10 Losses Reported by Drug Group

FY 12/13 - FY 16/17 (through May)

Drug Group	Dosage Units[1]	% of Total of All Drugs Reported[2]
Hydrocodone and Combos (All Forms)	3,359,429	42.4%
Benzodiazepines	1,304,920	16.5%
Oxycodone and Combos	710,558	9.0%
Promethazine w/Codeine and Combos	632,562	8.0%
Codeine and Combos	311,721	3.9%
Hydro/Oxymorphone and Morphine	288,325	3.6%
Carisoprodol and Combos	260,072	3.3%
Amphetamines and Combos	226,595	2.9%
Tramadol and Combos	214,102	2.7%
Dex/Methylphenidate	115,440	1.5%
Grand Total[3]	7,925,005	100.0%

[1] Dosage Units were determined by dividing liquid oral medications in milliliters by the teaspoon or tablespoon, as appropriate, and adding to solid dosage form counts.

[2] Total does not equal 100% since only the top 10 drug groups are shown. Drug counts only include those reported to the Board of Pharmacy.

[3] Grand Total includes all drug groups and dosage unit losses reported.

Top 10 Losses Reported by Drug Name

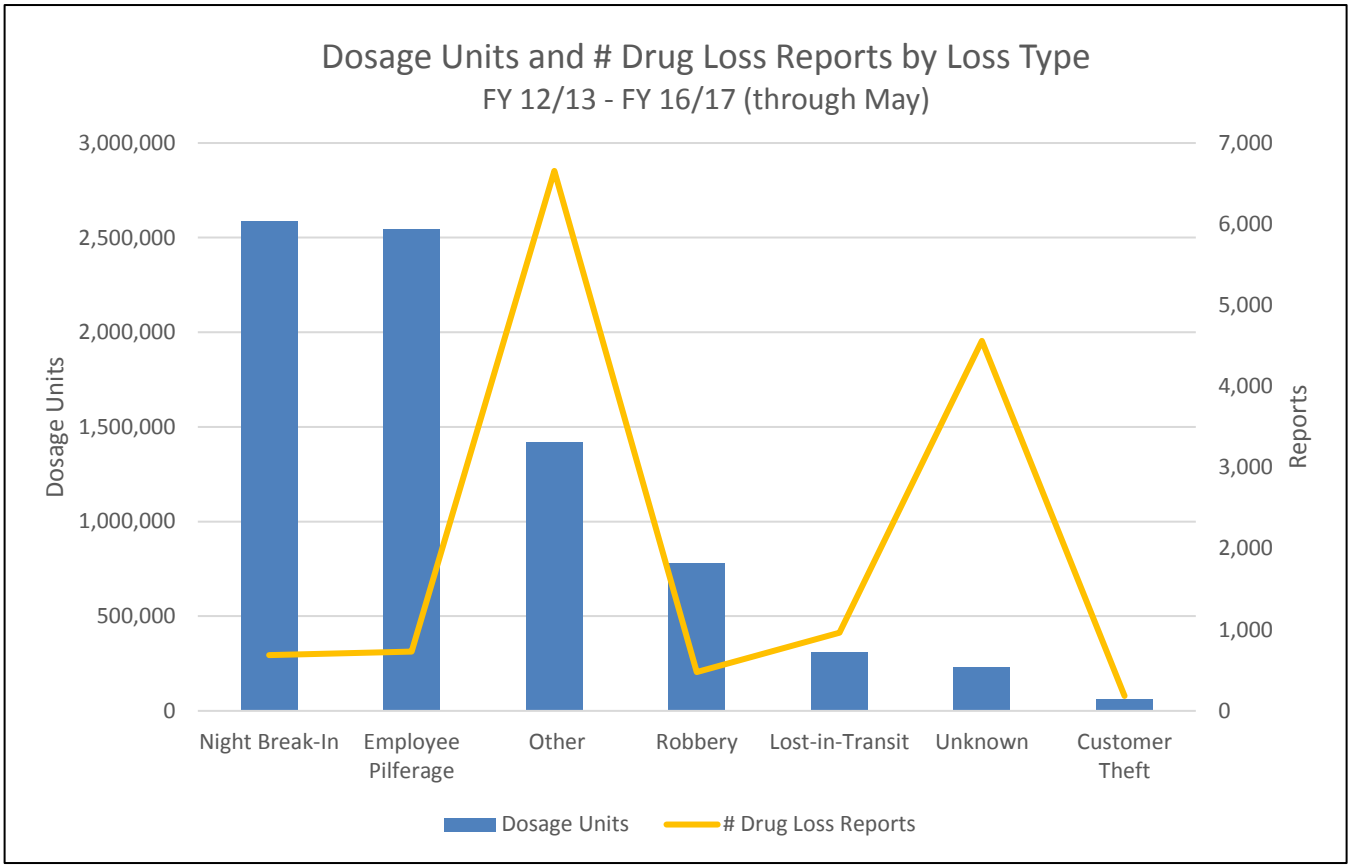
FY 12/13 - FY 16/17 (through May)

Drug Name	Dosage Units[1]	% of Total of All Drugs Reported[2]
Hydrocodone/APAP	3,080,336	38.9%
Alprazolam	849,971	10.7%
Promethazine/Codeine	626,956	7.9%
Oxycodone	460,098	5.8%
Carisoprodol	260,070	3.3%
Oxycodone/APAP	248,104	3.1%
Hydrocodone	234,229	3.0%
Tramadol	208,039	2.6%
Codeine/APAP	201,413	2.5%
Amphetamine Salts	163,434	2.1%
Grand Total[3]	7,925,005	100.0%

[1] Dosage Units were determined by dividing liquid oral medications in milliliters by the teaspoon or tablespoon, as appropriate and where known, and adding to solid dosage form counts.

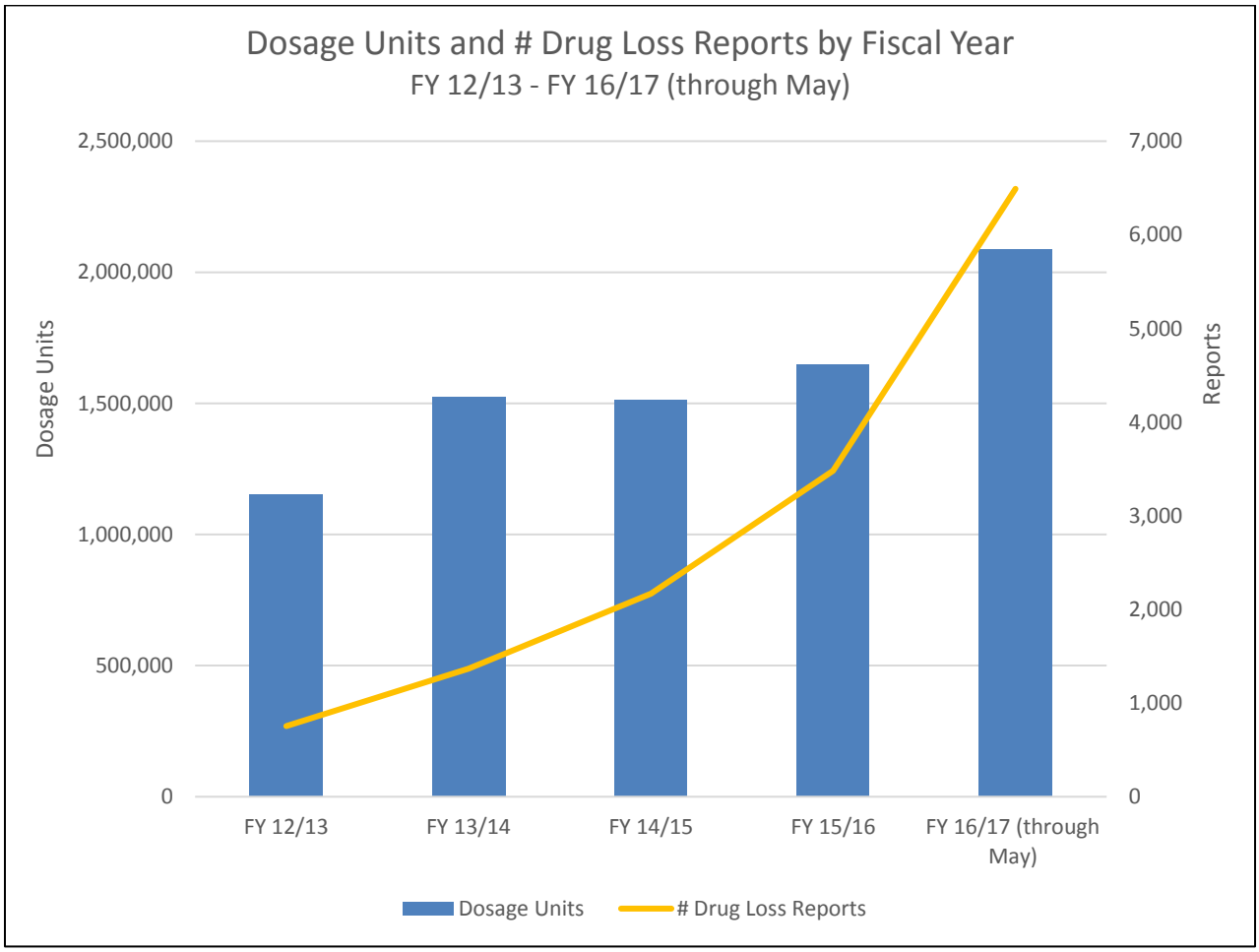
[2] Total does not equal 100% since only the top 10 drugs are shown. Drug counts only include those reported to the Board of Pharmacy.

[3] Grand Total includes all drug names and dosage unit losses reported.



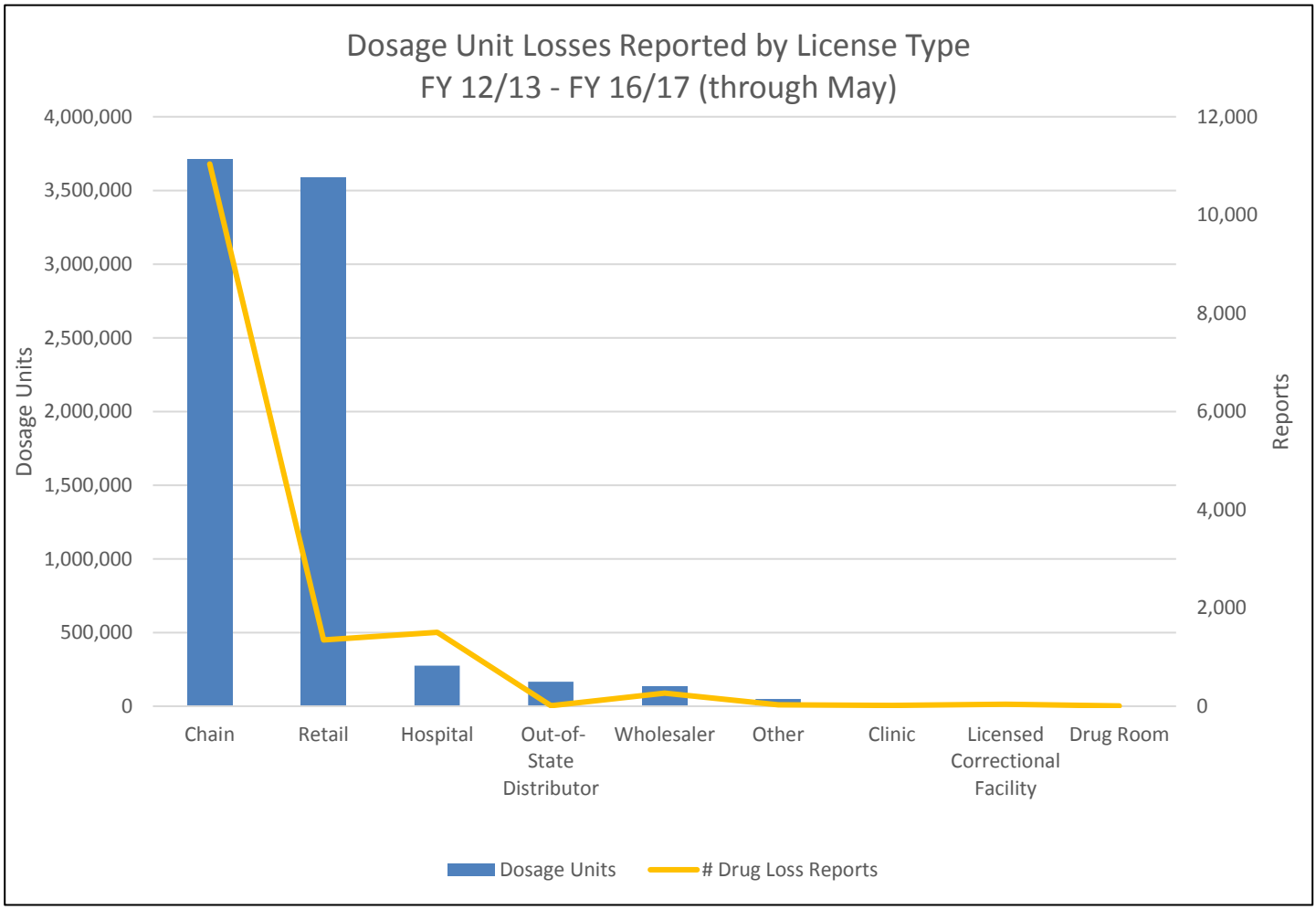
Loss Type	Dosage Units	# Drug Loss Reports
Night Break-In	2,584,901	686
Employee Pilferage	2,542,754	732
Other	1,418,426	6,656
Robbery	777,610	480
Lost-in-Transit	310,118	964
Unknown	230,752	4,559
Customer Theft	60,445	184
Grand Total	**7,925,005**	**14,261**

[1]"Other" category includes losses due to operational errors, manufacturer or distributor short, or environmental/natural disaster.
[2]Unknown category loss type was either not reported or was unknown.
[3] One very large loss (1.6 million dosage units+) of Benzodiazepines due to and out-of-state lost-in-transit drug loss was not included due to skewing of the data.



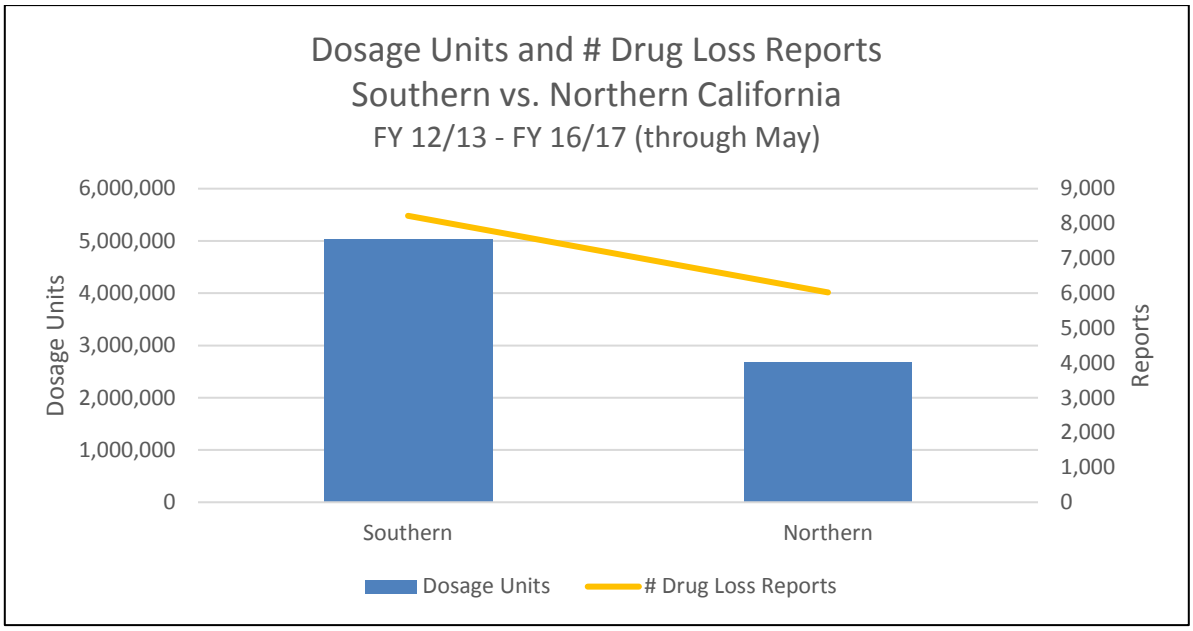
Fiscal Year Reported	Dosage Units	# Drug Loss Reports
FY 12/13	1,151,704	754
FY 13/14[1]	1,524,833	1,367
FY 14/15	1,513,696	2,168
FY 15/16	1,646,380	3,481
FY 16/17 (through May)	2,088,392	6,491
Total	**7,925,005**	**14,261**

[1] One very large loss (1.6 million dosage units+) of Benzodiazepines due to and out-of-state lost-in-transit drug loss was not included due to skewing of the data.



License Type	Dosage Units	# Drug Loss Reports
Chain	3,710,972	11,039
Retail[1]	3,588,628	1,352
Hospital	274,716	1,505
Out-of-State Distributor	165,273	10
Wholesaler	132,651	265
Other[2]	49,117	30
Clinic	3,196	16
Licensed Correctional Facility	413	38
Drug Room	39	6
Grand Total	**7,925,005**	**14,261**

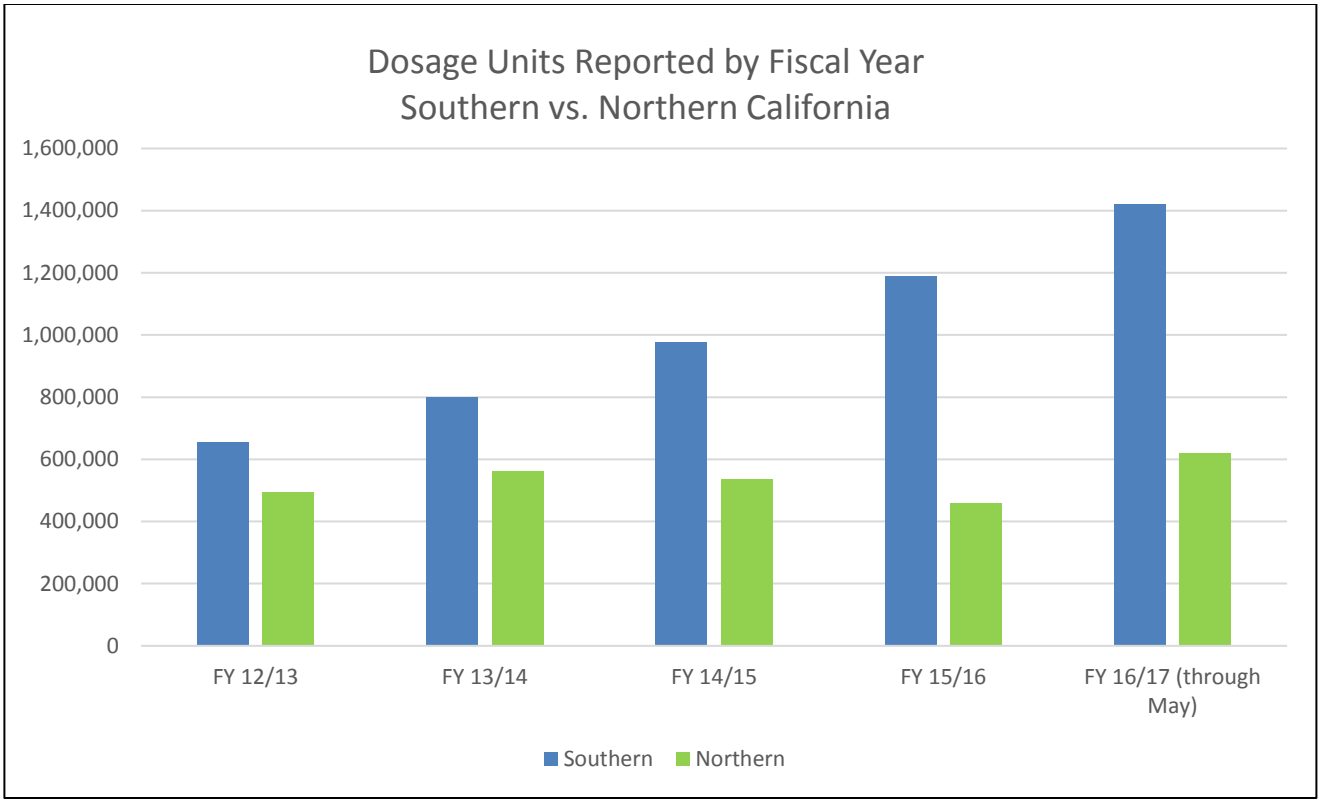
[1] "Retail" stores are community-based, independently controlled and operated businesses.
[2] "Other" category includes losses due to operational errors, manufacturer or distributor short, or environmental/natural disaster.



Region	Dosage Units	# Drug Loss Reports
Southern[1]	5,038,589	8,221
Northern[2]	2,670,749	6,022
Total [3]	**7,709,338**	**14,243**

[1] Southern California Counties: Imperial, Los Angeles, Orange, Riverside, San Bernardino, San Diego, Santa Barbara, and Ventura.
[2] Northern California: All remaining counties not included in Southern California.
[3] The Totals will not equal the total dosage units reported in some previous tables since out-of-state licenses are not included here.

Region	% Total Dosage Unit Losses Reported by California Licensees
Southern	65.4%
Northern	34.6%
Total	**100.0%**



Region	Dosage Units	# Drug Loss Reports	Units per Drug Loss Report
Southern	5,038,589	8,221	613
Northern	2,670,749	6,022	443
Total	***7,709,338***	***14,243***	**Avg. 541**

Region	Dosage Units	# Reporting Licenses (Licensees)	Units per Reporting License
Southern	5,038,589	2,164	2,328
Northern	2,670,749	1,554	1,720
Total	***7,709,338***	***3,718***	**Avg. 2,074**

Note: The Totals in this chart and these two tables will not equal the total dosage units reported in some previous tables since out-of-state licenses are not included here.

Dosage Unit Losses and % by License Type
Southern vs. Northern California
FY 12/13 - FY 16/17 (through May)

Region	Dosage Units per Region and Loss Type	% Total Dosage Units per Region and Loss Type
Southern		
Night Break-In	2,011,612	26.1%
Employee Pilferage	1,661,199	21.5%
Other	727,712	9.4%
Robbery	369,170	4.8%
Unknown	144,323	1.9%
Lost-in-Transit	102,283	1.3%
Customer Theft	22,290	0.3%
Southern Total	*5,038,589*	*65.4%*
Northern		
Employee Pilferage	881,555	11.4%
Night Break-In	571,271	7.4%
Other	527,814	6.9%
Robbery	408,440	5.3%
Lost-in-Transit	157,085	2.0%
Unknown	86,429	1.1%
Customer Theft	38,155	0.5%
Northern Total	*2,670,749*	*34.6%*
Grand Total	***7,709,338***	***100.0%***

[1] The Grand Total will not equal the total dosage units reported in some previous tables since out-of-state licenses are not included here.

Attachment 2

State of California

BUSINESS AND PROFESSIONS CODE

Section 4104

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within 14 days of the receipt or development thereof, the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) The report required in subdivision (c) shall include sufficient detail to inform the board of the facts upon which the report is based, including an estimate of the type and quantity of all dangerous drugs involved, the timeframe over which the losses are suspected, and the date of the last controlled substances inventory. Upon request of the board, the pharmacy shall prepare and submit an audit involving the dangerous drugs suspected to be missing.

(e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

(Amended by Stats. 2011, Ch. 646, Sec. 1. (SB 431) Effective January 1, 2012.)

Attachment 3

Proposed Agenda for
August and October
Pharmacy Conferences

7:30-8:15	Registration	
8:15-8:30	Welcoming Remarks	15 minutes
8:30-10:00	LE Drug Diversion Trends, Counterfeit/Stolen/Altered Prescriptions Common Drugs of Abuse Loss Prevention (Employee Theft) Reporting Procedures for Counterfeit/Stolen/Altered Scripts	90 minutes
10:00-10:15	Break	15 minutes
10:15-11:00	Pharmacy Burglaries/Robberies	45 minutes
11:00-11:45	Corresponding Responsibility	60 minutes
11:45-12:15	Drug Take-Back Processes in California	30 minutes
12:15	Lunch Break	
1:15-1:45	How to Prepare for Pharmacy Inspections by the Board of Pharmacy (Where to find requirements for secure prescription paper)	45 minutes
1:45-2:45	How to Prepare for a DEA Inspection and Compliance with the Combat Methamphetamine Enforcement Act	60 minutes
2:45-3:00	BREAK	
3:00- 3:30	California's Prescription Drug Monitoring Program - CURES	30 minute
3:30-4:30	Training for CA Pharmacists to provide Naloxone Pursuant to the State's Pharmacist Protocol	60 minutes
4:30	Evals/Wrap Up	
	Total	7 Hours

Pharmacist Training on Opioid Abuse

November 07, 2017 6:00pm-9:00pm
Catamaran Hotel
3999 Mission Blvd, San Diego, CA 92109
San Diego, CA

6:00pm-7:00PM

Appropriate Versus Illegal Opioid Prescribing: A Medical Expert's Review

Dr. Tim Munzing, MD is the Family Medicine Residency Program Director- Kaiser Permanente Orange County He has been a Medical Expert Consultant for DEA, Medical Board of California, FBI and multiple other law enforcement Agencies.

7:00PM-8:00PM

Corresponding Responsibility and Opioid Prescribing; Trends and Case Studies

Supervisory Inspector Tony Ngondara is a licensed CA Pharmacist with previous experience in pharmaceutical marketing, hospital sterile compounding and retail pharmacy. He joined the California State Board of Pharmacy in September 2012 and currently supervises the Prescription Drug Abuse Team focusing on proactive research of wholesaler sales and pharmacy dispensing of commonly abused drugs.

8:00pm-9:00PM

Training for CA Pharmacists to provide Naloxone, Pursuant to the State's Pharmacist Protocol

Dr. Nathan Painter is an Associate Clinical Professor, UCSD School of Pharmacy and Certified Diabetes Educator. He manages a pharmacist-run clinic at UCSD Family Medicine Clinics. Dr. Painter serves as coordinator for several courses at UCSD, including a Prescription Drug Abuse course, is the faculty advisor for the GenerationRX project, and is a master trainer for naloxone in California.

California Opioid Policy Summit

November 8-9, 2017

Catamaran Hotel, San Diego

Register Now

$125 Registration Fee. Limited Scholarships Are Available

Conference Registration: www.sandiegorxabusetaskforce.org

Conference Highlights

- **Plenary Sessions Include: State of the State, Fentanyl Trends, Enforcement Options, Local Coalition Efforts and Medication Assisted Treatment**
- **Discipline/Strategy Breakout Sessions for Treatment, Policy, Media, Law Enforcement and Prevention**
- **Regional Networking Sessions**
- **And details coming soon for two special events:**
  - **Special Pharmacy Opioid Training on Tuesday Evening 11/8**
  - **Parent/Coalition Convening on Wednesday Evening 11/9**

Conference planned by:

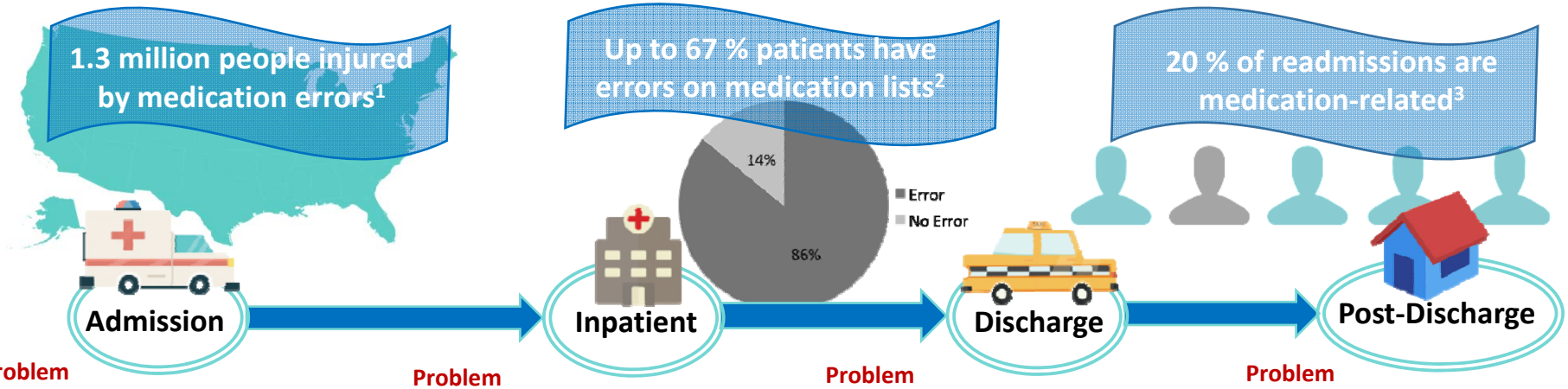
SDI HIDTA
San Diego - Imperial HIDTA

California Health Care Foundation

Attachment 4

Safe Medication Transitions:

Evidence-Based Solutions



Problem

- 1 in 5 hospitalizations result from treatment complications, of which, 1/2 are medication-related[4]
- 7.4 errors per medication list[5]
- 5.3% of patients have accurate medication histories

Evidence

- 20.3% of pharmacist medication histories had at least 1 postoperative medication discrepancy related to home medications compared to 40.2% of the nurse-conducted medication histories[9]
- Pharmacist-conducted medication reconciliations resulted in 16% reduction in all visits to the hospital and a 47% reduction in visits to the emergency department. Drug–related readmissions were reduced by 80%[14]

Problem

- During hospitalization, medication errors occur in up to 50% of adult and 75% of pediatric patients[6]
- Over 1/3 of hospitalized patients had medication order errors - 85% originated with the medication history[7]

Evidence

- Clinical pharmacy services reduced prevalence of discrepancies by 40% compared to usual care. [15]
- For patients on complex medication regimens,i.e., 10 medications per day or 5 new medications started, pharmacists reduced number of medications by 12% and number of doses by 19%. [25]

Problem

- ↑ # of medications at discharge results in a statistically higher rate of readmissions; >6 discharge medications predicts 30-day readmissions
- 80% of patients have at least 1 medication discrepancy at discharge.[9]

Evidence

- Pharmacists identified discrepancies in 49% of pts at discharge; preventable ADEs occurred in 1% of patients who received discharge education and follow up compared vs 11% of patients who received usual care[16]
- Discharge medication lists completed by pharmacists resulted in an absolute risk reduction of 46.5% when compared to usual care.[17]

Problem

-Post-discharge adverse drug events occur in up to 11% of patients, of which 1/3 are preventable[10]
-52% of patients had > 1 clinically important error
- Up to 90% of hospital-to-SNF discharge summaries contained one or more DRPs[11,12,13]

Evidence

-Post-discharge pharmacist follow up with discharge education reduced readmissions and ED visits vs usual care (39% to 24.8%).[18]
- Post-discharge pharmacist reconciliation and education reduced readmissions and ED visits vs usual care (0% vs 40.5%).[19]

Safe Medication Transitions: Evidence-Based Solutions

Medication discrepancies or errors occur in up to 70% of patients at admission or discharge contributing to adverse drug events, ED visits and readmissions. Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

Pharmacist

- A study comparing medication reconciliation performed by pharmacists to ED providers found that pharmacists identified 1096 home medications compared with 817 home medications identified by ED providers. 78% of medications documented by ED providers were incomplete and were supplemented with information by the pharmacists.[21]
- Patients who received pharmacist medication reconciliation and counseling had a readmission rate of 16.8% vs the usual care arm of 26% (p=0.006).[24]
- In a randomized trial, pharmacists provided medication counseling, reconciliation at admission and discharge, and a follow up phone call after discharge as part of a care coordination bundle. Patients in the intervention arm had a reduction in 30 day readmissions (10% vs 38.1%, p=0.04) and time to first readmission or ED visit (36.2 days vs 15.7 days, p=0.05).[27]
- Another study found that patients who received discharge medications and follow up phone calls by pharmacists had nearly half the risk of readmission as those who did not receive a pharmacist phone call (5.0% vs 9.5%, p<0.05).[25]
- Post-discharge pharmacist follow up can reduce readmission from skilled nursing facilities by 25%. [20]

Pharmacy Technician

- In the ED, a pre-post study found that pharmacy technicians created an accurate medication history 88% of the time compared to 57% of the time when nurses completed the history (p<0.0001).[22] Nurses were 7.5 times as likely to make an error than pharmacy technicians (p<0.0001).
- Another study found that nurses created an accurate medication list only 14% of the time compared to pharmacy technicians who created an accurate list 94.4% of the time (p<0.0001).[23]
- A randomized controlled study to evaluate the accuracy of admitting medication histories performed by pharmacists, pharmacist-supervised pharmacy technicians (PSPTs) and usual care (nurses, physicians) demonstrated a statistically significant reduction in admitting medication history errors performed by pharmacists and PSPTs vs usual care(p<0.0001). There was also a significant reduction in the severity of errors intercepted (p<0.0001).[5]

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

References-pending updates

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Attachment

Top 20 Recall Alerts by Manufacturer (May 2014 - May 2017)	Total
Hospira	67
Teva Pharmaceuticals	43
Baxter Healthcare Corporation	38
Actavis	20
Dr Reddy's	19
Mylan Pharmaceuticals, Inc.	17
American Health Packaging	16
Sun Pharmaceutical Industries, Inc	15
Pfizer	15
Fresenius Kabi USA, LLC	14
Sandoz	14
Zydus Pharmaceuticals	13
Akorn	12
Qualitest Pharmaceuticals	11
Major Pharmaceuticals	11
Hi-Tech Pharmacal Co.	8
GlaxoSmithKline	8
Valeant Pharmaceuticals	8
West-Ward Pharmaceuticals	7
PharmaTech, LLC	4

Total Number of Recalls Sent (May 2014 - May 2017)	Total
Recalls	785

Hospira	Date Sent
Labetalol Hydrochloride Injection	5/20/2014
Heparin Sodium in 5% Dextrose Injection	6/9/2014
MARCAINE VIAL	6/19/2014
Fentanyl Citrate Injection	6/27/2014
Heparin Sodium in 5% Dextrose Injection Expansion	7/1/2014
Lactated Ringers and 5% Dextrose Injection	7/14/2014
Lidocaine HCI Injection	7/30/2014
LTA® 360 Kit	8/6/2014
BUPIVAC TTV 0.5% 30ML HW 25	9/8/2014
Buprenorphine Hydrochloride Inj.	9/9/2014
Heparin Sodium	9/12/2014
HEPAR SOL 500ML 7620-03 HW 18	9/22/2014
Succinylcholine Chloride Injection	9/23/2014
QUELICIN FTV 2CMG 10MLHW25NOV+	9/24/2014
Hydromorphone Hydrochloride Injection	10/2/2014
Hydromorphone Hydrochloride Injection	10/7/2014
Vancomycin Hydrochloride for Injection	10/9/2014
LifeCare line of flexible intravenous solutions	10/15/2014
1% Lidocaine HCI for Injection	10/16/2014
Various products	10/20/2014
MEROPEN INJ 1GM/30ML FTV HW 25	10/27/2014
GemStar Infusion Pump	11/5/2014
Vancomycin Hydrochloride for Injection	11/7/2014
DACARBAZ INJ 200MG FAUL 20ML	11/26/2014
Fentanyl Citrate Injection	12/3/2014
MitoXANTRONE Injection	12/4/2014
0.9% Sodium Chloride Injection	12/22/2014
Propofol Injectable Emulsion	12/24/2014
MitoXANTRONE Injection	12/24/2014
0.9% Sodium Chloride Injection, USP, 250 mL	1/21/2015
Ketorolac Tromethamine Inj., USP	1/26/2015
ketorolac tromethamine injection, USP	2/11/2015
5% Dextrose Injection, USP, 250 mL, ADD-Vantage™ Unit	3/9/2015
0.9% Sodium Chloride Injection	3/9/2015
Lactated Ringer's Irrigation	3/12/2015

0.9% Sodium Chloride lnj.	4/7/2015
Ketorolac TR FTV 30MG 1ML HW 25	4/14/2015
BUPIVAC TTV 0.5% 30ML HW 25	4/24/2015
Magnesium Sulfate Inj.	5/20/2015
Magnesium Sulfate Inj.	5/21/2015
KETOR TR FTV 30MG 1ML HW 25	7/2/2015
SOD CHL SOL AV 50ML HW CS50	7/2/2015
Ketamine Hydrochloride Inj.	8/20/2015
1% Lidocaine HCIInjection	8/25/2015
MitoXANTRONE Injection	8/27/2015
AMIDATE SYRUSP40MG20MLLFS+ND10	9/30/2015
MAGNESIUM SULFATE IN WATER FOR INJECTION	1/6/2016
NORMOSOL-M SOL 1000ML HW CS12	2/3/2016
Various products	3/9/2016
QUELICIN FTV 2CMG 10ML HOSP 25	3/17/2016
8.4% Sodium Bicarbonate Injection	3/22/2016
AMIDATE SYRUSP40MG20MLLFS+ND10	3/24/2016
MAGNES SUL FTV 50% 20ML HW 25	3/28/2016
MAGNES SUL FTV 50% 20ML HW 25	3/28/2016
VANCOMY VL 10GM BULK HW1	5/11/2016
DIAZEPAM CPJ 5MG/ML 2ML LLHW10	6/29/2016
LIDOCAINE 5%+DEX 7.5% AMP 2MLHW25	7/1/2016
Bupivacaine Hydrochloride Injection	8/5/2016
DOBUTAM VL 12.5MG 20ML HW 10	8/15/2016
MARCAINE VIAL	9/22/2016
FENTAN AMP 0.05MG/ML HW 10X2ML	11/4/2016
CEFTRIAX VL 1GM/15ML H/W 10	11/4/2016
Vancomycin Hydrochloride for Injection	1/25/2017
Vancomycin	2/7/2017
METRONIDAZOLE PBV 500MG 1CML HW24@	2/16/2017
25% Dextrose Injection,	4/24/2017
Levophed Norepinephrine Bitartrate Injection	5/19/2017

Teva	Date Sent
DEXTROAMPH TAB 10MG TEV 100@	5/2/2014
Fluvastatin Capsules USP, 20 mg	6/2/2014
Carbidopa LEV TB 25/100 TEV 1M@	6/6/2014
APRI TAB BARR 6X28@	6/19/2014
Kariva (desogestrel/ ethinyl estradiol and ethinyl estradiol) Tablets	6/19/2014
Velivet™ (desogestrel and ethinyl estradiol tablets - triphasic regimen)	6/19/2014
Mircette (desogestrel/ethinyl estradiol and ethinyl estradiol) Tablets	6/19/2014
Carbidopa and Levodopa Tablets USP, 25mg/100mg	7/9/2014
AMPHETAM SALT TB 10MG TEV 100@	10/9/2014
Fluoxetine Capsules USP	4/15/2015
NIFEDIP ER TAB 90MG TEV 100@	4/20/2015
ADRUCIL® (fluorouracil injection, USP), 5g/100mL (50mg/mL)	4/29/2015
QVAR (beclomethasone dipropionate HFA), 40mcg Inhalation Aerosol	5/7/2015
Zebeta (bisoprolol fumarate), 10mg, Tablets	5/12/2015
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets	6/25/2015
ADRUCIL PBV 5GM TEV 5@	7/27/2015
Clomiphene Citrate Tablets	9/21/2015
IRBESARTAN and HYDROCHLOROTHIAZIDE Tablets	10/21/2015
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets	11/17/2015
NABUMET TAB 750MG TEV 100@	11/23/2015
CAPECITABINE Tablets USP	12/22/2015
PARICAL CAP 1MCG TEV 30@	2/8/2016
amikacin sulfate injection USP	3/10/2016
Linezolid Injection 600 mg/300 mL	4/28/2016
Divalproex Sodium Delayed-Release Tablets USP	5/19/2016
MITOXANTR MDV 2MG/ML TEV 10ML@	6/3/2016
ALBUTEROL SYRP 2MG TEV 16OZ@	6/29/2016
Zecuity patch	6/30/2016
AMOXICILLIN/S 400/5ML TEV 50ML@	6/30/2016
Amikacin Sulfate Injection USP	8/3/2016
CLARAVIS CAP 10MG BARR 3X10@	8/9/2016
mitoXANTRONE Injection USP	9/15/2016

PARICALCITOL CAP	9/27/2016
DIVALPROEX SOD DR TB 250MG TEV100@	10/21/2016
Children's Quasi® 40 meg and Qnasl™ 80 meg (beclomethasone dipropionate) Nasal Aerosol	11/2/2016
RISEDRONATE SOD DR TB 35MG TEV 1X4@	12/2/2016
AMOXICILLIN for Oral Suspension USP	12/22/2016
Mimvey® Lo (estradiol and norethindrone acetate tablets USP)	2/3/2017
BUPREN/NAL HCL TB 8/2MG TEV30@	2/9/2017
RISEDRONATE SOD DR TB 35MG TEV	2/21/2017
PrednisoLONE Oral Solution USP, 15 mg/5 mL	3/30/2017
Clozapine Tablets USP, 25 mg	4/25/2017
Paliperidone Extended-Release Tablets, 3mg, 90 count bottles	6/1/2017

Baxter	**Date Sent**
RAPID-FILL SYR STRIP	5/6/2014
Brevibloc Premixed Injection solution bags	6/19/2014
Various	7/15/2014
20% ProSol -sulfite-free (Amino Acid) Injection, 2000 mL VIAFLEX Plastic Container	8/5/2014
Potassium Chloride Injection	9/12/2014
INTRA VIA Container	9/17/2014
200MG DOPAMINE HYDROCHLORIDE	9/30/2014
Heparin Sodium in 0.9% Sodium Chloride Injection	11/7/2014
Highly Concentrated Potassium Chloride Injection	11/12/2014
CLINIMIX E 4.25/10 sulfite-free	11/26/2014
Sodium Chloride M-BAG 0.9%	12/10/2014
Luer caps	12/10/2014
FLUCONAZOLE SOD 2CMG/1CML BAX 10	12/29/2014
Four Lead TUR Irrigation Set	1/15/2015
9% Sodium Chloride lnj. USP and 5% Dextrose Injection, USP	3/19/2015
CLINIMIX E 2M ML 5/20 4 and SODIUM CHLORIDE IV 0.9% 50ML BAX 96	3/25/2015
Various	3/30/2015
intravenous (IV) solutions	4/13/2015
Vascu-Guard Peripheral Vascular Patch	6/4/2015
Heparin Sodium and 0.9% Sodium Chloride Injection	6/4/2015
0.9% Sodium Chloride Injection, USP	7/20/2015

intravenous (IV) solutions	7/20/2015
intravenous (IV) solution	8/3/2015
0.9% Sodium Chloride Injection, USP, 100 mL MINI-BAG VIAFLEX Container	9/3/2015
0.9 % Sodium Chloride Injection, USP, 250 ml VIAFLEX Plastic Container	12/16/2015
SOD CHL 0.9% 250ML and DEXTR SOL 70% 2MML	12/21/2015
RAPID-FILL SYR STRIP	12/23/2015
intravenous (IV) solutions	1/6/2016
Various	1/22/2016
0.9% Sodium Chloride Irrigation, USP, 500 ml Plastic Pour Bottle	2/5/2016
Brevibloc DOUBLE STRENGTH Premixed Injection Esmolol Hydrochloride in Sodium Chloride	4/12/2016
COSEAL Surgical Sealant	5/16/2016
50mm 0.2 Micron Filter	8/26/2016
TRANSDERM SCOP MULTPK PATCH 24	9/6/2016
50mm 0.2 Micron Filter	9/23/2016
10% Premasol Sulfite-Free-Amino Acid Injection 2000mL	12/7/2016
FLUCONAZ SOD 2CMG/1CML BAX 10	12/7/2016
Fluconazole Injection, USP and Milrinone Lactate 5%	5/22/2017

Actavis	**Date Sent**
Vancomycin HCl Capsules USP, 125mg and 250mg	8/26/2014
Diclofenac Sodium/Misoprostol DR Tablets	10/2/2014
Diclofenac/Misoprostol DR 75mg/0.2mg Tablets, 60 Count	10/17/2014
DEXTROAMPH CAP ER 15MG ACT 90	2/11/2015
VANCOMY CAP	2/17/2015
CARTIA XT CAP 300MG WAT 90@	3/30/2015
CORDRAN TAPE 4MCG SML ROLL	4/16/2015
Desmopressin Acetate Tablets 0.1mg	6/24/2015
Metformin Hydrochloride ExtendedRelease Tablets 1000mg	9/28/2015
AMPHETAM SALT TAB	2/18/2016
CIPROFLOX OPH DR 0.3% ACT	3/21/2016
GLIPIZIDE ER TB 2.5MG WAT 30@	7/1/2016
DEXTROAMPH CAP ER 10MG ACT90@	7/12/2016
ACETASOL HC SOL 1% 10ML and HYDRO AC O/SOL 1%-2% ACT 10ML@	8/3/2016
Ramipril Capsules, USP 1.25 mg	9/1/2016

NIFEDIPINE CAP 10MG ACTA 100@	10/7/2016
NIFEdipine 10mg Capsules, USP	10/18/2016
GLIPIZIDE 2.5 MG ER Tablets	1/31/2017
GLIPIZIDE ER TB 2.5MG WAT 30@	1/31/2017
LEVOFLOX OS 0.5% ACTA 5ML@	2/9/2017

Dr Reddy	**Date Sent**
METOPROL ER TAB 25MG DR/R 100@	5/28/2014
Amlodipine Besylate and Atorvastatin Calcium Tablets	5/8/2015
LEVALBUT SOL 0.31MG/3ML DR/R 25@	5/21/2015
DIVALPROEX ER	6/5/2015
Rivastigmine Tartrate Capsules USP 1.5mg 60 Count	8/5/2015
AMLODIPINE/ATOR	8/17/2015
PARICAL CAP 1MCG DR/R 30@	11/5/2015
Allopurinol Tablets 100mg, 100Ct Bottles	12/30/2015
PARICAL CAP	2/12/2016
Zoledronic Acid Injection, 5mg/100ml	3/4/2016
Ondansetron Tablets USP, 4mg, 30ct bottles	4/1/2016
ONDANS TAB 4MG DR/R 30@	5/24/2016
SIROLIMUS TAB 1MG DR/R 100@	6/10/2016
Olanzaplna Tablets, 2.5mg, 30ct	10/20/2016
Fluconazole Tablets	2/1/2017
Moxlfloxacln HCI Tablets,400mg 30ct	2/13/2017
ZENATANE CAP	2/17/2017
RIVASTIGM CAP 1.5MG	3/16/2017
ZENATANE 30MG CAP DR/R 30@	5/25/2017

Mylan	**Date Sent**
Metoprolol Succinate ER Tablets, USP	7/14/2014
NICARDIPINE SD 2.5MG/ML 10X10ML	1/30/2015
Haloperidol Decanoate Injection, 100mg/mL	2/19/2015
HALOP DEC SDV	3/23/215
METHOTR SDV 25MG/ML PFIZ 2ML5	3/30/2015
GEMCITAB LYO SUV 200MG PFIZ 1	4/1/2015

Calcium Chloride Intravenous Infusion 10%w/v	4/23/2015
Various	4/24/2015
GEMCITAB LYO SUV	4/30/2015
Mycophenolic Acid Delayed-release Tablets, 180mg, Bottles of 120	5/21/2015
Gemcitabine for Injection, USP	6/9/2015
METHOTR SDV 25MG/ML	6/10/2015
CAPECITABINE TB UPS 500MG MYLN 120@	7/30/2015
MECLIZ TAB 25MG UD UDL 100@	11/4/2015
TEMOZOLOMIDE CAP	1/24/2017
ATORVASTATIN	3/22/2017
EPIPEN	4/3/2017

American Health Packaging, Inc.	**Date Sent**
AHP Ibuprofen Tablets and AHP Oxcarbazepine Tablets	7/2/2014
OXCARBAZEP TB 300MG and IBUPROFEN TB, USP, 600MG	7/9/2014
AHP MethylPREDNISolone Tablets	10/13/2014
AHP Mercaptopurine Tablets	12/16/2014
AHP Benzonatate Capsules USP 100mg	1/9/2015
BENZONATATE SGC100MG	1/13/2015
Various	6/5/2015
Amlodipine Besylate 5mg TB and Azithromycin 250mg TB	6/9/2015
DESMOPR AC TB 0.1MG UD AHP 30@	7/2/2015
HYDROCHL CAP 12.5MG AHP 100	11/4/2015
AMPHET SLT and DEXTROAMPHET TB	8/29/2016
PARICALCITOL CP 1MCG UD AHP 30	10/4/2016
PHENOBARBITAL TAB 60MG WEST100	10/4/2016
NIFEdipine 10mg Capsules, USP	10/18/2016
GlipiZIDE Extended Release Tablets	2/6/2017
CYCLOSPORINE CAP	2/15/2017

Sun Pharmaceuticals	**Date Sent**
Venlafaxine Hydrochloride Extended-Release Tablets	9/29/2014
KETOR TR OS 0.5% CARA 3ML@	1/27/2015
LEVETIR ER TAB 750MG CARA 60	1/27/2015
Ergoloid Mesylates Tablets, USP, 1 mg	3/12/2015
Absorica (Isotretinoin) capsules	3/29/2015
Clonidine Hydrochloride Tablets	7/9/2015
Imipramine HCl Tablets, USP	7/17/2015
Felodipine Extended-Release Tablets	7/17/2015
Bupropion Hydrochloride Extended-Release Tablets USP (SR), 200 mg	7/17/2015
FELODIPINE ER TB 2.5MG MUT 100@	7/30/2015
FIBRICOR TAB and FENOFIB ACID TB	10/5/2015
Alendronate Sodium Tablets USP, 70 mg	2/12/2016
SULFAMETH+TRIMETH TAB 8C/160 MUT 100@	2/18/2016
ALFUZOSIN ER TB 10MG CARA 100@	4/12/2017
Metformin Hydrochloride Oral Solution	4/20/2017

Pfizer	**Date Sent**
ALPRAZOL TAB 1MG GRE 500@	6/25/2014
Depo-Medro140mg/1ml VL	8/1/2014
TORISEL 25MG/ML+1.8ML DILU KIT	10/13/2014
ALPRAZOL TAB 0.25MG GRE	12/19/2014
OXECTA TAB	2/27/2015
NORPACE CR CAP 150MG	12/3/2015
LYRICA CAP 50MG 90	1/14/2016
NORMOSOL-M SOL 1000ML HW CS12	2/3/2016
ROBITUS PK/C DM CGH&CH CON 8OZ	2/18/2016
Zoloft (sertraline HCl) 100 mg tablets	5/2/2016
CYTOTEC TAB 200MCG UD 100	9/13/2016
PREMARIN TAB 1.25MG 1000	9/16/2016
LEVOXYL TAB 200MCG 100	11/9/2016
PROTONIX	12/1/2016
QUILLIVANT	3/8/2017

Fresenius Kabi USA, LLC	**Date Sent**
FOSPHEN INJ 50MG/ML	5/5/2014
SOD BICAR SDV 4.2% 5ML	7/16/2014
PROPRAN SDV 1MG/ML APP 10	8/20/2014
Haloperidol Decanoate Injection, 50mg / mL	10/20/2014
Gentamicin Injection	11/14/2014
HEPAR L/F SDV 10U 10ML APP 25	12/29/2014
Heparin Lock Flush Solution	2/25/2015
RIFAMPIN VIAL 600MG APP 20ML	6/9/2015
HALOPERIDOL DEC VL 50MG APP 1ML	4/13/2016
CISTRACURIUM BES SDV 20MG/10ML APP10	4/13/2016
Sensorcaine®-MPF MPF (bupivacaine HCl) Injection	4/26/2016
OCTREOTIDE INJ and PPX OCTREOTIDE	5/10/2016
MIDAZ MDV 5MG/ML 5ML APP 10	12/21/2016
Fluphenazine Decanoate Injection	3/20/2017

Sandoz	**Date Sent**
Cefpodoxirne Proxetil 200 mg,	5/23/2014
Orphenadrine Citrate ER 100 mg Tablets	7/16/2014
ALPRAZOL TAB 0.25MG SAN 1000@	7/29/2014
FOMEPIZOL VL 1GM/ML SAN 1.5ML@	3/12/2015
Children's Certirizine	4/23/2015
TEMOZOLOMIDE CAP	9/2/2015
DICLOXAC CAP	7/1/2016
Phenylephrine	8/31/2016
L-CYSTEINE	11/15/2016
NADOLOL TAB 40MG SAN 1000@=	1/3/2017
DONEPEZIL TAB 10MG SAN	1/5/2017
TRANSDERMAL SCOPOLAMINE PATCH 4	2/3/2017
Pioglitazone and Glimepiride	2/15/2017
PILOCARPINE HYDROCHLORIDE OPHT SOL 4%	4/4/2017

Zydus Pharmaceuticals	**Date Sent**
PROMETH TAB 25MG ZYD 100	5/15/2014
Topiramate Tablets, 200mg	9/17/2014
Benzonatate Capsules, 200mg	9/29/2014
Benzonatate Capsules, 200mg	12/1/2014
Benzonatate Capsules, 100mg	12/23/2014
BENZONATATE SGC100MG	1/13/2015
Risperidone OD Tablets	1/15/2016
BROMOCRIP CAP 5MG ZYD 30@	5/11/2016
Venlafaxine	7/22/2016
Bupropion HCL ER Tablet	12/21/2016
ATENOLOL TAB	3/8/2017
Divalproex Sodium DR Tablets	3/16/2017
Divalproex Sodium DR Tablets and Target Divalproex Sodium DR	5/12/2017

Akorn	**Date Sent**
Rifampin for Injection, USP, 600 mg/vial	8/7/2014
Fluticasone Propionate Nasal Spray USP, 50 mcg	3/3/2015
Ful Glo, Fluorescein Sodium	4/6/2015
HYDROXYZ SYRP	4/9/2015
Indocyanine Green for Injection, USP	4/23/2015
RIFAMPIN LYO VL 600MG AKOR 20ML	8/25/2015
CHLORHEXIDINE GLUC OR	4/6/2016
SULFACET OPH SOL 10% AKOR15ML@	5/18/2016
Visine and NAPHAZOLINE HCl SOL 0.1% 15ML@	9/1/2016
DESOXIMETAS OINT 0.25%	12/7/2016
Sulfamethoxazole & Trimethoprim Oral Suspension	3/16/2017
IC-GREEN KIT USP 25MG	5/30/2017

Qualitest	**Date Sent**
OXY/APAP TAB 10MG/325MG Q/P100	9/3/2014
Methylprednisolone Tablets	9/11/2014
AHP MethylPREDNISolone Tablets	10/13/2014
Children's QPAP APAP Susp.	10/21/2014
AMLODIPINE BES 10MG Q/P 1000@	2/17/2015
PROMETH DM SYRP Q/P 16OZ@	2/24/2015

DISULFIRAM TAB 500MG Q/P 100	6/16/2015
Allopurinol Tablets	7/22/2015
Lisinopril Tablets	8/4/2015
Hydrochlorothiazide CAP 12.5MG Q/P 3000@	10/8/2015
RANITIDINE SYRP 15MG/ML Q/P 16OZ@	10/22/2015

Major Pharmaceuticals	**Date Sent**
Fish Oil Cholesterol Free 1000 mg softgels	5/16/2014
APAP PN&FEVCLD SUSP MMP 2OZ@ and MAPAP SUSP CHERRY MMP 4OZ@	7/29/2014
Thera w/Beta Carotene TB	1/6/2015
ALL DAY ALLER CHL 10MG MMP 12	4/24/2015
Amlodipine Besylate 10mg and Tamsulosin HCl 0.4mg CP	5/8/2015
Azithromy, Tamsulos, Amlodipine	5/11/2015
OXYCOD HCL TB 5MG UD MMP 100	6/12/2015
Eye Wash/Eye Irrigating Solutions	9/8/2016
LOSARTAN POT TB 50MG UD LUP100	11/15/2016
ARIPIPARZOLE TB 2MG UD MMP 30	12/30/2016
FLUCONAZ TB	2/7/2017

Hi-Tech	**Date Sent**
FASTIN TAB HI-T 60	7/24/2014
VIT C LIQ 500MG/5ML HI-T 16OZ@	7/30/2014
Liquid Vitamin C	8/27/2014
Ferrous Sulfate Elixir	1/2/2015
VIT C LIQ 500MG/5ML HI-T 16OZ@	1/16/2015
Fluticasone Propionate Nasal Spray USP	3/3/2015
Sulfamethoxazole and Trimethoprim Oral Suspension	3/19/2015
FLUTICAS NAS SP 50MCG HI-T 16GM@	3/20/2015

GSK	**Date Sent**
Panadol Advance® 100 ct	7/18/2014
FLULAVAL® QUADRIVALENT TF PFS 10s	4/17/2015
Sensodyne & Biotene	7/22/2015
BACTROBAN	9/21/2015
VENTOLIN HFA 200DOSE W/COUNTER	12/7/2015

BREATHE/RIGHT CLR STRIP LGE 30	4/6/2016
BACTROBAN	7/25/2016
VENTOLIN HFA 200DOSE W/COUNTER	3/22/2017
Ventolin	5/19/2017

Valeant Pharmaceuticals	**Date Sent**
Locoid Cream, 0.1%HCB, 15 grams	10/9/2014
HYDROCORT BU CRM 0.1%ROUS15GM	10/10/2014
VIRAZOLE VIAL 6GM 4	1/6/2015
BROMFEN O/S 0.09% B/L 1.7ML	9/8/2015
FENOGLIDE TAB 120MG 90	9/10/2015
CYCLOPEN OP/S	1/28/2016
Lodrane D (Brompheniramine Maleate/Pseudoephedrine HCl) capsules	5/24/2016
SECONAL SODIUM CAP 100MG 100	6/30/2016

West-Ward Pharmaceuticals	**Date Sent**
ISONIAZID TB 100MG	7/1/2014
ETHAMBUTOL TAB 100MG VERS 100	10/21/2014
FENTAN VL 50MCG/ML 5ML WEST 25	2/17/2015
PHENOBARBITAL TAB 60MG WEST100	10/4/2016
PREDNISON TAB 1MG ROX 100@	10/4/2016
FUROSEM TAB 20MG ROX 1000@	1/24/2017
Phenobarbital Tablets, USP and Amitriptyline Tablets, USP 50mg (100)	5/8/2017

PharmaTech, LLC	**Date Sent**
Rugby Polyvitamin Liquid, UPC 05368-45080, 50 ml	3/13/2015
POLY VIT	4/13/2015
Diocto Liquid	7/18/2016
all liquid products	8/10/2016

Attachment 6

State of California

HEALTH AND SAFETY CODE

Section 11153.5

11153.5. (a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes.

(b) Anyone who violates this section knowing, or having a conscious disregard for the fact, that the controlled substances are for other than a legitimate medical purpose shall be punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars ($20,000), or by both that fine and imprisonment.

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

(Amended by Stats. 2011, Ch. 15, Sec. 149. (AB 109) Effective April 4, 2011. Operative October 1, 2011, by Sec. 636 of Ch. 15, as amended by Stats. 2011, Ch. 39, Sec. 68.)

Attachment 7

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of **part 1305** of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is

given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in **Sec. 1301.72**. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of thiafentanil, carfentanil, etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

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

Attachment

California State Auditor
California State Auditor Report Number : 2016-127

Home-Generated Sharps and Pharmaceutical Waste
By Designating a Lead Agency, the State Could Increase Proper Disposal

Summary

HIGHLIGHTS

Our review concerning home-generated sharps and pharmaceutical waste highlighted the following:

- The State has not assigned oversight responsibility to a specific state agency for the disposal of home-generated sharps and pharmaceutical waste.
- Consumers receive conflicting guidance regarding the proper disposal of sharps and pharmaceutical waste.
- The State does not maintain an accurate and accessible list of collection sites for sharps and pharmaceutical waste disposal.
- Because it already provides oversight for all state-managed solid waste-handling programs, CalRecycle may be best-positioned to oversee household pharmaceutical and sharps waste.
- California could improve its collection and disposal of home-generated sharps and pharmaceutical waste by adopting programs and practices that other states and countries use.

Results in Brief

When consumers improperly dispose of home-generated sharps and pharmaceutical waste, the waste can pose an unnecessary risk to others and to the environment. Sharps waste—which consists of used needles, lancets, and other medical devices with sharp points or edges—can potentially result in disease transmission. On the other hand, pharmaceutical waste—which consists of prescription and over-the-counter medications—can harm water quality or be misused. Agencies that provide advice offer consumers different, and sometimes conflicting, guidance about how and where to dispose of these types of waste. For example, some agencies recommend that consumers use official collection programs to dispose of pharmaceutical waste, but others recommend placing it in the trash or flushing it down the toilet. Similarly, state agencies generally recommend that consumers dispose of home-generated sharps waste in approved disposal containers, but some federal agencies recommend putting this waste in heavy plastic containers, making it illegal to transport in California if the local enforcement agency has not approved the container. These inconsistencies may confuse

consumers, increasing the likelihood that they will dispose of home-generated sharps and pharmaceutical waste in unsafe or environmentally harmful ways.

Conflicting guidance regarding the disposal of sharps and pharmaceutical waste is in part the result of the fact that the State has not assigned oversight of this issue to a specific state agency. Rather, a number of different agencies have related responsibilities depending on how the waste is collected and processed. Specifically, the California Department of Resources Recycling and Recovery (CalRecycle), the California Department of Public Health (Public Health), the California State Board of Pharmacy, and the Department of Toxic Substances Control all play roles related to the processing of this waste. By placing oversight responsibility with a single agency, the State could ensure the creation of a unified educational campaign promoting consistent and proper disposal methods. We believe CalRecycle may be best-positioned to oversee household pharmaceutical and sharps waste because it already provides oversight for all state-managed solid waste-handling programs.

If the State assigned responsibility to a single agency, that agency could also help to ensure that all Californians have access to and awareness of collection sites and other means of sharps and pharmaceutical waste disposal. Although our analysis suggests that about 89 percent of consumers live within a 20-minute drive of sites for proper disposal, these consumers may not be aware of this access because no state agency maintains an accurate and comprehensive list of such sites. Both Public Health and CalRecycle maintain lists of collection sites; however, these lists are difficult to access and contain numerous errors. Further, our analysis suggests that about four million Californians may not live within 20 minutes of collection sites. An oversight entity could ensure that the State implements options to help these consumers, which might include subsidizing the use of mail-back containers to dispose of sharps and pharmaceutical waste.

California has more than sufficient capacity to process all of the State's home-generated sharps and pharmaceutical waste; however, laws and regulations discourage processing pharmaceutical waste within the State. In California, sharps are generally sterilized at one of the State's 18 medical waste facilities and then deposited in landfills. Home-generated sharps waste represents less than 1 percent of the available capacity of these facilities. If pharmaceutical waste includes controlled substances, the DEA requires collectors to ensure that such waste is rendered irretrievable, which usually means some form of incineration. Although three incinerators operate in the State that could dispose of pharmaceutical waste, government recommendations and legal requirements discourage these in-state incinerators from accepting pharmaceutical waste. Consequently, collection programs dispose of pharmaceutical waste by hauling it to out-of-state incinerators. Both the out-of-state and in-state incinerators have more than sufficient capacity to handle any future increases in the amount of the State's home-generated pharmaceutical waste.

California could improve its collection and disposal of home-generated sharps and pharmaceutical waste by adopting programs and practices that other states and countries use. For example, the state of New York requires all pharmacies to display that state's approved pharmaceutical disposal methods and requires all hospitals to accept household sharps for disposal. Canada uses extended producer responsibility programs (EPR programs) to assign the cost for disposal of pharmaceutical and sharps waste to the producers or manufacturers of the products, although in California these costs could ultimately be transferred to consumers through price increases. Several California counties have also begun implementing EPR

programs but have encountered delays, mainly due to the resistance of the sharps and pharmaceutical industries.

In addition, at the Legislature's request, in 2010 CalRecycle provided options for statewide pharmaceutical waste collection programs. Although we have concerns about three of the four options CalRecycle outlined, one of its proposed models generally aligns with our audit recommendations. Specifically, this option focuses on the Legislature's assigning oversight responsibility to a single state agency, which could then adopt regulations that might increase consumers' proper disposal of pharmaceutical waste.

Summary of Recommendations

To foster consumers' proper disposal of sharps and pharmaceutical waste, the Legislature should provide CalRecycle statutory oversight responsibility for home-generated sharps and pharmaceutical waste disposal and provide CalRecycle additional resources to the extent it can justify the need. This responsibility should include the following activities:

- Developing and implementing a public education campaign about home-generated sharps and pharmaceutical waste. CalRecycle should coordinate this campaign with local, state, and, to the extent possible, federal agencies to ensure consumers receive consistent guidance regarding proper disposal methods.
- Maintaining an up-to-date, well-publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites.
- Increasing consumer access to proper disposal sites in underserved areas.

To increase in-state options for processing California's home-generated pharmaceutical waste, the Legislature should consider expressly authorizing municipal solid waste incinerators to burn limited quantities of home-generated pharmaceutical waste, but only after considering environmental impacts.

To ensure consistency throughout the State, the Legislature should adopt standard requirements for counties to follow when implementing EPR programs. These requirements should limit any additional costs the programs may impose on consumers.

Agency Comments

Although we only have recommendations directed to the Legislature, we provided a draft redacted copy of our report to CalRecycle for review and comment because we are recommending that it become the lead state agency over the disposal of sharps and pharmaceutical waste. In its response, CalRecycle took issue with certain information in our report and it also expressed significant reluctance in taking on this leadership role.

Attachment

Section	Summary of Request	Recommendation	Basis
1735.1 (l)	Amend the definition of "daily" to specify that electronic monitoring of temperatures is allowable.	Reject	Clarification on the ability to use an electronic monitoring system can be done through education including an FAQ.
1735.1(n)	Amend the definition of "dosage unit" to beyond one administration and allow for one "dosage unit" to be one prescription.	Reject, but offer amendments in other areas to address, at least in part, the underlying issue.	After having the opportunity to review examples of preparations provided and receiving verbal input, board staff is offering language intended to ensure patients have timely access to the medications needed while minimizing risk. The staff recommended language is provided in CCR section 1751.7 (e)(1) and (e)(2)(C).
1735.1(r)	Update the definition of hazardous to mirror USP < 800> by July 1, 2018.	Agree	Ensuring a common understanding is appropriate.
1735.1	Recommend addition of a definition of "sterility."	Reject	Clarification of sterility can be found in USP. This issue can be addressed through education including an FAQ.
1735.1	Add a definition of "stability."	Reject	Clarification of stability can be found in USP. This issue can be addressed through education including an FAQ.
1735.2 (a)	Remove the requirement to document prescriber authorization to compound a product.	Reject	Documentation is necessary to confirm prescriber authorization.
1735.2(c)	Expansion of prescriber office use provisions and change in the definition of "reasonable quantity."	Reject	If the federal government makes changes in this area it may be appropriate to reevaluate the board's definition.
1735.2(d)	Change regulation to	Reject	Under both USP chapters <795> and <797> and

Note: Information is provided here for convenience and to facilitate discussion, that information is not intended to be legal advice.

Section	Summary of Request	Recommendation	Basis
	indicate that prohibitions to compounding only apply to human drugs.		California law, the compounding of veterinary products must meet the same standards and preparations for humans.
1735.2(i)	Clarification of the board's interpretation of "identical."	Accept in part	Proposed language and/or an FAQ can be used to explain further the board's requirement. The language for this section will be provided during the meeting. Further, staff notes that because of the subtle yet substantial differences, analogs can have greatly differing biological activity. Some examples include the group of amphetamines such as methamphetamine, amphetamine and phenethylamine.
1735.2(i)(1)	Clarify the conditions under which a BUD can be extended for a non-sterile compounded preparation.	Accept	Under USP <795>, pharmacists are provided with the factors to consider when establishing a BUD. Amendments are being offered by staff to establish similar requirements.
1735.2(i)(2)	Change the requirements to extend a BUD.	Accept in part	Given the current construct of the regulation section it is difficult to follow. The language needs clarification to ensure clear understanding of the requirements. This applies to sections 1735.2(i)(3) and (i)(4) as well. Language for this section will be provided during the meeting.
1735.2 (i)(3)	Change the requirements to extend a BUD.	Accept in part	Both USP <797> and board regulations establish the criteria for when a BUD can be extended for a sterile product. Board staff is offering suggested language to clarify that the provisions in CCR 1735.2(i)(3) only apply to sterile preparations.

Note: Information is provided here for convenience and to facilitate discussion, that information is not intended to be legal advice.

Section	Summary of Request	Recommendation	Basis
			Language for this section will be provided during the meeting.
1735.2(i)(5)	Concern with the conditions for establishing a shorter BUD.	Reject	The language establishing the shorter BUD is not new. In the prior version of the regulation, this provision was included in CCR 1735.2(h).
1735.2	Make stability, container closure, sterility and testing frequency consistent with USP standards.	Accept in part	Standards for the establishment of a BUD are found in USP <795> and USP <797> for CSPs. Language to restructure the language will be provided during the meeting.
1735.2 (3)	Recognition that potency over time studies can be used to validate stability of a preparation and assign extended beyond use dates.	Reject	USP, PCAB, board experts and outside experts all agree that the use of potency over time studies is not sufficient for the extension of a BUD.
1735.6(e)	Create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics.	Reject	Given the changes in USP <800>, this request would create conflict with those provisions.
1735.1 & 1735.8	Add definitions for "simple compounding", "moderate compounding" and "complex compounding" with additional modification to 1735.8 quality assurance requirements applying to only sterile or nonsterile	Reject	The board's regulation as currently written provide the flexibility necessary to account for the varying ranges of nonsterile compounding through the quality assurance plan that is developed for the specific practice site.

Note: Information is provided here for convenience and to facilitate discussion, that information is not intended to be legal advice.

Section	Summary of Request	Recommendation	Basis
	complex compounding		
1735.8(c)	Development of a list of compounds and dosage forms that would be specifically subject to analytical testing.	Reject.	After review of the examples provided, board staff believes the regulation is appropriate. Education can be completed with the development of an FAQ to provide guidance on the board's expectation. Further, staff is recommending a change under section 1735 that will exempt the mixing of nonhazardous drug from a manufacturers kit from the definition of compounding.
1751.1(a)(5)	Clarify where the smoke studies must be done and establish a frequency.	Agree	Proposed language is provided.
1751.3	Clarification on what environments require a sampling plan.	Reject	The sampling plan should be developed using a pharmacist's professional judgement.
1751.3(c)	Provide detailed description of what the SOPs need to include for sterilization and depyrogenation process.	Reject	The SOPs should be determined based on the pharmacist's professional judgement.
1751.4	Clarify that cleaning must be done when hazardous drugs are being compounded as well as what environments must be cleaned.	Reject	Cleaning must be done consistent with board requirements and pursuant to a pharmacist's professional judgement. USP provides standards that should be referenced.
1751.4(d)	Add a definition of germicidal to allow the use of a ready-to-use germicidal detergent including sterile water.	Accept in part	Staff recommend a different approach and have provided draft language.
1751.4(d)(1)	Clarify that cleaning does	Accept in part	Staff recommend striking a balance between the

Section	Summary of Request	Recommendation	Basis
	not need to happen daily, but rather every day the facility is used to prepare sterile drug products.		need to clean and the frequency. Experts agree that the approach being offered is appropriate.
1751.4(g)(1)	Create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics.	Reject	Given the changes in USP <800>, this request would create conflict with those provisions.
1751.4(k)	Remove the minimum room temperature.	Accept	Recommended language would be consistent with USP requirements.
1751.4(g)(1)	Recommend adding a requirement for two pairs of standard gloves for all hazardous compounding.	Reject	This issue will be reevaluated in a future revision.
1751.6(e)(2)	Provide alternative training requirements for staff only involved in the supervision of personnel compounding but not compounding themselves.	Reject	The pharmacy must ensure appropriate training of both the staff performing the compounding and supervising the compounding which can be different depending on the functions the staff is performing. Staff suggests an FAQ in this area.
1751.7(e)(1)	Allow for an alternative method of testing as those described in USP <71> to perform end product testing. Also, exempt irrigations from pyrogen testing.	Accepting in part	Draft language will allow for an alternate testing, specifically RMM. Draft language provided.
1751.11	Add provisions to	Reject	Reevaluation of this change would be appropriate

Note: Information is provided here for convenience and to facilitate discussion, that information is not intended to be legal advice.

Section	Summary of Request	Recommendation	Basis
	establish requirements for sterilization and depyrogenation.		after revisions to USP <797> are completed.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

CALIFORNIA RETAILERS ASSOCIATION
980 Ninth Street, Suite 2100 Sacramento, CA 95814
(916) 443-1975 calretailers.com

July 6, 2017

Virginia Herold
Executive Officer
Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

RE: Compounding Quality Assurance Requirements under 16 CCR § 1735.8

Dear Ms. Herold,

On behalf of our community pharmacies operating within the State of California, the California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) thank you for the opportunity to once again submit written comments concerning 16 § CCR 1735.8, pertaining to compounding quality assurance provisions. Specifically, 16 CCR § 1735.8 requires that "any pharmacy engaged in compounding…shall maintain a quality assurance plan… (that) shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis".

Representatives from our member companies appeared at the June 2, 2017 Enforcement and Compounding Committee meeting and discussed the impact of this rule upon patient safety and patient access to simple and moderate compounded drug preparations. We believe that, as a result of **16 § CCR 1735.8,** patients in the state of California would suffer:

a. **An increased risk of experiencing dangerous drug interactions:**

   If pharmacies ceased compounding due to the cost of such required testing and analysis, patient's profiles may be split between two pharmacies, increasing the difficulty for our pharmacists to adequately complete their "duty to review drug therapy and patient medication record prior to delivery".

b. **A reduction in access to healthcare:**

   Patients would suffer a decrease in access to compounded drug product if the only pharmacy in their geographic area ceased compounding, with rural areas being the most vulnerable, and such patient access issues may be acute in urban areas as well.

   Patient access issues may lead to non-adherence to medication, which has resulted in higher health care costs and an increase in the prevalence of conditions that directly impact patient health, according to a New England Journal of Medicine article by Osterberg and Blaschke entitled "Adherence to Medication".

The Committee asked our members to provide the Board's staff with a list of commonly compounded drug products. This list was provided to your Board's staff on June 29, 2017 and is also attached to this letter for your reference. The list is mainly comprised of different formulations of "Magic Mouthwash" and commercially available topical Rx item combinations, and it contains a few non-commercially available suspensions. Please note that the list contains no sterile or nonsterile complex compounded drug products.

In order to avoid unintended impacts to patient care and access, we respectfully submit the following language for consideration by the Enforcement and Compounding Committee on July 12, 2017. Our suggested definitions originate from the United States Pharmacopeia Chapter 795, and our suggested revisions only pertain to nonsterile simple and moderate compounding.

16 CCR § 1735.1 Compounding in Licensed Pharmacies

"Simple compounding" means making a preparation that has a United States Pharmacopeia compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include oral liquids (i.e. solutions, suspensions) and topicals (i.e. creams, ointments, lotions, gels).

"Moderate compounding" means making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include oral dosages (i.e. capsules, tablets), suppositories, and troches.

"Complex compounding" means making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include specialized transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.

16 CCR § 1735.8. Compounding Quality Assurance

(a) Any pharmacy engaged in simple compounding, moderate compounding or complex compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) 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.

(c) For any pharmacy engaged in sterile compounding or nonsterile complex compounding the ~~The~~ quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis for any pharmacy engaged in sterile compounding or nonsterile complex compounding.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

CRA and NACDS thank the Board for considering our comments and suggested rule changes.

Sincerely,

Angie Manetti
California Retailers Association

Mary Staples
National Association of Chain Drug Stores

Examples of Commonly Prepared Non-Sterile Compounds by Community Pharmacists

Albertsons Companies, CVS Health, Rite Aid, and Walgreens

Compound Type	Ingredient 1	Ingredient 2	Ingredient 3 (if applicable)
Magic Mouthwash	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID LIQUID
	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID & GAS RELIEF LIQUID
	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID & GAS RELIEF LIQUID MAX STR
	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5 MG/5 ML	NYSTATIN 100,000 UNIT/ML SUSP
	LIDOCAINE 2% VISCOUS SOLN	ANTACID-ANTIGAS LIQUID	
	LIDOCAINE 2% VISCOUS SOLN	NYSTATIN 100,000 UNIT/ML SUSP	ANTACID-ANTIGAS LIQUID
	LIDOCAINE 2% VISCOUS SOLN	NYSTATIN 100,000 UNIT/ML SUSP	ANTACID LIQUID
	DIPHENHYDRAMINE 12.5MG/5ML	LIDOCAINE 2% VISCOUS SOLN	
	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID LIQUID	
	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID-ANTIGAS LIQUID	
	DIPHENHYDRAMINE 12.5 MG/5 ML	DEXAMETHASONE 0.5 MG/5 ML ELX	
	NYSTATIN 100,000 UNIT/ML SUSP	DIPHENHYDRAMINE 12.5MG/5 ML	ANTACID-ANTIGAS LIQUID
	NYSTATIN 100,000 UNIT/ML SUSP	PREDNISOLONE 15 MG/5 ML SYRUP	LIDOCAINE 2% VISCOUS SOLN
	NYSTATIN 100,000 UNIT/ML SUSP	PREDNISOLONE 15 MG/5 ML SYRUP	
	NYSTATIN 100,000 UNIT/ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	
	NYSTATIN 100,000 UNIT/ML SUSP	LIDOCAINE 2% VISCOUS SOLN	
	CARAFATE 1 GM/10 ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID LIQUID
	CARAFATE 1 GM/10 ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID-ANTIGAS LIQUID
	CARAFATE 1 GM/10 ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID-ANTIGAS MAX STR LQ
	CARAFATE 1 GM/10 ML SUSP	LIDOCAINE 2% VISCOUS SOLN	NYSTATIN 100,000 UNIT/ML SUSP
	CARAFATE 1 GM/10 ML SUSP	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5MG/5ML
	DEXAMETHASONE 0.5 MG/5 ML LIQ	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5MG/5ML
	DEXAMETHASONE 0.5 MG/5 ML LIQ	NYSTATIN 100,000 UNIT/ML SUSP	DIPHENHYDRAMINE 12.5MG/5ML
Non-Commercially Available Suspensions	HYDROCHLOROTHIAZIDE 50 MG TAB	ORA-SWEET-SF SYRUP	ORA-PLUS SUSPENDING VEHICLE
	OMEPRAZOLE DR 20 MG CAPSULE	SODIUM BICARB 8.4% VIAL	
	LANSOPRAZOLE DR 30 MG CAPSULE	SODIUM BICARB 8.4% VIAL	
	LANSOPRAZOLE DR 30 MG CAPSULE	ORA-SWEET ORAL SYRUP	
	TAMIFLU 75 MG GELCAP	ORA-SWEET-SF SYRUP	
	METRONIDAZOLE 250 MG TABLET	ORA-PLUS SUSPENDING VEHICLE	
	URSODIOL 300 MG CAPSULE	ORA-SWEET ORAL SYRUP	ORA-PLUS SUSPENDING VEHICLE
	METOPROLOL TARTRATE 100 MG TAB	ORA-PLUS SUSPENDING VEHICLE	ORA-SWEET ORAL SYRUP
	ATENOLOL 25 MG TABLET	FLAVOR SWEET SYRUP	FLAVOR PLUS SUSP
	LOSARTAN POTASSIUM 50 MG TAB	ORA-SWEET ORAL SYRUP	
Topical Preparations	TRIAMCINOLONE 0.1% CREAM	LUBRIDERM DAILY MOISTURE LOT	
	TRIAMCINOLONE 0.1% CREAM	EUCERIN CREME	
	TRIAMCINOLONE 0.1% CREAM	AVEENO DAILY MOISTURIZING LOT	
	TRIAMCINOLONE 0.1% CREAM	CETAPHIL CREAM	
	TRIAMCINOLONE 0.1% CREAM	SSD 1% CREAM	
	TRIAMCINOLONE 0.1% CREAM	UREA 40% LOTION	EUCERIN ORIGINAL LOTION
	TRIAMCINOLONE 0.1% CREAM	SARNA ANTI-ITCH LOTION	
	TRIAMCINOLONE 0.1% OINTMENT	AQUAPHOR 41% ORIGINAL OINTMENT	
	TRIAMCINOLONE 0.5% CREAM	MUPIROCIN 2% OINTMENT	
	HYDROCORTISONE 2.5% CREAM	AQUAPHOR 41% ORIGINAL OINTMENT	
	HYDROCORTISONE 2.5% CREAM	MOISTURIZING THERAPY CREAM	
	HYDROCORTISONE 2.5% CREAM	BETA CARE CREAM	
	HYDROCORTISONE 2.5% CREAM	ECONAZOLE NITRATE 1% CREAM	

Examples of Commonly Prepared Non-Sterile Compounds by Community Pharmacists

Albertsons Companies, CVS Health, Rite Aid, and Walgreens

Topical Preparations, Continued	HYDROCORTISONE 2.5% CREAM	KETOCONAZOLE 2% CREAM	
	HYDROCORTISONE 2.5% OINTMENT	AQUAPHOR OINTMENT	
	KETOCONAZOLE 2% CREAM	ALCLOMETASONE DIPRO 0.05% CRM	
	KETOCONAZOLE 2% CREAM	DESONIDE 0.05% CREAM	
	KETOCONAZOLE 2% CREAM	FLUOCINONIDE 0.05% OINTMENT	
	LIDOCAINE 5% OINTMENT	MUPIROCIN 2% OINTMENT	NYSTATIN 100,000 UNITS/GM OINT
	MUPIROCIN 2% OINTMENT	NYSTATIN 100,000 UNITS/GM OINT	ZINC OXIDE 20% OINTMENT
	DESONIDE 0.05% CREAM	SELENIUM SULFIDE 2.5% LOTION	
	CLOBETASOL 0.05% CREAM	CETAPHIL MOISTURIZING CREAM	
	FLUOCINONIDE 0.05% CREAM	UREA 20% CREAM	AQUAPHOR OINTMENT
	MOMETASONE FUROATE 0.1% OINT	PETROLATUM JELLY	
	BETAMETHASONE VA 0.1% CREAM	EUCERIN CREME	

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	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID & GAS RELIEF LIQUID MAX STR
	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5 MG/5 ML	NYSTATIN 100,000 UNIT/ML SUSP
	LIDOCAINE 2% VISCOUS SOLN	ANTACID-ANTIGAS LIQUID	
	LIDOCAINE 2% VISCOUS SOLN	NYSTATIN 100,000 UNIT/ML SUSP	ANTACID-ANTIGAS LIQUID
	LIDOCAINE 2% VISCOUS SOLN	NYSTATIN 100,000 UNIT/ML SUSP	ANTACID LIQUID
	DIPHENHYDRAMINE 12.5MG/5ML	LIDOCAINE 2% VISCOUS SOLN	
	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID LIQUID	
	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID-ANTIGAS LIQUID	
	DIPHENHYDRAMINE 12.5 MG/5 ML	DEXAMETHASONE 0.5 MG/5 ML ELX	
	NYSTATIN 100,000 UNIT/ML SUSP	DIPHENHYDRAMINE 12.5MG/5 ML	ANTACID-ANTIGAS LIQUID
	NYSTATIN 100,000 UNIT/ML SUSP	PREDNISOLONE 15 MG/5 ML SYRUP	LIDOCAINE 2% VISCOUS SOLN
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	NYSTATIN 100,000 UNIT/ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	
	NYSTATIN 100,000 UNIT/ML SUSP	LIDOCAINE 2% VISCOUS SOLN	
	CARAFATE 1 GM/10 ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID LIQUID
	CARAFATE 1 GM/10 ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID-ANTIGAS LIQUID
	CARAFATE 1 GM/10 ML SUSP	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID-ANTIGAS MAX STR LQ
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	CARAFATE 1 GM/10 ML SUSP	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5MG/5ML
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	TAMIFLU 75 MG GELCAP	ORA-SWEET-SF SYRUP	
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	METOPROLOL TARTRATE 100 MG TAB	ORA-PLUS SUSPENDING VEHICLE	ORA-SWEET ORAL SYRUP
	ATENOLOL 25 MG TABLET	FLAVOR SWEET SYRUP	FLAVOR PLUS SUSP
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Topical Preparations	TRIAMCINOLONE 0.1% CREAM	LUBRIDERM DAILY MOISTURE LOT	
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	TRIAMCINOLONE 0.1% CREAM	UREA 40% LOTION	EUCERIN ORIGINAL LOTION
	TRIAMCINOLONE 0.1% CREAM	SARNA ANTI-ITCH LOTION	
	TRIAMCINOLONE 0.1% OINTMENT	AQUAPHOR 41% ORIGINAL OINTMENT	
	TRIAMCINOLONE 0.5% CREAM	MUPIROCIN 2% OINTMENT	
	HYDROCORTISONE 2.5% CREAM	AQUAPHOR 41% ORIGINAL OINTMENT	
	HYDROCORTISONE 2.5% CREAM	MOISTURIZING THERAPY CREAM	
	HYDROCORTISONE 2.5% CREAM	BETA CARE CREAM	
	HYDROCORTISONE 2.5% CREAM	ECONAZOLE NITRATE 1% CREAM	

Examples of Commonly Prepared Non-Sterile Compounds by Community Pharmacists

Albertsons Companies, CVS Health, Rite Aid, and Walgreens

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	KETOCONAZOLE 2% CREAM	DESONIDE 0.05% CREAM	
	KETOCONAZOLE 2% CREAM	FLUOCINONIDE 0.05% OINTMENT	
	LIDOCAINE 5% OINTMENT	MUPIROCIN 2% OINTMENT	NYSTATIN 100,000 UNITS/GM OINT
	MUPIROCIN 2% OINTMENT	NYSTATIN 100,000 UNITS/GM OINT	ZINC OXIDE 20% OINTMENT
	DESONIDE 0.05% CREAM	SELENIUM SULFIDE 2.5% LOTION	
	CLOBETASOL 0.05% CREAM	CETAPHIL MOISTURIZING CREAM	
	FLUOCINONIDE 0.05% CREAM	UREA 20% CREAM	AQUAPHOR OINTMENT
	MOMETASONE FUROATE 0.1% OINT	PETROLATUM JELLY	
	BETAMETHASONE VA 0.1% CREAM	EUCERIN CREME	

californiapharmacistsassociation

June 23, 2017

Laura Hendricks, Associate Analyst
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Dear Ms. Hendricks,

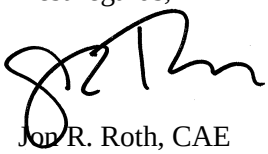
Thank you for your correspondence of June 21, 2017 in which you requested examples of the types of medication regimens that would be necessary to support the CPhA proposed amendment to the definition of dosage [1735.1(n)]. This change is recommended to ensure the definition of dosage unit is clearly intended to allow the compounding pharmacist to fulfill a prescriber's request for a patient to receive a prescribed course of therapy that involves multiple dose units of medication. Below please find several examples where allowing for the compounding pharmacist to complete a course of therapy pursuant to the prescriber's direction is necessary.

- IV Drug shortages medications, including IV antibiotic (tobramycin, cefotaxime, cefotetan), talc powder, electrolytes (sodium bicarbonate, sodium acetate, phosphates) when a manufactured product is identified as being in shortage. Licensed Sterile Compounders are often a resource to supply hospitals and clinics, using bulk powders with a duration anywhere from 30 to 60 days. USP guidelines allow for compounding these types of medications for a series of days. Reference: https://www.accessdata.fda.gov/scripts/drugshortages/
- Dexamenthasone 24mg/ml Otic Irrigation Sterile Solution: This medication is used for tympanic inflammation that can potentially lead to deafness. Routinely, an ENT physician will order this to administer in the office. One dose can accommodate one (1) ear and second dose may be needed for a second ear for treatment. Reference: Laryngoscope 117: Jan 2007
- Calcium and Sodium EDTA: Medication used for chelation therapy for patients, for arterial calcification or high calcium score, heavy metal poisoning. EDTA powder is compounded for weekly or two-week duration of therapy. References: i) Guldager B, Jelnes R, Jorgensen SJ. et al. EDTA treatment of intermittent claudication: a double-blind, placebo-controlled study. J Intern Med.1992;231:261-267. ii) Van Rij AM, Solomon C, Packer SG, Hopkins WG. Chelation therapy for intermittent claudication: a double-blind, randomized, controlled trial. Circulation.1994;90:1194-1199.
- Sodium Phenylbutrate IV infusion: Medication is often prescribed 2-5x per week for neurological complications associated with chronic lyme disease. Reference: i) Curr Pharm Des. 2013;19(28):5076-84. ii) Drugs R D. 2011 Sep; 11(3): 227–249.
- Methylcobalamin: Often dispensed in MTVs for autistic pts that cannot methylate. Reference: http://www.drneubrander.com/videos.php?playlist=5
- Glutathione: Used in autistic patients, Parkinson's patients, and for treatment of lyme disease.
- Sodium Bicarbonate: Used for metabolic acidosis. This is not currently commercially available and is creating access to therapy problems for hospitals.

- Papaverine/phentolamine/alprostadil (aka Trimix): This medication dispensed as a 5 or 10ml MDV for each patient pursuant to a prescription over a course of therapy.
- Ophthalmic antibiotic injections: Unlike self-administered ophthalmic medications, it is our understanding that these medications would not be exempt from the regulation. If patients are required to wait 14 days for the sterility/pyrogen test results, the delay in therapy could result in blindness.

Thank you again for requesting this additional information. We believe these examples and others demonstrate the importance of ensuring patient access to a course of therapy as prescribed and therefore necessitate an amendment to the definition of dosage in 1735.1(n).

Best regards,



Jon R. Roth, CAE
Chief Executive Officer

California State Board of Pharmacy
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www.pharmacy.ca.gov

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT AND COMPOUNDING COMMITTEE
DRAFT MEETING MINUTES

DATE: June 2, 2017

LOCATION: Sheraton Park Hotel
1855 S. Harbor Blvd.
Anaheim, CA 92802

COMMITTEE MEMBERS PRESENT: Amy Gutierrez, PharmD, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member

COMMITTEE MEMBERS NOT PRESENT: Greg Lippe, Public Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Julia Ansel, Chief of Enforcement
Tom Lenox, Chief of Enforcement
Laura Freedman, DCA Staff Counsel
Christine Acosta, PharmD, Supervising Inspector
Laura Hendricks, Staff Analyst

Note: The webcast of this meeting may be found on the board's website.
http://www.pharmacy.ca.gov/about/meetings_enforcement.shtml

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 8:33 a.m. Board members present: Amy Gutierrez, Valerie Munoz, Stanley Weisser, and Allen Schaad.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

John Gray, pharmacist from Keck Medical Center of USC, read the following statement.

> *I would like to request the addition of an agenda item to the next appropriate Board meeting. Section 1735.6(e) in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations states: "Hazardous drug compounding shall be*

completed in an externally vented physically separate room…". Based on recent sterile compounding license inspections and personal discussions with Board of Pharmacy inspectors, it is evident that the Board is interpreting this regulation to mean that "Hazardous drug compounding shall be completed in an externally vented physically separate room which is separately vented from the room's primary engineering controls." In practice, depending upon the characteristics of the negative pressure room and the Biological Safety Cabinets, it is possible to meet the room performance requirements described in sections 1735.6(e)(1)&(2) and 1735.1(e)(2) by externally exhausting the room air through the grille in front of the BSC, which is manufactured, tested, and certified for this specific purpose as a PEC.

I would like to request that the Board review the actual language and its current interpretation of Section 1735.6(e). In doing so, I would encourage the Board to recognize that external venting of a negative pressure room for hazardous drug preparation via a Class II Type A2 BSC is not a threat to patient or employee safety and is one appropriate mechanism to meet the external venting requirement described in Section 1735.6(e).

The committee thanked Dr. Gray and requested a picture to help illustrate the flow of room air out of a negative pressure room for hazardous drug preparation via the biological safety cabinet.

Douglas Barcon, pharmacist, asked the committee to consider how AB 443, which would allow optometrists to provide certain vaccinations, might affect the practice of pharmacy.

Dieter Steinwetz, pharmacist from Coast Compounding Pharmacy, asked the committee to consider reevaluating the pharmacy technician ratio in compounding pharmacies.

III. Review and Discussion of Board's Compounding Regulations, CCR Section 1735 et seq., and Section 1751 et seq., and Relevant Chapters of USP Pharmacopeia relating to Compounding

President Gutierrez explained that CCR section 1735 et seq., and CCR section 1751 et seq., establish the requirements for compounding drug preparation.

President Gutierrez stated that Business and Professions Code (BPC) section 4127.1 requires the board to adopt regulations to establish policies, guidelines and procedures to implement Article 7.5, Sterile Drug Products. BCP 7127.1 also requires the board to review any formal revisions to General Chapter 797 of the United States Pharmacopeia and the National Formulary (USP-NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official.

President Gutierrez noted that updates to USP 797 are pending, but there is currently no timeline for their finalization.

President Gutierrez reported that in April 2015, the board formally initiated a rulemaking to promulgate the board's compounding regulations. The final version of the regulation language was adopted by the board on January 19, 2016, and approved by the Office of Administrative Law on September 13, 2016. She added that the effective date of the regulations was January 1, 2017.

President Gutierrez explained that since adoption by the board, both the committee and board have received public comment regarding the impact of the regulations on patient populations, including

animals. Although comments have been provided in several areas, many of the comments are focused on the board's requirements for the assignment of a Beyond Use Date (BUD).

President Gutierrez reported that during the committee's April meeting, a presentation was provided by Road Runner Pharmacy regarding concerns about the board's regulation relating to the requirements for the establishment of the BUD of veterinary products. The committee was advised of some of the challenges for compounding medications for their patient population. The committee was also advised about the cost impacts of the board's current regulations and the resulting impact on consumers and their pets. President Gutierrez explained that after hearing the presentation and public comments about the board's regulation, the committee determined it was necessary to schedule a special meeting to focus on several different aspects of the board's compounding regulations.

President Gutierrez stated that during the May 2017 board meeting, members heard comments on the issue, including reference to the DQSA and its lack of applicability to veterinary compounding. She explained that since the May meeting, board staff has confirmed that the provision of the DQSA relates specifically to human drug compounding, meaning the compounding provisions for 503A and 503B provisions apply only to human drugs. President Gutierrez also noted that California pharmacy law does not differentiate between compounding for humans versus animals. Staff has confirmed with USP (Untied State Pharmacopeia) that all compounding chapters apply to human and animal patients and that USP <795> includes a section specific for animal patients.

IV. Discussion on Possible Recommended Changes to the Board's Compounding Regulations, CCR Section 1735 et seq, and Section 1751 et seq

President Gutierrez explained that at this meeting, committee members will have the opportunity to discuss possible changes to the board's compounding regulations being brought forward by both staff and stakeholders.

President Gutierrez reviewed the following recommended changes provided by board staff.

- 1735 Compounding in Licensed Pharmacies: Board staff does not believe that the mixing of ingredients from a compounding kit purchased from an FDA approved manufacturer needs to be included in definition of compounding if done according to the manufacturer instructions.

- Section 1735.2 Compounding Limitations and Requirements; Self-Assessment: Board staff recommends changes to the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products including changes to 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

- Section 1751.1 Sterile Compounding Recordkeeping Requirements: Staff recommends clarifying the requirements for smoke studies, including both the applicable area where such studies must be performed (ISO Class 5) as well as the frequency in which they must be conducted (semi-annually).

- Section 1751.4 Facility and Equipment Standards for Sterile Compounding: Staff recommends clarifying that cleaning must be done whenever hazardous drugs are being compounding as well as clarifying where the cleaning must occur.

Eric Kastango, from Critical IQ, thanked the board for working on harmonizing the California regulations and the USP chapters wherever possible as this will protect human and animal patients. He noted that in light of the BP syringe problem that occurred several years ago the board must be very cognizant of what type of containers compounded medications are being stored in in order to ensure they maintain their stability.

President Gutierrez asked Dr. Kastango if he had any recommendations on areas where the board should focus. Dr. Kastango responded that the board should harmonize the terminology used in its regulations with those used in USP. He also stated that there are major differences between potency over time and stability – mainly that potency over time does not look at impurities or the inactive drug once it has been subject to degradation. Dr. Kastango also stated that there are differences between cleaning and disinfecting, he noted that he agreed with the comments submitted by CPhA in this area.

Senator Stone thanked the board for being receptive to the concerns being raised by the regulated public. He stated that the goal for compounding pharmacists to ensure that their patients receive save and effective medications. Senator Stone added that these compounding pharmacies must have the ability to continue to provide their patients with these very important compounded medications in a safe manner. The committee thanked Senator Stone for attending the meeting and for his support.

Note: All written comments submitted to the committee were provided in the meeting materials and have also been provided immediately following these minutes.

Jon Roth, representing the California Pharmacists Association, reviewed the following changes being requested by CPhA.

- 1735.1(l) Amend the definition of "daily."
- 1735.1 (n) Amend the definition of dosage unit to beyond one administration and allow for the dosage unit to be considered a quantity prescribed.
- 1735.1 Add a definition of sterility.
- 1735.2 (i)(1) – (3) Amend the BUD requirements.
- 1735.2 (4) Change requirements relating to the extension of BUD provisions to what appears to be allowing analogous versus identical ingredients.
- 1735.2 (5) Correct the drafting error where the board inadvertently indicated that shorter dating can be done.
- 1735.2 (6) Request recognition of potency over time study as applicable to the compounded formulations can be used to validate stability and assign extended beyond use dates.
- 1751.1(a)(5) Clarify smoke studies in an ISO Class 5 certified space.
- 1751.4(d) Clarify that cleaning does not need to happen daily, but rather every day the facility is used to prepare sterile drug compounds.
- 1751.4(k) Remove minimum room temperature requirement.
- 1751.6(e) Correct typo by removing redundant "sterile" and indicate that training can vary for someone only directly supervising individuals compounding, not performing it themselves.
- 1751.7(e)(1) Allow for an equivalent method of testing as those described in USP 71 and exempt pyrogen testing from irrigation.

The committee thanked Mr. Roth for his testimony and asked him to provide an example of the medications that would be covered under 1735.1 (n).

Erik Tosh and Anthony Grzib, representing The International Academy for Compounding, spoke in support of the testimony provided by CPhA, especially their request to change requirements in 1735.2 (4) relating to the extension of BUD provisions to what appears to be allowing analogous versus identical ingredients.

President Gutierrez asked Allen Schaad to lead the discussion on Kaiser's comments as she is employed by Kaiser.

Corbin Bennett, representing Kaiser, reviewed the following changes being requested by Kaiser.

- 1735.1(r) and 1735.6(e) Requests changing the hazardous provisions to mirror the requirements in USP 800.
- Requests clarification on smoke study environments.
- 1751.4(d) Requests that the regulation specify that ready-to-use germicidal detergent, including sterile water, is acceptable.
- 1751.4(g)(1) Requests addition of a requirement for two pairs of standard gloves for all hazardous compounding.
- 1751.3 and 1751.4 Request clarification on the need for sampling for the segregated compounding areas outside of the ISO-5 environment. Question: Is the sampling plan and procedures for nonviable particle samples as well as violation air and surface limited to ISO certified areas, or does it also apply to segregated compounding area outside the ISO environment.
- Request clarification if a pharmacy can contract with another pharmacy for compounded products or just parenteral.

Erik Tosh, Vice President of Professional Services at Letco Medical, stated that Letco Medical supports the comments made by CPhA and Kaiser. Dr. Tosh asked the board to modify 1735.2(i) as the board's interpretation of "identical" is too limiting.

Mark Johnston, Senior Director of Regulatory Affairs for CVS, Laura Churns, Legislative and Regulatory Affairs for Albertsons and Rob Mullens, Divisional Pharmacy Vice President for Rite Aid, asked the board to amend 1735.8 (c) so that retail pharmacies can continue to provide simple non-sterile compounded medications to their patients at a reasonable cost.

Mr. Johnston explained that much of the compounding done in retail pharmacies are simple and moderate, non-sterile compounding (e.g magic mouthwash prepared from a kit or the mixing of two creams from a manufacturer's packaging). He advised the committee that costs associated with complying with 1735.8 exceed total profitability and therefore it is not fiscally responsible to compound low volumes necessary for their patients.

Laura Churns provided examples of how patients would be negatively impacted if retail pharmacies are no longer able to provide simple, non-sterile compounded medications such as magic mouthwash and Tamiflu. The committee asked if the presenters could provide additional examples of the types of simple, non-sterile compounds they would like to have exempted from the definition of "compounding."

Mr. Mullens explained that patients in rural communities rely on their local retail pharmacies to provide them with simple, non-sterile compounded medications. President Gutierrez asked if the comments made by the presenters only referred to topical and oral non-sterile medications. Mr. Mullens confirmed.

Mr. Schaad asked if the presenters could provide a partial list of the compounding medications provided by these retail pharmacies.

Mr. Weisser expressed his support for these pharmacies providing their patients with these simple non-sterile compounded medications. Mr. Mullens noted that while it is not done very frequently, it is often for children or critically ill patients.

President Gutierrez asked if a compounding log is kept for these medications. Mr. Johnson confirmed that a compounding log is kept.

Rick Rhoads, Director of Compounding at University Compounding Pharmacy, reviewed the following recommended amendments.

- 1735.1(r) Harmonize the definition of hazardous to mirror the USP <800> definition
- 1735.1 Add a definition of "Stability"
- 1735.2(i)(3) Change the requirements to extent a BUD
- 1735.6(e) & 1751.4(g)(1) Create and exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics
- 1751.3(c) Provide detailed description of the information standard operating procedures (SOP) must include for sterilization and depryogenation processes
- 1751.11 Add provisions to establish requirements for sterilization and depryogenation

There were no questions from the committee or the public.

Lee Martin, PIC for Road Runner Pharmacy, reviewed the following requested amendments. He also noted that the board's regulations far exceed USP standards in a number of areas.

- 1735.2(a) Remove the requirement to document a prescriber's authorization to compound a product
- 1735.2 Make stability, container closure, sterility and testing frequency consistent with USP standards

President Gutierrez clarified that Road Runner is asking the board to align with USP 795 for non-sterile compounding. Dr. Martin confirmed that they would like the board's regulations to mirror USP 795 for non-sterile compounding.

Adam Landsmen, Regional Sales Manager for Road Runner Pharmacy, stated that he has seen many of their competitors ignoring the board's compounding regulations. He expressed concern that there is an uneven playing field for pharmacies that are spending money to comply with the regulations. President Gutierrez asked the presenters to keep their comments to specific sections of the regulations that they would like amended.

Note: Road Runner Pharmacy provided documents to the board, however DCA legal counsel asked that the board not review the documents as they contained a complaint against another licensee. Staff collected the documents.

Anthony Grzib, director of pharmacy compliance for Wedgwood Pharmacy, and Rachel Pontikes, national counsel for Wedgwood Pharmacy, spoke in support of CPhA's recommendation to modify 1735.2 (i) to amend the BUD requirements. Dr. Grzib also reviewed the following requested amendments.

- 1735.2(c) Change the prescriber office use provisions to expand the conditions under which prescriber office dispensing can be done and change the definition of reasonable quantity.
- 1735.2(d) Change regulation to indicate that the prohibitions to compound only apply to human drugs.

President Gutierrez asked what type of medications Wedgewood Pharmacy compounds. Dr. Grzib responded that they compound sterile and non-sterile veterinary medications.

Dr. Grzib also noted that due to the extensive cost that the pharmacy would have to pay to conduct stability testing, and they would have to reduce the number of sterile products that they can provide to California patients.

President Gutierrez asked if other states that Wedgewood Pharmacy operates in permit prescriber office use. Ms. Pontikes asserted that there are only 15 states that require patient specific compounding and the rest of the states allow for prescriber office use. She noted that this only applies for veterinary medicine.

A representative from Golden Gate VPC spoke in support of the comments submitted by CPhA.

The committee recessed for a break at 9:51 a.m. and returned at 10:07 a.m.

Steve Pomerance, representing Town Center Pharmacy, stated that his pharmacy wants to comply with the regulations and asked where he could find a copy of the regulations. Ms. Sodergren directed Mr. Pomerance to speak with Christine Acosta, Supervising Inspector. Ms. Herold added that the board has a self-assessment form available in its website that will guide pharmacists through the requirements.

Ken Schell, representing Sharp Health, thanked the committee for their efforts and encouraged them not to simply adopt the USP chapters in totality. He expressed concern with the specific temperature ranges that are outlined in 1735.1. Dr. Schell also asked the board to consider allowing central repackaging pharmacies to provide compounded products to outpatient pharmacies.

Jerry Green, representing San Diego Compounding Pharmacy, stated that most California compounding pharmacists are following the regulation and want to provide the best care to their patients. He expressed his opposition to the board's new BUD requirements. Mr. Green noted that on bad pharmacy should not negatively impact the other compounding pharmacies who are doing the right thing.

Mike Cooks, representing Central Admixture Compounding Services, agreed with the comment that Dr. Kastango made at the beginning of the meeting, that potency tests over time do not demonstrate stability. He also noted that USP has an FAQ on their website as well as a study outlining the difference between potency and stability testing.

David Joseph, representing Absolute Pharmacy in Florida, expressed his support for the comments made by CPhA and Dr. Kastango. Mr. Joseph stated that the tragedy in New England was not caused by under regulation, it was caused by the lack of enforcement of the existing regulations. He added that USP 797 and 795 are good standards for compounding and if followed protect the public.

David Smith, representing A&O Specialty Pharmacies, stated that it would very difficult to coordinate a 14-day BUD for a pediatric patient that needs an oral suspension medication. He suggested allowing for a 30-day BUD for oral non-sterile compounded medications.

David Kazarian, representing Pharmetric Lab and Infuserve America, recommended that the board harmonize its regulations with USP, specifically by allowing for alternative sterility testing methods. Dr. Kazarian thanked the board and Dr. Christine Acosta for providing guidance on complying with the regulations. He also cautioned the board to not make the regulations so onerous that patients can no longer get safe medication in a timely manner.

Eric Feinstein, representing Axia Pharmacy, spoke in support of previous commenters and encouraged the committee to base their regulations on scientific data. He also explained that according to Business and Professions code 4127.7 all compounding must be done in an ISO 5 setting. He stated that this requirement is not logical as you wouldn't want high-risk, non-sterile powders to aerosolize into the HEPPA filters.

Joe Gartner, representing Good Pharma Compounding Pharmacy, expressed his concern that the regulations would potentially make it difficult for female patients to obtain hormone creams at a reasonable price.

Sam and Anthony Barrack, representing Innovative Compounding Pharmacy, stated that the FDA should not have jurisdiction over compounding pharmacies in California. They asked the board to consider the cost increase that patients may face due to the board's regulations. They also stated that it undermines the pharmacists credibility with a patient when the pharmacists has to inform the patient that a medication that they have been using now has a shorter BUD.

Bob Bretzel, President of Script Works Pharmacy, explained that suspensions are commonly used in the veterinary practice. He asked the committee to differentiate between suspensions used in veterinary practices and solutions used for human medications when they are drafting the requirements for stability testing and BUDs.

Sarah Bonsonte, a pharmacy technician, stated that the increased costs of compounded medications because of the board's regulations will negatively impact small businesses and patients.

Robert Easton, representing Scripts Health, asked the board to amend the regulations to only require smoke studies every 6 months in ISO Class 5 settings. He explained that smoke studies will require the hospital's fire alarm system to be disabled during the study.

A pharmacist from Children's Hospital of Orange County explained that not only small businesses are affected by the cost of complying with the sterile compounding regulations. She asked the board to carefully consider the definitions of identical vs. analogous. She stated that there are shortages of certain medications and supplies and she encouraged the committee to not make it more difficult to obtain or compound these medications that are in short supply by requiring shorter BUDs. The pharmacist also spoke in support of the board's current language defining hazardous drugs.

Dana Gordon, Central Avenue Pharmacy, spoke in support of CPhA's recommended amendments.

Joe Gartner, representing Good Pharma Compounding Pharmacy, expressed his concern with having to inform patients that hormonal creams they are being prescribed are considered hazardous.

Christine Versical, from DynaLabs, stated that since January 1, 2017, DynaLabs has received approximately 5,000 samples from California pharmacies. She explained that the potency failure rate for those samples was only 1.8 percent. Ms. Versical added that the sterility, endotoxin, and particulate matter testing had zero failures. Ms. Versical also offered to share information with the board from the USP regarding the definitions of potency over time, stability and sterility.

Trish Cook, pharmacist from Taylor's Compounding Pharmacy in Florida, stated that the definition of the quality assurance plan in 1735.8(c) is ambiguous. She asked the board to modify the definition to clarify if the definition applies to non-sterile or sterile compounding.

1735.8(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

President Gutierrez explained that the committee would review each of the staff recommendations provided in the meeting materials and either approve the recommendation and/or provide direction on how to modify the language based on the comments received during the meeting. Below is a summary of each staff recommendation and the committee's action.

Staff Recommendation - 1735 Compounding in Licensed Pharmacies: The mixing of ingredients from a compounding kit purchased from an FDA approved manufacturer will not be included in definition of compounding if done according to the manufacturer instructions.

Jenny Partridge, compounding pharmacist, noted that some of the kits contain hazardous materials and should not be included in this exemption. The committee agreed that this exemption should only apply to non-hazardous kits.

The committee agreed with the staff's recommendation, but asked that language be added to ensure that it only apply to non-hazardous kits.

Motion: The mixing of ingredients from a non-hazardous compounding kit purchased from an FDA approved manufacturer will not be included in definition of compounding if done according to the manufacturer instructions.

M/S: Weisser/Schaad

Support: 4 Oppose: 0 Abstain: 0

Staff Recommendation - Section 1735.2 Compounding Limitations and Requirements; Self-Assessment: Board staff recommends changes to the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products including changes to 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

President Gutierrez explained that this modification would allow pharmacies to use published studies to extent the BUD for aqueous solutions.

The committee agreed with the staff recommendation.

There were no comments from the public.

Motion: Change the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products including changes to 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

M/S: Weisser/Schaad

Support: 4 Oppose: 0 Abstain: 0

Staff Recommendation - Section 1751.1 Sterile Compounding Recordkeeping Requirements:
Staff recommends clarifying the requirements for smoke studies, including both the applicable area where such studies must be performed (ISO Class 5) as well as the frequency in which they must be conducted (semi-annually).

The committee agreed with the staff recommendation.

A pharmacist from Central Compounding Pharmacy stated requiring smoke studies every six months is beyond the requirements of GMPs and asked that smoke studies only be required when there is a change in the hood. It was noted that the six-month requirement for smoke studies in ISO Class 5 areas is consistent with USP 797.

Motion: clarifying the requirements for smoke studies, including both the applicable area where such studies must be performed (ISO Class 5) as well as the frequency in which they must be conducted (semi-annually).

M/S: Weisser/Munoz

Support: 4 Oppose: 0 Abstain: 0

Staff Recommendation - Section 1751.4 Facility and Equipment Standards for Sterile Compounding:
Staff recommends clarifying that cleaning must be done whenever hazardous drugs are being compounding as well as clarifying where the cleaning must occur.

The committee agreed with the staff recommendation.

There were no comments from the public.

Motion: Clarify that cleaning must be done whenever hazardous drugs are being compounding as well as clarifying where the cleaning must occur.

M/S: Munoz/Schaad

Support: 4 Oppose: 0 Abstain: 0

President Gutierrez next reviewed the comments submitted in writing by stakeholders. Below is a summary of each comment.

1735.1: Amend the definition of "daily" in 1735.1 to specify that electronic monitoring of temperatures is allowable.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting. She also noted that it might be best for this issue to be clarified in an FAQ.

Dosage Unit: Amend the definition of "dosage unit" to beyond one administration and allow for one "dosage unit" to be one prescription.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

Sterility: Recommend addition of a definition of sterility for clarity.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

1735.2 (4): Change requirements relating to the extension of BUD provisions to what appears to be allowing analogous versus identical ingredients.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

1735.2 (5): Correct the drafting error where the board inadvertently indicated that a shorter dating can be done.

Ms. Sodergren noted that staff would like to review the language to ensure that this is in fact a drafting error.

1735.2 (6): Recognition of potency over time study as applicable to the compounded formulations can be used to validate stability and assign extended beyond use dates.

Ms. Sodergren asked that staff be allowed time to research the comment and provide a recommendation at the next committee meeting.

1751.4 (d): Clarify that cleaning does not need to happen daily, but rather every day the facility is used to prepare sterile drug compounds.

President Gutierrez asked staff to research this item and provide a recommendation at the next committee meeting. A member of the public noted that a clean room is actually cleaner when you do not enter it.

1751.4(k): Remove the minimum room temperature requirement.

Anne noted that staff has researched this item and they believe that removing the minimum room temperature requirement is consistent with USP. She added that staff will bring draft language to the next meeting.

1751.6(e): Correct typo by removing redundant “sterile” and indicate that training can vary for someone only directly supervising individuals compounding, not performing it themselves.

Ms. Sodergren stated that she would like the opportunity to discuss with DCA Legal what the ramifications of this change would be before staff provides a recommendation.

1751.7(e)(1): Allow for an equivalent method of testing as those described in USP 71 and exempting pyrogen testing from irrigation.

President Gutierrez asked staff to perform a technical review of this recommendation and provide a recommendation at the next meeting.

1735.1(r) and 1735.6(e): Request hazardous provisions in 1735.1(r) and 1735.6(e) mirror requirements in USP 800.

Ms. Sodergren commented that staff would like the opportunity to discuss with item with subject matter experts.

1751.4(d): Requests that the regulation specify that ready to use germicidal detergent including sterile water is acceptable.

Ms. Sodergren stated that this could be clarified in an FAQ. The committee agreed with her statement.

1751.4(g)(1): Adding a requirement for two pairs of standard gloves for all hazardous compounding.

Ms. Sodergren stated that staff will confirm that USP does require two gloves and that the outer gloves must be sterile.

1751.3 and 1751.4: Request clarification on the need for sampling for the segregated compounding areas outside of the ISO-5 environment. Question is the sampling plan and procedures for nonviable particle samples as well as violation air and surface is limited to ISO certified areas or also for segregated compounding area outside the ISO environment.

Ms. Sodergren stated that staff would like to discuss with DCA counsel if this could be clarified in an FAQ or is modification to the regulation would be required.

Contracting with Another Pharmacy: Request clarification if a pharmacy can contract with another pharmacy for compounded products or just parenteral. As part of the comment it is indicated that the clarification is being sought when waiver requests are denied.

Ms. Sodergren responded that this is a statutory provision and staff would discuss this item with DCA counsel.

Stability: Recommend an addition of a definition of stability.

Ms. Sodergren stated that staff will review USP and determine if this addition is necessary.

1735.1 (i)(3): Change the requirements to extend a BUD.

Ms. Sodergren noted that 1735.2(i)(3) applies to all sterile and non-sterile compounded products. She added that the staff recommendation is to add in the word “sterile” to clarify that this section only applies to sterile compounded products. President Gutierrez asked staff to research this and provide a recommendation at the next meeting.

1735.6 (e): Create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics.

Ms. Sodergren stated that staff would like to research this item prior to providing a recommendation.

SOPs for sterilization and depyrogenation process: Provide detailed description of what the SOPs need to include for sterilization and depyrogenation process.

Ms. Sodergen stated that staff will research this item and noted that she is not sure that this would require a change to the regulation.

1751.11: Add provisions to establish requirements for sterilization and depyrogenation

Ms. Sodergren stated that these are provisions proposed in the proposed new USP 797, she recommended waiting until USP finalizes their provisions before the board makes any modifications. President Gutierrez stated that when staff is researching these items it the issue is pending with the new USP 797 the language should not be modified until USP finalizes their language.

1735.2 (a): Concern with the requirement that the pharmacy note on the prescription that the prescriber authorized compounding when the approval is given verbally (for veterinary products).

Ms. Sodergren stated that the board's regulation nor USP differentiate between veterinary and human products. She offered to further research the topic.

1735.2(c): Change the prescriber office provisions to expand the conditions under which prescriber office dispensing can be done and changing the definition of reasonable quantity.

President Gutierrez stated that veterinary industry does not have the option to purchase from a 503B pharmacy, they must use a 503A facility or a manufacturer. Ms. Sodergren responded that staff is researching is veterinary compounding pharmacies can elect to be licensed as a 503B pharmacy. Ms. Pontikes, representing Wedgwood Pharmacy, asserted that 503B facilities cannot make veterinary products and veterinary compounding pharmacies cannot become registered as a 503B facility. Ms. Sodergren stated that staff will continue to research this.

Jenny Partridge, compounding pharmacist, noted that at the January 2017 Enforcement Committee meeting the committee voted to allow the use of double filtration system in lieu of external venting. Dr. Partridge stated that at the following board meeting the board did not vote to ratify the committee's recommendation. Staff stated that they would review the minutes to confirm what action the board took on the committee's recommendation to allow for the use of a double filtration system in lieu of external venting.

Jon Roth, representing CPhA, asked if the board's motion to change the establishment of the BUD to more closely align with the requirements of USP <795> (for nonsterile products) and USP <797> for sterile products applies to both sterile and non-sterile products. Ms. Sodergren responded that staff will be looking at BUDs for both sterile and non-sterile products in sections 1735.2(i)(1), 1735.2(i)(2) and 1735.2(i)(3).

President Gutierrez thanked the public for their participation and adjourned the meeting at 11:55 a.m.

Attachment

Board of Pharmacy

Draft Staff Recommendations

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug preparation from chemicals or bulk drug substances

(b) "Compounding" does not include any of the following:

(1) The reconstitution of a drug pursuant to a manufacturer's direction(s)~~, nor does it include~~

(2) T~~t~~he sole act of tablet splitting or crushing, or of capsule opening~~, or~~

(3) T~~t~~he addition of flavoring agent(s) to enhance palatability

(4) The combining of nonhazardous ingredients from prepackaged kits supplied by a FDA registered manufacturer for a topical or oral preparation completed in conformance with the manufacturer's instructions.

(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).

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

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) "Ante-area" means an area with ISO Class 8 or better air quality 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 cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

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

(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

(e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile

preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ~~ventilation~~ exhaust. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) "Displacement airflow method" means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific

pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

(r) Until July 1, 2018, "~~H~~hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge. Effective July 1, 2018, "hazardous" means any drug identify by NIOSH and that exhibit as at least one of the following six criteria:

(1) Carcinogenicity

(2) Teratogencitiy of developmental toxicity

(3) Reproductive toxicity in humans

(4) Organ toxicity in low doses in human or animals

(5) Genotoxicity

(6) New drugs that mimic existing hazardous drugs in structure or toxicity.

(s) "Integrity" means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in

aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

(v) “Non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

(w) “Parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.

(x) “Personal protective equipment” means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

(y) “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. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.

(z) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(aa) "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. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber’s practice environment.

(ab) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) “Process validation” means demonstrating that when a process is repeated 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.

(ad) “Product” means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(ae) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(af) “Segregated sterile compounding area” means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile 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. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

(ag) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

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

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug 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 preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug 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.

(c) A "reasonable quantity" that may be 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 preparation that:

(1) Is ordered by the prescriber or the prescriber's agent 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 office administration; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, 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 preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an 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 commercially available 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, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential 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.

(8) Instructions for storage and handling of the compounded drug preparation.

(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed

after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

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

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

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

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

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

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

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

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

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

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

(ii) the dosage form and its components,

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

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

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

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

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

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

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

(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

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

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

(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

(k) 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 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.

(l) Packages of ingredients, both active and inactive, 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.

(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.

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

1735.3. Recordkeeping for Compounded Drug Preparations.

(a) For each compounded drug preparation, pharmacy records shall include:

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) 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. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2,

subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient 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 (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug product preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) 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 last in effect. 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).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1735.4. Labeling of Compounded Drug Preparations.

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) 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), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures 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. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) 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.

(4) 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.

(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by

the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer’s specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

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

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each ~~PEC~~ BSC in the room shall also be externally vented except that a BSC used only for nonsterile compounding may use a redundant-HEPA filter in a series; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

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

1735.7. Training of Compounding Staff.

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an ongoing 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.
(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

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

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.
(b) 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.
(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.
(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.
(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

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

Article 7. Sterile Compounding

1751. Sterile Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile drug 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 compounding.

(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 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 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:

(1) Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.

(2) Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

(4) There shall be a refrigerator and, where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections

4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile Compounding Recordkeeping Requirements.

(a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

(1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments 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 tests.

(4) Results of viable air and surface sampling.

(5) Biannual ~~V~~video of smoke studies in all ISO Class 5 certified spaces.

(6) Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

(b) 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, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) 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).

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

1751.2. Sterile Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy that compounds sterile drug preparations shall include the following information on the labels for each such preparation:

(a) The telephone number of the pharmacy. The telephone number is not required on the label for sterile drug preparations administered to inpatients within the hospital.

(b) Instructions for storage, handling, and administration.

(c) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

1751.3. Sterile Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable

personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen sterilization methods.

(2) End-product evaluation, quantitative, and qualitative testing.

(d) Policies and procedures shall be immediately available to all personnel involved in

compounding activities and to board inspectors.

(e) All personnel involved must read the policies and procedures before compounding sterile drug preparations. All personnel involved must read all additions, revisions, and deletions to the written policies and procedures. Each review must be documented by a signature and date.

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

To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile Compounding.

(a) No sterile drug 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 drug preparations.

(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent ~~and sterile water~~. The use of a sporicidal agent is required to be used at least monthly. When hazardous drugs are being compounded decontamination with an inactivating agent shall take place before each cleaning. Any dilution of the germicidal detergent, sporicidal agent, or inactivating agent shall only be done with sterile water.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least every 48 hours and at minimum must be cleaned each day prior to compounding.~~at least daily~~. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage, shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment, and the segregated sterile compounding areas shall be cleaned at least

monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. 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-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet 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 that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom 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.

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) 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.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to

1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable 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. Viable 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 pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

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

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

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

1751.5. Sterile Compounding Attire.

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) Personal protective equipment must be donned and removed 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.

(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

(5) 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 cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

(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).

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

1751.6 Sterile Compounding Consultation; Training of Sterile Compounding Staff.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations.

(e) Pharmacies that compound sterile drug 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:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

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

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

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The quality assurance program shall include at least the following:

(1) Procedures for cleaning and sanitization of the sterile preparation area.

(2) Actions to be taken in the event of a drug recall.

(3) Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, 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 the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile

preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) 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.

(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant unless a validated rapid microbial method (RMM) test is performed and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. Validation studies (method suitability) for each formulation using a RMM test shall be kept in a readily retrievable form at the licensed location. 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. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

(C) Preparations noted as "Currently in Shortage" on the FDA website for a single patient on a one time basis for 21 days or less pursuant to a prescription. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need as part of the pharmacy record.

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

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, 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 an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the

requirements in 1751.4(f)(1)-(3), 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 or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), 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.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile 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.

(e) 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 (d), 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. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. 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.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

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

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) 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 shall be labeled with a beyond use date and 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. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) 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 shall be labeled with a beyond use date and 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 storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

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

1751.10. Sterile Compounding Reference Materials.

In any pharmacy engaged in compounding sterile drug preparations, there shall be current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy.

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

Attachment

Top 10 Compounding Case Citations and Fines

Closed in Fiscal Year 2016/17

Violation Code	Number of Citations	% of total	Average
1735.2 Compounding Limitations and Requirement Examples: Compounding log, assignment of BUD	70	14.61%	$2,902
1751.4 Facility and Equipment Standards for Sterile Compounding Examples: Cleaning schedule, PEC/room certifications	64	13.36%	$1,675
1735.7 Training of Compounding Staff Examples: no ongoing competency, not able to demonstrate knowledge	45	9.39%	$2,035
1735.4 Labeling of Compounded Drug Preparations Examples: not to listing BUD, or lot number on label	39	8.14%	$2,228
1735.5 Compounding Policies and Procedures Examples: failure to review P&Ps yearly, not having all required P&Ps	39	8.14%	$2,538
1735.3 Records of Compounded Drug Products Examples: not having a master formula or compounding log	37	7.72%	$2,623
1751.6 Sterile Compounding Consultation: training of sterile Staff Examples: Failure to provide a consultation, not having staff training	31	6.47%	$1,462
1735.8 Compounding Quality Assurance Examples: not having a written QA plan, no qualitative or quantitative analysis	28	5.85%	$1,531
1751.7 Sterile Compounding Quality Assurance and Process Validation Examples: not having a written QA plan, staff not having process validation	21	4.38%	$1,708
1735.6 Compounding Facilities and Equipment Examples: not using equipment in accordance with manufactures specifications, not calibration equipment prior to use.	15	3.13%	$1,975
Grand Total	*479	100.00%	$2,021

*479 Total Citations Issued to 193 Licensees.

Compounding Inspection Data

Fiscal Year 2016/17

As of 6/30/17:

- Number of licenses:
  - In state: 741 sites with 882 sterile compounding pharmacies
    - 331 community pharmacies with 331 sterile compounding licenses; 406 hospitals with 547 sterile compounding licenses; 4 correctional facilities with 4 sterile compounding licenses
  - Out of state: 91 non-resident pharmacies with 91 non-resident sterile compounding licenses
- Number of inspections conducted:
  - Total: 1,063
    - New: 88; Renewal: 975
- Number of corrections and violations issued:
  - Total: 1,720 issued at 578 locations
    - 1,580 corrections issued at 526 locations; 140 violations issued at 52 locations
- Overview of corrections and violations issued:
  - 526 locations issued corrections /1,063 inspections conducted:
    - ~ 49% of locations inspected received a correction
  - 52 locations issued violations /1,063 inspections conducted:
    - ~ 5% of locations inspected received a violation
- Top corrections and violations:
  - 298 (17%) issued for noncompliance with facility and equipment standards (1751.4)
    - 120 (7%) issued for not cleaning compliantly or not cleaning on the required schedule (1751.4(d))
  - 184 (11%) issued for noncompliance with records of compounding limitations and requirements (1735.2)
    - 86 (5%) issued for noncompliance with master formula requirements (1735.2(d) and 1735.2(e))
    - 24 (3%) issued for noncompliance with BUD assignment (1735.2(i) and 1735.2(h))
  - 96 (6%) issued for noncompliance with sterile compounding quality assurance and process validation (1751.7)
    - 47 (3%) issued for noncompliance with process validation (1751.7(b))
    - 17 (1%) issued for noncompliance with a written quality assurance plan (1751.7(a))
  - 93 (5%) issued for noncompliance with sterile compounding recordkeeping requirements (1751.1)
    - 46 (2.6%) issued for compliance with a video smoke study (1751.1(a)(5))
    - 13 (<1%) issued for noncompliance with log or other documents of inspections for expired or recalled items (1751.1(a)(10))
  - 23 (1%) issued for noncompliance with hazardous room requirements (1735.6(e))

Attachment

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Complaints/Investigations					
Received	792	659	780	662	2893
Closed	790	623	956	747	3116
4301 letters	4	9	8	7	28
Pending (at the end of quarter)	2441	2459	2241	2241	2241
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance / Routine Team	1063	1158	1014	879	879
Drug Diversion/Fraud	450	429	456	413	413
RX Abuse	171	151	172	153	153
Compounding	126	114	121	150	150
Probation/PRP	75	79	68	66	66
Outsourcing	N/A	N/A	N/A	80	80
Mediation/Enforcement **	252	228	123	189	189
Criminal Conviction	304	300	287	311	311
Application Investigations					
Received	154	159	80	114	507
Closed					
Approved	110	71	96	66	343
Denied	10	15	30	19	74
Total ***	147	109	161	115	532
Pending (at the end of quarter)	111	161	86	98	98
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	114	117	139	53	423
Citations Issued	589	379	537	430	1935
Total Fines Collected ****	$447,974.15	$585,750.00	$446,932.60	$760,731.40	$2,241,388.15

* This figure includes reports submitted to the supervisor and cases with SI awaiting assignment.

** This figure include reports submitted to the citation and fine unit, AG referral, as well as cases assigned to enf. Staff

*** This figure includes withdrawn applications.

****Fines collected (through 6/30/2017 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	105	68	79	99	351
Accusations Filed	73	56	70	37	236
Statement of Issues Filed	5	7	7	7	26
Petitions to Revoke Filed	4	0	3	2	9
Pending					
Pre-accusation	255	240	218	241	241
Post Accusation	278	252	241	214	214
Total*	573	519	490	468	468
Closed					
Revocation					
Pharmacist	4	2	5	5	16
Intern Pharmacist	1	0	0	1	2
Pharmacy Technician	37	33	26	13	109
Designated Representative	0	0	1	1	2
Wholesaler	0	0	1	0	1
Sterile Compounding	0	0	1	0	1
Pharmacy	4	2	2	3	11
Revocation,stayed; suspension/probation					
Pharmacist	1	1	6	6	14
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	2	1	2	5
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Pharmacy	0	0	1	0	1
Revocation,stayed; probation					
Pharmacist	8	17	10	17	52
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	4	1	5	3	13
Designated Representative	0	0	0	0	0
Wholesaler	1	0	0	0	1
Sterile Compounding	0	0	1	1	2
Pharmacy	5	10	6	6	27
Surrender/Voluntary Surrender					
Pharmacist	7	8	6	9	30
Intern Pharmacist	0	1	0	3	4
Pharmacy Technician	10	10	8	8	36
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Sterile Compounding	0	0	1	0	1
Pharmacy	3	9	9	5	26

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Public Reproval/Reprimand					
Pharmacist	5	2	6	14	27
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	2	0	3
Designated Representative	0	0	0	1	1
Wholesaler	0	0	0	1	1
Sterile Compounding	0	0	0	2	2
Pharmacy	0	1	3	6	10
Licenses Granted					
Pharmacist	0	1	1	2	4
Intern Pharmacist	0	2	0	0	2
Pharmacy Technician	1	2	2	1	6
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Pharmacy	0	0	0	0	0
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	4	3	2	12
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Pharmacy	0	0	0	0	0
Cost Recovery Requested**	$307,270.00	$620,180.11	$396,277.52	$657,335.40	$1,981,063.03
Cost Recovery Collected**	$132,381.11	$275,441.13	$299,714.67	$290,846.70	$998,383.61

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions					
Interim Suspension Order	0	0	1	1	2
Automatic Suspension / Based on Conviction	0	0	1	0	1
Penal Code 23 Restriction	2	3	3	1	9
Cease & Desist - Sterile Compounding	0	0	1	1	2

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Probation Statistics					
Licenses on Probation					
Pharmacist	176	190	190	190	190
Intern Pharmacist	3	6	6	4	4
Pharmacy Technician	37	36	36	36	36
Designated Representative	1	1	1	0	0
Pharmacy	54	56	60	62	62
Sterile Compounding	10	10	12	12	12
Wholesaler	5	5	5	3	3
Probation Office Conferences	15	36	31	23	105
Probation Site Inspections	141	126	151	168	586
Successful Completion	5	4	12	12	33
Probationers Referred to AG for non-compliance	0	4	0	4	8

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of June 30, 2017.

California State Board of Pharmacy
Citation and Fine Statistics
April 1, 2017 - June 30, 2017

438 Citations were issued this quarter

Total dollar amount of fines issued this fiscal year $475,450.00

***This amount also reflects payment of citations issued prior to July 1, 2009.**

The average number of days from date case is opened until a citation is issued is 382.73

Average number of days from date case is routed to Citation Unit to date citation is issued 22.21

482 citations are closed. The average number of days from date citation is issued to date citation is closed is 174.94

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine**	PIC no fine**	TCH with fine	TCH no fine
438	169	35	74	78	89	48	51	0

Citation Breakdown by Miscellaneous license type

Wholesalers	Designated	Clinics	Drug Room	Exempt Hosp.	Hosp. Pharmacy	Misc.*	Unlicensed Premises	Unlicensed
4	3	0	0	0	6	8	9	1

*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

**These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	34%	1716 - Variation from prescription	39%	1716 - Variation from prescription	30%
11164(a)/1761(a) - Prescriptions for schedule II, III, IV, and controlled substance: form and content; record of practitioner dispensing schedule II controlled substance/No pharmacist shall compound o	17%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	21%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	28%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	13%	11164(a)/1761(a) - Prescriptions for schedule II, III, IV, and controlled substance: form and content; record of practitioner dispensing schedule II controlled substance/No pharmacist shall compound o	7%	1735.2(j) - Compounding Requirements- Pharmacist-in-Charge shall complete a compounding self-assessment prior to any sterile injectable compounding is performed in pharmacy and must be completed bef	8%
1735.2(j) - Compounding Requirements- Pharmacist-in-Charge shall complete a compounding self-assessment prior to any sterile injectable compounding is performed in pharmacy and must be completed bef	6%	1735.2(j) - Compounding Requirements- Pharmacist-in-Charge shall complete a compounding self-assessment prior to any sterile injectable compounding is performed in pharmacy and must be completed bef	7%	11164(a)/1761(a) - Prescriptions for schedule II, III, IV, and controlled substance: form and content; record of practitioner dispensing schedule II controlled substance/No pharmacist shall compound o	6%
1761(a)&(b)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/A pharmacist shall not compound or dispense a prescription for a con	5%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	6%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%
11164/1761 - Prescribing, Filling, Compounding or Dispensing Prescription for Controlled Substance; Requirements/Erroneous or uncertain prescriptions	5%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that phar	4%	11164/1761 - Prescribing, Filling, Compounding or Dispensing Prescription for Controlled Substance; Requirements/Erroneous or uncertain prescriptions	5%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	5%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a pat	4%	1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist-in-charge	5%
4231(d)/1732.5 - Failure to provide documentation substantiating completion of continuing education/Renewal Requirements for Pharmacist	5%	1707.3 - Duty to review drug therapy	4%	1735.2(d) - Compounding Limitations and Requirements	5%
4076(a)(4)/4077(a) - Prescription Container - Requirements for Labeling/The name of the prescriber…/Dispensing Dangerous Drug in Incorrectly Labeled Container	5%	1714(c) - Operational Standards and Security; the pharmacy must be maintained in a sanitary condition	4%	1764/56.10 et seq. - Unauthorized disclosure of prescription and medical information	5%

Attachment

CALIFORNIA END O LI E OPTION ACT 2016 DATA REPORT

For more information:
https://www.cdph.ca.gov/Programs/CHSI/Pages/End-of-Life-Option-Act-.aspx
Contact: EOLInfo@cdph.ca.gov

California Department of PublicHealth CDPH

Executive Summary

California's End of Life Option Act (EOLA) became effective on June 9, 2016. The Act allows terminally ill adults living in California to obtain and self-administer aid-in-dying drugs.[1] The Act requires the California Department of Public Health (CDPH) to provide annual reports under strict privacy requirements. CDPH's reporting requirements are outlined in Health and Safety Code section 443.19 (b), which reads:

> *(b) On or before July 1, 2017, and each year thereafter, based on the information collected in the previous year, the department shall create a report with the information collected from the attending physician followup form and post that report to its Internet Web site. The report shall include, but not be limited to, all of the following based on the information that is provided to the department and on the department's access to vital statistics:*
>
> *(1) The number of people for whom an aid-in-dying prescription was written.*
>
> *(2) The number of known individuals who died each year for whom aid-in-dying prescriptions were written, and the cause of death of those individuals.*
>
> *(3) For the period commencing January 1, 2016, to and including the previous year, cumulatively, the total number of aid-in-dying prescriptions written, the number of people who died due to use of aid-in-dying drugs, and the number of those people who died who were enrolled in hospice or other palliative care programs at the time of death.*
>
> *(4) The number of known deaths in California from using aid-in-dying drugs per 10,000 deaths in California.*
>
> *(5) The number of physicians who wrote prescriptions for aid-in-dying drugs.*
>
> *(6) Of people who died due to using an aid-in-dying drug, demographic percentages organized by the following characteristics:*
>
> *(A) Age at death.*
>
> *(B) Education level.*
>
> *(C) Race.*
>
> *(D) Sex.*
>
> *(E) Type of insurance, including whether or not they had insurance.*
>
> *(F) Underlying illness.*

This report presents data as reported to CDPH from the EOLA-mandated physician reporting forms received between June 9, 2016, and December 31, 2016, and reflects information on individuals who were prescribed aid-in-dying drugs in 2016. The information collected has been aggregated to protect the privacy of the individuals. Subsequent annual reports will encompass 12 months of data.

For the partial year ending December 31, 2016, 191 individuals received prescriptions under EOLA. 111 individuals died following their ingestion of the prescribed aid-in-dying drug(s). Of the 111 individuals,

[1] Assembly Bill x2 15 (Eggman), Chapter 1, Statutes of 2015.

87.4 percent were 60 years of age or older, 96.4 percent had health insurance, and 83.8 percent were receiving hospice and/or palliative care. As this report covers only six-months of data, caution should be exercised in drawing conclusions based on the numbers reported.

Introduction

The EOLA allows an adult diagnosed with a terminal disease, who meets certain qualifications, to request an aid-in-dying drug from a physician. The Act requires physicians to use forms specified in statute for submitting information to CDPH. CDPH is responsible for collecting data from these forms, and preparing an annual report. Data presented in this report is based on the information contained in physicians' forms and California death certificates as of December 31, 2016.

More information on the Act, reporting process, and required forms can be found here: https://www.cdph.ca.gov/Programs/CHSI/Pages/End-of-Life-Option-Act-.aspx.

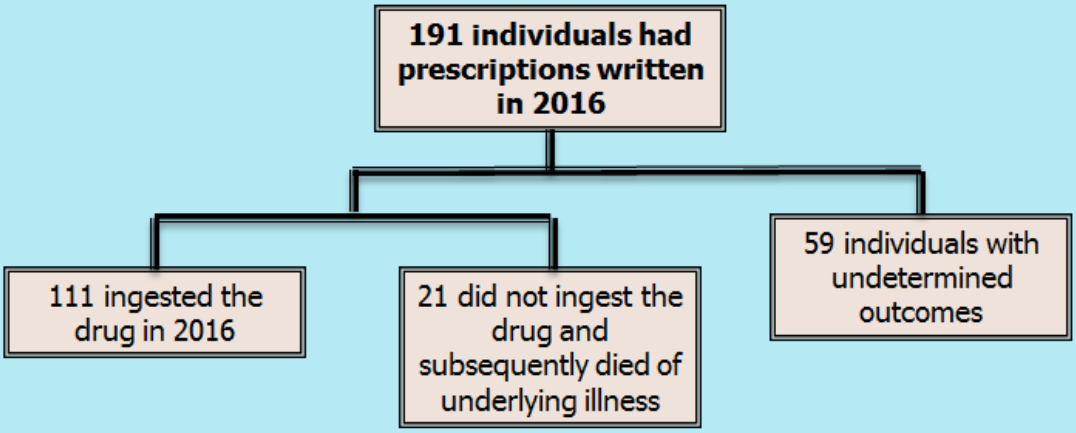
Participation in the End-of-Life Option Activities

From June 9, 2016 through December 31, 2016, 258 individuals started the end-of-life option process, as set forth in the Act, by making two verbal requests to their physicians at least 15 days apart. 173 unique physicians prescribed 191 individuals aid-in-dying drugs. Of the 191 individuals who were prescribed such drugs, 111, or 58.1 percent, were reported by their physician to have died following ingestion of aid-in-dying drugs prescribed under EOLA; and 21 individuals, or 11.0 percent, died without ingestion of the prescribed aid-in-dying drug(s). The outcome of the remaining 59 individuals, or 30.9 percent, who have been prescribed aid-in-dying drugs, is currently undetermined as there has been no outcome reported for these individuals within the time period covered by this report. A chart illustrating the outcomes is provided on the next page as Figure 1.

The rate for those who died following ingestion of aid-in-dying drugs was 6.06 per 10,000 total deaths[2] based on 183,265 deaths in California from June 9, 2016 to December 31, 2016.

[2] This rate does not include any deaths following the ingestion of prescribed drugs after December 31, 2016. Total deaths in California include only those deaths that occurred from 00:00 hours June 9, 2016, to 23:59 December 31, 2016, and is not based on all deaths occurring in California in 2016.

Figure 1: Summary of EOLA Prescriptions Written in 2016



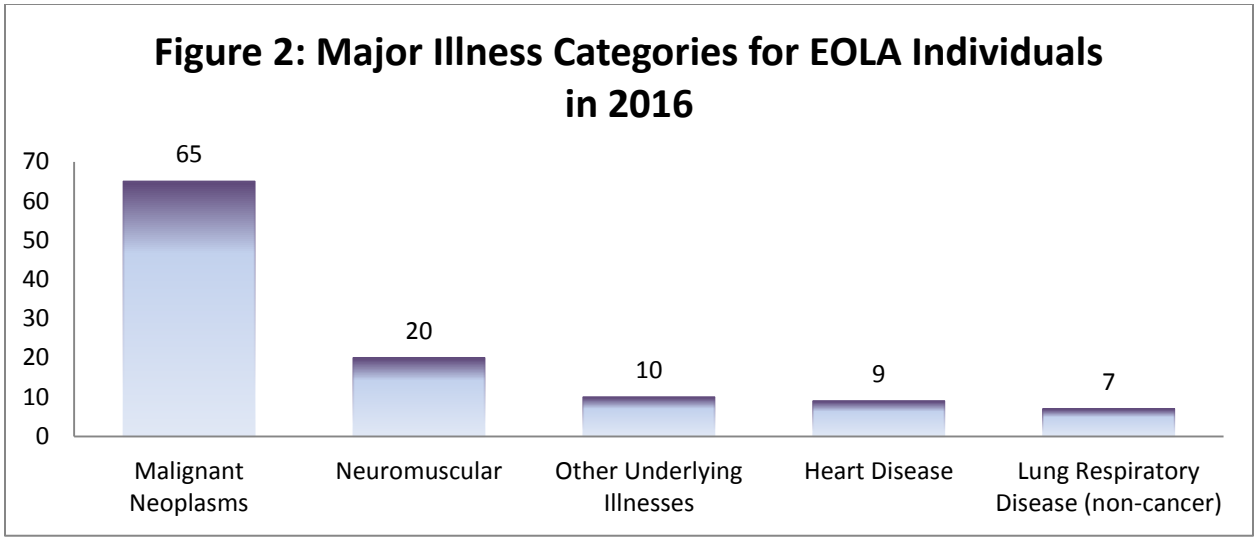
Characteristics of Individuals

Of the 111 individuals who died pursuant to EOLA during 2016, 12.6 percent were under 60 years of age, 75.6 percent were 60-89 years of age, and 11.7 percent were 90 years of age and older. The median age was 73 years. At the time of death, the decedents were 89.5 percent white, 54.1 percent were female; 83.8 percent were receiving hospice and/or palliative care, and 72.1 percent had at least some level of college education. A summary of this information is set forth in Table 1.

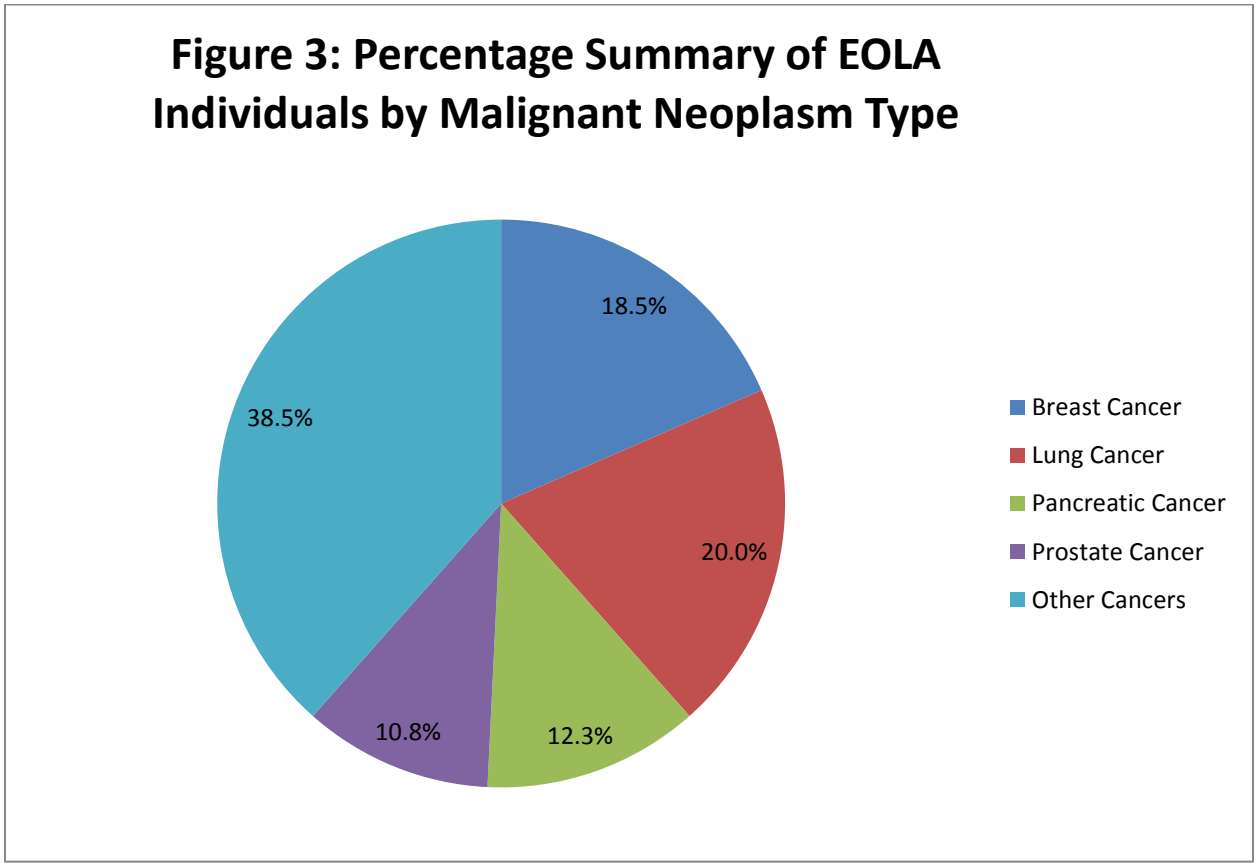
Of the 111 individuals who died pursuant to EOLA during 2016, the majority, or 58.6 percent, of their underlying illnesses, were identified as malignant neoplasms (cancer). Neuromuscular disorders such as ALS[3] and Parkinson's accounted for the second largest underlying illness grouping, totaling 18.0 percent. The remaining major categories of underlying illnesses were documented as: heart disease (8.1 percent), lung respiratory diseases (non-cancer) with 6.3 percent, and other underlying illnesses (9.0 percent). This data is presented below in Figure 2.

Certifiers (physicians, coroners, and medical examiners) report the underlying terminal disease as the cause of death on the death certificates. This approach complies with applicable law; best ensures the reliability and usefulness of data collected from the death certificate for state, national, and international surveillance purposes; and effectuates the California Legislature's intent to maintain the confidentiality of individuals' participation in the Act.

[3] Amyotrophic Lateral Sclerosis.



Among those with malignant cancer as the underlying terminal disease – the largest group of individuals who utilized the Act – lung cancer accounted for 20.0 percent, breast cancer accounted for 18.5 percent, pancreatic cancer comprised 12.3 percent, and 10.8 percent had prostate cancer. Other malignant neoplasms accounted for the remaining 38.5 percent, as shown below in Figure 3.



Most of the individuals who participated in EOLA had some form of health insurance. Medicare and/or Medi-Cal accounted for 56.8 percent of individuals, followed by public/private insurance at 30.6 percent. Ten individuals, or 9.0 percent, had undetermined health insurance coverage.

Table 1. Characteristics of the End of Life Option Act individuals who died following ingestion of aid-in-dying drug

Characteristics	2016 (N=111)	
Age	**N (%)**	
Under 60	14	(12.6)
60-69	25	(22.5)
70-79	30	(27.0)
80-89	29	(26.1)
90 and Over	13	(11.7)
Median Year (range)	73	(41-99)
Gender	**N (%)**	
Male	51	(45.9)
Female	60	(54.1)
Education	**N (%)**	
No High School Diploma	6	(5.4)
High School Diploma or General Educational Development	25	(22.5)
Some College no Degree	16	(14.4)
Associate, Bachelor or Master Degree	51	(45.9)
Doctorate or Professional Degree	13	(11.7)
Race/Ethnicity	**N = 114[4] (%)**	
White	102	(89.5)
Asian	6	(5.3)
Black	3	(2.6)
Hispanic	3	(2.6)
End of Life Care	**N (%)**	
Hospice and/or Palliative Care		
Enrolled	93	(83.8)
Not Enrolled	13	(11.7)
Unknown	5	(4.5)
Insurance	**N (%)**	
Medicare	49	(44.2)
Medi-Cal	4	(3.6)
Medicare/Medi-Cal (Dual Eligible)	10	(9.0)
Private Insurance	21	(18.9)
Medicare/Medi-Cal and Private Supplemental Insurance	13	(11.7)
Has Insurance but Unknown Type	10	(9.0)
No Insurance	4	(3.6)
Illness	**N (%)**	
Malignant Neoplasms	**65**	**(58.6)**
Breast	12	(18.5)
Lung	13	(20.0)
Prostate	7	(10.8)

[4] Numerator includes EOLA individuals of multiple races and/or ethnicities.

Pancreatic	8	(12.3)
Other	25	(38.5)
Lung Respiratory Disease (non-cancer)	**7**	**(6.3)**
Heart Disease	**9**	**(8.1)**
Neuromuscular	**20**	**(18.0)**
Other	**10**	**(9.0)**

6/13/2017

Attention Turns to Nonpharmacy Sterile Compounding Activities

Cheryl A. Thompson
Director
News Center

In the year since investigators entered a New York City oncology clinic in search of the source of an outbreak of fungal bloodstream infections involving 17 patients, information has emerged suggesting that healthcare facilities without a pharmacy professional go unmonitored for adherence to sterile compounding standards.

Three of the 17 patients, all with cancer, died less than 90 days after diagnosis with *Exophiala dermatitidis* or *Rhodotorula mucilaginosa* bloodstream infection, said investigator Amber M. Vasquez of the Centers for Disease Control and Prevention (CDC).

Whether the infections contributed to the patients' demise may never be known, she said.

What is known, Vasquez said during a CDC-hosted webinar, is that all 17 patients had a central venous catheter that had been flushed at least once with fluid from a 1-L bag of heparin-vancomycin-ceftazidime lock solution compounded at the clinic on February 7, 2016.

Inspections of nonpharmacy settings. FDA has "recently done a couple of inspections" at physician offices in response to complaints about compounding activities, the agency's Sarah Rothman told the Pharmacy Compounding Advisory Committee on May 8.

One of those inspections occurred because of an outbreak of infections at a physician office in New York, she said.

"We haven't been focusing on physicians," Rothman said of the more than 350 inspections conducted since enactment of the Drug Quality and Security Act through November 27, 2016.

But because FDA knows there are concerns about compounding in physician offices, she said, the agency has been considering how best to focus its resources and has been speaking with state medical boards, the National Association of Boards of Pharmacy, and CDC.

"Egregious" practice conditions. Vasquez said investigators learned that the single-physician oncology clinic had the following routine for preparing syringes of heparin-antimicrobial lock solution: Compound the 1-L bag. Store it in a refrigerator. Use 10-mL syringes to access the bag multiple times each morning to prepare a batch for use throughout the day. Continue accessing the bag until empty, which could be up to 8 weeks after the day on which the solution was compounded.

Unfortunately for the investigators, she said, nothing remained of the bag involved in the February 7, 2016, compounding incident when they arrived on the scene in late May. Their initial clue came on May 24 from an infectious diseases physician who notified the New York City Department of Health and Mental Hygiene that 2 patients with *E. dermatitidis* bloodstream infection admitted to the same hospital had received care at the same oncology clinic.

Through whole genome sequencing, Vasquez said, the team identified a single source of the outbreak: the compounded lock solution.

"So we performed an infection-control assessment to determine what might have gone wrong with the i.v. flush solution," she said.

Joel Ackelsberg, with the New York City health department, said he had "never [before] heard the word egregious used so many times by so many people to describe" conditions in a healthcare provider's office.

"An i.v. flush solution that was stored in the refrigerator for up to 2 months was improperly prepared in a biological safety cabinet that was last tested and failed inspection in 2014 and which was situated next to a refrigerator and in which improper technique was used to prepare parenteral medications," he said during the webinar.

Problems aplenty. Among the slides of the clinic shown by Vasquez was a photo of the biological safety cabinet. It had a sticker stating "REJECTED" in red and a date roughly 2 years before the outbreak.

Another photo showed the interior of the refrigerator used to store the 1-L bag and flush syringes. There was grime on the floor of the refrigerator. A self-sealing bag held moldy-looking materials. The same refrigerator, Vasquez said, had reportedly also been used to store the staff's food items.

"Not good at all," declared Nitika Agarwal, director of specialty, oncology, and infusion pharmacy for DuPage Medical Group in Illinois, in assessing the clinic's sterile compounding practices after viewing the slides.

Agarwal, who was not part of the investigation and was not speaking on behalf of her employer, said the slides showed the clinic had obvious problems.

"No wonder things didn't work out," she said.

Among the problems mentioned by Agarwal was the lack of any onsite pharmacy professional —"critical pieces of the sterile compounding [operation]."

Vasquez had reported that sterile compounding activities at the clinic were performed by a nurse who had no pharmaceutical training and whose performance had not been assessed before the investigators' arrival.

Agarwal said any pharmacy technician trained in sterile compounding who walked into a work area like the one shown in the photos would sense that the conditions were inappropriate.

"Even at home, you would not leave anything [in the refrigerator] with the moldy stuff around it"—let alone store i.v. medications alongside food rather than in a refrigerator dedicated to drug storage, she said. "You can't even fathom that anybody would practice in that situation."

DuPage Medical Group, she said, has a pharmacy technician working at every infusion site where sterile compounding activities occur and separates each site's sterile compounding area from the other work areas in accordance with *United States Pharmacopeia* chapter 797.

"It's very, very important—no matter what the setting is—that patient safety comes first," Agarwal said.

Changes needed. Willis Triplett, a principal with the group known as Comply 797 and a consultant with ASHP's consulting services unit, said many of the nation's oncologists do not believe they need to handle sterile products in the same way that hospital pharmacies do.

"I've been at many, many oncology practices in the last year," Triplett said. "And every one of them has had a biological safety cabinet, but they don't know how to use it. I'll walk into an oncology practice and the rear air return [grill] on the biological safety cabinet will have vials sitting on it," disrupting the unidirectional airflow.

But his concern is not restricted to oncology practices.

"There's infusion clinics everywhere," Triplett said, noting the ones operated by allergists and immunologists to administer i.v. immune globulin and others operated by rheumatologists and gastroenterologists to infuse tumor necrosis factor inhibitors.

Nine states have laws, regulations, or policies that specifically apply to compounding activities by healthcare practitioners who are not pharmacists, according to the results of a 2015 survey by the Government Accountability Office (https://www.gao.gov/assets/690/681096.pdf); 23 states had no such law, regulation, or policy, and representatives of the remaining states either did not know the answer (17) or did not respond (1).

New York, where the outbreak occurred, lacks laws specific to compounding, the survey report states.

That lack of specificity frustrates Ackelsberg.

"After speaking with the New York State Department of Health, which has an office that addresses clinical misconduct, it became clear that there was a considerable regulatory gap in regard to pharmacy-related and infection-prevention practices by outpatient physicians, specifically oncologists," Ackelsberg said during the webinar. "They could rescind the provider's license if an investigation uncovered maleficence, but there was no ongoing oversight of outpatient provider settings other than a requirement for them to take an online infection-control course every 4 years."

The city's health department commissioner on May 31 issued a cease-and-desist order to the oncology clinic, relying on the department's authority to abate public nuisances, Ackelsberg said.

On October 5, the department lifted the order, Vasquez said. The clinic had completed remediation efforts under the guidance of an infection control practitioner and pharmacist, demonstrated workers' ability to safely prepare and deliver medications, and stopped compounding.

A recording of CDC's April 18 webinar, with slides, is available online (http://www.youtube.com/watch?v=dtM1lQYCdZ8).

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