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

ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT

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

Part I. Enforcement Matters

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

Attachment 1

Relevant Law

CCR Section 1715.6 establishes a requirement for the owner to report any loss of controlled substances within 30 days to the board.

CFR Section 1301.76(b) establishes a requirement for reporting a significant drug loss to the Drug Enforcement Administration.

Background

At prior meetings, the committee has discussed the federal and state requirements for the reporting of lost controlled substances.

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 not consider it a "significant" loss; in a small pharmacy, several thousand lost pills – especially a Schedule II drug – would be a significant loss.

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

Committee Discussion

The committee was provided with statistics on drug losses, including the top 10 losses reported by drug name from FY 2012/13 through May 2017 and a comparison of dosage units lost versus cause of loss (e.g. employee pilferage versus night break-in). The committee requested additional data elements for consideration at future meetings.

Additionally, the committee noted that amending the regulation to include "significant" may be too subjective. As such, amending the regulation would be problematic and would not meet the Office of Administrative Law's criteria for clarity.

The committee noted that it would be beneficial to continue to review drug loss data and determine what effect, if any, the board's inventory regulation has on drug losses. This would allow for pre- and post- data analysis. The committee requested that going forward additional data elements be provided.

The committee will reassess the drug loss reporting requirement after review and analysis of post implementation of the inventory reconciliation requirements.

A copy of the drug loss data reviewed by the committee is provided in **Attachment 1**.

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

Attachment 2

Relevant Law

Business and Professions Code (BPC) 4104 in part establishes the requirements for a pharmacy to notify the board within 14 days of specified information including theft, diversion or self-use of dangerous drugs.

Background

During the May board meeting, 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 theft or working under the influence. Based on reports to the board under section 4104, the board has opened 112 case investigations.

Committee Discussion

The committee discussed the issue and considered language that could be used to facilitate implementation of the requirement. The committee agreed that the requirement, if pursued, should only apply to drug thefts.

The committee did not take action on this item but requested that staff collect data on drug losses reported to police versus those not reported as well as the case outcomes. This item will be brought back to the committee for further discussion after the data is available.

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

c. Update on the Development of the Continuing Education Training from the Board on 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 six 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.

Committee Discussion

The committee was advised that 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 committee was provided with the tentative training schedule including:

- 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 three-hour training session from 6 to 9 p.m. 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).

Committee Recommendation: Award continuing education credits for individuals attending the training sessions.

Attachment 3 includes the draft agendas for the respective training sessions.

d. Discussion and Consideration of Safe Medication Transitions for Patients Upon 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 after discharge, including emergency department visits and readmissions. Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

Committee Discussion

The committee heard a presentation from Dr. Rita Shane on The *Safe Medication Transitions: Evidence-Based Solutions Infographic.* The presentation highlighted the benefits to patients when pharmacists and trained technicians are involved in

medication reconciliation as part of the admission and discharge of a patient from a hospital. Dr. Shane shared her recommendations for pharmacy staff to ensure the accuracy of the medication lists at admission and discharge for high-risk patients.

The committee discussed the findings of the study and the benefits to patient outcomes.

Committee Recommendation: Refer a portion of this issue to the Communication and Public Education Committee to develop consumer education materials highlighting the importance of maintaining and conveying medication history to health care providers in a hospital and the importance of understanding how medication lists change at discharge. Further, refer the role a pharmacy technician can play to the Licensing Committee to consider what, if any, changes should be made to the functions a pharmacy technician may perform in a hospital.

A copy of the presentation is provided in **Attachment 4**.

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

Attachment 5

Background

At the request of the board, 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. The largest 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. They are listed according to how the recall and manufacturer's name was submitted.

Committee Discussion

The committee discussed the information provided and requested that staff further separate the data to identify what recalls were to the patient level versus the pharmacy level for the last year. The committee did not take action on this item.

Recent Update

Staff reviewed recalls from manufacturers between July 1, 2016, and June 30, 2017. Staff identified 263 recall alerts, 21 of which were to the patient level. Some examples of recalls at the patient level included a topical skin product recalled for potential microbial contamination, incorrect labeling of blister cards, potential labeling mix-ups for various strengths of phenobarbital tables, and potential lack of sterility assurance.

f. Discussion and Consideration of Request for Wholesalers to Report Suspicious Drug Sales to the Board

Relevant Laws

Health and Safety Code (HSC) section 11153.5 prohibits a wholesaler from furnishing controlled substances for anything other than a legitimate medical purpose.

Code of Federal Regulations Title 21, Part 1301, section 1301.74 (a) (b) requires a DEA registrant to make a good faith inquiry with either the DEA or the appropriate state controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance. Further, this section requires notification to a DEA field office of suspicious orders, including 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 sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida for multiple years. McKesson also agreed to compliance terms for five years that include 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.

Committee Discussion

The committee discussed action taken by Oregon requiring wholesale distributors to report "suspicious orders" to the Oregon Board of Pharmacy. The rule went into effect on July 1, 2017.

The committee reviewed the language adopted by Oregon:

> *"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)*

The committee considered if California should pursue a similar mandatory reporting requirement and considered possible language that could be used to implement such a requirement:

> 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. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Committee Recommendation: Pursue a mandatory reporting requirement either through statute or regulation.

A copy of the relevant law is provided in **Attachment 6**.

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

Attachment 7

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.

Committee Discussion

The committee noted 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 to take this leadership role.

The committee did not take action on this item.

California State Auditor Summary of Report Number 2016-127 is provided in **Attachment 7**. The full report may be found at the link below.

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

Part 2. Compounding Matters

h. Discussion and Consideration of Amendments to the Board's Compounding Regulations, California Code of Regulations, Title 16, Division 17, Articles 4.5 (Sections 1735-1735.8) and 7 (Sections 1751-1751.10)

Attachment 8

Relevant Law

CCR section 1735 et seq. and CCR section 1751 et seq. establish the requirements for compounding drug preparation.

BPC 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 Jan. 19, 2016, and approved by the Office of Administrative Law on Sept. 13, 2016. The effective date of the regulations was Jan. 1, 2017.

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

In response to the comments, the committee held a special meeting on June 2, 2017, on the board's compounding regulations. The committee reviewed written comments and recommendations from board staff and members of the regulated public and heard public comments during the meeting. At the 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.

Committee Discussion

The committee considered possible changes to the regulations requested by members of the regulated public as well as staff recommendations to each of those changes.

After discussion and consideration of both written and public comment, the committee provided guidance to staff in several areas. The committee noted in several areas that changes were not necessary as the underpinning of the board's regulation is that a pharmacist use professional judgment.

The committee's recommendations are summarized below and categorized into different outcomes:

Development of FAQs

- Section 1735.1: Augment the board's current FAQs to include and specify that electronic monitoring of temperatures is allowable and to provide reference to the appropriate chapters of USP for information on sterility and stability.
- Section 1735.2: Provide guidance on the board's interpretation of "identical" as referenced in the section.
- Section 1738.8(c): Provide guidance on the board's expectation related to the quality assurance program and annual testing requirement.
- Section 1751.6(e)(2): Provide additional guidance on the training requirements for personnel involved in compounding including reinforcing the requirement for the pharmacy to determine the appropriate training.

Attachment 8 includes meeting materials from both the June 2 and July 12 Enforcement Committee Meetings. Since the committee meeting, several additional comments have been received. Comments received before July 21, 2017 9:00 am are provided.

Regulatory Amendments Requiring Emergency Adoption Procedure

Attachment 9

In addition to the FAQs, the committee identified sections of the board's regulations that should be amended via the emergency adoption procedures.

Committee Recommendation: Pursue regulatory amendment to CCR Section 1735.2 (i)(1) relating to the establishment of beyond use dates for nonsterile drug preparations requiring **emergency adoption** procedures to avoid serious harm to the public peace, health, safety, or welfare.

The proposed language is included in **Attachment 9**.

Regulatory Amendments Pursuant to Regular Rulemaking Procedure

The committee identified additional areas of the regulations that require amendment that do not meet the threshold for emergency adoption. Below is a list of the relevant sections.

- CCR Section 1751.1(a)(5), clarifying where smoke studies must be performed as well as the frequency.
- CCR Section 1751.4(k), conforming the room temperature requirements to be consistent with USP.

The committee agreed with the proposed changes but did not make a formal recommendation.

The proposed language is included in **Attachment 10**. The committee also requested that additional research be considered by board staff for consideration at a future meeting. Those areas include:

- CCR 1735, regarding the possible exemption from the definition of compounding the mixing of ingredients from an FDA kit.
- CCR 1735.1(r), regarding the board's definition of "hazardous drug."
- CCR 1735.2(a), regarding the requirement to document a prescriber's authorization to compound a product.
- CCR 1735.2(i)(2)-(4), regarding the BUD for sterile drug products.
- CCR 1751.4(d), regarding where decontamination needs to occur.
- CCR 1751.4(d)(1), regarding the frequency of cleaning.
- CCR 1751.4(g)(1), regarding the allowance of alternate containment strategies for some hazardous drugs.
- CCR 1751.7(e)(1), regarding the allowance of alternative testing methods.

The remainder of the sections identified was rejected for reasons specified in the recommendation grid. The committee noted some of the requests would be appropriate for reconsideration after USP Chapter 797 revisions are finalized, and others may be appropriate for reconsideration after USP Chapter 800 provisions take effect.

i. Discussion and Consideration of the Status of Waiver Requests for Compounding Construction Compliance Delays Pursuant to Title 16, California Code of Regulations, Sections 1735.6 and 1751.4 and the Process for Review and Appeals of Such Requests

Background

Title 16 of (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.

A waiver application must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated. Initial review of the application is performed by staff led by the executive officer, who approves or denies the 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 that is reviewed by two board members, currently Allen Schaad and Victor Law. The goal of the waiver process is to secure full compliance at the earliest possible time and no later than the implementation of USP <800> on July 1, 2018.

Committee Discussion

The committee was advised that the review process is ongoing, as 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 that have been denied a waiver have been informed of the appeal process.

Ms. Herold said the deadline for waivers is July 1, 2017. Many facilities that have been approved for a construction waiver have a report due to board staff on Nov. 1, 2017, that should document their current status. Many approved waivers have an expiration date of Jan,.1, 2018. The status report will provide the licensee with an opportunity to explain why it may need an extension if it will not be in compliance by Jan. 1, 2018.

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

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

Part 3. Enforcement Statistics

j. Enforcement Statistics

Attachment 11

Attachment 11 contains end-of-fiscal year enforcement statistics and a three-year comparison. A review of the three-year comparison reveals the board completed about 600 more investigation in FY 2016/17 versus FY 2014/15. Over the three-year period there has been a slight increase (8 percent) in the number of cases referred to the Attorney General's Office. Pharmacy technicians represent the greatest number of

licenses revoked by the board, while pharmacists represent the greatest number of licensees placed on probation.

k. Future Meeting Dates

The committee's next meeting is scheduled for September 15, 2017.

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)

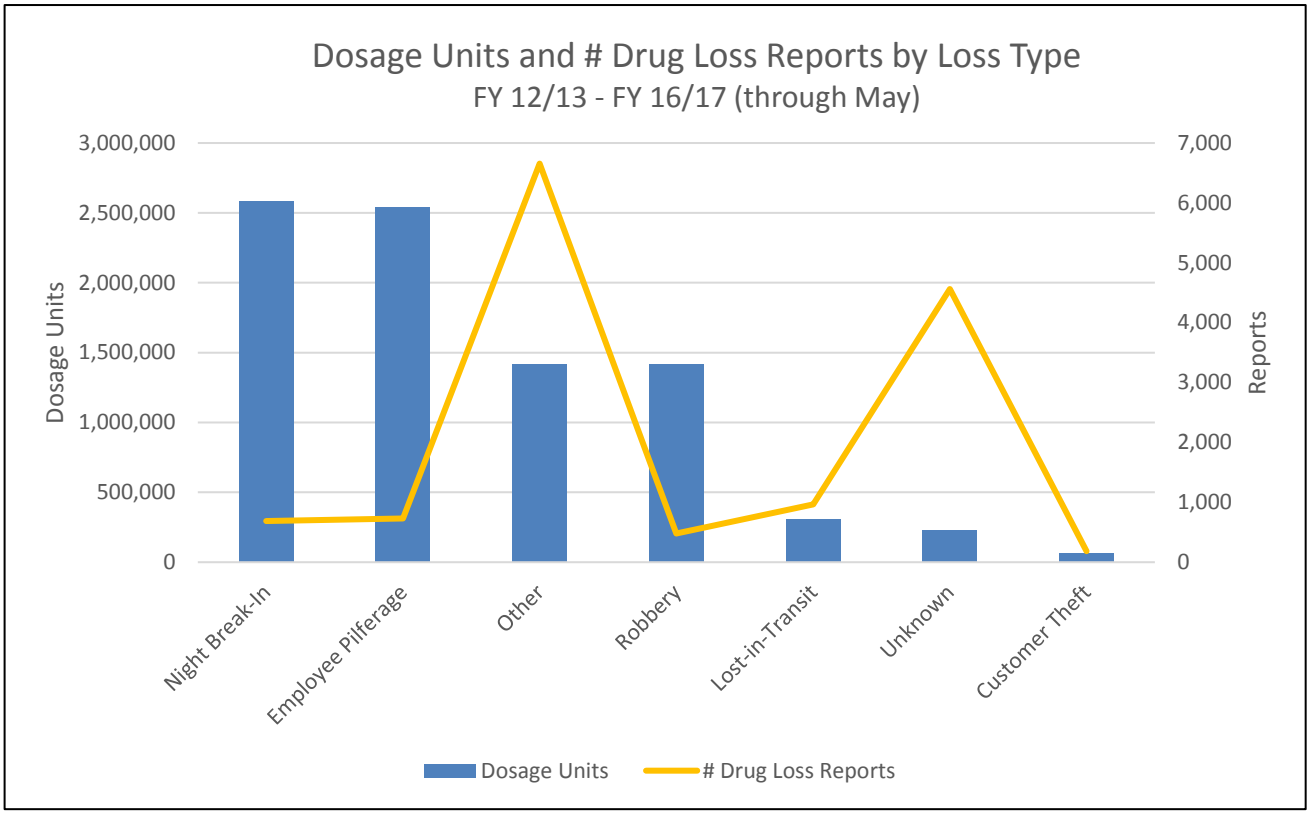
Drug Name	Dosage Units[1]	% of Total of All Drugs Reported[2]
Hydrocodone/APAP	3,080,336	38.9%
Alprazolam	849,971	10.7%
Promethazine/Codeine	626,956	7.9%
Oxycodone	460,098	5.8%
Carisoprodol	260,070	3.3%
Oxycodone/APAP	248,104	3.1%
Hydrocodone	234,229	3.0%
Tramadol	208,039	2.6%
Codeine/APAP	201,413	2.5%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

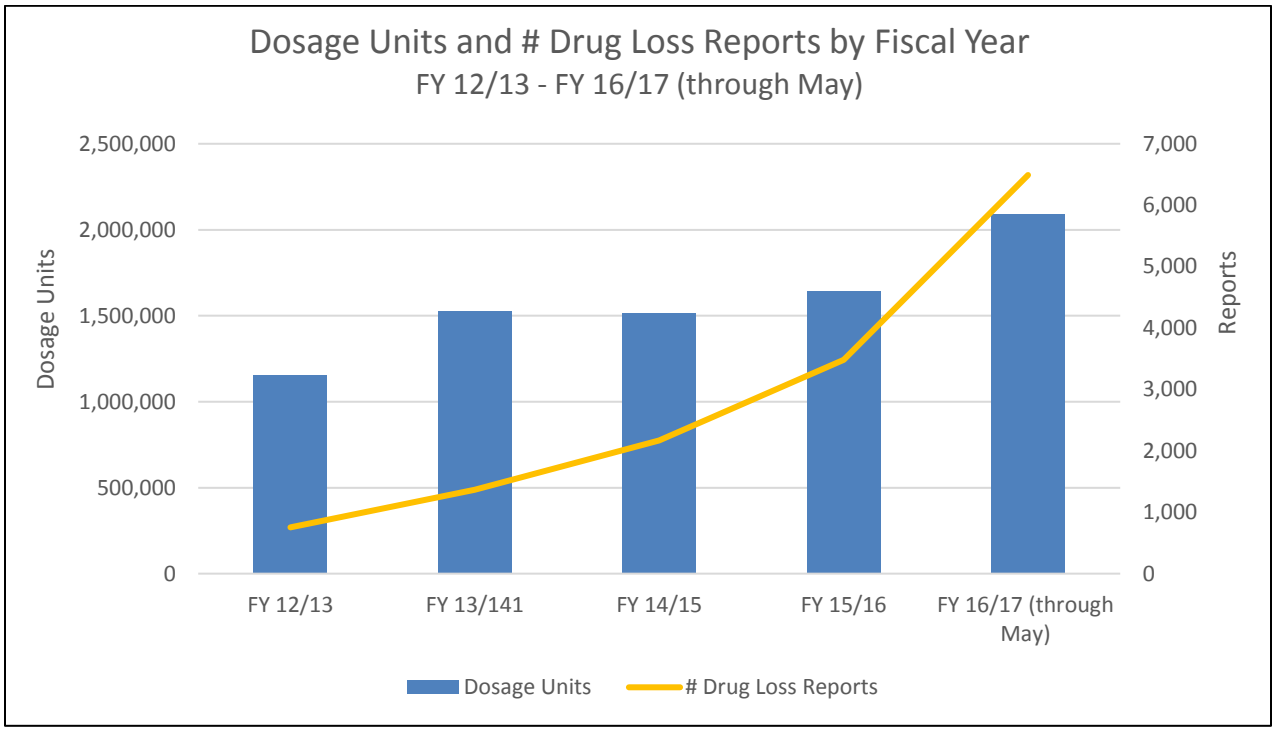
[3] Grand Total includes all drug names and dosage unit losses reported.

Revised 7/18/2017



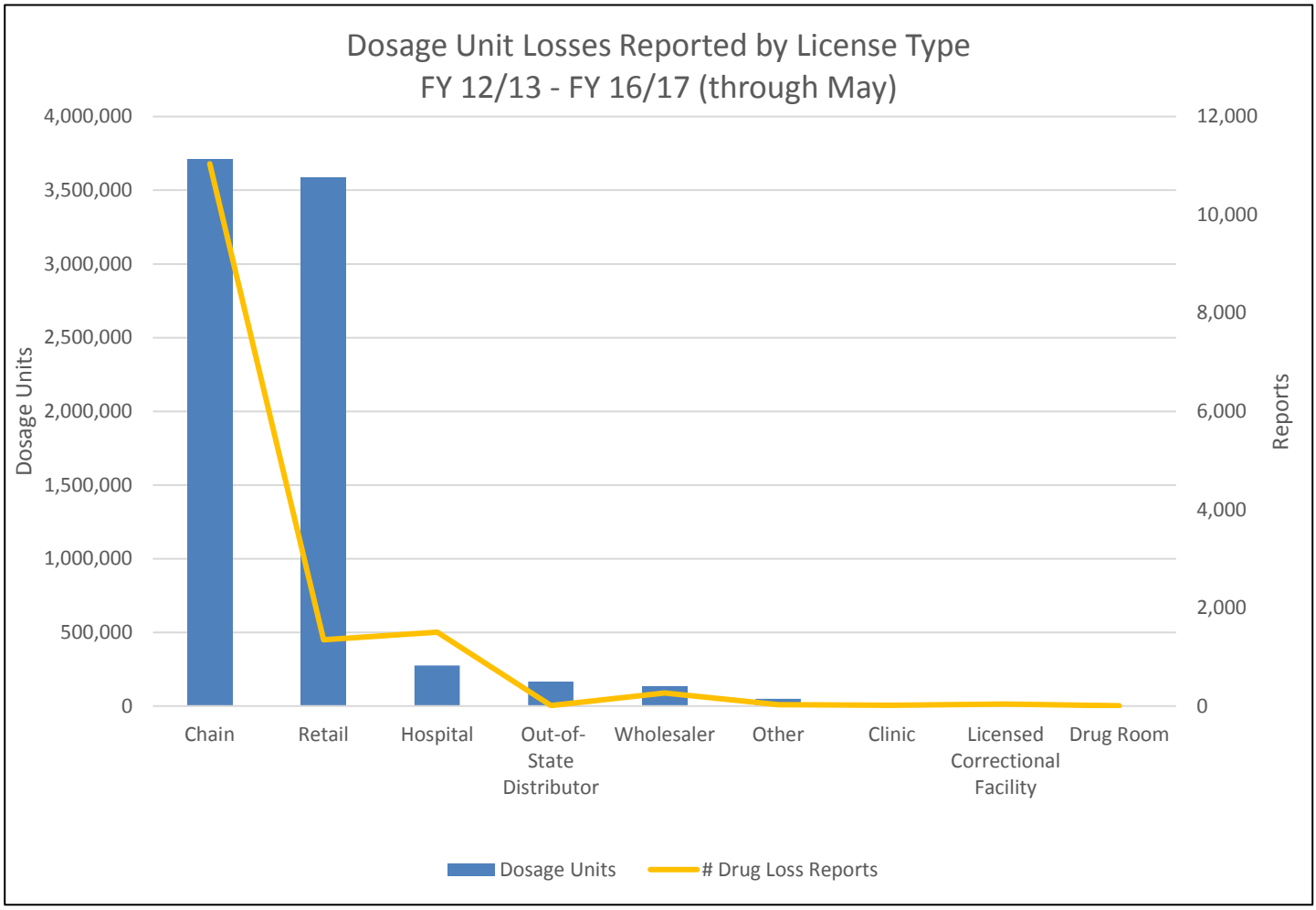
Loss Type	Dosage Units	# Drug Loss Reports
Night Break-In	2,584,901	686
Employee Pilferage	2,542,754	732
Other[1]	1,418,426	6,656
Robbery	777,610	480
Lost-in-Transit[3]	310,118	964
Unknown[2]	230,752	4,559
Customer Theft	60,445	184
Grand Total	**7,925,005**	**14,261**

[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.



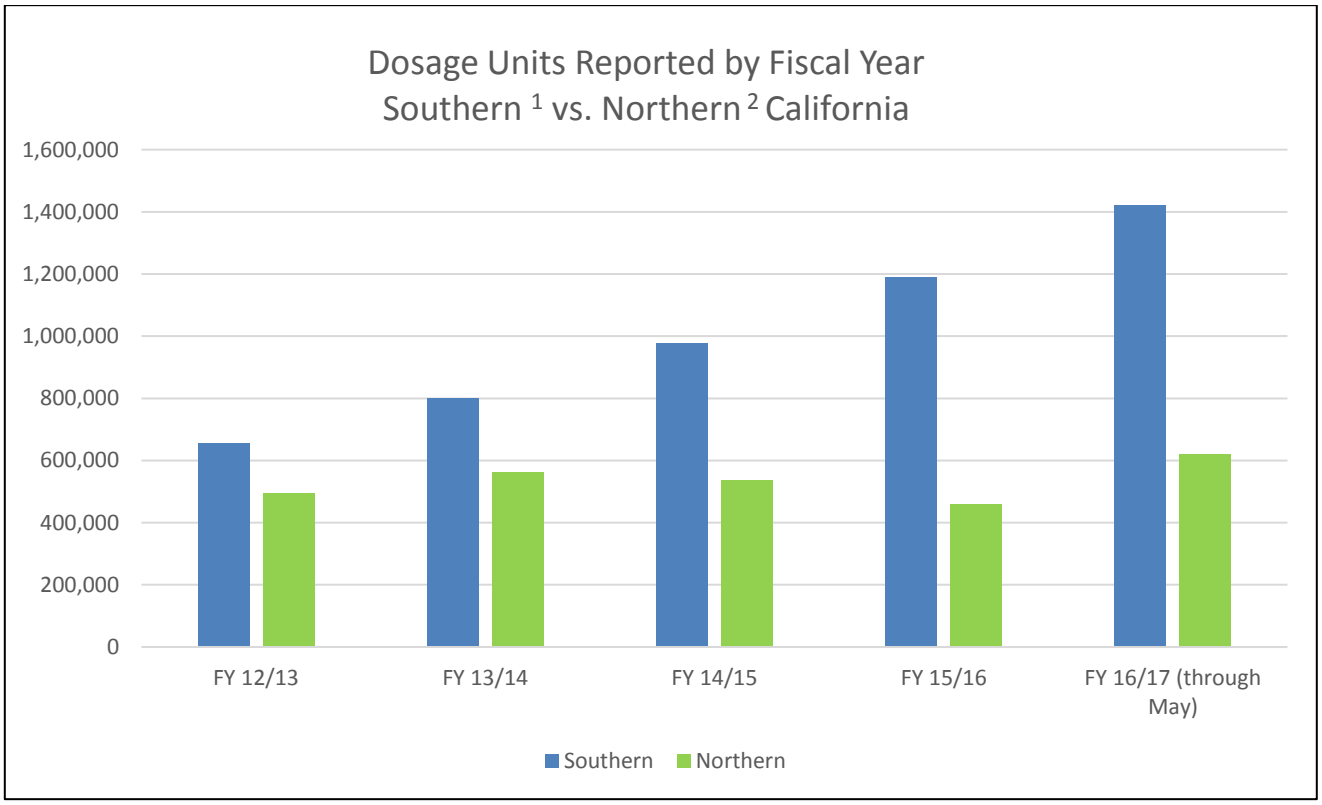
License Type	Dosage Units	# Drug Loss Reports
Chain	3,710,972	11,039
Retail[1]	3,588,628	1,352
Hospital	274,716	1,505
Out-of-State Distributor	165,273	10
Wholesaler	132,651	265
Other[2]	49,117	30
Clinic	3,196	16
Licensed Correctional Facility	413	38
Drug Room	39	6
Grand Total	**7,925,005**	**14,261**

[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.

Northern and Southern California Comparisons

(Pages 5 – 9)

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



[1] Southern California Counties: Imperial, Los Angeles, Orange, Riverside, San Bernardino, San Diego, Santa Barbara, Ventura, San Luis Obispo, and Kern.

[2] Northern California: All remaining counties not included in Southern California.

Note: The Totals in this chart, and the following charts and tables, will not equal the total dosage units and drug loss reports in some previous tables and charts since out-of-state licenses are not included for the Southern and Northern California comparisons.

Licensee #s and Controlled Substance (CS) Losses Reporting Statistics

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

Region	# Licensees per Region during the reporting period[8]	% of Total California Licensees[1]	% of Total California Licensees Reporting[2]	% of Regional Total Licensees Reporting Drug Losses[3]	% of Total Dosage Unit Losses Reported by California Licensees[4]	% of Total Drug Loss Reports by California Licensees[5]
Southern	8,774 [a]	61.5%	15.2%	24.7%	65.4%	57.7%
Northern	5,491 [b]	38.5%	10.9%	28.3%	34.6%	42.3%
Total	***14,265*** [c]	**100.0%**	**26.1%**		**100.0%**	**100.0%**

Region	Dosage Units	# Drug Loss Reports	Average Dosage Units per Drug Loss Report[6]
Southern	5,038,589 [d]	8,221 [g]	613
Northern	2,670,749 [e]	6,022 [h]	443
Total	***7,709,338*** [f]	***14,243*** [i]	**Avg. 528**

Region	# Dosage Unit Losses Reported by California Licensees	# Reporting Licensees	Average Dosage Units per Reporting License[7]
Southern	5,038,589 [d]	2,164 [j]	2,328
Northern	2,670,749 [e]	1,554 [k]	1,719
Total	***7,709,338*** [f]	***3,718*** [l]	**Avg. 2,024**

Notes on calculations for all three tables above:

[1] Southern (a/c*100); Northern (b/c*100)

[2] Southern (j/c*100); Northern (k/c*100)

[3] Southern (j/a*100); Northern (k/b*100) – No total % since denominators are not the same

[4] Southern (d/f*100); Northern (e/f*100)

[5] Southern (g/i*100); Northern (h/i*100)

[6] Southern (d/g); Northern (e/h); Avg. of Avgs. (613+443/2)

[7] Southern (d/j); Northern (e/k); Avg. of Avgs. (2,328+1,719/2)

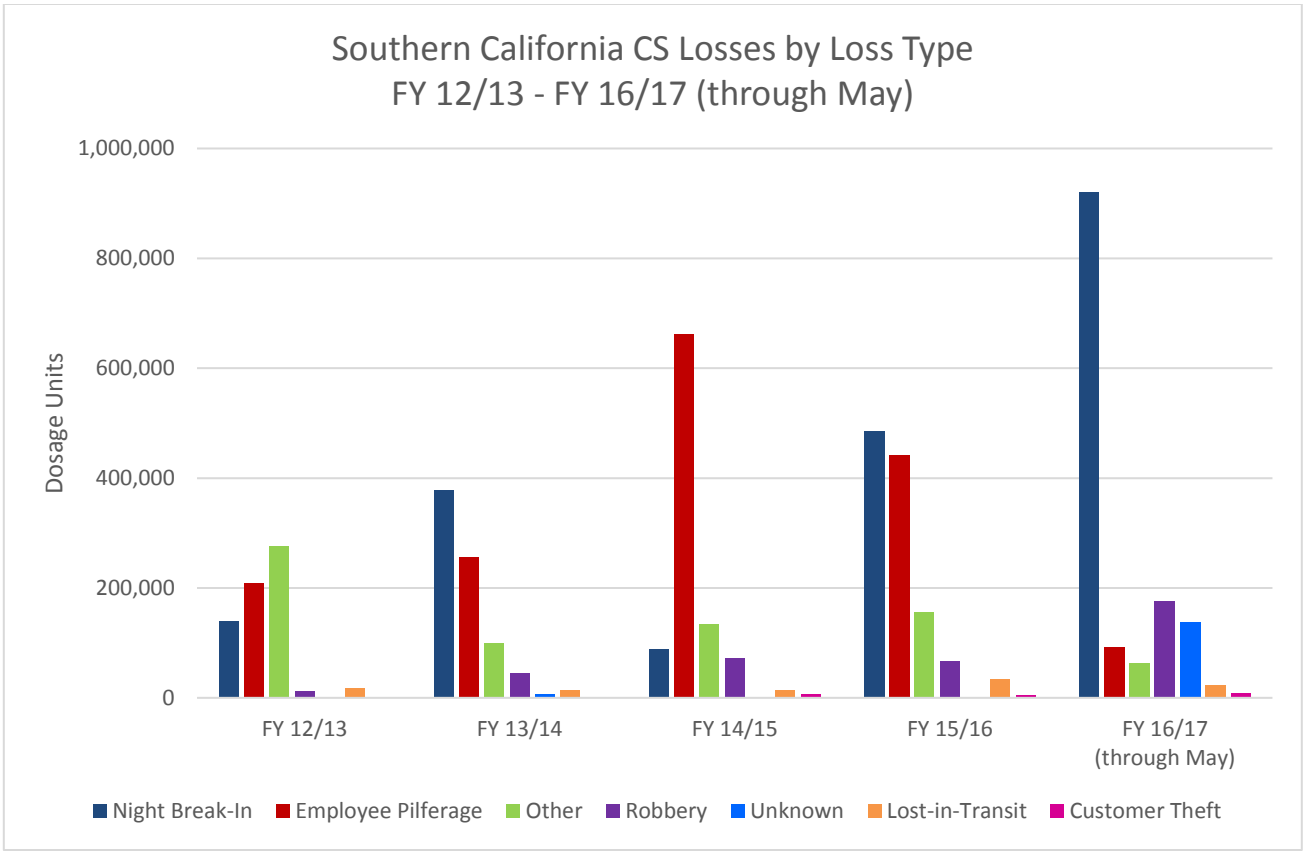
[8] Any individual license # active at any time during the FY12/13 - FY16/17 (through May) timeframe

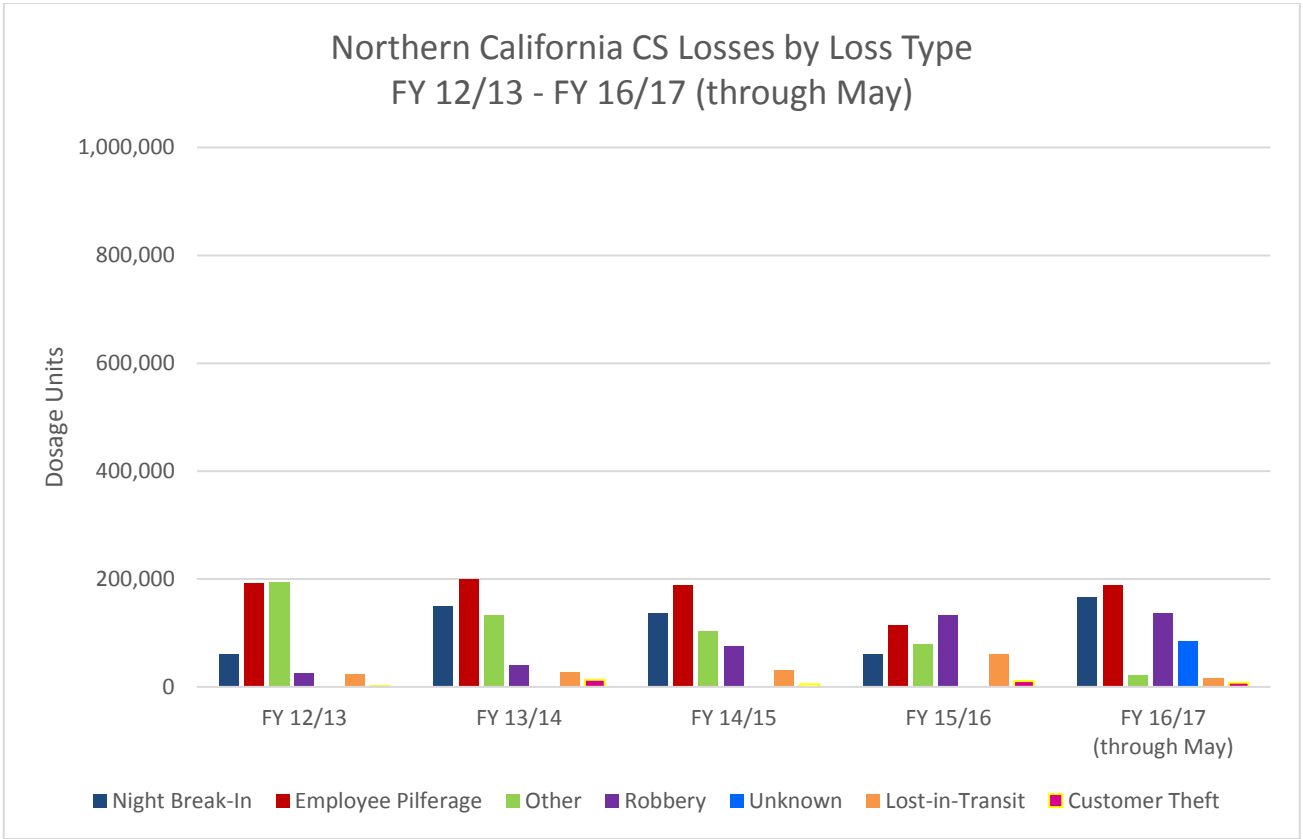
Dosage Unit Losses and % by Loss Type

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	21.6%
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 report in some previous tables since out-of-state licenses are not included here.


Southern California CS Losses by Loss Type
FY 12/13 - FY 16/17 (through May)
1,000,000
800,000
600,000
400,000
200,000
0
Dosage Units
FY 12/13
FY 13/14
FY 14/15
FY 15/16
FY 16/17 (through May)
Night Break-In
Employee Pilferage
Other
Robbery
Unknown
Lost-in-Transit
Customer Theft


Northern California CS Losses by Loss Type
FY 12/13 - FY 16/17 (through May)
1,000,000
800,000
600,000
400,000
200,000
0
Dosage Units
FY 12/13
FY 13/14
FY 14/15
FY 15/16
FY 16/17 (through May)
Night Break-In
Employee Pilferage
Other
Robbery
Unknown
Lost-in-Transit
Customer Theft

Southern California CS Losses by Loss Type and FY
FY 12/13 - FY 16/17 (through May)

	FY 12/13	FY 13/14	FY 14/15	FY 15/16	FY 16/17 (through May)	Total
Night Break-In	139,497	377,437	88,590	485,104	920,984	***2,011,612***
Employee Pilferage	208,599	256,399	661,873	442,358	91,970	***1,661,199***
Other	276,395	99,122	133,898	155,972	62,324	***727,712***
Robbery	11,199	44,238	71,762	66,067	175,904	***369,170***
Unknown	594	5,898	89	495	137,247	***144,323***
Lost-in-Transit	17,357	13,961	14,332	33,327	23,305	***102,283***
Customer Theft	494	1,634	6,350	5,475	8,338	***22,290***
Grand Total	*654,135*	*798,690*	*976,895*	*1,188,797*	*1,420,072*	***5,038,589***

Northern California CS Losses by Loss Type and FY
FY 12/13 - FY 16/17 (through May)

	FY 12/13	FY 13/14	FY 14/15	FY 15/16	FY 16/17 (through May)	Total
Night Break-In	60,646	148,659	136,625	59,609	165,733	***571,271***
Employee Pilferage	192,173	199,236	187,466	113,704	188,977	***881,555***
Other	192,606	132,335	101,832	79,148	21,893	***527,814***
Robbery	24,473	40,445	75,528	132,940	135,054	***408,440***
Unknown	31	1,011	17	691	84,679	***86,429***
Lost-in-Transit	23,015	27,213	30,285	60,464	16,108	***157,085***
Customer Theft	1,382	12,949	5,048	10,982	7,795	***38,155***
Grand Total	*494,325*	*561,846*	*536,801*	*457,538*	*620,238*	***2,670,749***

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:

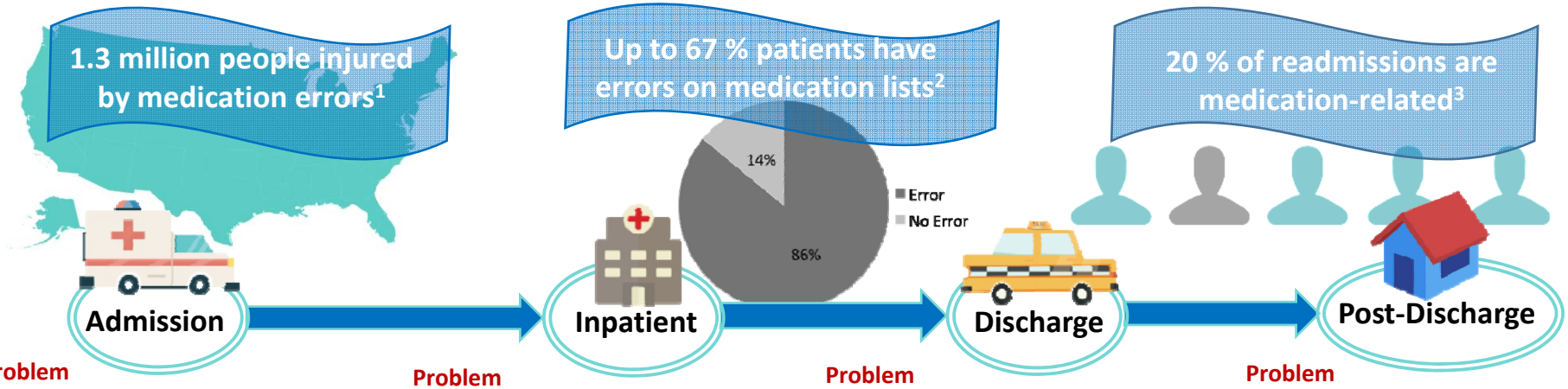
SDI HIDTA
San Diego - Imperial HIDTA

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

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Safe Medication Transitions:

Improving Safety of Medication Lists Using Evidence-Based Solutions

Rita Shane, Pharm.D., FASHP, FCSHP
Chief Pharmacy Officer
Cedars-Sinai Medical Center, Los Angeles
Assistant Dean, Clinical Pharmacy
UCSF School of Pharmacy

BACKGROUND

- **Medication discrepancies occur in up to 70% of patients at hospital admission or discharge. (Leapfrog Hospital Survey Fact Sheet 3/17)**
- Medication histories or lists are entered into electronic health records (EHR) by a variety of individuals with varying knowledge about medications across different healthcare settings
- These lists are used to create hospital medication orders and discharge prescriptions resulting in continuation of inaccurate and/or incorrect medications
- Medication reconciliation cannot be accurate if medication lists are inaccurate
  - Medication reconciliation is required by The Joint Commission and the Center for Medicare/Medicaid Services as part of Meaningful Use

75% of hospital executives concerned patient medication data are incomplete, inaccurate (Becker's Hospital Review, 6/22/17)*

Top 3 concerns

- Inconsistent practices across departments, disciplines and shifts (59.7%)
- Patients being discharged with an incorrect medication list (47.9%)
- Difficulty importing external medication history, including home medications (46.2%)

*Survey of 120 administrators

CURRENT SITUATION

- Absence of designated “owner” to ensure accuracy of lists results in redundant work and rework by nurses, physicians and pharmacists
- Nurses indicate that obtaining a medication list for a complex patient can take an hour
- Physicians don’t have sufficient time to obtain an accurate list and order based on previous medications listed
- Lack of defined process puts patient at risk for significant harm during hospitalization and at discharge

SOURCES OF MEDICATION LISTS

Errors introduced in any of these settings can become "hardwired" into the pt record

Home

- Pt
- Family members
- Caregivers
- Home Health nurses

Outpatient Settings

- Certified medical assistants
- Physicians
- Community pharmacies
- Patients

ED/Hospital

- Nurses
- Physicians
- Pharmacists
- Pharmacy technicians
- Pharmacy residents, students

Skilled Nursing Facility

- Nurses
- Physicians

Medications Reconciliation

Medications prior to Admission	Discharge Medications	Change	Reason/Comment
Aspirin (Ethics Enteric Coated Aspirin) 100mg Enteric coated Tablets mane	–	Stopped	Patient now on warfarin
Dipyridamole (Pytazen SR) 150mg Sustained Release Tablets twice daily	–	Stopped	Pt now on warfarin
Simvastatin (Arrow Simva) 20mg Tablets at night	**Simvastatin (Arrow Simva) 40mg Tablets** at night 1 month, cc monthly (Script)	Changed	Optimise cholesterol lowering
Felodipine (Felo ER) 10mg Extended Release Tablets mane	**Felodipine (Felo ER) 5mg Extended Release Tablets** mane 1 month, cc monthly (Script)	Changed	BP drop during admission
Allopurinol (Apo-Allopurinol) 100mg Tablets once daily	**Allopurinol (Apo-Allopurinol) 100mg Tablets** once daily 1 month, cc monthly (Script)	Continued	
–	**Metoprolol succinate (AFT-Metoprolol CR) 23.75mg Controlled Release Tablets** PO OD 1 month, cc monthly (Script)	Started	Regular med
–	**Warfarin sodium (Marevan) 1mg Tablets** As per INR 1 month (Script)	Started	AF

Remove — 1 tablet nocte with food — Edit
Script ☐ Close Control

Remove — **Enalapril maleate (Multichem Enalapril) 10mg Tablets** — Started — Edit — Changed from Captopril due to rash
Take 1 tablet BD
Script ☐ Close Control

Add Medication Prior to Admission | Add Discharge Medication

Medications Prior to Admission populated from "Medication History Form" finalized by Dr Anabel ROSE (Pharmacist) 2 days ago.

https://image.slidesharecdn.com/p27jackson1-101105005205-phpapp01/95/electronic-medication-reconciliation-improving-patient-safety-through-emedicine-admission-and-discharge-management-22-728.jpg?cb=1289401793, accessed 7/8/17

CMS 2012-MEANINGFUL USE

- Any licensed healthcare professional and *credentialed medical assistants*, can enter orders into the medical record
- Credentialed medical assistants are:
  - Certified medical assistants-graduates of an accredited medical assisting program
    - Training requirements: 2-6 units of pharmacology training. (based on 4 California programs)
    - 2 yr experience
  - Medical assistants (who are not certified) who have completed a required order entry course

1. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_1_CPOE_MedicationOrders.pdf,accessed 9/20/16
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MEDICAL ASSISTANTS

Requirements for Order Entry into Electronic Health Records

- 2 yr recent experience in a health care facility under the supervision of a licensed health care provider (LHP)
- Application signed by supervising LHP attesting proficiency in areas including pharmacology
- Completion of Assessment-Based Recognition in Order Entry (ABR-OE) Qualifying Courses-5 courses
  - Foundation of Order Entry in Health Care
  - How Medical Assistants Can Meet CMS Requirements
  - Medical Records: The Legal Document
  - Clinical Laboratory: Keeping Up With CLIA
  - Anatomy, Physiology and Disease Screenings

https://learning.aama-ntl.org/Public/Catalog/Home.aspx, accessed 7/8/17

ADMISSION

Problem

- 82% of patients >65 years old have at least 1 discrepancy on their medication list
- 7.4 errors per medication list in high risk patients
- 5.3% of patients on ≥5 medications have accurate lists

Minimizing Errors in Medication Histories Obtained at Hospital Admission

Randomized Controlled Trial

- **Usual Care: MD or RN**
- **Pharmacist**
- **Trained Technician**

- High Risk Patients* admitted via Emergency Dept
- 300 pt enrolled; 283 in final analysis
- Median age: ~76 (range: 50-83)
- Median # of meds" 14 (range; 10-19)

**High risk:≥ 10 chronic meds, Acute MI, CHF, admitted from SNF, on anticoagulants, insulin, narrow therapeutic drugs, history of transplant*

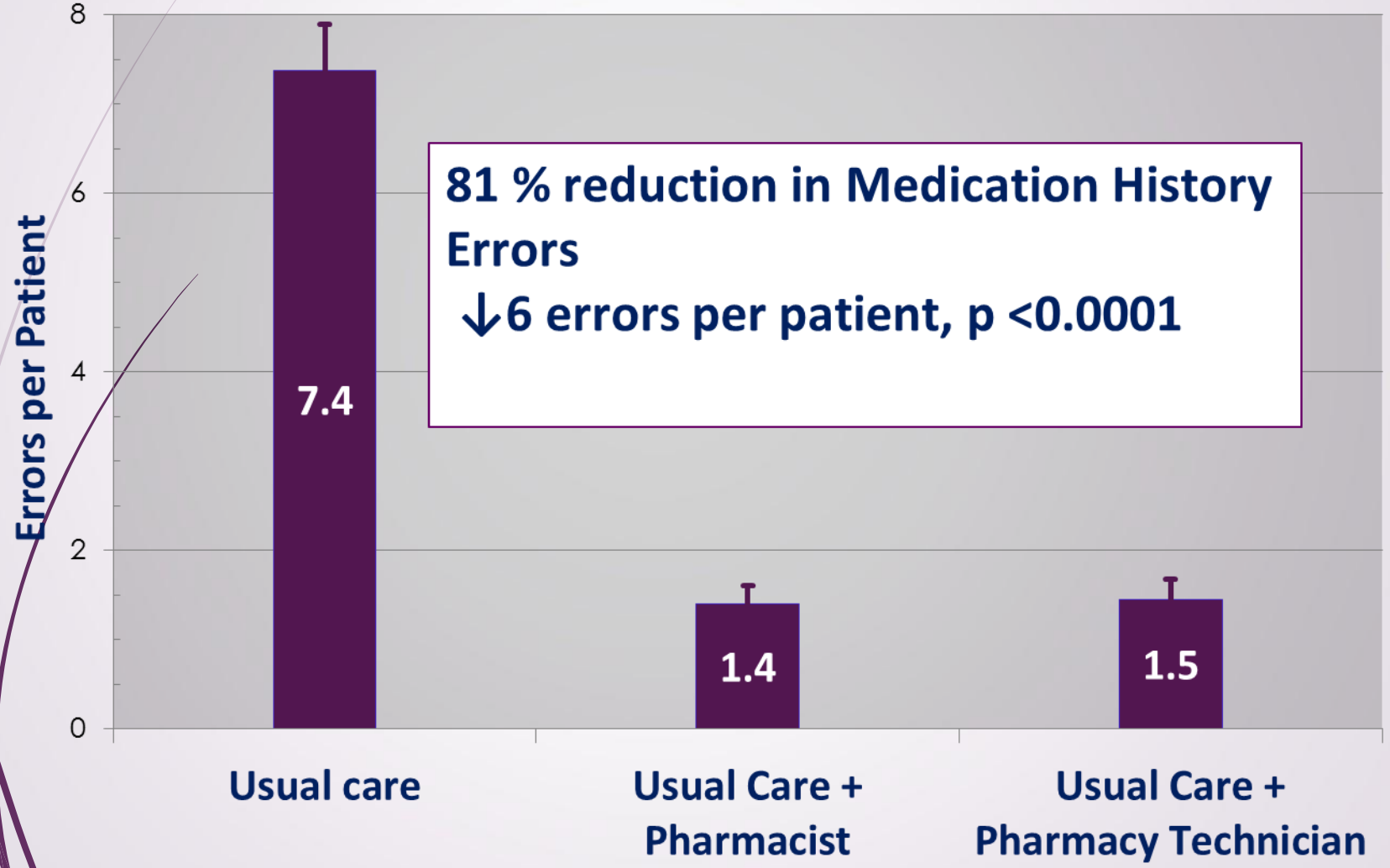
Pevnick JM NC, Jackevicius CA, Palmer KA, et al. Minimizing Medication Histories Errors for Patients Admitted to the Hospital Through the Emergency Department: A Three Arm Pragmatic Randomized Controlled Trial of Adding Admission Medication History Interviews by Pharmacists or Pharmacist-Supervised Pharmacy Technicians to Usual Care. J Patient-Centered Res Rev 2015;2:93.Research was supported by NIH/National Center for Advancing Translational Science UCLA CTSI Grant Number KL2TR000122.

Minimizing Errors in Medication Histories Obtained at Hospital Admission

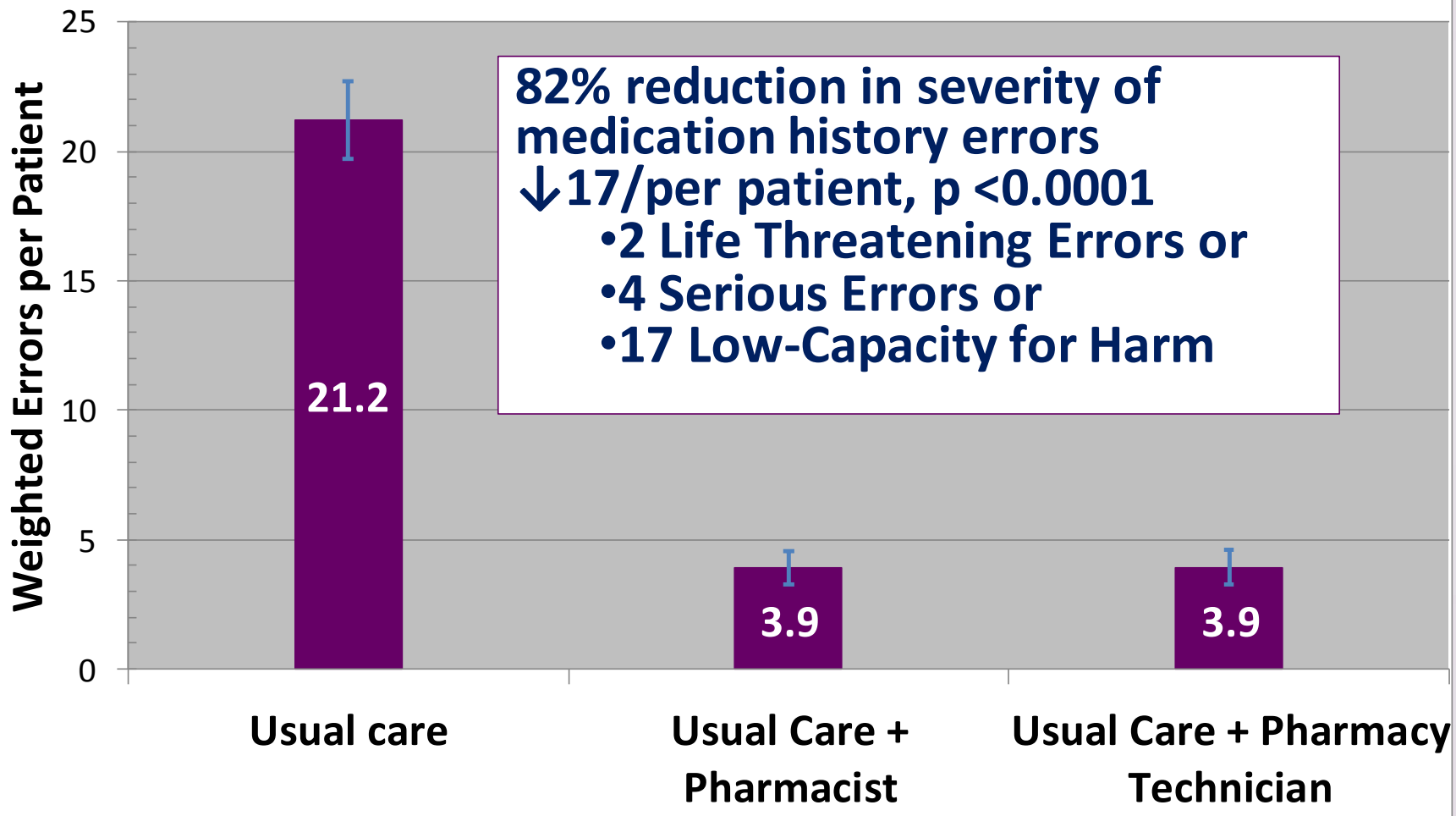
Randomized Controlled Trial

- Pt histories independently evaluated within 24 hr by gold standard pharmacist (proven study methodology)
- Gold standard pharmacist took patient history, compared with history taken, determined # errors and severity of errors:
  - Low capacity for harm: vitamin, laxative
  - Serious: beta blocker for hypertension
  - Life Threatening: transplant drug

Results: **Number** of Errors



Results: **Severity** of Errors



Examples of Admission Drug-Related Problems (DRPs) Resolved

Admission Med List	Drug-Related Problem Identified and Resolved	DRP Type	Capacity for Harm
Metho-trexate	DRP: Ordered as 10 mg daily Finding: Order was weekly	Wrong fre-quency	Life-threatening Pancytopenia
Keppra®	DRP: Ordered as 100mg po BID Finding: Pt reports taking 1000mg mg BID.	Wrong Dose	Significant Seizures
Amlodipine	DRP: amlodipine 10mg daily Finding: MD reordered. Family indicated pt stopped taking due to swelling-allergic reaction	Allergy	Life-threatening-Significant Anaphylaxis

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
- 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%

INPATIENT

Up to 67% of patients have errors on medication lists

Problem

- During hospitalization, medication errors occur in up to 50% of adult and 75% of pediatric patients
- Over 1/3 of hospitalized patients had medication order errors - 85% originated with the medication history
- Up to 59% of medication history errors can cause harm

EVIDENCE

- Hospital pharmacists reduce me
  ("*How To Make Hospitals Less Dead*
- Clinical pharmacists intercept
  errors originating from inaccur
  lists
- At discharge, uncorrected err
  discharge prescriptions


In the Zone on the Web

THE WALL STREET JOURNAL.

How to Make Hospitals Less Deadly

Doctors' errors annually kill hundreds of thousands of Americans. Here are five reforms that would bring down the death toll.

• **Bring in the pharmacists.** A breakthrough in 20th-century care was allowing nurses to make rounds with doctors: Now it's time to include pharmacists. Doctors have only glancing knowledge of how an ever-multiplying number of drugs interact with diet, age, disease, body type and each other. Erroneous medication orders kill thousands of Americans annually, according to the Journal of the American Medical Association. **Putting pharmacists in patient areas decreased errors by 45%, and cut errors leading to death or severe harm by 94%,** according to a 2001 study.

*Wall Street Journal, May 17, 2016

DISCHARGE

Problem

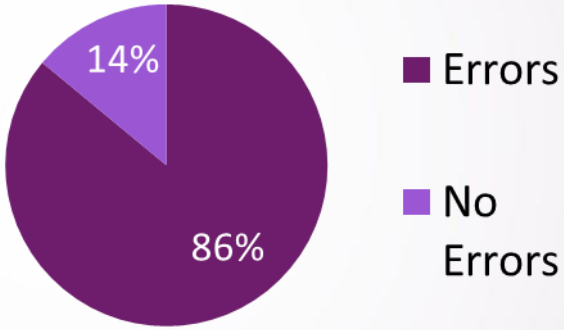
- Up to 80% of patients have at least one medication list discrepancy upon leaving the hospital
- ↑ # of medications at discharge results in a statistically higher rate of readmissions
- >6 medications at discharge is independently associated with 30-day readmissions (26% higher likelihood)

EVIDENCE

- Pharmacists identified preventable ADEs in 1% of patients who received discharge education and follow up compared with 11% of patients who did not receive these benefits.
- Discharge medication lists completed by pharmacists resulted in an absolute risk reduction of 46.5% when compared to usual care.

POST-DISCHARGE

Problem



- Post-discharge adverse drug events occur in up to 19% of patients, of which 1/3 to 2/3 are preventable
- Up to 90% of hospital-to-SNF discharge summaries contained one or more DRPs

EVIDENCE

- Post-discharge pharmacist follow up with discharge education reduced readmissions and ED visits vs usual care (39% to 24.8%).
- - Post-discharge pharmacist reconciliation and education reduced readmissions and ED visits vs usual care (0% vs 40.5%).
- Post-discharge pharmacist follow up can reduce readmission from skilled nursing facility by 25%.

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 ($p<0.0001$).
  - Nurses were 7.5 times as likely to make an error than pharmacy technicians ($p<0.0001$).
- 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 ($p<0.0001$).

Rx Pharmacist

- Pharmacists identified 1096 home medications compared with 817 home medications identified by ED providers. 78% of medications documented by ED providers were incomplete.
- Pharmacists involved in transitions of care roles significantly reduce readmissions compared to usual care

  Medication histories, discharge counseling, review of discharge medication lists and post-discharge follow up

  - Results
    - Readmission rate 16.8% vs the usual care arm of 26% (p=0.006).
    - 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).
    - Reduction in 30-day readmissions (5.0% vs 9.5%, $p<0.05$).

SUMMARY

- Medication discrepancies or errors in medication lists occur in up to 70% of patients at admission or discharge contributing to adverse drug events, ED visits and readmissions.
- High risk patients are the most vulnerable for harm.
- Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.
- Having pharmacy staff perform medication histories supports the health care team by allowing nurses and physicians to focus on acute patient care needs.



Accurate medication list

Increased accuracy of inpatient orders

Increased accuracy of discharge prescriptions

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

Attachment 5

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

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 8

June Enforcement Committee Meeting Materials

Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 4.5. Compounding

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

§ 1735.1. 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. This external venting 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. This external venting 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) “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.
(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.
Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

§ 1735.2. 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 a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.
(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:
(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
(B) the chemical stability of any one ingredient in the compounded drug preparation;
(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
(D) 180 days for non-aqueous formulations,
(E) 14 days for water-containing oral formulations, and
(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.
(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.
Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

§ 1735.3. 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 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).
Note: 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.
Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4301, Business and Professions Code.

§ 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 in the room shall also be externally vented; 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 on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
(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.

Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 7. Sterile Compounding

16 CCR § 1751
§ 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 505.7 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.
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.

§ 1751.01. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients. [Renumbered]
Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

§ 1751.02. Policies and Procedures. [Renumbered]
Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§ 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) Video of smoke studies in all ISO 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).
Note: 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 label 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.”
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.

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

§ 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.
(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned 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 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 505.7.1 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).
Note: 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.
Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

§ 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 and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. 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.

Note: 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.
Note: 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.

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

§ 1751.11. Furnishing to Home Health Agencies and Licensed Hospices. [Renumbered]
Note: Authority cited: Sections 4005 and and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

§ 1751.12. Obligations of a Pharmacy Furnishing Portable Containers. [Renumbered]
Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

May 19, 2017

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Herold,

We thank the California Board of Pharmacy, Compounding & Enforcement Committee for being receptive to scheduling an interim meeting of the Committee to consider modification to certain provisions within 16 CCR § 1735 and 1751 related to the compounding regulations that went into effect January 1, 2017.

As the largest statewide association representing pharmacists in the country, the California Pharmacists Association (CPhA) has been working closely with our members in the compounding pharmacy community on implementing these important measures to ensure optimal patient safety and access to high quality compounded medications.

As with any significant policy and regulatory implementation such as those contained in the new California compounding provisions, we have received significant feedback regarding a few provisions that we believe the Committee and full Board of Pharmacy should consider modifying to ensure that safety and accessibility to compounded medications are optimized. It is understandable and reasonable to suggest that the Board would anticipate the need for modifications now that the regulations have been in place for five months and practitioners have begun to comply with the requirements. Our recommendations are based on best practices in the compounding profession as well as international standards and reference points in the United States Pharmacopeial (USP) for compounding both non-sterile and sterile medications.

In addition to changes related to specific regulatory sections, we are also recommending changes to the compounding Frequently Asked Questions (FAQ) document produced by the Board. We understand that the Board FAQs are not regulations and as such are not enforceable, however they are used by practitioners and Board inspectors as guidance and a beneficial reference in furtherance of complying with the regulations. We have included those recommended changes as well.

We look forward to attending the June 2nd meeting and again appreciate the Committee's time and interest in these matters on behalf of the patients that our members serve.

Best regards,

Jon R. Roth, MS, CAE
Chief Executive Officer

1735.1(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. Electronic monitoring and recording of daily refrigerator and freezer temperature may be used to satisfy the provisions of this section.

Need for Recommended Change: This change is necessary to provide clarity that electronic monitoring and recording of temperature is acceptable. Further, we believe this ensures a more precise and continuous measure of refrigerator and freezer temperature ranges and allows pharmacies that are not staffed daily to ensure compliance with the requirement.

…

1735.1(n) "Dosage unit" means a quantity prescribed ~~sufficient~~ for ~~one~~ administration to one patient.

Need for Recommended Change: This change is recommended for ensuring 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. An example of this would be a patient whose prescriber writes a prescription for a compounded medication that requires individual dose vials daily for 10 days. Each vial is only used once and discarded resulting in 10 dosage units being needed for the prescribed course of therapy. The existing definition would prohibit this patient access to the prescribed care because it is restricted to one administration.

…

1735.1 proposed new definitions to be added:

For purposes of this section, sterility may be defined as:

(a) The application of a lethal process to sealed containers to achieve a predetermined sterility assurance level of greater than 10^{-6} or a probability of less than one in one million of a nonsterile unit, or,

(b) Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent. Membranes must be documented to retain 100% of a culture of 10^{7} microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar).

Need for Recommended Change: These definitions are derived from the USP 797 glossary and are necessary to clarify the methods for obtaining sterility in compounded sterile preparations.

…

1735.2(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), in the absence of stability information applicable to the compounded formulation, 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,

(E) 14 days for water-containing oral formulations, and

(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

(2) For sterile compounded drug preparations, in the absence of stability information applicable to the compounded formulation, 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) In the absence of sterility testing conducted in accordance with USP Chapter 797, ~~T~~the beyond use date assigned for sterility in section 1751.8.

Need for Recommended Change: Modification to sub-section 2(D) is necessary to clarify that the beyond use dates contained in section 1751.8 are only applicable to sterile compounds that do not undergo sterility testing, consistent with USP 797.

(3) Extension of a beyond use date for sterile compounded drug preparations exceeding those in section 1751.8 is only allowable when supported by the following:

(A) Sterility testing methods are supported by Method Suitability Tests,

(B) Container closure types are supported by Container Closure Integrity Tests, and

(C) ~~Stability Studies~~ Sterility testing performed in accordance with USP 797.

Need for Recommended Change: Modifications to sub-section 3 are necessary to clarify the types of testing needed to ensure sterility beyond the timelines as set forth in section 1751.8, consistent with USP 797.

(4) In addition to the requirements of paragraph one (1) and paragraph three (3), the stability of drugs or compounded drug preparations tested and studied shall ~~be identical in~~use ingredients, ~~specific and essential~~ compounding steps, ~~quality reviews,~~ and packaging analogous to ~~as~~ the finished drug or compounded drug preparation as demonstrated by scientific publications referenced in the judgement of the pharmacist.

Need for Recommended Change: These modifications are critically important to bring the regulation consistent with USP 797 and are necessary because the standard of meeting "identical" characteristics in a compounded preparation to any studied drug is a nearly impossible standard to achieve.

In particular, USP/NF monographs ensure that active pharmaceutical ingredients (API) and excipients meet specific standards of purity and suitability for use as drugs. However, there can be acceptable slight variances in assay, moisture, and other relevant USP monograph requirements. These variances are within the specific monograph requirements but yield differences that would dictate that the API is not *identical* from lot to lot, yet are analogous to the studied drugs and do not impact the final preparation.

Additionally, stability studies use a specific lot of API and/or excipient for that particular study. It is highly unlikely that any facility, including hospitals, use the *identical* API or drug (same as original study lot) as was used in the study. Stability studies are performed to ensure that the compounded preparation has a predictable potency over a period of time. Requiring that ingredients be identical would disqualify a substantial body of scientific and authoritative data performed and/or published by qualified sources.

Further, very few stability studies outline every compounding step, process and equipment to be used in the preparation of the compounded end-product. For example, Trissel's Handbook of Injectable Drugs provides tabular charts of expected BUD for particular combinations of API/drug and IV solution. 'Specific and essential compounding steps' and 'quality reviews' are not listed as a standard in the literature for most studies footnoted.

Similar to APIs, it is believed that the competent compounding pharmacist will have the training and experience to perform the essential compounding steps consistently. Requiring steps be *identical* will again invalidate a large body of stability studies performed and/or published by qualified sources. These include studies published on a wide range of aqueous-containing compounded preparations such as creams and sterile parenteral solutions.

Lastly, removing the standard of *identical* is also necessary because in many cases stability studies simply state that the compounded preparation was placed in a container with only a general description of the container type given. As with the API and compounding steps, it is believed that the pharmacist will use professional judgment to determine if the container is equivalent to produce an analogous preparation. For example, a published study may conclude that compounded preparation XX was stable for YY time in an amber plastic bottle. The type of plastic may not be specified. The use of term identical precludes use of this scientifically valid study to develop an otherwise safe, replicated preparation.

...

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

> *Need for Recommended Change*: We believe this is a drafting error in the original regulation. The judgment of the pharmacist is necessary to establish dating longer than what is set forth in the section, not shorter than what is set forth in the section.

…

(6) For the purpose of sections 1735.2(i)(1) and 1735.2(i)(2), a potency over time study applicable to the compounded formulation may be used to validate stability and assign extended beyond use dates of compounded preparations. [*new sub-section*]

> *Need for Recommended Change*: Modifications to section 1, 2, and addition of a new section 6 are necessary to bring the regulation regarding potency over time studies consistent with USP 795 (nonsterile) and USP 797 (sterile) standards. This addition also provides clarity to the current regulations that a potency over time study is acceptable for both nonsterile compounding and stability studies for sterile compounded drug preparations.

…

1751.1(a)(5) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

> (5) Video of smoke studies in all ISO Class 5 certified spaces.
>
> *Need for Recommended Change*: Specifying smoke studies in Class 5 ISO certified spaces brings the regulation up to standard with Current Good Manufacturing Practices (CGMP). Smoke studies outside of Class 5 spaces are not a standard since the smoke study is isolated to the laminar flow hood to visualize air flow.

…

1751.4(d) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned ~~at least daily~~each day the facility is used to prepare a sterile drug compound. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

> *Need for Recommended Change*: The objective of cleaning an ISO Class 5 space is to ensure sterility of the space between sterile drug preparations. However, not all pharmacies engage in sterile compounding daily, therefore requiring daily cleaning on days where no sterile compounding has occurred invites undue contamination risk due to personnel entering a sterile environment in order to comply with the regulation. Inviting risk of unnecessarily entering a sterile environment in order to again clean the sterile space between days where preparations occurred is a greater risk to patient safety.

…

1751.4(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature not to exceed ~~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.

> *Need for Recommended Change*: This change seeks to clarify the ambiguity in complying with the temperature provision of the regulation (range of degrees versus "or cooler"). It is clearer to state the temperature as a maximum and remove reference to the specific range. Doing so also provides flexibility for the pharmacy to meet personnel comfort and carries no risk.

…

1751.6(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

> (2) Each person engaged in ~~sterile~~ compounding sterile drug preparations 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 ensure each person engaged in compounding sterile drug preparations successfully demonstrates 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.
>
> (3) Each pharmacist responsible for, or directly supervising and controlling persons engaged in compounding sterile drug preparations, aseptic techniques or practices must demonstrate competency in evaluating the skills of those persons engaged in compounding sterile drug preparations.
>
> *Need for Recommended Change*: Ensuring the person engaged in compounding sterile preparations successfully demonstrates aseptic technique is necessary for contributing to a sterile environment and patient safety. However, it is not necessary for supervising pharmacists, who are not engaged in compounding, to demonstrate aseptic technique, and in fact, invites undue contamination risk due to unnecessary personnel entering a sterile environment in order to comply with the regulation. We do agree that additional regulatory language may be necessary that specifies the manner in which a supervising pharmacist shall demonstrate competency to assess the pharmacist engaged in compounding as having met the aseptic practice skills assessment.

…

1751.7(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 performed in accordance with USP chapter 71 ~~compliant and~~ or an equivalent method. If sterility testing methods other than those described in USP Chapter 71 are used, the testing method must demonstrate documented equivalent or superior

effectiveness as USP chapter 71 methodology. ~~P~~pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits~~, before dispensing~~. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic, irrigation, and inhalation preparations.

Need for Recommended Change: This change brings consistency and uses language from USP 797, which allows end product sterility to be achieved using USP 71, or alternative methods that meet or exceed the USP 71 standard. The proposed changes ensure consistency and clarity as to the standard that all sterility testing methods must meet pursuant to USP 797. The addition of irrigation preparations to the exemptions for pyrogen testing are consistent with the other preparations listed for exception. After preparation, irrigations are often placed into nonsterile delivery mechanisms for patient care. Pyrogen testing these medications is therefore unnecessary and delays patient care.

5. Under what conditions can a BUD be extended?

As specified in CCR section 1735.2(i)(1-6), a beyond use date can be extended if it is supported by a potency over time study applicable to the compounded formulation. In addition, ~~A~~as specified in CCR section 1735.2(i)(3), a BUD for a sterile compounded preparation can be extended if it is supported by the following:

(A) Sterility testing methods are supported by Method Suitability Tests, AND

(B) Container closure types are supported by Container Closure Integrity Tests, AND

(C) ~~Stability Studies~~ Sterility testing performed in accordance with USP 797.

Need for Recommended Changes to FAQ #5: Modifications to this FAQ are necessary to align with the recommended changes pursuant to CCR 1735.2(i).

…

14. Can I use a stability study done by a third party to assign the BUD of my compounded preparation?

The pharmacist performing or supervising the compounding is responsible for exercising his or her professional judgment with regard to beyond use dating. CCR section 1735.2(i)(4) does not prohibit reliance on third-party stability studies, if all of the following conditions are met:

- The drugs or compounded drug preparation tested and studied use ~~are identical~~ analogous ~~in~~ ingredients.
- ~~The specific and~~ There is no substantial variation in the essential compounding steps ~~and quality reviews are identical~~.
- The packaging of the finished drug or compounded drug preparation is ~~identical~~ equivalent to the packaging of the drug or compounded drug preparation tested or studied.

Need for Recommended Changes to FAQ #14:

Modifications to this FAQ are necessary to align with the recommended changes pursuant to CCR 1735.2(i)(4).

May 19, 2017

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd, Suite N 219
Sacramento, CA 95834
Sent via Email to: Virginia.Herold@dca.ca.gov

Re: International Academy of Compounding Pharmacists Supports the California Pharmacists Association's Modifications to Sections 1735 and 1751

Dear Ms. Herold:

The International Academy of Compounding Pharmacists (IACP) represents more than 3,600 pharmacists, technicians, students, and members of the compounding community who focus on the specialty practice of pharmacy compounding. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians to create customized medication solutions for patients and animals whose health care needs cannot be met by manufactured medications. IACP works diligently to preserve patient access to these vital compounded medications.

IACP would like to thank the California Board of Pharmacy, Enforcement & Compounding Committee (the "*Committee*") for this opportunity to present thoughts on current regulations applicable to compounding pharmacies. IACP supports the Committee's mission to ensure that patients throughout the State of California receive safe, effective and quality compounded medications. IACP understands and supports the need to protect public health. However, when developing and implementing regulations, it is essential to preserve patient access to vital compounded medications, the physician-patient-pharmacist triad, and the right of a patient to choose their pharmacist. Prescribers must have the right to prescribe medications that best fit the needs of their patients and patients.

IACP has reviewed the current California regulations and has heard from pharmacists as well patients that specific provisions of the regulations are causing significant constraints in patients being able to access care resulting in decreasing patient access to vital compounded medications. Additionally, IACP had the opportunity to review the recommendations being submitted by the California Pharmacists Association (CPhA) and would like to take this opportunity to express full support for the CPhA's proposed modifications to Sections 1735 and 1751 of the California Code of Regulations. The proposed changes are necessary to ensure that Sections 1735 and 1751 conform to other standards currently governing compounding pharmacies. The CPhA's recommendations will safe-guard patient safety and place the regulations in line with best practices while also preserving patient access to compounded medications.

In particular, CPhA's amendments to Section 1735.2(i), related to beyond use dates, are necessary to ensure consistency and clarity among all requirements governing compounding pharmacies. As it stands, the current iteration of Section 1735.2(i) is confusing and compounding pharmacies often struggle to determine what testing requirements apply under the circumstances. In addition, the testing requirements set forth in Section 1735.2(i) appear to exceed USP <795> and <797> standards. In fact, they appear to mimic current Good Manufacturing Practices ("*cGMP*") requirements, which are applicable to drug manufacturers and not compounding pharmacies.

Unlike drug manufacturers, compounding pharmacies prepare unique medications for particularized medical needs when a prescriber determines a commercially available drug is not suitable for treatment. The Food Drug & Cosmetic Act ("*FDCA*") requirements for manufactured drugs, including cGMPs, were not designed for these specialized medications. CGMP testing practices are extremely expensive and are therefore not economically practical when small amounts of customized drug product are being produced. This is one of the very reasons why commercial drug manufacturers only produce very large quantities of medication in standardized strengths and dosage forms. Compounding pharmacies cannot, therefore, with any economic feasibility, comply with cGMP testing requirements. If compounding pharmacies were required to comply with cGMP, the increased cost to do so would either be passed on to patients or result in pharmacies discontinuing compounding activities. In either case, patients would suffer due to drastically increased prices and restricted access to necessary medications.

IACP appreciates the opportunity to fully support CPhA's recommendations and request full adoption. IACP wishes to work with the Committee toward the mutual goal of protecting and promoting the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals while preserving patient access to vital compounded medications.

Sincerely,

Cynthia Blankenship

Interim Executive Vice President, IACP

Of Counsel, Rose Law Firm

BOP CCRs 1735 & 1751 – Kaiser Permanente Requests for Clarification

1) **Clarify language regarding the definition of a hazardous drug CCR 1735.1(r)**

   1.) USP 800, Section 2 states "an entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles"
   2.) CCR 1735.1(r) – "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.
   3.) CCR 1735.6(e) requires a negative pressure room for all hazardous drug compounding
   4.) Compounding of all NIOSH drugs including Table 2/3 drugs requires a negative pressure room if an organization adopts the NIOSH list

   Request concordance with USP 800 definition of HD (all NIOSH tables) by 7/1/18.

2) **CCR 1751.1(a)(5) - Video of smoke studies in all ISO certified spaces.**
   - Request to clarify required locations for smoke studies. Does this include ISO 7 and ISO 8 certified spaces?
   - Request to clarify frequency of smoke studies. Required every 6 months or only during initial certification?

3) **CCR 1751.4(d) - Cleaning shall be done using a germicidal detergent and sterile water.**
   - Provide a cleared definition of germicidal.
   - Request to add after "Cleaning shall be done using a germicidal detergent and sterile water" the following: "The use of a ready-to-use germicidal detergent including sterile water is acceptable."

4) **CCR 1751.4(g)(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*.**
   - This is the only mention of "two pairs of sterile ASTM D6978-05 standard gloves".
   - Recommend adding a requirement for two pairs of ASTM D6978-05 standard gloves for all HD compounding

5) **CCR 1751.3 requires a sampling plan specific to viable air, surface and nonviable particle sampling. Additionally, CCR 1751.4 requires viable surface and air sampling shall be done at least every 6 months for all sterile to sterile compounding.**
   - Request to clarify need for a sampling plan for the segregated compounding area outside of the ISO-5 environment. Is the sampling plan and procedures for nonviable particle sampling as well as viable air and surface limited to ISO certified areas? OR does the BOP expect to see a sampling plan for segregated compounding area outside the ISO-5 environment?

BOP CCRs 1735 & 1751 – Kaiser Permanente Requests for Clarification

6) **CCR 1735.6(f) states "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)."**

   CCR 4123. Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
   Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

   - CCR 4123 allows for compounding of parenteral (sterile) products from one licensed pharmacy to another licensed pharmacy.
   - Request to clarify if non-sterile hazardous drugs fall under CCR 4123 for pharmacies with waiver denials.

LETCO MEDICAL

QUALITY COMPOUNDING STARTS HERE

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May 22, 2017

VIA FEDERAL EXPRESS

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

RE: INTERPRETATION OF THE WORD "IDENTICAL" IN COMPOUNDING REGULATIONS

Dear Ms. Herold:

Please accept this letter from Letco Medical LLC ("Letco") in support of the comments to be provided at the June 2, 2017 Enforcement and Compounding Committee Meeting. Letco is a licensed California wholesale distributor (WLS 6763) and appreciates the opportunity to present its concerns to the Board.

We respectfully ask the Enforcement and Compounding Committee and the Board to address its interpretation of the word "identical" in CCR Sections 1735 et seq., and specifically C.C.R. § 1735.2(i). This section of the compounding regulations allows a pharmacy to extend a beyond use date (BUD) if the extension is supported by Method Suitability, Container Closure Integrity and Stability testing. To rely on those studies, subsection 4 requires that "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."

Our request for clarity is focused on the word "identical". It has come to our attention that the Board and/or others in the industry are interpreting that term very narrowly. Specifically, it has been stated that the word "identical" means that a compounder must use the same manufacturers for the active and inactive ingredients, exactly the same container closure, and the same NDC used in the underlying studies to rely on the extended BUD supported by those test results. This interpretation is problematic as it is unnecessarily restrictive, outside of industry standards, limits California patients' access to safely compounded drugs, and benefits only a small number of participants in this market.

Such a narrow interpretation of "identical" is unreasonable and burdensome. Active pharmaceutical ingredients as well as excipients and dietary supplements are often produced by only one manufacturer globally and are then repackaged into smaller containers, resulting in different NDCs for the exact same product. These repackaged products are in smaller, more user-friendly volumes that eliminate pharmaceutical waste and decrease costs to health care consumers. Allowing a pharmacy to rely on third party studies for extended BUDs, but requiring them to use only the exact same components used in the supporting studies limits a pharmacy's ability to source product freely in the marketplace in times of a shortage, product discontinuation and/or to find a better price. Under this narrow reading of the rule, if the pharmacy or hospital itself performed the testing, this interpretation also invalidates those studies if the NDC changes. For example, if the manufacturer holding the NDC stops producing that product, either based on an emergency or a business decision, pharmacies and hospitals would need to conduct their own expensive testing on different analogous products so that they can continue to compound the medication. These restrictions unreasonably limit a compounding pharmacist's ability to

compound a product needed by a patient, when there is no evidence or scientific authority that supports an interpretation that the referenced studies are only reliable when the exact same NDC is used.

Furthermore, this narrow interpretation is unnecessary if the goal is to protect the health and safety of California residents. A broader interpretation of "identical" as referring to analogous products is consistent with <USP 797> and USP/NF monographs that ensure the active pharmaceutical ingredients, excipients, and dietary supplements meet standards for suitability and purity; therefore, ingredients from different manufacturers are safe to use interchangeably. It is for these reasons that the prevailing standard nationwide is to allow pharmacies to rely on third-party studies but use analogous underlying components – and not solely the same NDCs – a prevailing standard that has shown to be safe and effective.

Finally, there are only a few entities in our industry who are large enough to afford such studies, making this narrow interpretation hurtful to smaller wholesalers, pharmacies and hospitals who cannot produce their own studies. Larger wholesalers who can conduct their own studies using their own product lines benefit, as the narrow interpretation of "identical" would require pharmacies to use that wholesaler's products to adopt the extended BUDs from the studies that the wholesaler performed or commissioned. Smaller wholesalers cannot afford to conduct these studies for all of their products, and smaller hospitals and pharmacies cannot afford to conduct these studies on their own. This interpretation would have a significant effect on smaller wholesalers that provide the exact same product to pharmacies now, only with different NDCs. These smaller wholesalers may be forced to leave the California market, decreasing availability and increasing the price of the product for California pharmacies and the patients that receive these medications. Pharmacies have been using analogous products interchangeably for years safely and effectively; forcing them to alter their relied-upon suppliers and compounding processes to strictly replicate these studies may be difficult, expensive or even impossible based on availability.

All of these arguments also apply to the interpretation of "identical" as it applies to container closure systems. Different manufacturers can make analogous closure systems, or a pharmacy may elect to use a closure system that is analogous or *better* per USP standards, yet a strict interpretation of the word "identical" would limit the pharmacy to using the exact same closure system. As noted above, if that container manufacturer should have supply chain issues or cease manufacturing that container closure, the pharmacy would have to find a different study of that compounded drug using a different container closure. The pharmacy would then have to look at the remaining components of the new study to ensure that it has or can obtain access to that study's components, and may find that it has to purchase all new API and inert ingredients (hoping that all of those are still on the market) so that what they compound is strictly "identical" to the components in the new study.

In conclusion, we ask the Committee and the Board to adopt a more reasonable definition of "identical", either via rulemaking or through the adoption of a practical interpretation of the rule as written, that allows "identical" to be interpreted as it has been for decades and across the country in <USP 797> and traditional compounding resources. We ask the Board for an interpretation that the word "identical" means that the components in the compounded drug be of an analogous strength, form, and container closure as the product in the underlying study, and not that they be *exactly* identical to the components in the underlying study. Any different interpretation would affect the health and safety of California residents by arbitrarily and unnecessarily restricting a pharmacy's ability to rely on third party studies and components proven to be safe and effective, therefore restricting their ability to provide safe, effective, prompt and economical care to California patients.

We thank you for your thoughtful consideration of this request.

Sincerely,

LETCO MEDICAL, LLC:

By: 

Douglas E. Bowman
Chief Executive Officer

RITE AID PHARMACY

Daniel Miller
SVP, Pharmacy Regulatory Affairs

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March 13, 2017

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

Dear Executive Officer Herold:

Due to the new regulatory requirements enacted by your Board of Pharmacy, and the associated cost to maintain compliance, Rite Aid is considering discontinuing the practice of compounding in approximately 506 of our 583 California pharmacy locations. This difficult decision has been made after a thorough review of the amendments to §1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations, as well as Rite Aid business practices and fiscal responsibilities. The intent of this letter is to inform you of the financial implications of the newly amended regulation, and its potential consequences that restrict access to patient care. Please recognize that only *simple and moderate, non-sterile* compounding (e.g. magic mouthwash prepared from a kit or the mixing of 2 creams from a manufacturer's packaging) is currently permitted at Rite Aid pharmacies.

Section 1735.8 of the amended regulation titled Compounding Quality Assurance states that "*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.*" It has been determined that the cost associated with such required annual testing and analysis for 506 of our pharmacies far exceeds the total profitability of prescriptions compounded annually in the majority of our pharmacies. Therefore, it is not fiscally responsible for Rite Aid pharmacies that compound low volumes of necessary prescriptions for their patients to continue to do so.

Rite Aid will continue to prioritize and promote patient safety in all aspects of pharmacy practice. It is our hope that the said component of the newly amended regulation will be reconsidered in the near future to enhance patient care access to simple and moderate non-sterile prescription compounding for all California residents. Rite Aid and its predecessors have been serving California patients for over 50 years by compounding their prescribed non-sterile medications safely. Today, our pharmacies provide convenient access for all professional services in the community setting for immunization, dispensing, medication counseling, and compounding, when necessary. Pharmacists are highly educated professionals who are trained in Pharmacy School or College to compound many types of medications, and it is unfortunate that we may have to restrict their practice around this valuable patient service in the near future.

Sincerely,

Daniel Miller

Daniel Miller, R.Ph.
SVP, Pharmacy Regulatory Affairs

Proposed Changes to California Compounding Regulations
April 25th, 2017
Rick Rhoads, Pharm.D.

Introduction: The new California Compounding Regulations were a step in the right direction to protect patient safety in California, but there are still gaps pertaining to quality that should be addressed. There are also potential inconsistencies with the USP which may contribute to confusion in the industry. Although the best approach would be to adopt USP chapters <795>, <797>, and <800>, there may be good reasons it is not feasible for the board to do so.

As a "next step" to address the most pressing issues related to gaps and inconsistencies, the following changes to CCR 1735 and 1751 are proposed.

Proposal 1: Add detail to the process validation requirements in the policies and procedures section. This is important as there are currently no standards given in the regulations for verifying the effectiveness of sterilization and depyrogenation methods.

Proposed 1751.3 (c)
(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.~~
(1) A description of the sterilization and depyrogenation process, including the temperature, pressure (if applicable), duration, and permissible load conditions for each cycle.

(A) In addition, the SOPs must include a schedule and method for establishing and periodically verifying the effectiveness of the sterilization and depyrogenation methods selected, as well as the method for maintaining and cleaning the sterilizers and depyrogenation equipment.

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

Reference: Proposed Revision USP <797>

Proposal 2: Add a new section in 1751 for Sterilization and Depyrogenation requirements. Again, there are no current requirements in California regulations for sterilization and depyrogenation methods. Although there were many problems at NECC, some of the disastrous consequences could have been prevented if they followed the standards for cleaning, operating, and verifying the sterilizing cycles of their

autoclaves. These standards are needed for all the major methods of drug and component sterilization. The following language is essentially verbatim from the proposed revision of USP 797, which is very similar to the current version.

1751.11 Sterilization and Depyrogenation
(a) When selecting the sterilization method for each non-sterile to sterile CSP, personnel must take into consideration the nature of the components, its physical and chemical properties, and the intended container– closure system.

(b) The sterilization method used must sterilize the CSP while maintaining its physical and chemical stability (i.e., appropriate strength, purity, quality), and the packaging integrity of the CSP.

(c) Utensils and materials in direct contact with the components, the CSP, and the container–closure system must be sterilized and depyrogenated using appropriate methods. If sterilization and depyrogenation of container–closure systems is performed on site, the efficacy of each process must be established and documented, and the process must be shown to be reproducible.

(d) The following sections provide minimum requirements on specific sterilization methods.

(1) Sterilization by Filtration

(A) Commercially available sterile filters must be certified by the manufacturer as suitable for pharmaceutical use when used to sterilize CSPs. Sterilizing filters must be sterile and pyrogen-free and have a nominal pore size of 0.2 or 0.22 µm. They must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (i.e., pressure, flow rate, and volume filtered).

(B) The supervising pharmacist must ensure, directly or from appropriate documentation from the supplier, that the sterilizing grade filters 1) are chemically and physically stable at the pressure and temperature conditions that will be used; 2) have enough capacity to filter the required volumes; and 3) will yield a sterile filtrate while maintaining pre-filtration pharmaceutical quality, including strength of ingredients of the specific CSP.

(C) The filter dimensions and the preparation to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process.

(D) When CSPs are known to contain excessive particulate matter, to maximize the efficiency of the final sterilizing filtration, a pre-filtration step should be performed using a filter of larger nominal pore size, or a separate filter of larger nominal pore size should be placed upstream of (i.e., prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing grade filter.

(E) Filter units used to sterilize CSPs must be subjected to the manufacturers' recommended post–use integrity test, such as a bubble point test.

(2) Sterilization by Steam Heat

(A) The process of thermal sterilization using saturated steam under pressure (i.e., autoclaving) is the preferred method for terminal sterilization of aqueous preparations in their final, sealed container–closure system. Steam heat sterilization is not an option if moisture, pressure, or the temperatures used would degrade the CSP. Steam heat sterilization is also used to sterilize many components (e.g., elastomeric closures) and some types of equipment.

(B) To achieve sterility, all materials must be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile (i.e., kill any microorganisms, including bacterial spores that might be present).This is usually between 20 and 60 minutes at 121° saturated steam under a pressure of 15 psi. The duration of the exposure period must include sufficient time for the CSP or other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period.

(C) The sterilization cycle should be designed to achieve a SAL of 10^6. CSPs must be placed in suitable trays to allow steam to reach the CSPs without entrapment of air. Flat, stainless steel trays with low sides or ventilated bottoms will permit steam contact. When preparing plastic, glass, and metal devices or other items for steam sterilization, the items must be wrapped in low-lint protective fabric or paper or sealed in envelopes that will permit steam penetration and prevent post sterilization microbial contamination.

(D) Immediately before filling ampuls and vials that will be steam sterilized, solutions must be passed through a filter having a nominal pore size of not larger than 1.2 µm for removal of particulate matter.

(E) Sealed containers must be able to generate steam internally. Stoppered and crimped empty vials must contain a small amount of moisture to generate steam. Deep containers, such as beakers and graduated cylinders, should be placed on their sides to prevent air entrapment, or should have a small amount of water placed in them when steam sterilized.

(F) Porous materials and those items with occluded pathways (e.g., tubing) should only be sterilized by steam if the autoclave chamber has suitable cycles for dry goods, such as a pre-vacuum process to remove air before steam is sent into the chamber. Elastomeric closures and many other dry goods will need a drying cycle after steam exposure to remove condensed or absorbed moisture.

(G) The effectiveness of steam sterilization must be established and verified with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus, ATCC 12980, ATCC 7953 or equivalent, and other confirmation methods such as physicochemical indicators and integrators.

(H) The steam supplied must be free of contaminants and generated using clean water.

(I) The seals on the doors of autoclave chambers should be examined visually every day they are used for cracks or other damage, and the seal surfaces should be kept clean. A data recorder or chart must be used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure).

(J) Because the temperatures used to achieve sterilization by steam heat are lower than those used to achieve depyrogenation, materials in direct contact with the CSP (e.g., the container–closure system) must first undergo a depyrogenation process (e.g., dry heat or rinsing with pyrogen-free water) before being sterilized using steam heat, unless the materials used are certified to be pyrogen-free.

(3) Sterilization by Dry Heat

(A) Dry heat can be used only for those items that cannot be sterilized by steam or other means, when either the moisture would damage the material or the wrapping material is impermeable.

(B) Sterilization by dry heat requires higher temperatures and longer exposure times than sterilization by steam. The duration of the exposure period must include sufficient time for the CSP or other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the

sterilization period. Dry heat sterilization is usually done in an oven designed for sterilization at a temperature of 160° or higher, although sterilization processes at lower temperatures have been developed and validated. If lower temperatures are used, they must be shown to achieve effective sterilization.

(C) Heated air must be evenly distributed throughout the chamber, which is typically done by an air blower. The oven must be equipped with temperature controls and a timer. During sterilization, sufficient space must be left between materials to allow for good circulation of the hot air. A data recorder or chart must be used to monitor each cycle and the data must be reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time).

(D) The effectiveness of the dry heat sterilization method must be established and verified with each sterilization run or load using appropriate biological indicators such as spores of Bacillus atrophaeus, ATCC 9372, and other confirmation methods (e.g., temperature-sensing devices). Because the temperatures used to achieve sterilization by dry heat are lower than those used to achieve depyrogenation, materials in direct contact with the CSP (e.g., the container–closure system) must first undergo a depyrogenation process (e.g., dry heat or rinsing with pyrogen-free water) before being sterilized using dry heat, unless the materials used are certified to be pyrogen-free.

(4) Depyrogenation by Dry Heat

(A) Dry heat depyrogenation must be used to render glassware and other thermostable containers pyrogen-free.

(B) Depyrogenation processes typically operate at a range of temperatures from approximately 170° up to about 400°, depending on the exposure time. For example, a typical cycle would hold the items at 250° for 30 minutes. The duration of the exposure period must include sufficient time for the items to reach the depyrogenation temperature. The items must remain at the depyrogenation temperature for the duration of the depyrogenation period.

(C) The effectiveness of the dry heat depyrogenation cycle must be established and verified annually using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥3-log reduction in endotoxins.

Reference: Proposed Revision USP <797>

Proposal 3: The current definition of hazardous drugs in CA regulations creates uncertainty and confusion. NIOSH drugs other than anti-neoplastics are not included in the definition, but there is an implication they should be dealt with in a certain way, either by classifying as hazardous or conducting an assessment of risk. I have heard of enforcement issues related to this confusion as well. A better approach would be to harmonize the definition with USP <800> and allow for an AOR for drugs that are not antineoplastic. This makes it very clear and is consistent with the pharmacy's obligations under federal regulations. Currently if these drugs are classified as hazardous, there is no provision in the CA regulations to modify work practices based on the safety profile of the drug and dosage form. Several sections of the HD regulations are affected.

Proposed 1735.1 (r)

(r) "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

Proposed 1735.6 (e)

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

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs 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 in the room shall also be externally ~~vented~~ **exhausted**, and

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

(5) Exception: For dosage forms of other HDs on the NIOSH list that are not antineoplastics, the pharmacy may perform an assessment of risk to determine alternative containment strategies and/work practices to the above requirements.

(A) The assessment of risk must, at a minimum, consider the following: Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk), Risk of exposure, Packaging, Manipulation)

(B) If an assessment of risk approach is taken, the pharmacy must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least annually and the review documented.

Reference: USP <800>

1751.4. Facility and Equipment Standards for Sterile Compounding

(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) Exception: For dosage forms of other HDs on the NIOSH list that are not antineoplastics, the pharmacy may perform an assessment of risk to determine alternative containment strategies and/work practices to the above requirements.

(A) The assessment of risk must, at a minimum, consider the following: Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk), Risk of exposure, Packaging, Manipulation)

(B) If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least annually and the review documented.

Reference: USP <800>

Proposal 4: Modify and clarify the testing requirements for extending BUDs. These should be more specific and appropriate based on the type of compound. Also, it is not clear what is meant by 'method suitability test'. Generally, this term refers to a test associated with USP <71> sterility testing. Although method suitability is necessary for all USP <71> sterility testing, it seems to be an unnecessary requirement for extending the BUD.

Proposed 1735.2 (i)(3)
(3) Extension of a beyond use date is only allowable when supported by the following:
(A) ~~Method Suitability Test,~~
(A) Studies demonstrating chemical, physical, and microbiological stability, and
(B) Anti-Microbial Effectiveness Testing for multi dose containers, and
(C) Container Closure Integrity Testing for sterile preparations.

Reference: USP <1191> Stability Considerations in Dispensing Practice

Proposal 5: Add a definition for stability.

Proposed 1735.1
<u>"Stability" is defined as the extent to which a preparation retains, within specified limits, and throughout its period of storage and use (i.e., its shelf-life), the same properties and characteristics that it possessed at the time of its compounding.</u>

Reference: USP <1191> Stability Considerations in Dispensing Practice

Dear Board Member

Thank you for the opportunity to speak before the subcommittee on the ramifications of recent pharmacy regulations within the compounding industry.

Given the lateness of the meeting we did not have the chance to address concerns addressed by the enforcement team. At least 32 states have essentially adopted USP as their guidance in proper compounding procedures. With its GMP-like standards for ***non-sterile compounds***, 1735 far exceeds USP in a number of areas that, as noted in the meeting, are unwarranted and very expensive.

Stability

USP	1735
	There is no clarity about the nature of the stability testing. Our fear is that CA will insist on forced degradation testing for compounds which is inappropriate, unnecessary and sometimes misleading.

Container Closure

USP	1735
While compounders shall ensure containers meet USP requirements, "compounders are not expected to perform the tests".	Regardless of sterile versus non-sterile, 1735.2 requires BUD extension ONLY in the presence of **Container Closure Integrity testing,** Stability Studies and Method Suitability testing (addressed in USP 797 for STERILE items).

Sterility

USP	1735
No reference in USP for sterility of non-sterile compounds	Regardless of sterile versus non-sterile, 1735.2 requires BUD extension ONLY in the presence of Container Closure Integrity test, Stability Studies and **Method Suitability** testing (addressed in USP 797 for STERILE items).

Testing Frequency

USP	1735
No mention of annual testing	Specifies annual testing, regardless of consistency of formulation.

In 1735.2, *"the prescriber has approved use of a compounded drug either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding."*

Documentation of the use for a compound is equally problematic, especially in veterinary medicine, where there are many off-label conditions that can be associated with the use of a compound. Even the AVMA recommends this action might be best left to the individual medical record where quantity, lot number and rationale for the use of a compound can be noted.

In 1735.2, *"…using a purchase order or other documentation…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."*

USP makes no reference toward mandating forecasts for office stock items—an impossibility in the veterinary community.

Lastly, as you may know, the President has signed the Congressional Omnibus bill into law, H.R. 244. The language calls on FDA to release new guidance to allow **503A** pharmacists to compound for "office-use" for prescribers, hospitals and other health systems. Congress expressed concern that patient access is decreasing to compounded medications, due to FDA's implementation actions of prohibiting all office-use compounding even where "this practice is authorized in the vast majority of states and was intended to be allowable under DQSA."

California wisely allows for office stock for veterinary practitioners for acute needs until a follow-on prescription can be obtained. Clinics should be afforded the best possible dating for these medications, hence the need to pursue optimum Beyond Use Dating.

Thank you for your consideration of these issues in the June emergency meeting. I'm confident compounders will provide you with even more insight than these points.

Regards,

Bruce Dell, R.Ph.
General Manager

SENT VIA EMAIL

May 19, 2017

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Herold:

Wedgewood Village Pharmacy, LLC ("*Wedgewood*") would like to thank the California Board of Pharmacy, Enforcement & Compounding Committee (the "*Committee*") for this opportunity to present its thoughts on current regulations applicable to compounding pharmacies. Wedgewood believes in the Committee's mission to ensure that patients throughout the State of California receive safe, effective and quality compounded medications. With that in mind, Wedgewood fully supports the California Pharmacy Association's ("*CPhA*") proposed modifications to Sections 1735 and 1751 of the California Code of Regulations. The proposed changes ensure that Sections 1735 and 1751 conform to other standards currently governing compounding pharmacies.

In particular, CPhA's amendments to Section 1735.2(i), related to beyond use dates, are necessary to ensure consistency and clarity among all requirements governing compounding pharmacies. As it stands, the current iteration of Section 1735.2(i) is confusing and compounding pharmacies often struggle to determine what testing requirements apply under the circumstances. In addition, the testing requirements set forth in Section 1735.2(i) appear to exceed USP <795> and <797> standards. In fact, they appear to mimic current Good Manufacturing Practices ("*cGMP*") requirements, which are applicable to drug manufacturers and not compounding pharmacies.

Unlike drug manufacturers, compounding pharmacies prepare unique medications for particularized medical needs when a prescriber determines a commercially available drug is not suitable for treatment. The Food Drug & Cosmetic Act ("*FDCA*") requirements for manufactured drugs, including cGMPs, were not designed for these specialized medications. cGMP testing practices are extremely expensive and are therefore not economically practical when small amounts of customized drug product are being produced. This is one of the very

reasons why commercial drug manufacturers only produce very large quantities of medication in standardized strengths and dosage forms. Compounding pharmacies cannot, therefore, with any economic feasibility, comply with cGMP testing requirements. If compounding pharmacies were required to comply with cGMP, the increased cost to do so would either be passed on to patients or result in pharmacies discontinuing compounding activities. In either case, patients would suffer due to drastically increased prices and restricted access to necessary medications.

In addition, Wedgewood wishes to submit its own proposed amendments to Section 1735.2(c), related to office use, and Section 1735.2(d) (Attachment A). Wedgewood believes its proposed changes are necessary to ensure patient access to needed compounded medication. A copy of the proposed amendments are attached hereto. With respect to office use, prescribers are often presented with patients who have an immediate need for compounded medication. These patients cannot wait for a pharmacist to fill a prescription. As a result, prescribers must have office stock on hand to treat patients that present with urgent medical needs. In turn, compounding pharmacies must be allowed to dispense compounded medication for office use so that prescribers have access to compounded medication in advance of examining patients. The California Board of Pharmacy acknowledges the need for this practice within Section 1735.2(c), however within that section there is some office use quantity requirements that are unclear and potentially not practical.

For example, a veterinarian sees a variety of animal species and sizes on any given day. As a result, medication dosage amounts and frequencies vary greatly. It is neither practical nor reasonable to expect the veterinarian, in advance of knowing the species and size of the animal patient, to: (1) anticipate the quantity of drug sufficient to treat the patient; and (2) anticipate the amount of drug needed to be administered to the patient versus the amount of drug that constitutes a 120 hour supply for the patient. Wedgewood's proposed changes to Section 1735.3(c) ensure that California's regulations allow for the practical application of office use compounding.

As for Wedgewood's proposed amendment to Section 1735.2(d), Wedgewood has added the word "human" to clarify that the limitations of sub-sections (1) through (3) are applicable to only human health compounding. The language currently used in sub-sections (1) through (3) mirrors the language of the Drug Quality Security Act ("DQSA"), which only applies to human health compounding. DQSA was explicitly not intended for veterinary compounding. Moreover, the ASHP drug shortage list does not include veterinary drugs. The inclusion, therefore, of the term "human" in Section 1735.2(d) will ensure consistency with federal law.

Wedgewood is aware that other compounding pharmacies have stopped dispensing into California as a result of California's restrictive regulations. As a result, patients throughout the State of California may not be able to get the

compounded medications they need and may be forced to go untreated. Wedgwood believes the CPhA's proposed amendments, along with Wedgwood's own proposed amendments, will provide consistency and clarity among all requirements governing compounding pharmacies and allow patients who depend on compounded medications to continue to have full access.

Wedgewood appreciates the opportunity to present its proposed amendments to the Committee and is available to answer any questions the Committee may have. Wedgewood wishes to work with the Committee toward the mutual goal of protecting and promoting the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals.

Sincerely,

Marcy A. Bliss
President & CEO

Anthony Grzib
Director of Pharmacy Compliance

cc: A. Lynch – Pharmacist-in-Charge

Attachment: Attachment A

WEDGEWOOD VILLAGE PHARMACY, LLC
ATTACHMENT A

CCR 1735.2(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 use ~~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~~ concurred is a reasonable quantity for office use as determined by the prescriber considering the potential 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~~ compounding 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.

Need for Recommended Changes:

- Alterations to sub-section (1) are needed to account for the fact that compounded medications ordered for office use are often medications needed to treat immediate medical needs of patients who have not yet presented to the prescriber. As such, these medications are typically ordered by prescribers in advance of examining patients. Because of the variation of animal species and sizes that may present to the prescriber, medication dosage amounts and frequencies vary greatly. Therefore, it's neither practical nor reasonable to expect a prescriber, in advance of knowing the species and size of veterinary patients yet to be seen, to:
    - Anticipate the quantity of drug sufficient to treat each patient, and
    - Anticipate the amount of drug needed to be administered to each patient versus the amount of drug that constitutes a 120 hour supply for each patient.
- For the same reason, sub-section (3) needs to be altered to remove the requirement that the prescriber document these yet-to-be determined quantities of drug sufficient to treat each patient.

- Alterations to sub-section (4) are needed to remove the requirement that pharmacist establish and document a creditable basis for the quantity of compounded medication being ordered by the prescriber. In sub-section (1) and sub-section (3), the prescriber is permitted

to determine the amount of medication they're ordering from the pharmacy for office use based on the number of anticipated patients they may see and estimated quantities of medication they may need. It's unclear how a pharmacist can be accountable for establishing and documenting a creditable basis for the prescriber's patient forecast and medication quantity estimates.

- Alterations to sub-section (5) are needed to clarify that the standards used by the compounding pharmacy to produce the compounded medication are standards applicable to pharmacy compounding, not standards applicable to pharmaceutical manufacturing.

CCR 1735.2(d) No pharmacy or pharmacist shall compound a human 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.

Need for Recommended Change: The addition of the word "human" to section (d) is required to clarify the limitations of sub-sections (1) through (3) are applicable to only human health. The language used in sub-sections (1) through (3) mirror the language in the Federal DQSA, which itself is applicable to only human health. In addition, the ASHP drug shortage list does not include veterinary drugs.

Section	Requestor	Summary of Request	Background Information Provided Staff
1735	• Road Runner	1735 far exceeds USP in a number of areas	As part of the development of the board's regulations, consideration was given to USP requirements as part of the foundation for the regulations. USP is a scientific nonprofit organization that sets standards to the identity, strength, quality and purity for specific items, including medicines. The USP-NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Specific to compounded preparations, USP provides both general chapters and monographs. There are several relevant chapters used as reference when promulgating the current version of the regulations.
1735	Board staff	Expand the definition to include that combining ingredients from a manufacturer's kit does not constitute compounding.	Some FDA manufacturers sell compounding kits for oral and topical drug preparations, for example prescription mouthwash. These kits include the ingredients and compounding instructions. The kits are issued a national drug code (NDC) by the FDA. The Inclusion of a firm or its products in the NDC directory does not denote approval by the FDA of the firm or any of its marketed products, nor is it a determination that a product is a drug as defined by the Federal Food, Drug and Cosmetic Act.
1735.1 (l)	• CPhA • IACP	Amend the definition of "daily" to specify that electronic monitoring of temperatures is allowable.	Section 1735.1 includes definitions for various words and phrases that are then referenced throughout the remainder of the compounding regulations to ensure the board and its regulated public have a common understanding of terms used.

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Section	Requestor	Summary of Request	Background Information Provided Staff
1735.1(n)	• CPhA • IACP	Amend the definition of "dosage unit" to beyond one administration and allow for one "dosage unit" to be one prescription.	Aside from the definition, the term "dosage unit" is referenced in the definition of a "non-sterile-to-sterile batch" [1735.1(v)] The definition of "non-sterile-to-sterile batch" then determines several other requirements including when end product testing should occur and the quarantining of such products until the end product testing confirms sterility and acceptable levels of pyrogens. Non-sterile-to-sterile compounding is inherently the most risky form of compounding from a patient safety perspective.
1735.1(r)	• Kaiser • Rick Rhoads	Update the definition of hazardous to mirror USP < 800> by July 1, 2018	USP <800> was published on February 1, 2016 in the First Supplement to USP 39-NF 34. The USP Compounding Expert Committee approved a delayed official implementation date of July 1, 2018 to allow entities additional time to implement the standard. This chapter is designed to protect personnel and the environment when handling hazardous drugs. The definition of hazardous drug in USP <800> is any drug identified by at least one of the following six criteria: • Carcinogenicity • Teratogenicity or developmental toxicity • Reproductive toxicity in humans • Organ toxicity at low doses in humans or animals • Genotoxicity • New drugs that mimic existing hazardous drugs in structure or toxicity. The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other hazardous drugs used in healthcare.
1735.1	• CPhA • IACP	Recommend addition of a definition of sterility	According to USP <1211> within the strictest definition of sterility, a specimen would be deemed sterile only when there is complete absence of viable microoraganisms . This chapter notes that the sterility of a lot purported to be sterile

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Section	Requestor	Summary of Request	Background Information Provided Staff
			is therefore defined in probabilistic terms, where the likelihood of a contaminated unit or article is acceptably remote. This chapter along with USP <71> describe the methods by which sterility is tested as well as the various method that can be used for sterilization.
1735.1	Risk Rhoads	Add a definition of "stability"	USP <1191> defines stability as the extent to which a product retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of its manufacture. As part of this chapter, the responsibility of pharmacists as it related to stability are detailed.
1735.2 (a)	Road Runner	Remove the requirement to document prescriber authorization to compound a product. (Although not specifically stated, staff believes this request is specific to CSPs for animals.)	Section 503A, added to the Food, Drug & Cosmetic Act by the Food and Drug Administration Modernization Act in 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a state licensed pharmacy or federal facility, or by a licensed physician. A compounded drug preparation may be eligible for the exemptions under section 503A of the FD& C act only if it is, among other things, "compounded for an identified patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient." It is customary for a prescriber to notate that a compounded drug preparation is necessary for a patient. When such a notation is not included on a prescription and filling the prescription requires compounding, a pharmacy must contact a prescriber's office to seek approval. When such a

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Section	Requestor	Summary of Request	Background Information Provided Staff
			scenario occurs, the prescriber's approval must be noted on the prescription to memorialize the approval.
1735.2(c)	Wedgewood Village Pharmacy	Expansion of prescriber office use provisions and change in the definition of "reasonable quantity"	Compounding for prescriber office use is currently allowed in board regulation. Because the requirements for compounding a drug preparation are not as extensive as drug products that are manufactured, limitations are generally placed on compounding products for prescriber office use. Further, with the regulation of outsourcing facilities, the need for pharmacies to compound for prescriber office use is reduced because the preparation can be obtained from an appropriately licensed outsourcing facility. Because an entity that only compounds preparations for animal use is not eligible for licensure as an outsourcing facility by the FDA, the question becomes how prescriber's treating animal patients can otherwise take care of their patients. (An entity would be eligible for registration however if even one of the compounding preparations is for human.) Under FDA rules, compounding of animal drugs can be conducted in accordance with the provisions of section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(b)(4) and (5) and 21 CFR part 530. Under federal law a pharmacy may perform anticipatory compounding in "limited quantities before the receipt of a valid prescription order for an individual patient under specific conditions. "
1735.2(d)	Wedgewood Village Pharmacy	Change regulation to indicate that prohibitions to compounding only apply to human drugs	Under the provisions of FD&C Act there are three conditions under which compounding cannot occur including those that are demonstrably difficult to compound or essentially compounds of a commercially available product unless specified conditions are met.

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Section	Requestor	Summary of Request	Background Information Provided Staff
1735.2(i)	Letco Medical	Clarification of the board's interpretation of "identical"	The intent of the board's regulation is to ensure that the same ingredients or components are used. The use of different ingredients or components would require separate consideration when determining the appropriate beyond use dates.
1735.2(i)(1) related to BUDs for nonsterile products	• CPhA • IACP	Clarify the conditions under which a BUD can be extended for a non-sterile compounded preparation.	The beyond use date (BUD) is the date after which a compounded preparation should not be used. It is determined from the date the preparation is compounded. USP <795> notes that compounded preparations are intended for administration immediately for following short-term storage and BUD are established differently than an expiration date of a manufactured drug product. USP notes that a compounder should refer to the manufacturer for stability information and to the literature for applicable information on stability, compatibility and degradation and shall use his or her compounding education and experience.
1735.2(1)(2)	• CPhA	Change the requirements to extend a BUD	Standards for the establishment of a BUD are found in USP <795> and USP <797> for CSPs. As part of the standard in USP <797>, truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. The standard notes the preparation specific, experimentally determined stability data evaluation protocols are preferable to published stability information.
1735.2 (i)(3)	• Rick Rhoads • CPhA • Golden Gate VCP	Change the requirements to extend a BUD.	Standards for the establishment of a BUD are found in USP <795> and USP <797> for CSPs. As part of the standard in USP <797>, truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. The standard notes the preparation specific, experimentally determined stability data evaluation protocols are preferable to published

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Section	Requestor	Summary of Request	Background Information Provided Staff
			stability information.
1732.2(i)(3)	• Golden Gate VCP	Request that the board develop a list of drugs that do require the stability indicating assay.	The board is not aware of any such list.
1735.2(i)(5)	• Golden Gate VCP	Concern with the conditions for establishing a shorter BUD	The language establishing the shorter BUD is not new, under the prior regulation, this provision was included in CCR 1735.2(h).
1735.2	• Road Runner	Make stability, container closure, sterility and testing frequency consistent with USP standards.	Standards for the establishment of a BUD are found in USP <795> and USP <797> for CSPs.
1735.2	• Eye Care for Animals	No specific request was provided	
1735.2 (6)	• CPhA • IACP	Recognition that potency over time studies can be used to validate stability of a preparation and assign extended beyond use dates.	According to USP, tests for strength (potency) are designed to determine how much of an active ingredient is in a sample. Stability tests are used to determine an expiration date of a product or a BUD of a preparation. In the paper written by the USP Compounding Expert Committee, it was noted that being able to understand the difference between strength testing versus stability testing is the key to using the proper method to determine strength or stability, noting that determining the strength may or may not be stability indicating. It continues to state that when determining stability, the method must be stability-indicating noting that when using a stability-indicating method, both strength and stability can be determined. USP also included information on this as part of their FAQs, provided below - - **Q. Is there a difference between testing stability with a strength (potency) or a stability-indicating method?**

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Section	Requestor	Summary of Request	Background Information Provided Staff
			A. Yes, a strength (potency over time) test determines the amount of active ingredient in a preparation, however, it may not be able to separate the inactive ingredient from its degradation products and impurities for quantitation depending on the analytical methods used for the test. A stability-indicating method will be able to quantitate the active ingredient and its degradation products or related impurities in the preparation by separating the inactive ingredient from its degradation products and impurities, and to show a change in the concentration of the active ingredient with increasing storage time. A stability-indicating method is used to determine stability of a drug and used to establish the Beyond-Use Date.
1735.6(e)	• Rick Rhoads	Create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics	Antineoplastic include preparations such as chemotherapy drugs and are included under the general classification of hazardous drugs and defined by NIOSH. USP <800> provides the standards for the handling of hazardous drugs as defined by NIOSH.
1735.8(c)	• NACDS/CRA	Requests the board develop a list of compounds and dosage forms that would be specifically subject to analytical testing.	The regulation section cited establishes the quality assurance measures.
1751.1(a)(5)	• Board staff • CPhA • International Academy of Compounding Pharmacists • Kaiser	Clarify where the smoke studies must be done and establish a frequency	Smoke studies are used to verify air flow within a specified area. For purposes of this regulation, the smoke study is conducted to verify unidirectional airflow and sweeping action over and away from the compounding area and must be conducted under dynamic conditions.
1751.3	• Kaiser	Clarification on what	USP <797> provides standards for the environmental

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Section	Requestor	Summary of Request	Background Information Provided Staff
		environments require a sampling plan	sampling plan including noting that it should be done based on a risk assessment of the compounding activities performed. The standard indicated that the plan shall include sample location, method of collection, frequency or sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.
1751.3(c)	• Rick Rhoads	Provide detailed description of what the SOPs need to include for sterilization and depyrogenation process	Under the proposed revisions to USP <797>, the standards would provide more specificity to the pharmacy's SOPs regarding the sterilization and depyrogenation process. It is board staff's understating that <797> is still undergoing review and it is expected that another iteration of standards will be released for public comment. We are unaware of an anticipated dated for publication. Currently, USP <1211> provides a general description of the concepts and principles involved in the quality control of articles that must be sterile. Five methods of terminal sterilization, including removal of mircoorganisms by filtration and guidelines for aseptic processing are described in the informational chapter.
1751.4	• Board staff	Clarify that cleaning must be done when hazardous drugs are being compounded as well as what environments must be cleaned.	USP <797> notes that environmental contact is a major source of microbial contamination of compounded sterile preparations (CSP). USP notes that as such "scrupulous attention" to cleaning and disinfecting the sterile compounding area is requirement to minimize this as a source of CSP contamination. USP provides specific areas, surfaces and equipment as well as conditions when cleaning is required. Further, USP <800> establishes the requirements for cleaning environments and equipment where hazardous compounding is performed and build up the requirements of USP <797>. The USP <800> requirements are designed to

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Section	Requestor	Summary of Request	Background Information Provided Staff
			minimize exposure to staff as well as the preparations made. USP <797> Appendix II lists common disinfectants used in health care for inanimate surfaces and noncritical devices. Additionally, USP <1072> provides further information on disinfectants and antispectics.
1751.4(d)	• Kaiser	Add a definition of germicidal to allow the use of a ready-to-use germicidal detergent including sterile water.	Part of the USP <797> is the standard for cleaning and disinfecting the sterile compounding area including the appropriate cleaning agents to be used. As part of USP <800>, standards for cleaning areas where hazardous drugs are prepared are detailed, including the use of germicidal detergent with sterile water.
1751.4(d)(1)	• CPhA • IACP	Clarify that cleaning does not need to happen daily, but rather every day the facility is used to prepare sterile drug products.	As noted above cleaning requirements are detailed in several chapters of USP. USP <797> establishes the minimum frequency of cleaning and disinfecting in compounding areas. Specifically it provides ISO Class 5: At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected. Counters and easily cleanable work surfaces: Daily Floors: Daily Walls: Monthly Ceilings: Monthly Storage shelving: Monthly
1751.4(g)(1)	Rick Rhoads	Create an exception allowing a	Antineoplastic include preparations such as chemotherapy

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Section	Requestor	Summary of Request	Background Information Provided Staff
		pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics	drugs and are included under the general classification of hazardous drugs and defined by NIOSH. USP <800> provides the standards for the handling of hazardous drugs as defined by NIOSH.
1751.4(k)	CPhA IACP	Remove the minimum room temperature	As part of its standards, USP <797> includes specifications for the compounding facilities, including room temperature. USP determined that compounding facilities shall provide a comfortable and well-lighted working environment, which typically includes a temperature of 20 degrees C or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.
1751.4(g)(1)	Kaiser	Recommend adding a requirement for two pairs of standard gloves for all hazardous compounding	USP <800> establishes, as part of the standard, the types of gloves that must be worn when personnel are involved in the compounding of hazardous drugs. The standard requires the compounding of sterile hazardous preparations with two pairs of gloves, including the outer glove that shall be sterile (including the outer glove in the CACI).
1751.6(e)(2)	CPhA IACP	Provide alternative training requirements for staff only involved in the supervision of personnel compounding but not compounding themselves.	USP <797> establishes with great specificity the training requirements someone must meet prior to preparing CSPs.
1751.7(e)(1)	CPhA IACP	Allow for an alternative method of testing as those described in USP <71> to perform end product testing. Also, exempt irrigations from pyrogen testing.	The informational chapter of USP <1223> provides background on the validation of alternative microbiological methods. A pyrogen is defined as any substance that can cause a fever and includes bacterial endotoxins and exotoxins. USP <151> provides background on appropriate pyrogen tests.

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Section	Requestor	Summary of Request	Background Information Provided Staff
1751.8	Eye Care for Animals	No specific request was made	
1751.11	Rick Rhoads	Add provisions to establish requirements for sterilization and depyrogenation	USP <797> is currently undergoing revision. Part of the draft revisions include standards for sterilization and depyrogenation. It is board's staff understating that <797> is still undergoing review and it is expected that another iteration of standards will be released for public comment. We are unaware of an anticipated dated for publication. Currently, USP <1211> provides a general description of the concepts and principles involved in the quality control of articles that must be sterile. Five methods of terminal sterilization, including removal of mircoorganisms by filtration and guidelines for aseptic processing are described in the informational chapter.
BPC 4123	Kaiser	Clarification if the provisions allowing for compounding by another pharmacy under a contract apply to non-sterile hazardous drugs.	B&PC 4123 allows a pharmacy to contract to compound drugs for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy. The contractual arrangement must be reported to the board. The provisions of this section are limited to parenteral. As such non-sterile hazardous drug preparations would not be covered under this provision.

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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

May 31, 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 members operating chain pharmacies in the state of California, the California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) want to convey our strong concerns with a provision in the rules under 16 CCR § 1735.8 pertaining to compounding quality assurance requirements. We appreciate the California Board of Pharmacy (Board) considering our comments on this matter.

Specifically, 16 CCR § 1735.8 (c) requires that pharmacies engaged in compounding practices have a quality assurance plan in place that, among other things, "include[s] 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." In the retail pharmacy setting, the volume of compounding is low and is generally limited to simple and/or moderate non-sterile compounding. The requirement to provide routine testing for simple compounds will lead to various unintended consequences and most importantly will not serve the spirit of the regulation. Analytical testing of simple compounds is not an appropriate measure of potency, but rather more suitable to identify systemic compounding technique errors or equipment flaws only evident in complex compounding. Many retail pharmacies are finding that the cost of complying with this requirement will be exorbitantly high. Without adequate profit to cover the cost of providing the compounding service, many retail pharmacies may eventually stop providing simple and/or moderate non-sterile compounding services. If pharmacies cannot afford to provide this service, it will limit patent access to the important medications.

To maintain patient access to simple and/or moderate non-sterile compounded medications at their local pharmacy, we urge the Board to pursue rulemaking to revise 16 CCR § 1735.8 (c) to specify that the requirement for routine testing and analysis does not apply to simple and/or moderate non-sterile compounded medications. With the majority of retail pharmacy compounding done with commercially available FDA approved ingredients, we believe this change poses little risk to public health and safety. We recommend a more direct approach to this issue and suggest the Board create a list of compounds and dosage forms specifically subject to analytical. This will help ensure that complex compounds that pose the highest risk to public safety are the main focus of such testing.

CRA and NACDS thank the Board for considering our comments on this issue.

Sincerely,

Angie Manetti
California Retailers Association

Mary Staples
National Association of Chain Drug Stores

cc: Amy Guittierez

Eye Care FOR ANIMALS

Frank J. Frassetto III, ACHE, BSHM, CRT
Chief Operating Officer
8145 E. Indian Bend Road, Scottsdale, AZ 85250
480.682.6912 (direct) ~ ff@eyecareforanimals.com

To: California Board of Pharmacy – Executive Committee and Board Members

Re: Compounding Regulations – Effective January 1, 2017.

Members of the Board,

I am writing once again in request of your assistance in modifying the current compounding regulations in place (specifically 1735.2 and 1751.8), which are preventing our patients from receiving appropriate care in a timely manner, (otherwise known as a delay in treatment or in many cases no viable treatment options). Compounders are left with no alternative but to cease and desist shipping medications due to these regulations leaving us with fewer options, in many cases surgical removal of the eye.

I have been physically attending every meeting since my initial correspondence dated April 4, 2017 in preparation for the April 18 meeting. Since that time, you have briefly discussed this issue (3 times in total), but have yet to take any course of action/modification which would allow our Doctors to practice appropriate veterinary medicine within the State of California. Although I fully understand that changing regulations is a "process", I also feel that no course of action is equally as detrimental as the present direction of moving the agenda item from one meeting to the next.

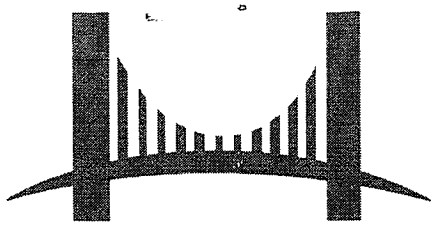
As pointed out during each meeting (by Roadrunner, Diamondback, CVMA, AVMA, and countless others), we are in a holding pattern (by the Board's design), in which no clear cut ruling has been offered which would account for the veterinary side of compounding and/or the ability for my organization to provide necessary care within the confines of your borders. Our California practices are forced to utilize sub-standard treatments for our patient's conditions that would cause legal upheaval should this be occurring in the human healthcare market. There comes a time in which preventing care (as has been done since January 1) can no longer be considered an "oversight" as initially suggested in my correspondence. At this point, we are left with the impression that although you are aware this issue exists, it is not important enough for anyone challenged with protecting the public (or our veterinary patients in this situation), to make a change in their best interests.

I am firmly requesting some sort of amicable remedy be placed into motion during the June 2, 2017 meeting, which would alleviate the continued delays in treatment, forced offerings of sub-standard care, and continued medical complications for our patients.

I will once again be attending the upcoming meeting and welcome any questions posed by the Board which may assist not only our patients, but the entire veterinary community.

Respectfully,

Frank J. Frassetto III, ACHE, BSHM, CRT



GOLDEN GATE VCP

YOUR BRIDGE TO EXCEPTIONAL VETERINARY COMPOUNDED CARE

05/12/2017

To: California Board of Pharmacy
Executive Officer
Compounding Committee and Full Board Members

Re: Newly Adopted Compounding Regulations

Members of the Enforcement and Compounding Committee,

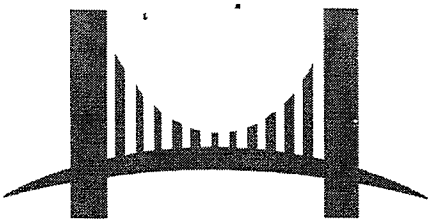
We would first like to commend you for taking on the daunting task of developing and implementing new compounding regulations. Overall a fine job was done and we appreciate that you listened to the compounding community when developing the regulations. We are heartened that you are willing to again listen to the community's feedback.

We are a small independent operation doing business only in the state of California. Our family ownership group runs two licensed compounding pharmacies: Ross Valley Compounding Pharmacy and Golden Gate Veterinary Compounding Pharmacy. Golden Gate Veterinary Compounding is one of the only dedicated veterinary compounding pharmacies in the state. We were at the forefront of PCAB accreditation, originally receiving accreditation in 2010. Since then we have maintained our accredited status adding sterile accreditation in 2014. We feel we are uniquely positioned to provide constructive feedback.

At both Ross Valley and Golden Gate Vet our primary concern is the health and safety of our patients. We strive to provide the highest quality compounds and service for our respective patient populations and can say with confidence that is what we have done over the last several decades of operation. We are USP and ACHC/PCAB compliant pharmacies.

We have two primary areas of concern and they are outlined below.

1525 E. Fransisco Blvd Suite #2B, San Rafael, CA 94901



GOLDEN GATE VCP

YOUR BRIDGE TO EXCEPTIONAL VETERINARY COMPOUND CARE

1) Beyond Use Dating:

1735.2.i.3

"(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"

As mentioned by several speakers at the April 18th meeting, the requirement of these tests to extend the beyond use date (BUD) of a non-sterile oral preparation goes above and beyond USP and any other recognized compounding standards. While the BUD dating standards do correspond to USP standards it is the specific requirement of these 3 tests that goes above and beyond the USP requirement. We recommend the regulations be changed to align with the standards set forth in USP 795 which state: "These maximum BUDs are recommended for non-sterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation".

Also, as mentioned by several of the speakers at the April 18th meeting, there is a lack of clarity around *"(C) Stability Studies"*. It appears that many in the compounding community, including our team, have interpreted this to mean that a Stability Indicating Assay test is now required. These are the tests that were mentioned that can run tens of thousands of dollars. Based on the response by the committee, this may or may not be the case, so we would just ask that some clarity be provided as to what testing is going to be required by the Board.

We would also ask that the Board consider the arguments presented at that meeting for the consideration of HPLC Potency Testing as a suitable alternative to a Stability Indicating Assay. If done correctly, a Bracketed Potency over Time Assay will provide more than suitable stability information for the vast majority of compounds. Based on the data we have seen there are only a handful of drugs that are commonly presented as having issues with accurate HPLC testing due to indiscernible degradation peaks – doxycycline comes to mind as one that is commonly referenced. As an alternative to requiring Stability Indicating Assays for all compound BUD extensions, it may be more prudent to identify the few drugs for which this testing would be most appropriate and require the more rigorous testing only for those particular compounds. Ultimately, if Stability Indicating Assays are required the vast majority of independent compounding pharmacies will not be able to afford such testing and will likely begin to go out of business. Those that can afford to test and do move forward with testing will likely be forced to pass those costs along to consumers. Either scenario significantly limits access to these essential medications.

While we agree that in the absence of appropriate data, conservative BUDs should always be implemented for compounded products, the restrictive nature of recent regulatory changes

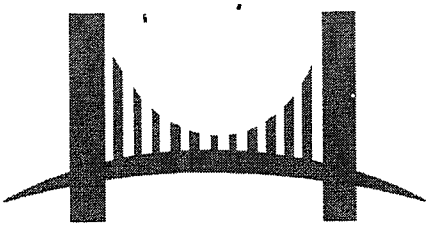
has led to compounding practices that are potentially ineffective and have the potential to cause real harm to patients. Many pharmacies are replacing established, potency study-backed formulas, many of which have years of clinical experience behind them to further justify their use, with new formulas, many of them in oil. On paper, putting a drug in an oil-based suspension seems like a good idea, because the lack of water allows for the pharmacy to assign a 180 day BUD. However, these formulas are even less studied than their aqueous counterparts. How do we know for sure that these new formulations do not have the same, or greater, potential for drug loss or other stability problems? Additionally, the solubility of most drugs is greatly decreased by placing them in an oleaginous environment, where even violent and repeated shaking of the bottle does not suspend the drug well for a long enough period of time to be confident that the correct dose is being administered. These issues, combined with the fact that, for our veterinary patients, the taste and "mouth feel" of oil-based suspensions can cause reactions such as extreme vomiting or aspiration, are why we use oil-based vehicles only as a last resort, where no other vehicle has been shown to be superior.

In many cases, veterinarians have prescribed these newly-formulated oil-based suspensions, and after trying them on the animals, have been forced to consider other dosage forms. For most cases, these liquid formulations were already a second or third-line option for the patient. Many times the patient is unable to safely be given a capsule or tablet, leaving the veterinarian and pet owner with very few options remaining when a viable liquid option is taken off the table.

1735.2.i.4

"(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."

While we generally agree with this statement, it is very restrictive as currently worded leaving no room for appropriate ingredient substitution or pharmacist's judgment in determining appropriateness of the assigned BUD when forced to substitute. As worded the substitution of one supplier's ingredient for another supplier's similar/equivalent ingredient would not be allowed. General suspending and sweetening agents come to mind. Each distributor/supplier is selling their own version but they are all essentially the same, with minor differences in ingredient make up. It is highly unlikely that substituting one for the other will have a negative impact on stability. It also does not leave room for substitution of equivalent USP/NF ingredients or packaging from different suppliers. We would recommend that the language be softened to allow for substitution of equivalent ingredients if the identical ingredient from the study is not available or stocked.



GOLDEN GATE VCP

YOUR BRIDGE TO EXCEPTIONAL VETERINARY COMPOUNDED CARE

2) Pharmacist's Judgment:

1735.2.i.5

"(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."

Pharmacist's judgment has always been included in previous versions of the regulations allowing for the pharmacist to determine if there is clinical, scientific, or other rationale for extending a BUD. One of the overarching themes that we see in these updated regulations is the removal of the pharmacist's ability to utilize professional judgment in extending a BUD. At our pharmacies, we have always taken the conservative approach, often utilizing a BUD that is shorter than what USP allows. We do not view this as utilization of "professional judgment" but more so our own conservative nature. The utilization of professional judgment was the result of patient conversations, clinical testing results (saliva and blood), potency testing, review of scientific literature, and the application of all that knowledge to determine if maybe a longer BUD was appropriate where standards were more limited. Professional judgment allowed us to determine that while there may not be published data to support, our experience and our knowledge allowed us to make an educated decision to extend a BUD with justification. As written there is no allowable extension of BUD without significant testing and no allowable extension based on pharmacist professional judgment.

Thank you for taking the time to hear our arguments. Again, as we stated, our ultimate concern is with our patient's well-being and we are concerned that without some clarity, these new regulations are going to ultimately limit patient access – both human and veterinary – to life saving compounded medications and lead to decreased compliance for those patients that do opt to try a compounded preparation.

Respectfully,

Erik Clausen, PharmD/MBA
Director of Pharmacy Operations
Golden Gate Veterinary Compounding Pharmacy/Ross Valley Compounding Pharmacy

July Enforcement Committee Meeting Materials

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

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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.

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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.

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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

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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	

Examples of Commonly Prepared Non-Sterile Compounds by Community Pharmacists

Albertsons Companies, CVS Health, Rite Aid, and Walgreens

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	LIDOCAINE 2% VISCOUS SOLN	DIPHENHYDRAMINE 12.5 MG/5 ML	ANTACID & GAS RELIEF LIQUID MAX STR
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	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	

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,

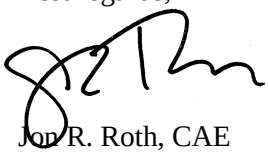
Thank you for your correspondence of June 21, 2017 in which you requested examples of the types of medication regimens that would be necessary to support the CPhA proposed amendment to the definition of dosage [1735.1(n)]. This change is recommended to ensure the definition of dosage unit is clearly 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

CCAP California Council for the Advancement of Pharmacy

July 11, 2017

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd., Suite N219

Transmitted electronically

RE: California Compounding Regulations: 1735.1(e)(1) and 1735.6(e)(3)

Dear Ms. Herold:

On behalf of the members of the California Council for the Advancement of Pharmacy, I am submitting proposed amendments for the above referenced sections of the California Compounding Regulations, for consideration by the Enforcement and Compounding Committee as well as the full Board of Pharmacy.

Regarding California Code of Regulations Section 1735.1. Compounding Definitions: (e)(1), the current regulations read:
For nonhazardous compounding a positive pressure differential of 0.02-to 0.05-inch water column relative to all adjacent spaces is required.

During the Enforcement and Compounding Committee of June 2, 2017, attendees learned that the Committee is approving some changes for the California regulations to become more in line with USP <797> (e.g., BUD). In light of this, I submit that it would be appropriate to follow General Chapter USP <797> for positive pressure rooms where nonhazardous drugs are compounded. General Chapter USP <797> reads that "for rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required." No maximum is stated. Given the opportunity for variety of elements/activities in a positive pressure room, the maximum could be higher than 0.05"w/c to control the particulate matter.

- Please consider the following amendment to CCR 1735.1(e)(1):
  For nonhazardous compounding a <u>minimum</u> positive pressure differential <u>between</u> ~~of~~ 0.02-to 0.05-inch water column relative to all adjacent spaces is required.

An additional amendment to the recent CSBP proposed amendments to compounding regulations would be to add “or CACI” to Section 1735.6.(e)(3) which would read (CCAP amendments are double underlined):

- Each ~~PEC~~ BSC and CACI in the room shall also be externally exhausted ~~vented~~ except that a BSC or CACI used only for nonsterile compounding may also use a redundant-HEPA filter in series.

Thank you for considering CCAP’s proposed amendments to Article 4.5 of Division 17 of Title 16 of the California Code of Regulations.

Respectfully,

Paige Talley

Paige Talley
Management Consultant
(916) 838-8362

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.

Additional Comments

Received Before July 21, 2017 at 9:00 a.m.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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

July 21, 2017

Amy Gutierrez, Pharm D.
President Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

RE: Compounding Quality Assurance Requirements under 16 CCR § 1735.8

Dear Dr. Gutierrez,

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".

This issue was discussed at the Enforcement and Compounding Committee meeting on July 12, 2017 and no action was taken to address our outstanding concerns with the aforementioned provision. We continue to stress the importance of addressing the impact this rule has upon patient safety and patient access to simple and moderate compounded drug preparations. Such testing is costly and unduly burdensome to pharmacies, threatening the access patients currently have to compounded drug product. Furthermore, 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".

We share the Board's concern for patient safety, yet there is disagreement on whether this level of scrutiny is necessary for simple and moderate compounded drug products. The U.S. Pharmacopeia (USP) 795 governs nonsterile compounding drug preparations and provides valuable guidance on the dispensing and administration of these products. Nowhere in the Chapter are there requirements to test for simple or moderate drug preparations, nor does any other state have such a requirement. In addition, it is unclear how the testing requirements drive quality assurance when the labs test for label strength and not the integrity of the compounded product. Without any research or data that has suggested the need for this testing, we strongly question whether this regulation is truly in the best interest of patients in light of its threat to patient access.

In order to avoid unintended impacts, we respectfully resubmit the following language for the full Board's consideration. Our suggested definitions originate from USP 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

July 19, 2017

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Herold,

The International Academy of Compounding Pharmacists (IACP) would like to provide the California Board of Pharmacy (the "Board") with information relevant to the Board's upcoming July 25, 2017 meeting. Specifically, within Part 2 of Agenda Item VI, the California Board of Pharmacy, Enforcement & Compounding Committee (the "Committee") will be providing the Board with proposed recommendations to CCR Sections 1735 – 1735.8 as a result of the Committee's June 2, 2017 and July 12, 2017 meetings. While IACP commends the Committee for collaborating with the compounding community in developing these proposed amendments, an area of major concerns that remains open is the Committee's perspective on the type of information a compounding pharmacist is permitted to use when assigning a Beyond-Use Date (BUD) to a sterile compound.

The Committee's proposed amendments to CCR Section 1735.2(i) includes changes to clarify the requirements for the assignment of a BUD to a non-sterile compound (CCR Section 1735.2(i)(1)). However, the Committee's proposal does not include amending or removing the requirement for a stability study to be performed on a compounded sterile preparation (CCR Section 1735.2(i)(3)(C)) in order for a compounding pharmacist to assign a BUD greater than 14 days for a non-frozen sterile preparation. The Committee, with support from Board staff, has expressed their intention to retain this stability study requirement and, in addition, has deferred to a single outside expert to establish the type of stability study they expect a compounded sterile preparation to undergo. IACP has great concern that the Committee's position on these stability studies, if upheld by the Board, will dramatically reduce the number of compounded sterile preparations available to California patients, leaving many without access to much needed medication.

Historically, compounding pharmacists have relied upon their education, experience, and a variety of other scientific factors to determine the BUD for sterile preparations. In fact, the Committee itself recognizes this in its proposed revisions to CCR 1735.2(i)(1) regarding non-sterile compounds. However, for reasons that remain unclear, the Committee has concluded that the factors acceptable for pharmacists to determine the stability of non-sterile compounds are unacceptable for determining the stability of sterile compounds, and instead must be replaced with stability studies. And while there are a number of different tests to demonstrate the stability of a compounded sterile preparation, the only method the Committee and Board staff are willing to accept is a stability study performed according to a validated test method incorporating forced degradation. These tests are extremely expensive and, as a result, would either greatly reduce the number of sterile compounds that pharmacies would be willing to test, or drastically increase the price of sterile compounded preparations, or both. In all scenarios, the

number of compounded sterile preparations available to California patients would be significantly reduced, leaving many patients in need of these medications untreated.

IACP feels this potential reduction in patient access to sterile compounded medication can be completely avoided without compromising the quality of sterile compounds. The type of stability study being recommended to the Committee is typically utilized by drug manufacturers to establish the shelf life of a new drug. In those situations, the drug being studied often contains a newly-created active pharmaceutical ingredient (API) that has never been used in any dosage form. In addition, the drug manufacturer likely desires to establish a shelf life of many years. Either of these two factors would justify the need to conduct the type of stability study described to the Committee. However, for a pharmacist who is utilizing an existing API with known stability characteristics in a sterile compound that is going to be assigned a BUD of only three to six months, a stability study performed according to a validated test method incorporating forced degradation is completely unnecessary. This type of stability study is not required by any other state board of pharmacy or compounding accreditation body. This point was expressed during the June 2nd and July 12th Committee meetings by many in the pharmacy community, some of whom offered scientifically sound alternative testing methods that would provide extremely reliable stability information at a cost that would be economically feasible for pharmacies. Unfortunately, there has been no indication from the Committee or Board staff that these alternatives are being considered.

IACP respectfully asks the Board to carefully weigh the overall impact on patient safety when hearing the Committee's recommendations related to extending the BUDs on compounded sterile preparations. IACP supports practice standards that require the highest level of quality for compounded medications to ensure patient safety. However, when those practice standards are not applicable to compounding pharmacies and restrict patient access to compounded medications with little to no effect on the quality of those compounds, the end result is patient safety that is compromised due to a lack of treatment.

IACP appreciates the opportunity to present its perspective to the Board and is available to answer any questions the Board may have. IACP looks forward to any opportunity to work with the Committee or the Board regarding this or any other matter to achieve the mutual goal of protecting and promoting the health and safety of Californians through continued access to high quality compounded medication.

Sincerely,

Baylor Rice, RPh, FIACP
IACP President

From:	Claudia Waters
To:	Sodergren, Anne@DCA
Subject:	My Patients Need Compounded Medications
Date:	Wednesday, July 19, 2017 8:17:22 AM

Claudia Waters
6060 Mazuela Dr.
Oakland, CA 94611

July 19, 2017

Dear Anne Sodergren,

Since January 1, 2017, veterinarians in the state of California have been forced to work around the lack of access to necessary compounded medications. The continued imposition of excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my patients pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

Compounded medicines saved my cat Luna's life numerous times. Also, the pharmacies are caring and helpful.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

The California Pharmacists Association (CPhA) recently submitted a number of sensible modifications to the current regulations. These modifications would allow extension of BUDs utilizing testing methods that do not require the enormous commitment of time and crushing financial burden of stability studies. Yet, at their July 12 meeting, the Enforcement and Compounding Committee rejected any meaningful changes suggested by CPhA. This is unacceptable!

While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my patients access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Claudia Waters

Hendricks, Laura@DCA

From: Keun Kim <jkim@socvets.com>
Sent: Thursday, July 20, 2017 1:58 PM
To: Sodergren, Anne@DCA
Subject: Changes Suggested By California Pharmacists Association Make Sense

Keun Kim
24801 Raton Drive
Lake Forest, CA 92630

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, veterinarians in the state of California have been forced to work around the lack of access to necessary compounded medications. The continued imposition of excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my patients pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

The use of compounded and off label medication has been a necessity for veterinarians due to the increase of published treatments for a variety of disorders but lack of phamaceutical manufacturers that will label medications for veterinary use. Subsequently, medications labeled for human use has been utilized. When our patients weight 3 kilograms and we are dosing out medications formulated for a 60 kilogram human being, it becomes impossible to split the medications and compounding has been our only feasible option.

The 72 hour dispensing of medication until a written prescription can be transmitted, fulfilled, then shipped to the client is physically not possible for medications that I consider urgent e.g. pain medications or antibiotics. On average, it takes 6-9 days for owners to receive their compounded meds.

I have compiled a list of over a dozen local compounding pharmacies and feel like I do my due diligance to find local sources for these compounded drugs but consistently fail.

The veterinary profession needs reputable, accountable, regulated, readily accessible and dispensable medications for us to treat our patients to the level where it is considered standard practice.

Enhancing safety, increasing accountability for all the different parties (compounding pharmacies, veterinarians) I feel is a good thing. However, the current level of rules and regulations held on both the compounding pharmacies and veterinarians have made it to my opinion - beyond reasonable - for veterinarians to treat patients where the only viable option is the use of compounded drugs.

Should you have read through this entire note and made it this far - I thank you for your time.

Respectfully,

Keun Kim

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

The California Pharmacists Association (CPhA) recently submitted a number of sensible modifications to the current regulations. These modifications would allow extension of BUDs utilizing testing methods that do not require the enormous commitment of time and crushing financial burden of stability studies. Yet, at their July 12 meeting, the Enforcement and Compounding Committee rejected any meaningful changes suggested by CPhA. This is unacceptable!

While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my patients access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Keun Kim

From:	Barbara Lairenson
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Tuesday, July 18, 2017 10:48:45 AM

Barbara Lairenson
615 N State St
Santa Barbara, CA 93101

July 18, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to or sub-optimal quality of, necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

My cat has been receiving a liquid medication for high blood pressure for years, with no problems. Several months ago I renewed her prescription and was told by the pharmacist that he had to change it to an oil base because of new rules. My cat hates the new medicine. She foams at the mouth and frequently refuses to take it. What used to be a pleasant experience is now miserable.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

The California Pharmacists Association (CPhA) recently submitted a number of sensible modifications to the current regulations. These modifications would allow extension of BUDs utilizing testing methods that do not require the enormous commitment of time and crushing financial burden of stability studies. Yet, at their July 12 meeting, the Enforcement and Compounding Committee rejected any meaningful changes suggested by CPhA. This is unacceptable!

While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Barbara Lairenson

Hendricks, Laura@DCA

From: JOSEPH LOBUE <JALAJM98@ME.COM>
Sent: Thursday, July 20, 2017 4:08 PM
To: Sodergren, Anne@DCA
Subject: Changes Suggested By California Pharmacists Association Make Sense

JOSEPH LOBUE
3359 LARGA AVE
LOS ANGELES, CA 90039

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

[Insert individualized story here. See Talking Points for prompts]

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Please reconsider the changes suggested by CPhA.

Sincerely,
JOSEPH LOBUE

From:	denise novis
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Wednesday, July 19, 2017 6:05:50 PM

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denise novis
7228 durango circle
carlsbad, CA 92011

July 19, 2017

Dear Anne Sodergren,

Since January 1, 2017, veterinarians in the state of California have been forced to work around the lack of access to necessary compounded medications. The continued imposition of excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my patients pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

Please allow us to have the medications that our Bella needs. Bella has 2 types of cancer and needs her medication.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my patients access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
denise novis

From:	Jennifer Sergeeff
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Wednesday, July 19, 2017 9:46:16 PM

Jennifer Sergeeff
2201 Juniperro Serra Blvd
Daly City, CA 94014

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, veterinarians in the state of California have been forced to work around the lack of access to necessary compounded medications. The continued imposition of excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my patients pain, suffering and cost of therapy, with no significant benefit to public safety.

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I've been a veterinarian for 18 years.
Cats and small dogs are NOT little humans. All human medications are not appropriate sized for our little loved ones.

By making veterinary compounding more restrictive, my small patients have lacked access to previous compounded medication/formulations, or in different "stable" formulations that do not help their disease as well as the former ones.

So since January 1, 2017--these restrictions have actively hurt my patients. This "protecting the public safety" rather than protecting our furry family members, is making them sicker. That should just not happen.

A majority of medications in cats is "off label" to start. We tell owners about drug risks. By adding another restriction, you are potentially shortening their quality of life by denying effective medications.

My personal cat is 17.5 years old. She is on compounded medication for intestinal disease. She's been going strong on this for 5 years; just changing the formulation to oil based for "stability" reasons for the last 6 months--she is not doing as well, losing weight, and less thrifty. Just because I live in California. If I moved back to the Midwest--she would have better access to medication she deserves than here. That is something to be ashamed of.

Legislating health under the guise of protecting the pets/public--leave that in the hands of the veterinary doctors and the owners. WE are a caring profession, known to be trustworthy and establish client-patient-vet relationships.

If you wish to protect the public safety---please focus on your human counterparts instead.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have

recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my patients access to the medications they need.

Please reconsider the changes suggested by CPhA.

Respectfully
Jennifer Sergeeff, DVM DACVIM (SA Internal Medicine)

From:	Michele Cavin
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Thursday, July 20, 2017 4:18:19 PM

Michele Cavin
5761 Brunswick ave
San diego, CA 92120

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, veterinarians in the state of California have been forced to work around the lack of access to necessary compounded medications. The continued imposition of excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my patients pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

Our cat Baxter died last year from renal lymphoma . We were able to get topical versions of steroids and anti nauseant drugs to help ease his last 6 months . We applied the creams to his ears . He had completely refused the oral meds we received from our regular vet . Without diamondback compounding pharmacy we would have had to put him to sleep 6 months earlier . The cream forms were not available to us here at any pharmacy. I am so gltateful were able to obtain these compounds that prolonged his life.

Requiring testing to establish beyond use dates is placing an unnecessary burden on the industry . Veterinary lifespans and treatment windows are much shorter . It worries me to think if my animals get sick now I might not be able to help them . Even placing an arbitrarily shorter exp date on the product would at least ensure these important products remain available for people like me .

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my patients access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Michele Cavin

From:	Beverley Altenderfer
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Thursday, July 20, 2017 4:18:22 PM

Beverley Altenderfer
740 Shell Ave #104
Martinez, CA 94553

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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[It is very important for parents of older fur babies to have access to medication that aid in the quality of life. The cost of pet care is high enough now without adding undue stress of higher cost of medication.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Beverley Altenderfer

From:	BETH KENDZIERSKI
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Thursday, July 20, 2017 4:18:24 PM

BETH KENDZIERSKI
4048 mistral drive
huntington beach, CA 92649

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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we almost lost our chocolate lab Mocha last year to a life threatening infection. As a result Mocha is on life long medications. Having the ability to get access to drugs that are correctly compounded at reasonable prices is immperative for Mocha's life and well being. Please do the right thing and don't restrict my access. Let's have better healthcare for our animals than we do for our citizens.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
BETH KENDZIERSKI

From: Charles Lee
To: Sodergren, Anne@DCA
Subject: My Pet Needs Compounded Medications
Date: Thursday, July 20, 2017 4:28:24 PM

Charles Lee
9 Saronna
Irvine, CA 92614

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Hello, we had a beloved feline family member that required compounded cancer treatment. We were lucky enough to find Diamond Back Drugs to reasonably offer us a temporary remedy. Although we recently lost our loved one, the medication provided us additional time with him we will always appreciate.

If we impose excessive regulations and testing, it will make future medications too expensive to consider. Please leave current safeguards in place as they are sufficient. Thank you.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Charles Lee

From:	Claire Alexander
To:	Sodergren, Anne@DCA
Subject:	My Pet Needs Compounded Medications
Date:	Thursday, July 20, 2017 4:38:19 PM

Claire Alexander
268 Ada Ave.
Mountain View, CA 94043

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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My cat recently needed a compounded opthalmic solution that was really difficult to find and delayed treatment by a week. He was in pain and suffered while we waited for it to be shipped.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Claire Alexander

From:	Rosemary Caldwell
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Pets Therapy
Date:	Thursday, July 20, 2017 5:08:23 PM

Rosemary Caldwell
2100 Budd St
Modesto, CA 95350

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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My older Maltese Dog needs a compounded medication for her health issues. If she doesn't take this medication she can hardly move. This has greatly improved her quality of life. Without it she will probably have to be put to sleep.

Our pets are like our children and we want the best for them, just like our real children. And to some people they are their children!

How would you feel if you could not get the medication for your child because of some new government regulations?

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Rosemary Caldwell

From:	Barbara Burdett
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Thursday, July 20, 2017 6:48:25 PM

Barbara Burdett
15756 Mussey Grade Rd
Ramona, CA 92065

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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[Insert individualized story here. See Talking Points for prompts]

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Please reconsider the changes suggested by CPhA.

Sincerely,
Barbara Burdett

From:	maria pappas
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Pets Therapy
Date:	Thursday, July 20, 2017 6:48:28 PM

---

maria pappas
4247 hilaria way
newport beach, CA 92663

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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My own cats
require
medications that must be
compounded. Because
of the specialized nature of feline medications, and the small doses I absolutely have no other choice than to utilize out of state veterinary compounding pharmacies. Currently I buy three month supplies. To ask me to buy more frequent and smaller supplies is not only
more expensive, but also more of a hardship given my psychiatric disabilities. I depend absolutely on being able to
buy cost effective and longer lasting supplies of my compounded veterinary medicines. Please do not place limits on what I may do to help my pets by making compounded medications more difficult and expensive to access. PLEASE!

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
maria pappas

From:	Amanda Prentiss
To:	Sodergren, Anne@DCA
Subject:	My Pet Needs Compounded Medications
Date:	Thursday, July 20, 2017 7:18:27 PM

Amanda Prentiss
13230 Johannesberg Way #19
Poway, CA 92064

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Midland Animal Clinic in Poway gave us the number to Diamondback because they told us that they weren't going to carry a necessary medication my dog needs. My dog Landon got sick with liver failure about 3yrs ago. He tried a couple different prescription meds before we found the right combination for him, where his liver levels would stabilize and go down to where we need them to be. Because of the milkthistle we get from this company, his levels have gone down so much compared to what they were (from the 700 range to The 200 range). The milkthistle I get from Diamondback and another medication from the doctor has helped him cope with his liver issue. Taking that away from him means that his liver levels will go up, and could possibly or eventually kill him. With that being said, I'm not sure how fast or how slow. I don't want him to be in any pain, and I believe that with both medications he does take, they have saved his life, and actually gave him a life to live where he knows love, joy, comfort and companionship. He's a very outgoing little 6yr old, 6lb chihuahua, who has a good life because of this medication. He is my baby boy, my everything. Please take this into consideration. I'm not ready to say goodbye to my baby. I'm not ready to tell him that I'll see him over the rainbow bridge. Are you really willing to do this, not just to my dog, but to others that require the same? Are you ready to tell these people that they have to say goodbye to their pets because of this decision? What would you do if they were denying necessary medications to your pet, your best friend, the one who is always around and shows you unconditional love? Would you stop and take it or would you fight and voice your opinion for change? All I ask is that you please reconsider the changes suggested by CPhA. Do not deny my pets, and others access to the medications they need on a daily basis to survive and thrive. They're part of our family.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Amanda Prentiss

From:	Agnes Telfer
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Thursday, July 20, 2017 7:48:30 PM

Agnes Telfer
745 Waterville Dr
Brentwood, CA 94513

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

My dog Tinker body does not absorb portiens he need a drug that thy give to cancer patients. This was $600.00 witch I could not afford. I found in Arizona Diamondback which compounds med for pets at a price I could afford. Please do not change regulations pet owners need compounded medications,

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

The California Pharmacists Association (CPhA) recently submitted a number of sensible modifications to the current regulations. These modifications would allow extension of BUDs utilizing testing methods that do not require the enormous commitment of time and crushing financial burden of stability studies. Yet, at their July 12 meeting, the Enforcement and Compounding Committee rejected any meaningful changes suggested by CPhA. This is unacceptable!

While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Agnes Telfer

From:	Barbara Bell
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Thursday, July 20, 2017 8:08:30 PM

Barbara Bell
1125 Bel Marin Keys Blvd
Novato, CA 94949

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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To Whom this May Concern,

My name is Barbara Bell and am a deaf individual who depends on Bernard, my hearing service dog. Right now he is suffering from Intestional lymphangictasia. He must take Chlorambucil Every Other Day and this medicine is very expensive. Diamondback Drugs at Arizona is the only place that sells them at a lower price. Bernard is surviving due to this medicine and prednisone which he has been taking since July of 2016. Without these meds or Diamondback Drugs' help, he would not be alive today. Please don't take away this dog's life from me.
Thank you,
Barbara Bell

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Please reconsider the changes suggested by CPhA.

Sincerely,

Barbara Bell

From:	Sandy Kelly
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Pets Therapy
Date:	Thursday, July 20, 2017 8:28:39 PM

Sandy Kelly
207 El Granada blvd
Half Moon Bay, CA 94019

July 20, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Since January 1, 2017 I have been unable to obtain compounded medicine I need for my cat, Willie.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Sandy Kelly

From:	Rebecca Snyder
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Pets Therapy
Date:	Thursday, July 20, 2017 9:38:43 PM

Rebecca Snyder
199 New Montgomery Street
San Francisco, CA 94105

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Please don't make it harder for us to obtain drugs for our pets. Buddy had an additional 4 very good years on chemo drugs. Without those drugs, he had maybe 6 months. I timed the monthly delivery perfectly, for 4 years - these drugs come in a cold pack and I needed to make sure that I ordered in time before his last pills were gone & ensure I was home when the cold pack arrived. The timing was important and once, for some reason, the drugs were not available and it was extremely stressful. I was ready to fly to Diamondback (Arizona where the drugs had to come from - I'm in California) or where ever I needed to go to get these drugs. Fortunately it worked out, but I'll tell you the stress of almost not having those drugs for Buddy was heartbreaking. Buddy passed away in August last year. I understand that once again pet owners are having difficulty in obtaining these compounded medications. If you are a pet owner, you can understand how devastating it would be if you could not help your pet when help was clearly available. If you don't have a pet, you can think that about a family member, because that is what these pets are to us. Thank you for your consideration in doing what you can to help us have access to these drugs, and without adding more costs to these drugs which are already quite expensive.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Rebecca Snyder

From:	Jennifer Johnson
To:	Sodergren, Anne@DCA
Subject:	My Pet Needs Compounded Medications
Date:	Friday, July 21, 2017 1:08:49 AM

Jennifer Johnson
15680 Reed Dr.
Fontana, CA 92336

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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[My Dog absolutely needs to have his compounded meds everyday. He has spindle cell carcinoma. His only hope is to stay on these meds!. Please don't jeopardize My dogs health!!!

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Jennifer Johnson

From: Robin Howard
To: Sodergren, Anne@DCA
Subject: Excessive Regulations Are Affecting My Pets Therapy
Date: Friday, July 21, 2017 6:09:12 AM

Robin Howard
1548 Iris Court
San Jose, CA 95125

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Please reconsider changing the requirements on beyond use dates. It can negatively impact pet owners across California. For example, I have a diabetic cat who needs long acting insulin. Despite the plethora of insulin options available to humans none are formulated for cats. Therefore I use small amounts of a human one - Lantus. Each vial costs me hundreds of dollars out of pocket but lasts 4 times as long with proper storage and dosing. If beyond use dating went into effect the cost for treating my cat would go up thousands of dollars a year. The FDA requires the pharmaceutical industry to do extensive stability testing of their products and has oversight of the safety of our medical products. Stability requirements should be in accordance to their guidelines.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Robin Howard

From:	vikie reyes
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Friday, July 21, 2017 7:49:29 AM

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vikie reyes
p o box 1415
Escondido, CA 92033

July 21, 2017

Dear Anne Sodergren,

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[Insert individualized story here. See Talking Points for prompts]

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Please reconsider the changes suggested by CPhA.

Sincerely,
vikie reyes

From:	Vanessa Schwartz
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Friday, July 21, 2017 7:59:32 AM

Vanessa Schwartz
1208 Marguerita Ave.
SANTA MONICA, CA 90402

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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This is a terrible situation. My dog uses compounded medications.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Vanessa Schwartz

From: Mary Jill Sofi
To: Sodergren, Anne@DCA
Subject: My Pet Needs Compounded Medications
Date: Friday, July 21, 2017 7:59:41 AM

Mary Jill Sofi
16165 Pauhaska Road
Apple Valley, CA 92307

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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A few years ago my Yorkie developed very bad eyes. Critically dry and deteriorating quickly. My Vet in California recommended cyclosporine A in MCT SOL (C)1% Opht. Not sure what that is but the company in Arizona, (Diamondback) filled the prescription and it worked. When she ran out I had to order it from a lab in San Francisco because of the change in laws. It was much more expensive and did NOT work as well... her eyes started changing. We were finally able to go back to Diamondback and pray that we will be able to get this medication again from Arizona. Please do not limit where we can receive this med from. We are retired and on a very limited budget! Thank you, Mary Jill Sofi.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Mary Jill Sofi

From:	Vicki Armstrong
To:	Sodergren, Anne@DCA
Subject:	My Pet Needs Compounded Medications
Date:	Friday, July 21, 2017 7:59:53 AM

Vicki Armstrong
1208 Sea Village Dr
Cardiff, CA 92007

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Please don't make it even more difficult and costly for me to obtain necessary compounded meds for my dog with hemangiosarcoma.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Vicki Armstrong

From:	susan grayson
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Pets Therapy
Date:	Friday, July 21, 2017 8:00:03 AM

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susan grayson
20946
Topanga, CA 90290

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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[Insert individualized story here. See Talking Points for prompts] Please, review your regulations and change them ..I can no longer use my pharmacy of my choice because they cannot comply with these new regulations.

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Please reconsider the changes suggested by CPhA.

Sincerely,
susan grayson

From:	Tracy Tierney
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Friday, July 21, 2017 8:00:12 AM

Tracy Tierney
5445 Broadway
Oakland, CA 94618

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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My pet's condition is serious but her compound medicines are critical in giving her a humane quality of life in an affordable way. Please don't further burden pet owners who need critical compound medication for their animals. It's the right thing to do! Thank you.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Tracy Tierney

From:	Marti Shaffer
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Friday, July 21, 2017 8:19:32 AM

Marti Shaffer
8408 Milky Way
Orangevale, CA 95662

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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I have had to use out of state compounding pharmacies for years to treat my dogs for a variety of ailments. My animals would have drastically shorten lives if I was unable to have the compounded pharmacies provide me with the drugs needed.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Marti Shaffer

From:	Diana Pohn
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Friday, July 21, 2017 8:19:37 AM

Diana Pohn
918 Passiflora Avenue
Encinitas, CA 92024

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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As a dog owner and dog rescuer we rely on compounded medications to help our medical and special needs dogs and puppy. It is critical we are continued to have access to these medications to save their lives.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Diana Pohn

From:	Sharon Harper
To:	Sodergren, Anne@DCA
Subject:	My Pet Needs Compounded Medications
Date:	Friday, July 21, 2017 8:29:42 AM

Sharon Harper
13690 Chalk Hill Rd.
Healdsburg, CA 95448-9041

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

my dog has 2 cancer mass tumors on his liver, the only medicine he can tolerate has to be compounded for him.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

The California Pharmacists Association (CPhA) recently submitted a number of sensible modifications to the current regulations. These modifications would allow extension of BUDs utilizing testing methods that do not require the enormous commitment of time and crushing financial burden of stability studies. Yet, at their July 12 meeting, the Enforcement and Compounding Committee rejected any meaningful changes suggested by CPhA. This is unacceptable!

While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Sharon Harper

From: Shelley Thraen
To: Sodergren, Anne@DCA
Subject: My Pet Needs Compounded Medications
Date: Friday, July 21, 2017 8:29:46 AM

Shelley Thraen
2245 Casa Alta
Spring Valley, CA 91977

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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I have had pet rabbits for years. They are wonderful pets and my whole life. Yet, they are extremely fragile and more so when ill. The compounding meds are what they need, and are the ones found to be safest for the with the regulations currently in practice in other states. Changing to almond base would literally put them in danger as we have no idea how they will react. I cannot risk this, yet they need the medicine. Please please don't change the compounding regulations that have been in effect for years. It literally is a matter of life in death in rabbits. The Medicine I've been using for years has been effective and completely safe

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Shelley Thraen

From:	Michael Smith
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Pets Therapy
Date:	Friday, July 21, 2017 8:39:40 AM

Michael Smith
839 W. Carroll Ave.
Glendora, CA 91741

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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My dog has seziers and these drugs have eliminated them.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Michael Smith

From:	Risa Schwartz
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Friday, July 21, 2017 8:39:44 AM

Risa Schwartz
603 Nestora Ave
Aptos, CA 95003

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Don't take my access to drugs away!

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Risa Schwartz

From:	Mary Nagelmann
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Pets Therapy
Date:	Friday, July 21, 2017 8:39:47 AM

Mary Nagelmann
166 Sherwood Dr
Westlake Village, CA 91361

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Ladies and Gentlemen:

Were it not for compounded veterinary medications, my animals would suffer greatly.

Human medications are tough enough. Please don't make it harder for us to care for our pets.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Mary Nagelmann

From:	Thomas McCurry
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Friday, July 21, 2017 8:49:38 AM

Thomas McCurry
3278 Laurice Avenue
Altadena, CA 91001

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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My pet, Squirt, has urinary leakage, which is helped greatly by a estrogen compounded medication. Please don't take this from me.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Thomas McCurry

From:	Jane Stuntebeck
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Friday, July 21, 2017 8:49:41 AM

Jane Stuntebeck
3240 S WESTMONT LANE #9
ONTARIO, CA 91761

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Diamond Back Drugs has been supplying a drug for me that I have failed to get from my Vet or anybody else in CA. I do not have time to spend googling locations and finding out I cannot get it. I have a 16 year old Boston Terrier that has serious health issues. The drugs are expensive. I should be able to obtain what I want and where I want at the price I want with my Vet's approval. Stop involving yourselves in the personal lives of a USA citizen and pet lover who is working, paying taxes, and not in debt and wants my freedom to choose who I purchase drugs from. If I was out of State and sick, I would get medical treatment. Stop interfering in personal pet care and concentrate on people abusing animals. (You remind me of Trump and his mindset.)

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my pets access to the medications they need.

Please reconsider the changes suggested by CPhA.

Most Sincerely,
Jane Stuntebeck

From:	Jean O"Neill
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Friday, July 21, 2017 8:49:49 AM

Jean O'Neill
656 San Elijo St
San Diego, CA 92106

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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My 5 year old Doxie mix, Gaby, suffers from seizures on a regular basis. After trying a myriad of medications, the best result has come from a combination of standard pharmaceutical meds combined with a compounded med that is administered every 8 hours. Without this combo we would have to consider the unthinkable - putting Gaby down. We have and will continue to spend money on keeping her healthy and with us, but if prices become exorbitant, her demise becomes a distinct possibility. She is one of three rescue dogs in our pack and an integral part of our family. To lose her because of excessive regulations is senseless and incomprehensible.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Jean O'Neill

From:	MARSHA JOHNSON
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Friday, July 21, 2017 8:49:53 AM

MARSHA JOHNSON
17619 EASTGATE AV
UPLAND, CA 91784

July 21, 2017

Dear Anne Sodergren,

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Since January 1st, I can longer use the pharmacy of my choice because they cannot comply with new regulations.
this has severly impacted the health of my cats. Please support our position

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
MARSHA JOHNSON

From:	Diana Lukin
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Friday, July 21, 2017 8:39:35 AM

Diana Lukin
1504 Oakhorne Drive
Harbor City, CA 90710

July 21, 2017

Dear Anne Sodergren,

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[Insert individualized story here. See Talking Points for prompts]brandi lived 3 yrs longer due to compound medications so hard to find compound pharmacies

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Please reconsider the changes suggested by CPhA.

Sincerely,
Diana Lukin

From:	Denise Thompson
To:	Sodergren, Anne@DCA
Subject:	Please Change Testing Requirements For Compounded Medications
Date:	Friday, July 21, 2017 8:39:37 AM

Denise Thompson
39650 Via Temprano
Murrieta, CA 92563

July 21, 2017

Dear Anne Sodergren,

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[Insert individualized story here. See Talking Points for prompts]

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Please reconsider the changes suggested by CPhA.

Sincerely,
Denise Thompson

From: Randall Tanaka
To: Sodergren, Anne@DCA
Subject: My Pet Needs Compounded Medications
Date: Friday, July 21, 2017 8:49:44 AM

Randall Tanaka
23002 Kathryn Ave
Torrance, CA 90505

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Randall Tanaka

From:	elizabeth buchanan
To:	Sodergren, Anne@DCA
Subject:	Excessive Regulations Are Affecting My Patients Therapy
Date:	Tuesday, July 18, 2017 8:39:45 PM

---

elizabeth buchanan
282 washburn drive
fremont, CA 94536

July 18, 2017

Dear Anne Sodergren,

Since January 1, 2017, veterinarians in the state of California have been forced to work around the lack of access to necessary compounded medications. The continued imposition of excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my patients pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

I used a compounding pharmacy for a number of years - some in Ca some in other states. I had a beautiful orange cat, Nathaniel m who was in a two year struggle against cancer. Without compounded drugs - I would have lost him very quickly. He was difficult to give drugs to - compounded formulas in both liquid and pill form made it easier to give him necessary drugs. He lived two long happy years due to these drugs. Which ,of course, added to my happiness.

I do not currently need a compounding pharmacy, but I am distressed to learn that I may not have access to one in the future.

If you have an animal, you should be able to give the best and easiest care possible. It os one of the responsibilities of pet ownership

Beth Buchanan

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my patients access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
elizabeth buchanan

From: Marsha Thompson
To: Sodergren, Anne@DCA
Subject: Changes Suggested By California Pharmacists Association Make Sense
Date: Friday, July 21, 2017 7:59:43 AM

Marsha Thompson
2372 Rudat Circle
Rancho Cordova, CA 95670

July 21, 2017

Dear Anne Sodergren,

Since January 1, 2017, pet owners in the state of California have been forced to suffer from the lack of access to necessary compounded medications. The continued imposition of these excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my pets pain, suffering and cost of therapy, with no significant benefit to public safety.

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I have had several cats that needed oral chemo and have been blessed to be able to find pharmacies that carry the meds but this number is dwindling and since these meds have been extremely effective it is distressing to me to think that it will become more difficult for these pharmacies to provide such life saving medication.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

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Please reconsider the changes suggested by CPhA.

Sincerely,
Marsha Thompson

From:	Rita Allen
To:	Sodergren, Anne@DCA
Subject:	Changes Suggested By California Pharmacists Association Make Sense
Date:	Tuesday, July 18, 2017 4:49:34 PM

Rita Allen
5760 Arboretum Dr
Los Altos, CA 94024

July 18, 2017

Dear Anne Sodergren,

Since January 1, 2017, veterinarians in the state of California have been forced to work around the lack of access to necessary compounded medications. The continued imposition of excessive, impractical and in most cases, unnecessary regulations regarding the establishment of Beyond Use Dates (BUDs) will only serve to increase my patients pain, suffering and cost of therapy, with no significant benefit to public safety.

The requirement to perform stability studies as the only means to extend a BUD has a disproportionate negative impact on pet owners and veterinarians. Stability studies are extremely expensive and time consuming. In human medicine, health insurance and Patient Assistance Programs mitigate the economic impact of expensive therapies. There are no such programs in veterinary medicine, and price is often the deciding factor between treatment and death. The requirement to perform stability studies will drive the price of commonly used compounded medications beyond the reach of the majority of pet owners.

compounded medication helped prolong my dog's life. Please don't block access to life-saving drugs.

At the past several meetings of both the California Board of Pharmacy and the Enforcement and Compounding Committee, board members have heard complaints and concerns about these regulations from Pharmacists, Prescribers, Patients and Pet owners. It is apparent that board members have recognized the negative impact that these regulations have on patient access to vital compounded medication and agree that these regulations must be changed.

The California Pharmacists Association (CPhA) recently submitted a number of sensible modifications to the current regulations. These modifications would allow extension of BUDs utilizing testing methods that do not require the enormous commitment of time and crushing financial burden of stability studies. Yet, at their July 12 meeting, the Enforcement and Compounding Committee rejected any meaningful changes suggested by CPhA. This is unacceptable!

While the Board of Pharmacy has a responsibility to protect the public safety, it also has a responsibility to listen to that public. Do not deny my patients access to the medications they need.

Please reconsider the changes suggested by CPhA.

Sincerely,
Rita Allen

Attachment 9

Proposal 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.

Attachment 10

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.

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.

Attachment 11

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.

SB 1441 – Program Statistics

Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

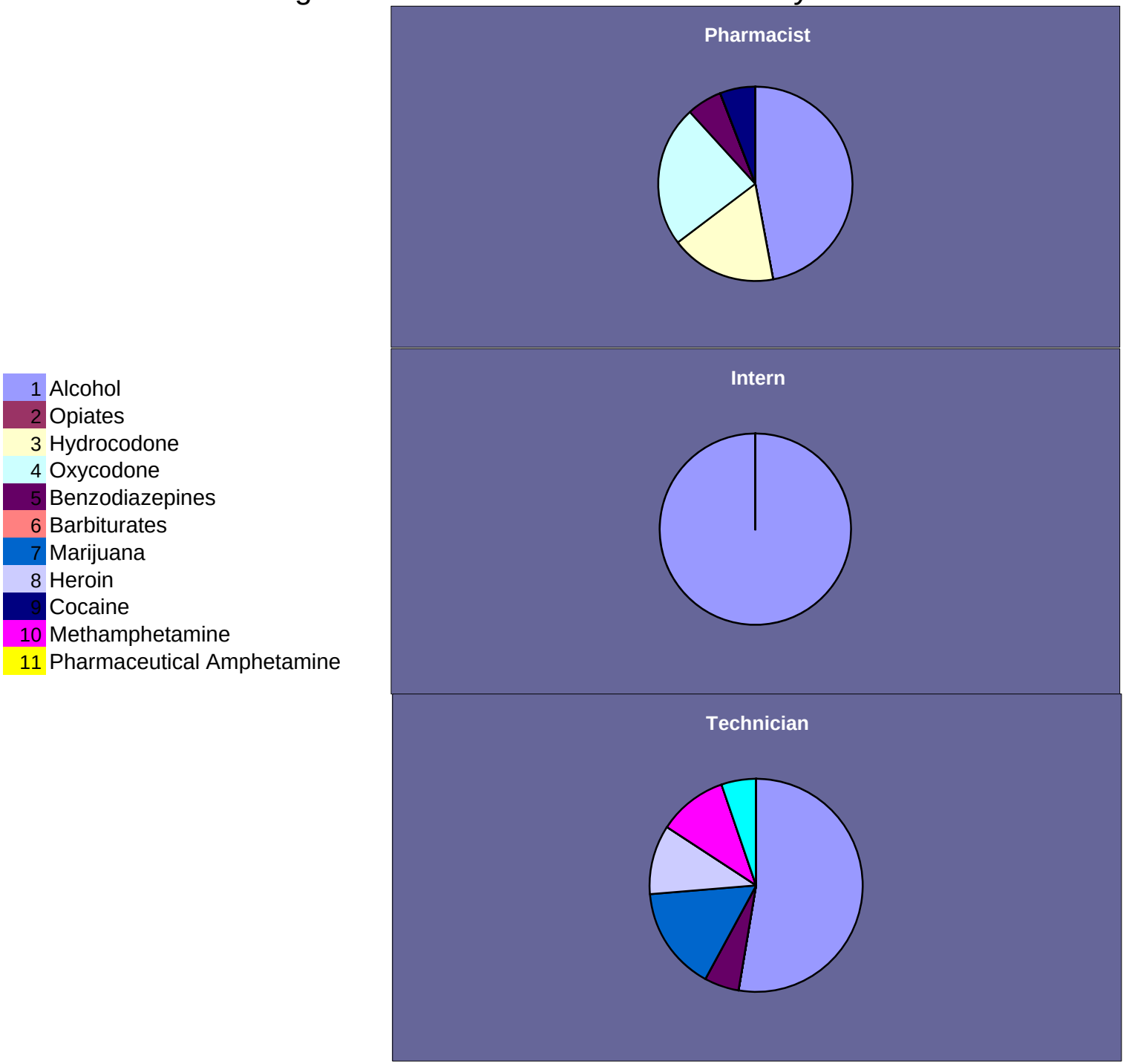
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 16/17
PRP Intakes					
PRP Self-Referrals					
PRP Board Referrals		3	3	3	9
PRP Under Investigation	3	1	1	1	6
PRP In Lieu Of		1			1
Total Number of PRP Intakes	3	5	4		12
New Probationers					
Pharmacists	2	2	4	4	12
Interns		2			2
Technicians	2	4	5	4	15
Total New Probationers	4	8	9	8	29
PRP Participants and Contracts					
Total PRP Participants	53	55	56	53	N/A
Contracts Reviewed	50	47	49	49	195
Probationers and Inspections					
Total Probationers	81	83	82	80	80
Inspections Completed	141	126	151	168	586
PRP Referrals to Treatment					
Referrals to Treatment	3	4	3	3	13
Drug Tests					
Drug Test Ordered	911	908	971	900	3690
Drug Tests Conducted	895	898	962	900	3655
Relapse					
Relapsed	1	3	2	1	7
Major Violation Actions					
Cease Practice/Suspension	4	9	7	1	21
Termination - PRP	2		2	2	6
Referral for Discipline				1	1
Exit from PRP or Probation					
Successful Completion	4	1	5	10	20
Termination - Probation	1			1	2
Voluntary Surrender	3	4	5	4	16
Surrender as a result of PTR	1	1		1	3
Public Risk	2		2	3	7
Non-compliance	19	7	18	5	49
Other	1		2	4	7
Patients Harmed					
Number of Patients Harmed	None	None	None	None	None

SB 1441 – Program Statistics

Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 16/17
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 16/17**
Alcohol	1	2	3	2	8
Ambien					
Opiates	3				3
Hydrocodone	1	2		1	4
Oxycodone	1				1
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana		1			1
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol		1		1	2
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 16/17**
Alcohol		2			2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 16/17**
Alcohol	1	2	4	3	10
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines	1				1
Barbiturates					
Marijuana	2	1			3
Heroin		1		1	2
Cocaine					
Methamphetamine	1		1		2
Pharmaceutical Amphetamine					
Phentermine				1	1
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2016 to June 2017



Printed on 7/13/2017

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 14/15	Total 15/16	Total 16/17
Complaints/Investigations			
Received	2653	3109	2893
Closed	2511	2898	3116
Pending (at the end of fiscal year)	2055	2345	2241
Cases Under Investigation (by Team) at end of fiscal year*			
Compliance / Routine Team	730	1079	879
Drug Diversion/Fraud	306	429	413
RX Abuse	104	124	153
Compounding	76	105	150
Probation/PRP	45	83	66
Outsourcing	N/A	N/A	80
Mediation/Enforcement**	328	199	189
Criminal Conviction	466	326	311
Application Investigations			
Received	780	547	507
Closed			
Approved	465	364	343
Denied	102	89	74
Total***	719	609	532
Pending (at the end of fiscal year)	185	109	98
Letter of Admonishment (LOA) / Citation & Fine			
LOAs Issued	138	233	423
Citations Issued	1176	1970	1935
Total Fines Collected ****	$1,607,674.61	$2,096,976.59	$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 Enforcement Staff

*** This figure includes withdrawn applications.

**** Fines collected (through 6/30/2015 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 14/15	Total 15/16	Total 16/17
Administrative Cases (by effective date of decision)			
Referred to AG's Office*	325	413	351
Pleadings Filed	262	342	271
Pending			
Pre Accusation	246	258	241
Post Accusation	341	279	214
Total *	598	602	468
Closed			
Revocation			
Pharmacist	10	18	16
Intern Pharmacist	1	3	2
Pharmacy Technician	160	112	109
Designated Representative	5	2	2
Wholesaler	3	0	1
Sterile Compounding	0	0	1
Pharmacy	3	6	11
Revocation,stayed; suspension/probation			
Pharmacist	15	10	14
Intern Pharmacist	1	0	0
Pharmacy Technician	1	1	5
Designated Representative	1	0	0
Wholesaler	0	0	0
Sterile Compounding	0	0	0
Pharmacy	0	3	1
Revocation,stayed; probation			
Pharmacist	31	43	52
Intern Pharmacist	2	1	0
Pharmacy Technician	24	18	13
Designated Representative	0	2	0
Wholesaler	1	1	1
Sterile Compounding	0	1	
Pharmacy	13	20	27
Surrender/Voluntary Surrender			
Pharmacist	15	19	30
Intern Pharmacist	0	1	4
Pharmacy Technician	39	28	36
Designated Representative	1	1	0
Wholesaler	1	1	0
Sterile Compounding	3	1	1
Pharmacy	9	19	26

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 14/15	Total 15/16	Total 16/17
Public Reproval/Reprimand			
Pharmacist	4	6	27
Intern Pharmacist	0	0	0
Pharmacy Technician	2	2	3
Designated Representative	0		1
Wholesaler	0	3	1
Sterile Compounding	0	2	2
Pharmacy	2	7	10
Licenses Granted			
Pharmacist	0	5	4
Intern Pharmacist	0	0	2
Pharmacy Technician	4	21	6
Designated Representative	0	0	1
Wholesaler	0	1	0
Sterile Compounding	0	2	0
Pharmacy	0	2	0
Licenses Denied			
Pharmacist	0	0	0
Intern Pharmacist	0	1	0
Pharmacy Technician	2	21	12
Designated Representative	0	0	0
Wholesaler	0	0	0
Sterile Compounding	0	0	0
Pharmacy	0	0	0
Cost Recovery Requested**	$167,196.73	$1,407,768.79	$1,981,063.03
Cost Recovery Collected**	$420,374.96	$7,497,523.24	$998,383.61

** This figure includes adminstrative penalties

Immediate Public Protection Sanctio			
Interim Suspension Order	7	11	2
Automatic Suspension / Based on Conviction	5	2	1
Penal Code 23 Restriction	5	26	9
Cease & Desist - Sterile Compounding	1	1	2

Probation Statistics

Licenses on Probation

Pharmacist	144	165	190
Intern Pharmacist	4	3	4
Pharmacy Technician	32	38	36
Designated Representative	4	1	0
Wholesaler	40	3	62

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 14/15	Total 15/16	Total 16/17
Sterile Compounding	5	11	12
Pharmacy	2	49	3
Probation Office Conferences	114	120	105
Probation Site Inspections**	354	447	586
Successful Completion	29	20	33
Probationers Referred to AG for non-compliance	9	9	8

As part of probation monitoring, the board requires licensees to appear before the lead 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.

SB 1441 – Program Statistics

Three Fiscal Year Comparison

Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

Board of Pharmacy	FY14/15	FY15/16	FY16/17
PRP Intakes			
PRP Self-Referrals	7	2	
PRP Board Referrals	11	7	9
PRP Under Investigation	5	5	6
PRP In Lieu Of	5	1	1
Total Number of PRP Intakes	28	13	12
New Probationers			
Pharmacists	23	14	12
Interns	2	1	2
Technicians	20	12	15
Total New Probationers	45	27	29
PRP Participants and Contracts			
Total PRP Participants	66	53	53
Contracts Reviewed	239	238	195
Probationers and Inspections			
Total Probationers	87	85	80
Inspections Completed	354	447	586
13			
Referrals to Treatment	17	15	13
Drug Tests			
Drug Test Ordered	3894	3783	3690
Drug Tests Conducted	3599	3708	3655
Relapse			
Relapsed	15	20	7
Major Violation Actions			
Cease Practice/Suspension	27	36	21
Termination - PRP	8	5	6
Referral for Discipline	7	6	1
Exit from PRP or Probation			
Successful Completion	15	18	20
Termination - Probation	10	3	2
Voluntary Surrender	25	11	16
Surrender as a result of PTR	1	1	3
Public Risk	8	6	7
Non-compliance	79	52	49
Other	5	9	7
Patients Harmed			
Number of Patients Harmed	None	None	None

Drug of Choice at PRP Intake or Probation			
Pharmacists	**FY14/15**	**FY15/16**	**FY16/17**
Alcohol	11	7	8
Ambien	4	1	
Opiates	5	1	3
Hydrocodone	6		4
Oxycodone	1		1
Morphine			
Benzodiazepines	3		
Barbiturates			
Marijuana	1	1	1
Heroin			
Cocaine			
Methamphetamine			
Pharmaceutical Amphetamine			
Phentermine			
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol	3		2
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine	1		
Intern Pharmacists	**FY14/15**	**FY15/16**	**FY16/17**
Alcohol	1	1	2
Opiates			
Hydrocodone			
Oxycodone			
Benzodiazepines			
Barbiturates			
Marijuana	1		
Heroin			
Cocaine			
Methamphetamine			
Pharmaceutical Amphetamine			
Phentermine	1		
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine			
Pharmacy Technicians	**FY14/15**	**FY15/16**	**FY16/17**
Alcohol	14	7	10
Opiates			
Hydrocodone	1	1	
Oxycodone			
Benzodiazepines	5	2	1
Barbiturates			
Marijuana	5	5	3
Heroin			2
Cocaine	2	2	
Methamphetamine	3	1	2
Pharmaceutical Amphetamine		2	
Phentermine			1
Methadone			
Zolpidem Tartrate			
Hydromorphone			
Clonazepam			
Tramadol			
Carisprodol			
Phendimetrazine			
Promethazine w/Codeine	1	1	