



ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT

Amy Gutierrez, PharmD, Chair, Board President

Greg Lippe, Public Member, Vice Chair

Stan Weisser, Licensee Member

Allen Schaad, Licensee Member

Valerie Muñoz, Public Member

Ricardo Sanchez, Public Member

Report of the Enforcement and Compounding Committee Meeting held on August 31, 2016. A copy of the August 31, 2016, Enforcement and Compounding Committee Meeting minutes are provided in **Attachment 9**.

XI. Enforcement Committee Related Items

Part 1: Enforcement Matters

- a. **University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy, Including Possible Modifications to the Study Parameters - Update and Discussion and Consideration of Modifications to the Pilot Program, if Necessary.**

Attachment 1

Background

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated storage device for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first time fills.

The study, which was originally scheduled to start in June or July of 2015, was delayed until January 2016.

At the February 2016 Board Meeting, the board approved a recommendation to ask UCSD to collect drug classification data as part of the study.

At the June 2016 Enforcement and Compounding Committee Meeting, Dr. Hirsch reported that the kiosk had about 200 users, which is approximately 4 percent of the 4,800 Sharp employees. The kiosk has 24-hour video surveillance and on-site monitoring.

Dr. Hirsch's statistics reported in February indicated there had been 534 total pickups at the kiosk and 334 of those pickups occurred during normal business hours. Additionally, 191 were identified as new prescriptions, 99 were refill prescriptions, and 234 were for over-the-counter (OTC) medications.

Dr. Hirsch stated they need to average 140 prescription pickups per month to reach the study target of 820; however, the current usage of only 80 pickups per month would fall short of that goal based on the current length of the study. Dr. Hirsch requested an extension to continue collecting data through December 2016 and proposed reporting back to the board in March 2017.

At the July 2016 Board Meeting, the board approved the committee's recommendation to:

- 1) allow UCSD to collect data through the first quarter of 2017,
- 2) allow UCSD to report the findings of the study at the May 2017 Board Meeting, and
- 3) allow UCSD to continue operating the kiosk until a decision is made at the May 2017 Board Meeting

Committee Discussion and Recommendation

Dr. Hirsch provided an update of the study via telephone and responded to questions from the committee. A copy of Dr. Hirsch's presentation is included in Attachment 1.

The data she reported includes there are now 289 registered users of the kiosk, which is 6 percent of the eligible campus employees.

Of total prescriptions dispensed since initiation of the study:

Total Medications Obtained: 943

- 72 percent were accessed during pharmacy working hours
- 28 percent were accessed after hours

New Prescription Medications Obtained: 313 (33.2 percent)

- 78 percent were accessed during pharmacy working hours
- 22 percent were accessed after hours

Refills: 237 (25.1 percent of all medication)

- 83 percent were accessed during pharmacy working hours
- 17 percent were obtained after hours

OTC: 393 (41.7 percent of all medication)

- 62 percent were accessed during pharmacy working hours
- 38 percent were accessed after hours

Sara Lake, a representative from the kiosk vendor, Asteres, who is working with Dr. Hirsch on this study was also present at the meeting and responded to questions from board members. She commented that as prescriptions are approved and loaded into the kiosk, patients receive a text to alert them that their medication is available for pick-up. New prescriptions are placed on hold until a telephone consultation has been completed. Consultations are available 24 hours per day, seven days a week. Upon request, consultations are available for refill prescriptions and OTC medications. If a pharmacist wishes to discuss a prescription with a patient, the pharmacist can place a hold on the medication.

In response to questions during the meeting, Ms. Lake explained that Dr. Hirsch completed a study in 2005/06 to research the quality of counseling for refill medications and that this study is not designed to study after hours consultation. Ms. Lake agreed to forward a copy of the study to Dr. Gutierrez and Executive Officer Herold, which can be found in **Attachment 1**.

Reports on the UCSD study will continue to be provided at each Enforcement and Compounding Committee Meeting while the study is underway.

b. CURES 2.0 Prescription Monitoring Program and Use of CURES by Pharmacists – Update and Discussion and Consideration of Next Steps, if Necessary

Attachment 2

Background

As of July 1, 2016, California law requires that all pharmacists with active licenses apply with the California Department of Justice (DOJ) to access CURES. The board has made considerable efforts to ensure pharmacists with active licenses were advised of this requirement. These efforts included a postcard mailing to all pharmacists in February 2016 and a letter sent exclusively to pharmacists who did not have their name listed in CURES at the end of May 2016. The letter triggered more than 2,000 inquiries to the board from pharmacists seeking to become registered or with questions on various issues. The board worked diligently with the DOJ over the following weeks to resolve every issue.

Committee Discussion and Recommendation

Ms. Herold estimated that perhaps 5 percent of registered pharmacists have not signed up for CURES. She stated that this fall, board staff will make another attempt to identify and reach out to pharmacists with active licenses who have not applied for access to CURES.

Ms. Herold commented that often retired pharmacists still hold active licenses and that some of these pharmacists may not have computer access and/or computer knowledge, and consequently may find the registration process difficult.

The board has created an alert system to notify new pharmacists that they must sign up for CURES. Also as board inspectors complete pharmacy inspections, they confirm that pharmacists registered for CURES.

Ms. Herold provided a copy of statistics related to individuals registered for CURES 2.0. Ms. Herold reported that as of August 25, 2016, there are 38,259 dispensers registered for CURES 2.0; most of these dispensers are pharmacists. Dr. Gutierrez commented that patient activity report data reflects that there are three to four times more prescribers than dispensers, yet the dispensers are running a significant number more of the patient activity reports. Both pharmacists and doctors are actively using CURES. Ms. Herold clarified that

“accessed” CURES means that they have logged into the CURES system, whereas patient activity report data reflects the actual use of CURES. A copy of the statistics provided at the meeting is included in **Attachment 2**.

There has been considerable growth since January 2016 in the number of pharmacist registrants and especially in the number of patient profile reports requested by pharmacists and physicians each month.

Ms. Herold stated that about four million controlled substance prescriptions are issued each month. Because patient names are not entered into the CURES system in the same manner each time, the actual number of patients being dispensed controlled substances cannot be readily determined.

Dr. Gutierrez reported that, as approved by the board in the July Board Meeting, researchers at the University California, Davis will be surveying pharmacists who renew their licenses in November to learn about their use and opinion of CURES 2.0. Physicians will participate in a related survey at the same time. Both survey results will be shared with the board. Dr. Gutierrez reported that at some point the board will discuss how CURES 2.0 reporting system will be linked with other states. Ms. Herold stated that all but three states (and California is one of them) are moving toward a single reporting system that will allow the sharing of data across state lines. A number of states are already participating in this system.

c. **Discussion and Consideration of Consumer Enrollment in Automated Refill Programs for Prescription Medications**

Attachment 3

Committee Discussion and Recommendation

Dr. Gutierrez reported that pharmacies have traditionally refilled prescriptions only upon the request of the patient or the patient’s prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs (“auto-refill”). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications.

The argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

In 2012 the *Los Angeles Times* and other media outlets reported issues that generated over 100 auto-refill complaints to the board received from late 2012 through 2013. Supervising Inspector Anne Hunt explained that patient complaints include:

- Allegations pharmacy staff enrolled patients in auto-refill programs without their

knowledge or consent because pharmacists were working under work quotas that directed or rewarded patient enrollment in these programs.

- Patients, or agents who picked up prescriptions for the patient, received prescriptions the patient did not request and had difficulty returning the prescriptions for a refund.
- When patients receive medications that they do not want, it increases the disposal of medication and waste.
- Constant robo calls to pick up medication that the patient did not want or request.
- Patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued or changed by their prescriber. Some of these events resulted in patient harm. This problem is compounded when the patient has multiple doctors and multiple prescriptions. Dr. Hunt stated that there does not appear to be a mechanism to address changes in drug therapy that occur when a prescription is discontinued, the strength is changed, or the patient has been prescribed two different drugs in the same class because one drug was not effective.

In response to the large number of complaints, Ms. Herold and other staff worked with the various agencies to address these concerns and explore possible violations of pharmacy laws and regulations.

In 2013, the Federal Centers for Medicare & Medicaid Services (CMS) proposed new regulations which resulted in additional rules for auto-refill programs for Medicare patients receiving prescriptions from mail order pharmacies. A copy of the CMS Memorandum dated October 28, 2013, regarding Clarification to the 2014 Policy on Automatic Delivery of Prescription for Employer Group Waiver Plans is included in **Attachment 3**.

Since 2013, the number of auto-refill complaints received by the board has decreased; however, the board continues to receive complaints related to these programs.

The committee discussed developing requirements for pharmacies to:

- Consider how often signed consent should be obtained (e.g., annually) and whether signed consent should be obtained separately for each prescription placed on auto-refill.
- With regard to pharmacies in the community practice setting, Dr. Gutierrez said the committee may wish to consider additional requirements for pharmacies to notify patients upon pick up, both verbally and in writing (on the receipt), if the prescription was refilled automatically. Notifying the patient that the prescription was refilled because it was on auto-refill might help to eliminate some of the confusion, or at least open a dialogue with the pharmacist to prevent potential harm to the patient from unwanted refills.
- With regard to mail order pharmacies, Dr. Gutierrez reported that the committee may wish to consider adding requirements consistent with guidance from CMS.
- With respect to both community pharmacies and mail order pharmacies, Dr.

Gutierrez reported that the committee may wish to consider requirements for written policies and procedures related to auto-refill. The policies and procedures might include procedures to ensure discontinued medications are removed from the auto-refill program and that drug therapy reviews are conducted by the pharmacist to prevent duplicate therapies.

Committee Recommendation:

Motion: Board staff will develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

d. **Discussion and Consideration of Statistics for Board Issued Citations and Fines**

Attachment 4

Committee Discussion and Recommendation

At this meeting, Board Chief of Enforcement Julie Ansel provided information regarding citations and fines issued by the board. A copy of Ms. Ansel's presentation which addresses agenda items d and e is included in **Attachment 4**.

Ms. Ansel commented that the top three licensees- pharmacies, pharmacists, and technicians - account for 90 percent of all fines. The remaining 10 percent of fines are spread across wholesalers, clinics, and hospitals.

Ms. Herold stated that a citation and fine or letter of admonishment is not considered formal discipline; it is more equivalent to a speeding ticket. The goal in issuing them is to get the licensee to examine what led to the violation and change his or her practices so that violations do not reoccur.

Assistant Executive Officer Anne Sodergren stated that approximately one third of the investigations opened by the board are as a result of a consumer complaint. The second leading cause of investigations is from DOJ-generated notifications to the Criminal Conviction Unit related to a licensee's arrest.

e. **Discussion and Consideration of Data Describing Medication Errors for Board Issued Citations and Fines**

Ms. Ansel clarified that her presentation includes both items d and e on the agenda – the number of citations and fines issued, and a more detailed look of the medication errors.

f. **Enforcement Statistics**

Attachment 5

Attachment 5 includes the first quarter report of the Enforcement Statistics, SB 1441 Program Statistics and Citation and Fine Statistics for Fiscal Year 2016/17. The committee briefly reviewed the statistics during the meeting.

g. **Future committee meeting dates**

The next Enforcement and Compounding Committee Meeting is January 4, 2017. Board staff is working with the Committee Chair to set meeting dates for 2017.

Part 2: Compounding Matters

a. **[Not Discussed at the August 31, 2016, Committee Meeting]**

Discussion and Consideration of Pharmacy Requests for Compliance Delays for Construction Pursuant to Title 16 California Code of Regulations, 1735.6(f) and 1751.4(i)

Attachment 5.5

At prior committee and board meetings and as permitted in the above regulation sections, the board has discussed a waiver process to permit pharmacies that need to structurally modify their facilities to comply with the new compounding regulations to obtain a delay in full compliance. During this part of the meeting, the board will have an opportunity to discuss the waiver process. A copy of the waiver authority from the board's compounding regulations is:

1735.6 (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.

Provided in **Attachment 5.5** are sample waiver forms that lay out the general information the board can use to make this assessment. There are two forms: one for community pharmacies, the second is for hospital pharmacies.

During this meeting, the board will have an opportunity to review the waiver process and establish a process for how the board will review the waivers (e.g., who will make the decision -- the staff, specific board members, committee or the full board).

1. Requests Received to Date

ATTACHMENT 5.5a

The board has received only a few waiver requests to date. However, most of the requests received have been incomplete and simply request a delay without responding to the information requested. Such requests are nonresponsive to the information the board needs to make a decision.

During this portion of the meeting, the board will have an opportunity to discuss the information submitted in waiver requests that have been received.

2. Process for Reviewing Future Requests

After a review of the few waiver requests received, the board will have an opportunity to determine the process for how waivers will be handled in the future.

b. Discussion and Consideration of Statistics on Compounding Violations Identified by the Board (2014-2016).

Attachment 6

Committee Discussion and Recommendation

At this meeting Supervising Inspector Christine Acosta, provided an overview of compounding violations identified by the board over the last several years which can be found in **Attachment 6**. Dr. Acosta commented on some of the data:

- Licensees do not always complete the compounding self-assessment form. This violation often occurs with new pharmacies or new PIC that fails to complete the assessment within the first 30 days. The assessment allows pharmacies to conduct their own gap analysis.
- Another frequent violation is not having a master formula.
- A discussion of room requirement violations revealed many licensees are not compliant with regulations with respect to compounding room requirements. Dr. Acosta provided examples, such as particle board in the clean room, not cleaning behind the hood, cardboard boxes next to the laminar flow hood, and laminar flow hoods that have non-porous material beneath them.

Dr. Acosta advised that board inspectors are doing a tremendous amount of education to get licensees ready for the change in regulations.

Dr. Gutierrez suggested that future meetings include detailed information on common violations so that the licensees can better understand trends and take preventative measures to comply with regulations.

Dr. Acosta remarked that there are several *The Script* articles in the works that will promote education and transparency. She also stated that the board is receiving more voluntary surrenders of sterile compounding licenses when licensees see that the board has a strong case against them. Licensees tend to not renew their license rather than go through the license revocation process.

Dr. Acosta confirmed that an inspection is required each time a permit is issued or renewed. The board is attempting to complete a full hospital inspection every two years. These inspections take two to three days to complete. Ms. Herold confirmed that our goal is to inspect all pharmacies every four years.

Ms. Herold remarked that sometimes sterile compounding compliance is harder to accomplish for smaller hospitals because they do not have the resources that larger hospitals have.

c. Discussion and Consideration of the Frequently Asked Questions about Sterile Compounding

Attachment 7

Dr. Acosta developed a *draft* of frequently asked questions (FAQ) regarding compounding. A copy of the draft FAQ can be found in **Attachment 7**. However, the final version of the FAQ will not be released until it has been fully reviewed by legal staff, Dr. Gutierrez, and Mr. Schaad and several senior staff.

Dr. Acosta replied to a public comment asking if all hormones should be considered hazardous. She stated that she would not consider all hormones hazardous; however, all hormones should be reviewed because they can be hazardous depending on what the pharmacist is doing with them and how they are being handled. This is the domain of the pharmacist-in-charge.

d. Discussion and Consideration of Frequently Asked Questions about Venting in Compounding Pharmacies

Dr. Gutierrez remarked that questions regarding venting in compounding pharmacies are addressed in the FAQs, which are still under review.

e. **Articles in the News, Including Discussion and Consideration of “Fraud Concerns Grow as Spending on Handmade ‘Compounded’ Drugs Soar”**

Attachment 8

Dr. Gutierrez reported that this article, which was published in the July 17, 2016, edition of *The Washington Post*, reports that government spending on compounded drugs under Medicare’s Part D rose 56 percent over the last year, with topical creams and gels among the costliest products. Over a four-year period, the federal workers’ compensation program reported an increase from 2.35 million to 214 million dollars. A copy of this article is included in **Attachment 8**.

Attachment 1

Study of Expanded Use of an Automated Delivery Device

UPDATE
AUGUST 31, 2016

Jan D. Hirsch, BPharm, PhD

UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences



Update

- ScriptCenter Kiosk
 - Operations Update
- Update on Study
 - Reminder: Research Design & Questions
 - IRB Amendment
 - Study Timeline Requested Revision

ScriptCenter Kiosk Sharp Memorial Hospital

Location Change June 2016



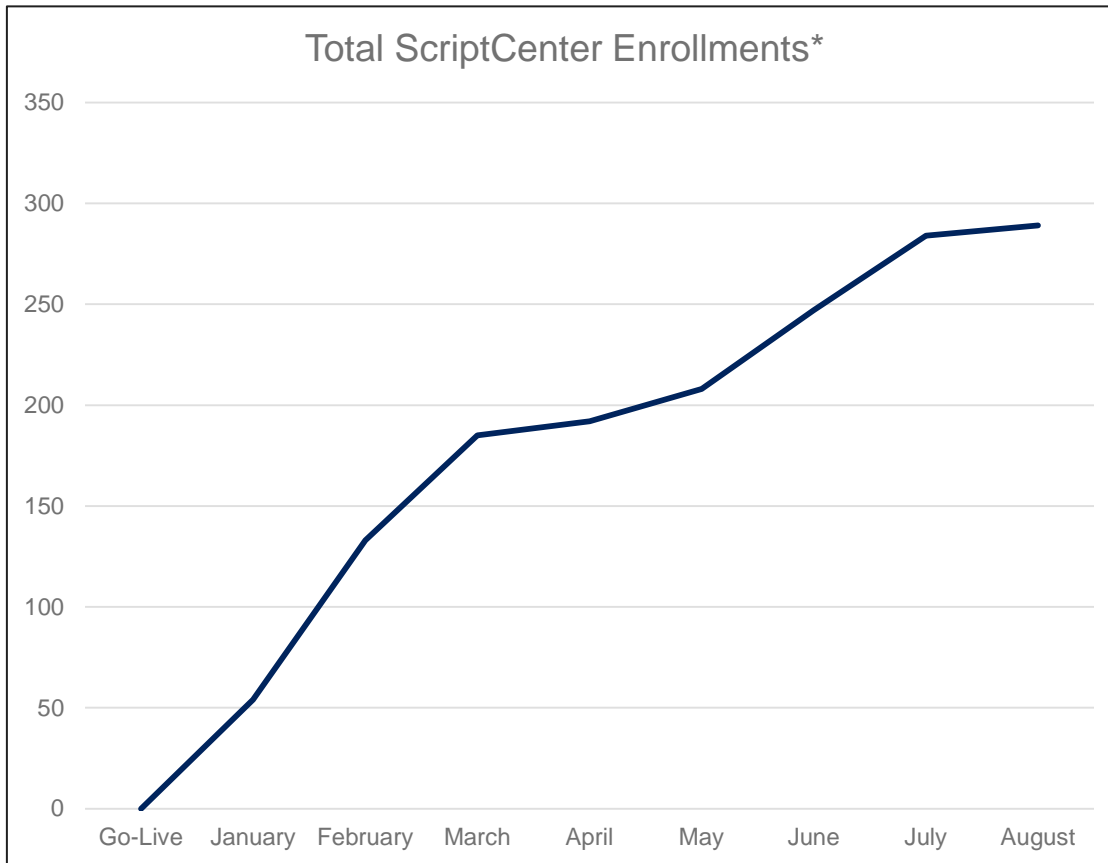
First Floor Lobby Sharp Memorial Hospital



ScriptCenter Kiosk Activity 1/20/16 through 8/9/16

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

ENROLLMENT



289 users
(6% Campus Employees)

Total Campus Employees
4,820

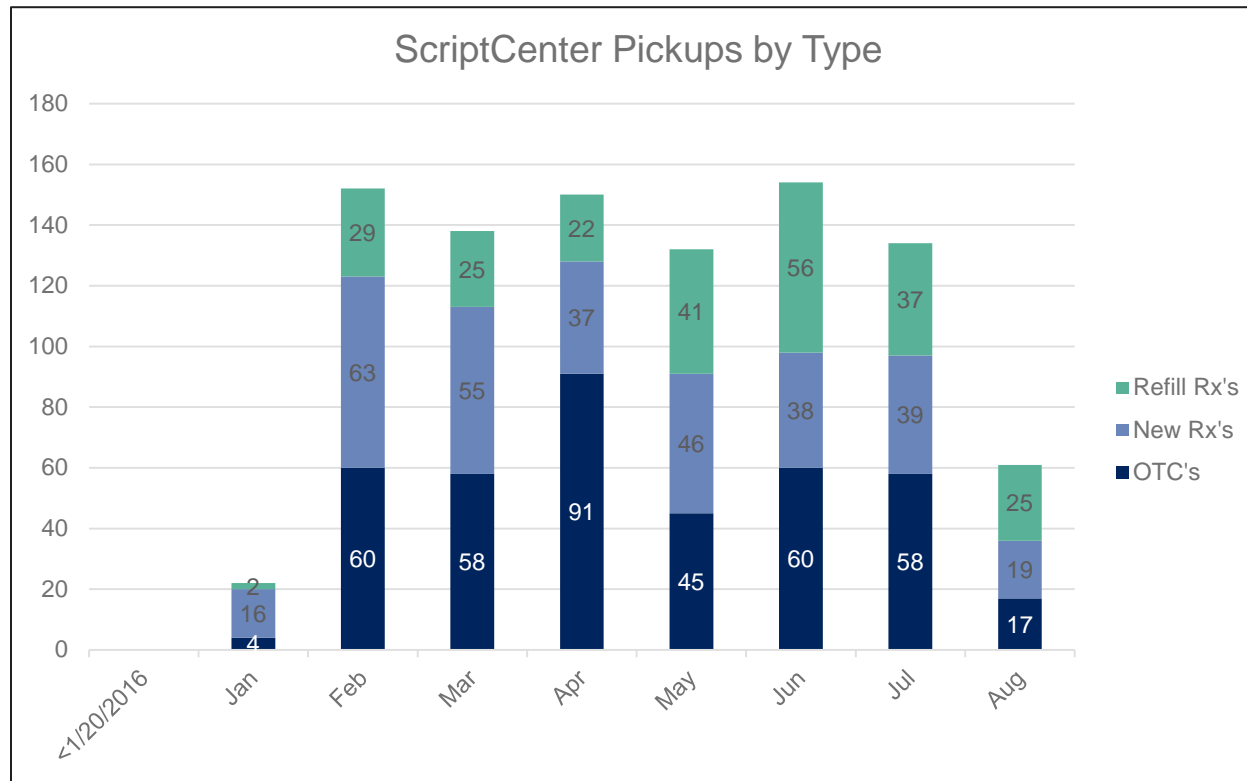
Day Shift = 2,592
PM+ Variable = 2,228

If estimate 2 per household
= 9,640

ScriptCenter Kiosk Activity 1/20/16 through 8/9/16

Pick-ups by Type

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16



- About 80 Rxs per month
- On track for number needed for study (820)
- 376 Rxs in study period
- Data collection expected complete end of December

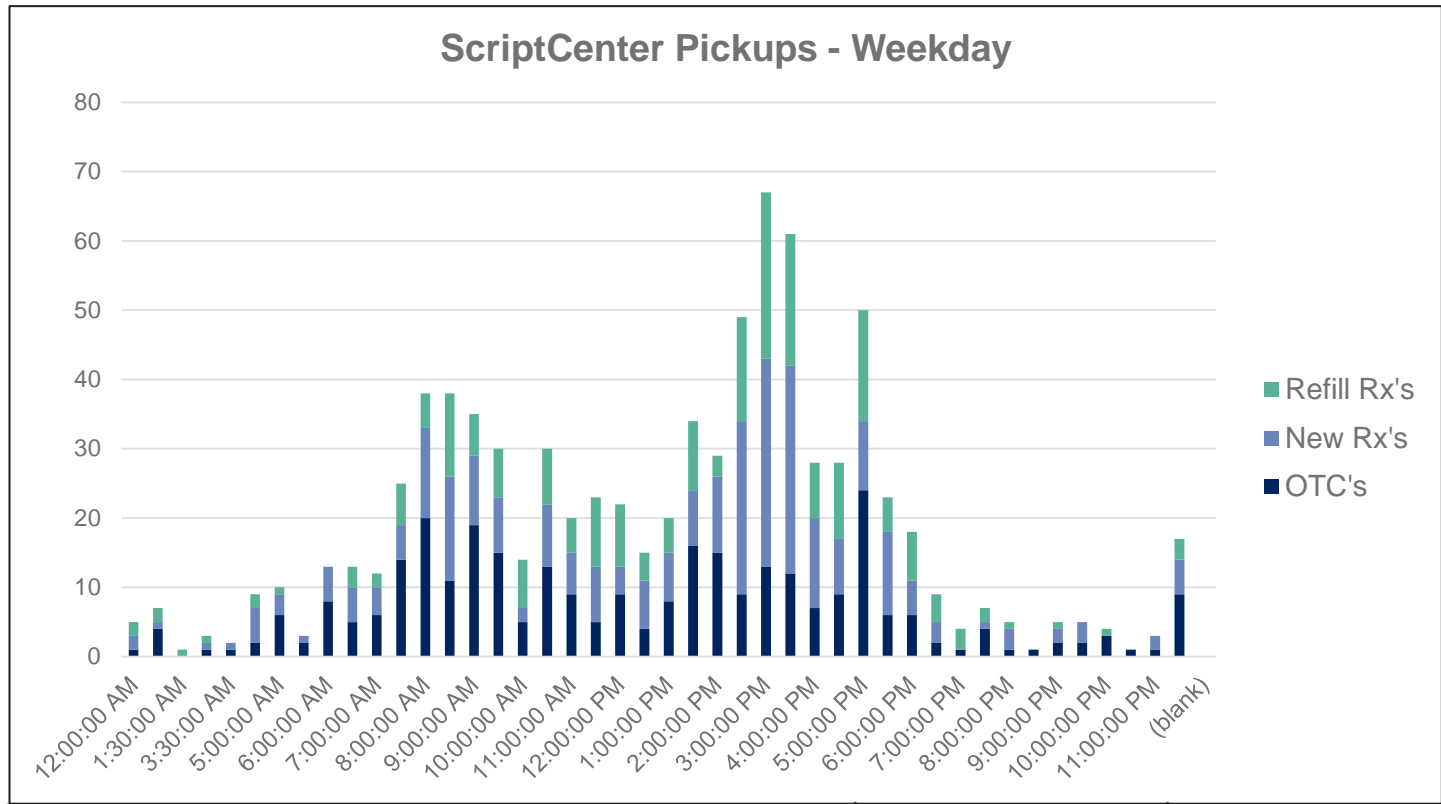
298 Users

Note: Higher 'new prescriptions' in the early months are due to a higher number of prescription transfers when went live. Many of these prescriptions are being turned into refills as time passes.

ScriptCenter Kiosk Activity 1/20/16 through 8/9/16

Pick-ups by Time Weekday

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16



Day Shift
2,592

PM +
Variable
2,228

298 Users

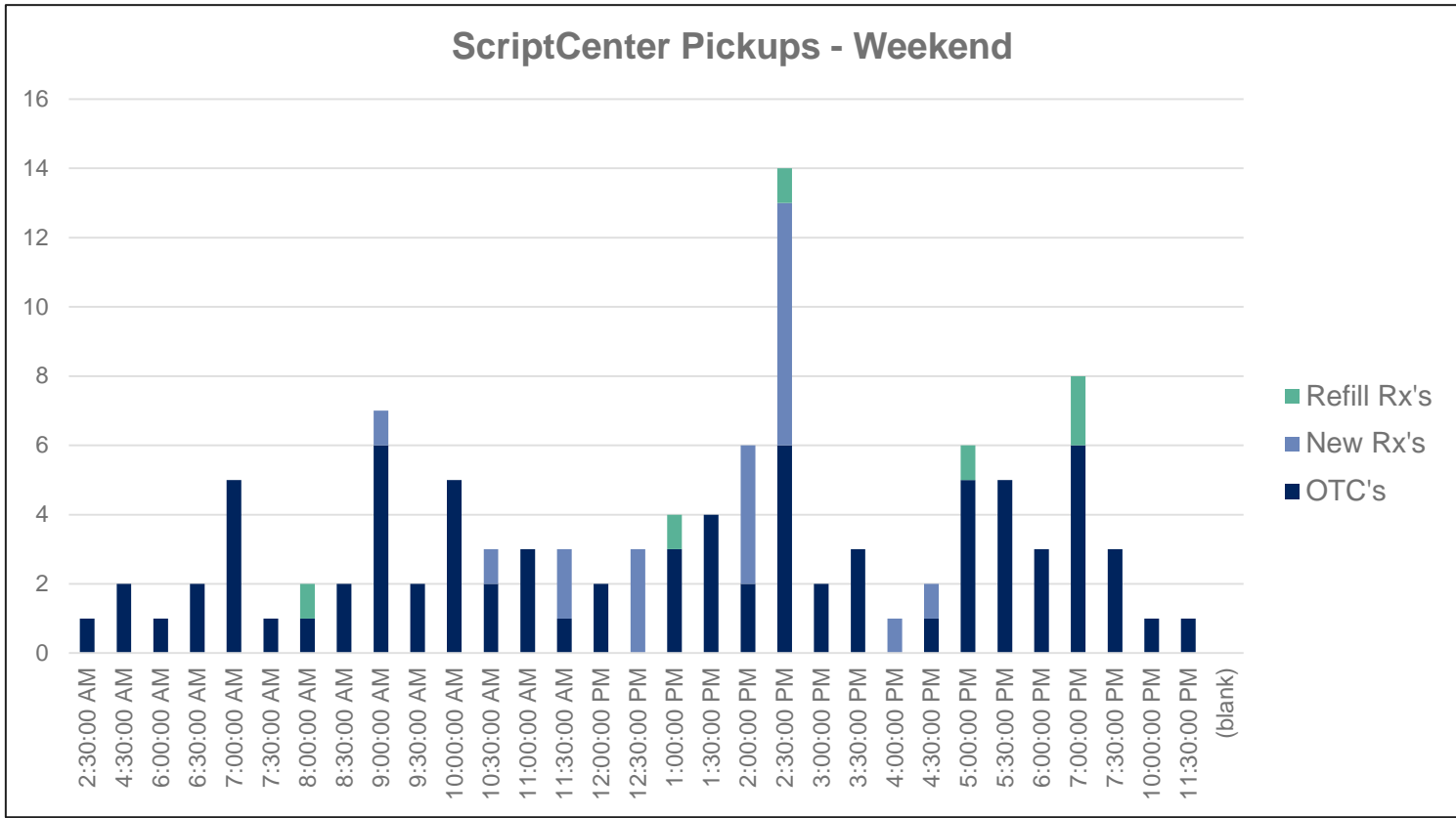
Pharmacy
Closed

Pharmacy
Closed

ScriptCenter Kiosk Activity 1/20/16 through 8/9/16

Pick-ups by Time Weekend

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16



Day Shift
2,592

PM +
Variable
2,228

298 Users



Pharmacy Closed

ScriptCenter Kiosk During vs. After Hours Pick-Up

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

943 Total Pickups

683 (72%) During pharmacy hours
260 (28%) After pharmacy hours

313 New Rx Pickups

243 (78%) During pharmacy hours
70 (22%) After pharmacy hours

237 Refill Rx Pickups

197 (83%) During pharmacy hours
40 (17%) After pharmacy hours

393 OTC Pickups

243 (62%) During pharmacy hours
150 (38%) After pharmacy hours

Day Shift 2,592

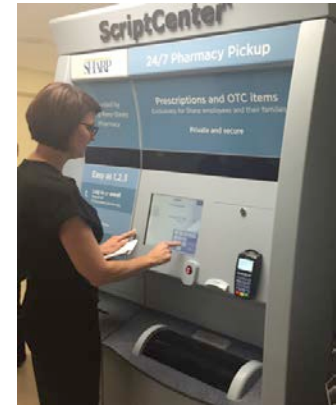
PM + Variable
2,228

298 Users

Data is through 8/9/16.

After hours includes weekday & weekend times pharmacy is closed.

ScriptCenter Kiosk Sharp Memorial Hospital



- No complaints received at Sharp
- Sample of testimonials *(have permission to share)*

“I work weekends and can now pick up my prescriptions when the Sharp Rees-Stealy pharmacy is closed. The 24/7 kiosk is so convenient that I no longer go to anywhere else. I am more comfortable managing my family’s prescriptions here at Sharp. The best part is the text notification alerting me that my medication is ready. This is one less call I have to make to the pharmacy to see if it was filled or if there were any problems. I got a co-worker to switch his pharmacy to Sharp. Very satisfied !!! ”

- *Alisa Valadez – LVN, Sharp Memorial Hospital*

“I love the ScriptCenter prescription pickup kiosk because I never wait in line like I did at other pharmacies. Transferring prescriptions for my family and me to Sharp Rees-Stealy was so easy. I work the night shift so this is super convenient for me. I have told my co-workers about ScriptCenter and highly recommend it for everyone.”

- *Wendell Hatten - Sharp Memorial Hospital Distribution Center*

Study Design

Quasi-experimental with non-randomized control group

- Pre-Kiosk Implementation Survey (Sharp Employees)

Study Start

6 months pre-kiosk
(September 2015 – February 2016)

Month 1: *March*

Month 6: *August*

Month 10: *December*

Regular Counter

- RTS rate*

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

Kiosk

- RTS rate
- Consultation Log
- Time to Pick-up
- Kiosk Patient Satisfaction

Regular Counter

- RTS rate*
- Consultation Log (Sample: New Rx's weeks of 5/23 & 6/6)
- Time to Pick-up*

RTS = Return to Stock

* For employees and dependents

Approved REVISED Study Timetable

- Q4 2015 Pre-kiosk 6-month data collection phase begins

- Q1 2016 Implement Kiosk device (1/20/16)
 Refine data collection tools & process
 Deployment of program/enroll patients

- Q2 - Q4 2016 Post-kiosk implementation
 March – December Data collection and analysis

- Q1 2017 Report Results to Board
 Continue Operate Kiosk



Questions?

UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

**Journal of the
American
Pharmacists
Association
Article**

Patient request for pharmacist counseling and satisfaction: Automated prescription delivery system versus regular pick-up counter

Jan D. Hirsch, Austin Oen, Suzie Robertson, Nancy Nguyen, and Charles Daniels

Abstract

Objectives: To assess the rate of patient-requested pharmacist counseling for refill prescriptions and satisfaction with pick-up process for patients using an automated prescription delivery system (APDS) versus those using a regular pick-up counter and to explore patient willingness to use an APDS as a tool for pharmacist monitoring of medication therapy outcomes.

Methods: In this uncontrolled, cross-sectional, survey study, we assessed use of APDS or the regular counter by 116 patients picking up refill prescriptions at two community pharmacies. The main outcome measures were number of patients requesting pharmacist counseling for refill prescriptions, patient satisfaction with pick-up process, and patient willingness to use an APDS to report medication therapy outcomes.

Results: None of the regular counter users and only two APDS users (3.7%) requested counseling for their refill prescription ($P = 0.126$). Almost all patients agreed that they were able to talk to a pharmacist about their prescription if they wanted to do so (95.1% regular counter and 92.3% APDS; $P = 0.268$). The majority (75%) of patients using APDS indicated that they would be willing to use the system to answer questions or perform simple tests to provide information that the pharmacist could use to improve medication effectiveness or reduce adverse effects.

Conclusion: Very few patients (ADPS or regular counter) asked to speak to a pharmacist about their refill medications, although it appeared that no perceived barriers to pharmacist access existed. Most APDS patients were willing to use this new technology to provide information about therapy outcomes to the pharmacist. Further exploration and testing of the APDS as a data collection tool to enhance pharmacist access to therapy outcomes is warranted.

Keywords: Automation, patient satisfaction, technology, counseling (patient).

J Am Pharm Assoc. 2009;49:73–77.
doi: 10.1331/JAPhA.2009.08037

An automated prescription delivery system (APDS) is a new technology, similar to an automated teller machine (ATM), that can be electronically integrated with a pharmacy's management system, allowing patients to use a password to pay for and pick up their refill prescriptions after the normal pharmacist dispensing and verification process has been completed.¹ The California Board of Pharmacy approved the use of APDS on January 26, 2007, but use on a case-by-case basis via a waiver system has been allowed since October 2004.² Key requirements were that APDS be used for previously dispensed prescriptions only, that the patient provide written consent expressing desire to use APDS, and that the APDS be located adjacent to the secure pharmacy area. In addition, the regulation specified that APDS should not be used if the pharmacist determines that a patient should be counseled on the dispensed medication and that the pharmacy must provide an immediate consultation with a pharmacist (in person or via telephone) if the patient so requests.

Traditionally, pharmacist contact has been facilitated through the prescription pick-up process when a clerk alerts

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the pharmacist of the need to counsel during the transaction (mandated by law only for new prescriptions in California). Obtaining refill prescriptions at an APDS “kiosk” separate from the regular counter removes patients from this process. At the advent of mail service pharmacy in the late 1980s, similar concerns were raised about changes in direct pharmacist and patient interaction. However, many of these initial concerns have been addressed by mail, fax, or phone service consultations and provision of written patient information.³

Implementing APDS technology has potential benefits and risks. Potential benefits for the patient are convenience, less waiting, and ability to pick up refill prescriptions after regular pharmacy hours. Possible benefits to the pharmacy include enhanced patient flow, less congestion, more pharmacist time for patients at the regular pick-up counter, and possibly reduced clerk labor needs. Possible risks of an APDS include lack of patient–pharmacist contact and, thus, less opportunity for pharmacist consultations and appropriate medication management interventions.⁴ Opponents of APDS have also argued that the system may not be secure or accurate.¹

Because the potential benefits of APDS technology are enticing, widespread adoption of this technology could be rapid and affect pharmacy practice considerably. Evaluating the effect of using APDS on patient–pharmacist interactions is warranted at this early stage of APDS evolution.

Objectives

We sought to assess the rate of patient-requested pharmacist counseling for patients using APDS versus those using a regular pick-up counter to obtain refill prescriptions, to assess the satisfaction of patients using APDS versus those using a regular pick-up counter to obtain refill prescriptions, and to explore patient willingness to use APDS in the future as a tool for pharmacist monitoring of medication therapy outcomes.

Methods

This study was conducted at two community pharmacies, which were under the same corporate ownership, in northern San Diego, CA. These pharmacies were the first in California to use APDS technology. The APDS (ScriptCenter—Asteres; Figure 1) had been in use for at least 12 months at each location prior to the study. The pharmacies were 15 miles apart within an upper-middle-class, primarily English-speaking area. Pharmacy operating characteristics were fairly similar at each site (Table 1). Using APDS did not change the manner in which the refill prescription was ordered by the patient or filled by the pharmacist. The only difference in the process was that completed prescriptions were placed inside the APDS instead of being placed in the traditional holding area for pick-up at the counter. A description of the technical and security features of the APDS used in this study can be found at www.asteres.com. Inclusion criteria were that the patient was receiving a refill prescription either at the regular counter or APDS, was able to read and understand written information, and was 18 years of age or older. Patients picking up their prescription at the APDS had already decided to do so before participating in this study

Table 1. Descriptive characteristics of pharmacy sites and survey respondents by site^a

Characteristic	Site 1	Site 2	P
Operating hours per week			
Pharmacy	82	82	
APDS	119	168	
Average no. prescriptions per day	250	232	
Average refill (%)	60	60	
n	39	77	0.021
No. regular counter (%)	15 (38.5)	47 (61.0)	
No. APDS (%)	24 (61.5)	30 (39.0)	
Gender, no. (%)			0.712
Men	14 (36.0)	25 (32.5)	
Women	25 (64.0)	52 (67.5)	
Age, no. (%) ^b			0.004
18–40 years	8 (22.2)	37 (48.1)	
41–64 years	20 (55.6)	36 (46.8)	
≥65 years	8 (22.2)	4 (5.2)	
Person picking up prescription, no. (%)			0.165
Patient	30 (76.9)	67 (87.0)	
Other for patient	9 (23.1)	10 (13.0)	

Abbreviation used: APDS, automated prescription delivery system.

^aPatients with complete data collected during study time periods.

^bMissing three patients for site 1.



Figure 1. The ScriptCenter, an automated prescription delivery system

Table 2. Characteristics respondents: regular counter versus APDS users (sites combined)

	Regular counter		APDS	<i>P</i>
	No. (%)	No. (%)	No. (%)	
n	62	54		
Gender ^a				0.786
Men	20 (32.8)	19 (35.2)		
Women	41 (67.2)	35 (64.8)		
Age ^b				0.186
18–40 years	20 (32.8)	25 (48.1)		
41–64 years	35 (57.4)	21 (40.4)		
≥65 years	6 (9.8)	6 (11.5)		
Person picking up prescription				0.053
Patient	48 (77.4)	49 (90.7)		
Other for patient	14 (22.6)	5 (9.3)		

Abbreviation used: APDS, automated prescription delivery system.

^aMissing for one regular counter patient.

^bMissing for two APDS and 1 regular counter patient.

and had been trained and received their username via regular pharmacy operations.

This study was approved by the University of California, San Diego, Human Research Protection Program. Data were collected during a 1-week period (February 5–10, 2007), Monday through Friday, 3:00 pm to 7:00 pm, and Saturday, 11:00 am to 2:00 pm. These times were chosen based on historical data indicating that they were the busiest days and times of the week. A student pharmacist, trained in the study data collection requirements, was stationed in the pharmacy area during these times to answer questions. The student was instructed not to reveal the specific objectives or comparative nature of the study. Data collection forms were completed for each patient picking up a refill prescription from the regular counter or APDS during the study period (Appendix 1 in the electronic version of this article, available online at www.japha.org). Questions regarding whether the patient or someone else picked up the prescription, if they requested to speak to a pharmacist, and, if so, the category of information needed (medication, payment related, or other) were self-reported by patients using the APDS and observed and recorded by the pharmacy clerk or attending student pharmacist for patients using the regular counter. All other questions were self-reported. Three questions assessed patient satisfaction with wait time, convenience of the pick-up process, and access to a pharmacist. A 5-point Likert-type scale (strongly agree to strongly disagree), was used to quantify responses as described previously.^{5,6} An additional question for APDS users assessed patient willingness to use the system in the future to answer questions or perform simple tests to provide information that the pharmacist could use to improve medication effectiveness or reduce adverse effects. Patients responded on a 5-point Likert-type scale ranging from very willing to strongly unwilling.

Statistical analyses were performed using SPSS version 15.0 (SPSS, Chicago). Descriptive statistics were calculated for each study variable. Frequency distributions were used to

Table 3. Counseling request and satisfaction: regular counter versus APDS users

	Regular counter		APDS	<i>P</i>
	No. (%)	No. (%)	No. (%)	
Asked to speak to a pharmacist?				0.126
Yes	0 (0.0)	2 (3.7)		
No	62 (100.0)	52 (96.3)		
Was able to talk to pharmacist if wanted ^a				0.268
Strongly agree	31 (50.8)	22 (42.3)		
Agree	27 (44.3)	26 (50.0)		
Not sure	1 (1.6)	2 (3.8)		
Disagree	0 (0.0)	2 (3.8)		
Strongly disagree	2 (3.3)	0 (0.0)		
Waited a long time to pick up prescription ^b				0.188
Strongly agree	1 (1.6)	2 (3.7)		
Agree	5 (8.2)	1 (1.9)		
Not sure	3 (4.9)	0 (0.0)		
Disagree	21 (34.4)	17 (31.5)		
Strongly disagree	31 (50.8)	34 (63.0)		
Overall process to pick up prescription was convenient ^b				0.583
Strongly agree	31 (50.8)	29 (53.7)		
Agree	22 (36.1)	22 (40.7)		
Not sure	2 (3.3)	0 (0.0)		
Disagree	3 (4.9)	2 (3.7)		
Strongly disagree	3 (4.9)	1 (1.9)		
Willing to use APDS to provide information to improve medication management ^c				NA
Very willing	NA	16 (30.8)		
Somewhat willing	NA	23 (44.2)		
Not sure	NA	8 (15.4)		
Unwilling	NA	5 (9.6)		
Strongly unwilling	NA	0 (0.0)		

Abbreviation used: APDS, automated prescription delivery system; NA, not applicable.

^aMissing for two APDS and one regular counter patient.

^bMissing for one regular counter patient.

^cMissing for two APDS patients.

examine patient demographics, to examine counseling rates, and to describe the responses to satisfaction questions. Comparisons among groups were conducted using chi-square analyses. Statistical significance was based on an alpha of 0.05.

Results

A total of 116 respondents returned completed surveys; 39 from site 1 and 77 from site 2 (Table 1). The majority of survey respondents were women and were picking up a prescription for themselves at each site. A larger percentage of respondents at site 1 were 65 years of age or older ($P = 0.004$) and used the APDS as opposed to the regular counter ($P = 0.021$) to pick up their refill prescriptions. Based on historical data for the average number of refill prescriptions dispensed per day at each site and an estimate of 1.5 prescriptions per patient, the 39 respondents at site 1 and 77 respondents at site 2 represented approximately 20% and 39% of the daily number of patients

picking up refill prescriptions during the study data collection time brackets, respectively.

When data from the two sites were combined for subsequent analyses due to small sample sizes at each site, the response rate was approximately 29%.

APDS versus regular counter users

No difference was observed in the gender or age distribution of respondents picking up their prescription at an APDS versus regular counter ($P = 0.786$ and $P = 0.186$, respectively) (Table 2). The patient was almost always the person picking up their refill prescription at the APDS (90.7%) compared with the regular counter, where 22.6% of prescriptions were picked up by someone other than the patient ($P = 0.053$).

Counseling requests and satisfaction

Very few patients asked to speak to a pharmacist when receiving their refill prescription (no regular counter users and only two [3.7%] APDS users; $P = 0.126$) (Table 3). One APDS patient had a question about payment and the other had a nonmedication question. Almost all patients agreed that they were able to talk to a pharmacist about their prescription if they wanted to do so (95.1% regular counter and 92.3% APDS; $P = 0.268$). The majority of regular counter and APDS users disagreed that they had waited a long time to pick up their prescription (85.2% regular counter and 94.5% APDS; $P = 0.188$) and agreed that the pick-up process was convenient (86.9% regular counter and 94.4% APDS; $P = 0.583$). The majority (75%) of patients using APDS also indicated that they would be willing to use the system to answer questions or perform simple tests to provide information that the pharmacist could use to improve medication effectiveness or reduce adverse effects.

Discussion

This is the first study, to our knowledge, that has systematically assessed the rate of patient request for pharmacist counseling for patients receiving their refill prescriptions at an APDS versus regular pharmacy counter. No significant difference was observed in the age or gender of patients using APDS or regular counter to pick up refill prescriptions. However, APDS users were more likely to be the patient picking up their own prescription compared with regular counter users. This was not unexpected because APDS requires a personal username and password for use.

Although pharmacist counseling for prescriptions has been generally accepted as an important part of the medication dispensing process and is required by law for new prescriptions in California, the results of this study suggest that counseling is rarely requested by patients for their refill prescriptions. Although only two patients asked to speak to a pharmacist about their refill medication, almost all patients (APDS and regular counter) felt that they were able to speak to a pharmacist if they had wanted to do so. The majority of patients also agreed that their wait time was not long and that the overall prescription pick-up process was convenient at both APDS and the regular counter. This implies that no perceived barriers to pharmacist

access for patients at the regular counter or APDS existed, but instead that patients simply did not feel the need to ask the pharmacist questions about their refill medication. Potential reasons for patients not asking questions about their refill medication include a lower need for information for a continuing medication compared with a new medication, availability of information via other sources (e.g., printed information with prescriptions or via Internet sources), or lack of patient time. A similar study of an ambulatory clinic-based community pharmacy in San Diego found a similar low rate (3%) of counseling for refill prescriptions despite the fact that patients receiving any prescription medications (refill or new) in this pharmacy were routinely asked if they would like to speak to a pharmacist.⁷

Any new prescription delivery technology will elicit controversy, but the possible future benefits should also be considered. It was encouraging that the majority of APDS users indicated that they were willing to use the system to answer questions or perform simple tests to provide information that the pharmacist could use to improve medication effectiveness or reduce adverse effects. Using APDS to collect patient-reported outcomes could fill an information void for the pharmacist. Most community pharmacists today do not have the same degree of access to documented clinical outcomes for patients as a physician or nurse would have in a clinic setting. Expanding the APDS scope to allow patients to answer simple questions about their symptom response or possible adverse effect occurrence or to electronically download laboratory values (e.g., blood glucose history since last visit) could provide pharmacists with outcomes data on an ongoing basis. Future research should investigate opportunities to optimize the use of APDS technology to expand the effectiveness of the pharmacist's role in medication therapy management.

Limitations

The major limitations of this study are that it was conducted on a small convenience sample of patients in only two pharmacies that were among the first to use APDS technology. Patients self-selected to use APDS or the regular counter for their refill pick up; however, this trend would occur in actual practice. Randomization, therefore, would have strengthened the study design but would not have been practical. Our observation period was limited to busy time periods in a single week, and our questionnaire had a very limited number of questions to minimize survey completion time; thus, the scope of our study is limited. Notably, the focus of our study was refill prescriptions because these were the only type of prescriptions delivered via APDS. Therefore, we only measured pharmacist counseling related to refill prescriptions. We did not examine any other patient-pharmacist interactions that occur throughout the course of pharmacy practice (e.g., new prescriptions, over-the-counter medication, disease questions, testing). Our results from two pharmacies cannot be considered representative of the APDS experience in community pharmacies overall but can be used to inform future studies.

Future studies need to include a larger number and wider

variety of pharmacies using APDS technology as its usage expands. Replicating this study at other pharmacy practice sites would provide, at a minimum, a benchmark for interpreting refill consultation rates—at APDS and the regular counter—that does not exist currently. In addition, although counseling for new prescriptions may be a legal requirement, measuring the rate of actual patient acceptance, and thus occurrence, of pharmacist counseling for new prescriptions is also warranted to provide a comparative value for refill counseling rates (APDS or regular counter). Further exploration and testing of APDS as a data collection tool that would give the pharmacist access to therapy outcomes is perhaps the most important next step. APDS technology has the potential to be more than a one-sided delivery mechanism; instead, it could be a new two-way communication system between the patient and the pharmacist for information that was not able to be systematically exchanged in the past. APDS could be used to facilitate the patient–pharmacist interaction to enhance the pharmacist’s ability to identify and resolve drug therapy problems and the patient’s knowledge of when to speak to a pharmacist (e.g., any new adverse effects).

Conclusion

Very few patients using APDS or the regular counter asked to speak to a pharmacist about their refill medications, although almost all patients believed that they could speak to a pharmacist if they had wanted to do so. Because the majority of patients agreed that their wait time was not long and that the overall prescription pick-up process was convenient, no perceived barriers to pharmacist access appear to exist; patients simply did not perceive the need to ask the pharmacist questions about their refill. Further exploration and testing of APDS as a data collection tool to enhance pharmacist access to ther-

apeutic outcomes is warranted. The effect of APDS technology on pharmacist–patient interactions and data collection in the context of prescription-specific counseling versus the broader, more multifaceted, role of pharmacists providing medication therapy management services would also be useful to explore.

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Appendix 1. Data collection form (APDS version)

1. Your Age: 18-40 41-64 65 and older

2. Your Gender: Male Female

3. Did you pick up your own prescriptions? Yes No

4. Did you request to speak to a Pharmacist? Yes No

5. If requested, why did you request to speak to pharmacist?

- Medication related questions
- Payment or insurance questions
- Other

6. I waited a long time to pick up prescription(s) from the ScriptCenter.

Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Overall the process to pick up prescription(s) was convenient

Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. I feel I was able to talk with a pharmacist if I wanted to do so.

Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. In the future, the ScriptCenter may collect information the pharmacist can use to help improve your medication's effectiveness or reduce any side effects you may experience.

Please indicate your willingness to answer questions or perform a simple test to gather this information.

Very Willing	Somewhat Willing	Not Sure	Unwilling	Strongly Unwilling
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Attachment 2

Individuals Registered	January 25, 2016	April 25, 2016	July 25, 2016	August 25, 2016
2.0 Prescribers	4,940	64,130	121,417	122,491
2.0 Dispensers	5,933	29,130	38,071	38,259
Pharmacists	N/A	17,219	29,639	30,096

Patient Activity Reports* *one month prior ending on the 25th	January 25, 2016	April 25, 2016	July 25, 2016	August 25, 2016
Prescribers	31,425	217,635	254,459	281,212
Dispensers	64,647	389,364	445,295	493,322

Access	January 25, 2016	April 25, 2016	July 25, 2016	August 25, 2016
Medical Doctor	49,881	142,106	161,499	173,484
Pharmacist	102,347	386,553	445,295	489,960

Attachment 3



CENTER FOR MEDICARE

DATE: October 28, 2013

TO: Employer Group Waiver Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

RE: Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions for Employer Group Waiver Plans

The Centers for Medicare and Medicaid Services (CMS) announced in the 2014 Call Letter that Part D sponsors should require their network retail and mail pharmacies to obtain beneficiary or authorized representative consent to deliver a prescription, new or refill, prior to each delivery. Beneficiaries cannot be required to use mail-order pharmacy, nor can plans auto-enroll Part D beneficiaries in automatic fill/automated refill and delivery programs (referred to in this memo generally as “automatic delivery programs”). This applies to all Employer Group Waiver Plans (EGWP) offered by Medicare Advantage-Prescription Drug Plan sponsors or stand-alone Part D sponsors.

CMS has been analyzing a request to allow EGWPs to continue offering automatic delivery programs, without obtaining consent prior to each delivery, if the automatic delivery program design supports beneficiary-directed care and minimizes beneficiary liability for unwanted shipments. CMS continues to track a large number of complaints related to automatic delivery programs. Complaints include beneficiaries reporting that they were auto-enrolled in automatic delivery programs, difficulty stopping auto-shipments, ongoing automatic credit card charges for unneeded/unwanted orders, and receiving unwanted items that their prescribing provider submitted directly to the pharmacy.

In a HPMS memo dated July 17, 2013, we proposed characteristics of EGWP automatic delivery programs that would meet CMS’ expectations for ensuring beneficiary-directed care and minimize beneficiary liability. After reviewing the comments submitted, we are now clarifying that for Calendar Year 2014 only, the policy for obtaining consent prior to each delivery is not required for beneficiaries in EGWP auto-ship programs if the following conditions are met and can be demonstrated upon request (including audit):

1. Enrollee participation in the automatic delivery program is voluntary and opt-in only;
2. The automatic delivery program only applies to prescription refills and does not apply to new prescriptions that are e-prescribed, faxed, mailed, or phoned-in directly to the pharmacy, even if the new prescription is a continuation of existing therapy;

3. The EGWP has easy to locate and easy to understand beneficiary materials on how to disenroll from automatic delivery programs, and the EGWP responds promptly to all disenrollment requests;
4. The EGWP will provide a full refund to the beneficiary and delete the prescription drug event (PDE) for any auto-shipped refill that the beneficiary reports as unneeded or otherwise unwanted. Beneficiary materials related to refunds must be easy to locate and easy to understand. Plans providing no-fee return of unneeded or unwanted drugs do not need to provide a full refund or delete the PDE when the prescription has been fully or partially used or consumed;
5. The EGWP will confirm whether the beneficiary wants to continue in the automatic delivery program at least annually and upon receipt of a new prescriptions from a provider, even if the new prescription is a continuation of existing therapy; and
6. The EGWP will promptly discontinue automatic delivery after notification that a beneficiary entered a skilled nursing facility, or elected hospice coverage.

EGWP sponsors interested in offering an automatic delivery program that does not feature obtaining consent prior to each delivery after January 1, 2014 must submit a request to PartDPolicy@cms.hhs.gov no later than December 18, 2013. EGWPs will need to submit the sponsor name, contract number(s), and whether the automatic delivery program will be applied to some or all of their EGWP contracts

CMS will be closely monitoring this and other EGWP-specific policies in the coming year to determine the best course of action starting in 2015.

For further questions on automatic delivery policy for 2014, please contact Marie Manteuffel at (410) 786-3447 or Marie.Manteuffel@cms.hhs.gov.

Pharmacy Self-Auditing

Control Practices to Improve Medicaid Program Integrity and Quality Patient Care—Booklet 4: Billing Practices





Content Summary

This booklet is the fourth in a four-booklet series that discusses areas of pharmacy practice prone to triggering audits that pharmacy health care professionals should examine. This booklet focuses on billing practices. The other booklets examine provider prescribing practices, controlled substance management, and invoices and claims management. The four booklets may be used together or independently as a self-audit to identify areas of risk as well as opportunity for improvement.

The Affordable Care Act of 2010 expanded Medicaid eligibility in States that have adopted Medicaid expansion. In such States, Americans who earn less than 138 percent of the Federal poverty level, \$33,465 for a family of four in 2015, are eligible to enroll in Medicaid.[1] The National Health Expenditure Projections Forecast for 2014–2024 estimates Medicaid spending will grow by 5.9 percent on average annually from 2015 through 2024.[2]

The Medicaid expansion will impact Medicaid prescription drug utilization and expenditures. Private insurers lose about 1 to 1.5 percent of expenditures to fraud, while Medicaid may be closer to 10 to 15 percent.[3] Experts estimate another 20 to 30 percent of Medicaid dollars are lost to abuse or unnecessary services.[4]

According to the Kaiser Family Foundation, the Medicaid program paid 520 million prescription claims and spent \$20.6 billion in total utilization expenditures in 2012, after recouping rebates.[5] The sheer volume of claims and expenditures requires Medicaid to protect itself from fraud, waste, and abuse.

Pharmacists' unique role in the health care system often allows for intervention before fraud, waste, or abuse occurs. Due to the high risk for improper payments, the Centers for Medicare & Medicaid Services (CMS) developed this toolkit to educate pharmacy providers on self-audit precautions related to invoice management, controlled substances management, proper billing practices, and proper prescribing practices. In addition, this toolkit addresses potential fraud, waste, and abuse related to pharmacy services and how to report them.

Pharmacy providers can identify areas of practice that require further scrutiny and can use these tools to educate staff about potential fraud, waste, and abuse.

Title 18 of the United States Code defines health care fraud as knowingly and willfully executing, or attempting to execute, a scheme to defraud a health care program or obtain money or property from a health care program under false pretenses.[6] Medicaid fraud artists intentionally submit false claims or misrepresent facts to obtain funds to which they are not entitled.[7]

Federal Medicaid regulations do not define waste. Waste is similar to fraud, but it is not usually associated with criminal actions.[8] Think of waste as overutilization or misuse of services. Abuse may encompass waste and includes any action that may cost the Medicaid system unnecessary dollars. Abuse may include improper payment for services, payment for services that fail to meet professionally recognized standards of care, or payment for services that are medically unnecessary.[9] Abuse includes reimbursement for claims to which the provider is not entitled, but health care professionals guilty of abuse do not intentionally misrepresent facts to obtain payment. Like waste, abuse is not usually associated with criminal actions.

The Federal False Claims Act (FCA) is an important tool for combating fraud. In general, the FCA imposes civil liability on people who knowingly submit a false or fraudulent claim or engage in various types of misconduct involving Federal government money or property. From January 2009 through the end of the 2013 fiscal year, the Justice Department used the FCA to recover more than \$12.1 billion in health care fraud.[10]

A 2012 Office of Inspector General (OIG) report identified 2,637 retail pharmacies with questionable billing practices. The investigation found suspect pharmacies billed high dollar amounts per beneficiary, billed a high number of prescriptions per beneficiary, or billed for a high number of prescriptions per physician prescriber.[11] As a result, the OIG recommends CMS strengthen oversight of pharmacies and pharmacy audits.[12] Pharmacists can take the initiative to self-monitor practices within the pharmacy to prevent, identify, and correct potential fraud, waste, or abuse.

The audit process is a means of reviewing pharmacy practices to ensure staff members uphold operational procedures. State and Federal programs, such as Medicaid and Medicare Part D, State licensing boards, the

United States (U.S.) Drug Enforcement Administration (DEA), the U.S. Internal Revenue Service (IRS), and other third-party payers, conduct pharmacy audits. Through the pharmacy self-audit tool, pharmacy staff members can evaluate daily practices, pinpoint potential audit triggers, and proactively address vulnerabilities. Like any developing habit, a self-audit can become a part of daily, weekly, or monthly tasks.[13] Pharmacy managers can customize the pharmacy self-audit to ensure it addresses all pharmacy-specific compliance and operational procedures. When developing the blueprint for a customized pharmacy self-audit, consider the different forms of prescription drug fraud, waste, or abuse that may occur in the particular pharmacy setting, and focus on these vulnerabilities.

Fraud, waste, or abuse may occur as a result of billing miscalculations—quantity miscalculations or days’ supply miscalculations. Fraud, waste, or abuse may also occur in the pharmacy as a result of inappropriate practices, including refill practices, overrides, partial fills, delivery documentation, or package size selection.

Pharmacists can help protect State Medicaid patients from harm and State Medicaid dollars from waste by educating staff members, providing billing job aids, and making sure all pharmacy staff members know what to do in the event a Medicaid billing error is discovered.

Billing Practices Self-Audit

This booklet (Booklet 4—Billing Practices) contains 15 of the 50 steps to conduct a pharmacy self-audit and examines common quantity and days’ supply billing errors. In addition, inappropriate refill practices, overrides, partial fill procedures, and package size selection are discussed. A thorough review of these steps as they pertain to pharmacy practice will help pharmacies preserve State Medicaid program integrity and improve the quality of patient care for State Medicaid beneficiaries. Consider each step, answer the questions listed, and examine existing policies and procedures to identify any audit triggers related to billing practices.

The three additional booklets in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” Toolkit (Booklet 1—Prescribing Practices, Booklet 2—Controlled Substances Management, and Booklet 3—Invoice Management) contain the remaining steps, with audit questions and detailed information regarding each step. The steps in the four booklets correspond to the steps in the document titled “Pharmacy Auditing and Dispensing: The Self-Audit Control Practices to Improve Medicaid Program Integrity and Quality Patient Care Checklist.”

Pharmacists represent a unique line of defense against fraud, waste, and abuse. Pharmacists may help uncover unnecessary costs to the Medicaid system by taking a close look at billing practices that include billing units, refill practices, overrides, partial fill procedures, package size selection, and proof of delivery documentation. If the following self-audit steps reveal potential overpayments, the self-audit toolkit explains what to do next.

36. Discuss billing procedures with staff to determine whether staff members correctly submit claims for drugs commonly submitted with improper billing units. Provide staff members with job aids associated with common types of quantity and/or days’ supply miscalculations. The examples below are not comprehensive but suggest potential targets for job aids.
 - Oral products;
 - Anti-migraine agents;
 - Bowel preparations;
 - Multi-drug/multi-month packs; and
 - Osteoporosis agents.

- Other dosage forms;
 - Inhalers;
 - Ophthalmic products;
 - Topical products; and
 - Vaginal products.
- Injections; and
- Kits.

Reimbursements and rebates are two components of Medicaid prescription drug programs. When a pharmacy dispenses a prescription for a Medicaid beneficiary, the State Medicaid agency (SMA) reimburses the pharmacy, and then pharmaceutical manufacturers provide statutorily-defined rebates to the SMA for each unit of drug that was dispensed. SMAs reimburse pharmacies using the National Council for Prescription Drug Program’s Billing Unit Standard (BUS), while pharmaceutical manufacturers submit rebates to SMAs using CMS unit of measure standards. Because SMAs must convert BUS units to CMS units, a pharmacy BUS claim submission error may also result in inaccurate pharmaceutical manufacturer rebates to the SMA.[14] If a pharmacy submits a claim for a drug with a National Drug Code (NDC) other than the NDC for the drug the pharmacy actually dispensed, the SMA may receive a rebate to which the State was not entitled or may not receive a rebate to which the State was entitled.

37. Review prescription requirements for non-controlled and controlled substances.[15, 16, 17]

- Date of issuance;
- Prescriber’s signature;
- Prescriber’s authority to prescribe (For example: mid-level prescribers versus physicians; State regulations versus Federal days’ supply regulations; and authorization to prescribe specific controlled drug schedules);
- Drug name;
- Drug strength;
- Drug dosage form;
- Quantity of drug prescribed;
- Directions for use;
- Number of refills authorized by the prescriber (if any);
- “Brand name medically necessary” if no generic substitution is allowed;
- If handwritten, controlled substance prescriptions must be written in ink or pencil that cannot be erased; and
- Prescribers must manually sign controlled substance prescriptions on the date issued.

38. Ensure staff members are able to correctly calculate a day’s supply for prescriptions.

- Multiply the number of doses per day by the number of days of therapy to determine the correct quantity to dispense; and
- Reverse-verify by dividing the quantity dispensed by the number of doses per day to determine the number of days’ supply.

39. Talk to pharmacy staff members about prescriptions written for odd quantities.

- Reduce the quantity dispensed to correspond to a number of days equal to or less than the plan-imposed maximum if the days' supply calculated by dividing the quantity dispensed by the number of doses per day exceeds the plan-imposed maximum allowable days' supply.

Upon review of the prescription, pharmacists may see quantities and days' supplies that do not align. Inaccurate claim submission of these types of discrepancies may lead to negative audit findings. For example, if the prescription presented is written for 100 tablets for a 30 days' supply, but the sig code states the drug should be taken three times daily, the pharmacist must either adjust the dispensed quantity to 90 tablets for 30 days or adjust the days' supply to 33.

40. Talk to pharmacy staff members about prescriptions written for doses that exceed Food and Drug Administration (FDA) labeling.

- Examine high doses with scrutiny;
- Consult the FDA label;
- Contact the prescriber to verify the dose if it exceeds FDA recommendations; and
- Document all communication on the hard copy.

Pharmacists should consult a drug reference if a prescribed dose appears in excess to determine if the dose prescribed is within FDA-labeled guidelines. The National Library of Medicine provides a free drug reference, DailyMed, accessible at <https://dailymed.nlm.nih.gov/dailymed/index.cfm> on the National Institutes of Health website. In addition, the FDA maintains a database of approved prescription labeling, Drugs@FDA, accessible at <https://www.accessdata.fda.gov/scripts/cder/drugsatfda/> on the FDA website. Simply enter the name of the drug, navigate to the drug in question, and consider the dosage and administration guidelines listed in the product label. If the dose prescribed exceeds FDA-labeled recommendations, contact the prescriber to verify the dose. Document the verification on the hard copy. Include the diagnosis and the reason for override on the hard copy, if available.

41. Talk to pharmacy staff members about prescriptions that include the use-as-directed sig code for dispensed quantities more than one billing unit per month.

- Shampoos—Document frequency of use and size of area to be treated;
- Creams and ointments—Document frequency of use and size of area to be treated;
- Migraine medications—Document number of headaches treated per month;
- Insulin—Document exact regular dosage and maximum daily dosage for any sliding scale directions; and
- Diabetic syringes, test strips, or lancets—Document maximum use per day.

Prescriptions that require more than one billing unit per month require more concise directions to accurately represent the days' supply. Contact the prescriber to determine the maximum daily dose and gather detailed information for each of these types of medications.

42. Talk to pharmacy staff members about refill practices.

- Do not push-bill or auto-refill without patient consent or request or when prohibited by State law;
- Do not refill and mail to patients without request or patient consent, and only perform patient outreach to initiate refills in attempts to improve medication adherence and clinical outcomes; and



- Do not use financial incentives to influence beneficiary decisions about when or where to fill prescriptions paid by a federally funded program.

Consider the risk for fraud, waste, or abuse if pharmacy staff members use inappropriate refill practices (for example: push-billing and auto-refills, refilling and mailing to patients without request or consent, or financial incentives). Push-billing occurs when pharmacy providers auto-refill prescriptions without beneficiary consent or request. The U.S. Department of Justice’s Civil Fraud Division investigated auto-refill practices at a major retail chain and alleged the chain auto-refilled and billed prescriptions without patient consent while pressuring pharmacists to meet 40 percent auto-refill enrollment goals.[18]

A suspect refill tactic targeted at Medicaid beneficiaries includes refilling prescriptions without a patient request and mailing the completed prescriptions to the beneficiary. Pharmacy providers should not auto-refill without a request from the beneficiary. Providers should only contact a beneficiary to solicit requests for medication refills if the pharmacy provider has assessed the beneficiary’s prescription history and the patient outreach is an attempt to improve the patient’s medication adherence and clinical outcome.[19]

Financial incentives influence a patient’s choice of pharmacy services for prescription refills and are prohibited. “Pharmacies are not allowed to improperly influence the decision-making of Medicare and Medicaid patients about where to fill prescriptions,” said Special Agent in Charge Glenn R. Ferry for the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). “Pharmacy chains that manipulate patient choices in this way will be held accountable.”[20] Financial incentives may include shopper loyalty programs that provide cents off gallons of gas or store credit, gift cards, or merchandise. Pharmacies should not waive copayments (if applicable) as an incentive for the patient to refill unneeded prescriptions. However, most States require a pharmacy to fill and dispense a Medicaid prescription, even if the beneficiary cannot pay the copayment or refuses to pay the copayment.

43. Consider possible patient-driven inappropriate refill practices.

- Counsel patients if stockpiling is suspected;
- Be aware of red flags that may indicate diversion and require further scrutiny; and

- If diversion is suspected, report concerns to the proper authorities.

Patients may stockpile—accumulate excessive and inappropriate amounts of prescription and over-the-counter drugs—for future use. Patient motives for stockpiling vary from fear of drug shortages or unexpected changes in prescription drug benefits to accumulation of drugs for the purpose of diversion or abuse.[21] Patients who stockpile may seek prescriptions from multiple prescribers, and unnecessarily accumulating drugs contributes to waste and abuse in the health care system.[22]

Drug diversion occurs when patients or other individuals divert drugs from the legal supply chain to an illegal supply chain for unlawful, often recreational, purposes. Drug diversion may occur anywhere along the supply chain: manufacturer, distributor, wholesaler, pharmacy, or end-user. Illicit drug distribution occurs in absence of a legal and medically necessary purpose. Costs of the prescription drug diversion epidemic to State Medicaid programs go far beyond the cost of the drug itself. Diversion results in additional costs to the SMA associated with emergency room visits, physician’s visits, and rehabilitation services.[23] Ensure pharmacy staff members are familiar with ways patients commonly divert prescription drugs, including: card sharing, medication sharing, prescription pad theft, forged or altered prescriptions, doctor shopping, and theft.

Red flags that may indicate diversion include:

- The patient requests to pay cash when insurance coverage exists;
- One patient drops off or picks up multiple similar prescriptions for two or more patients;
- Similar or identical prescriptions originate from the same prescriber or practice for inordinately large quantities of medications typically diverted;
- Groups of patients drop off similar or identical prescriptions for commonly diverted medications, often written by a prescriber who practices in another city or county;
- The patient is unable to provide identification when requested;
- The diagnosis given by the patient does not match the diagnosis given by the prescriber;
- The prescriber is unable or unwilling to give a diagnosis or provides the same diagnosis for all patients, such as back pain or degenerative disc disease;
- The prescriber is unavailable to speak directly with the pharmacist, will not return calls, or takes an unusual amount of time to respond to the pharmacist;
- The prescriber has not committed his or her DEA registration number to memory;
- The prescription does not contain all federally-mandated information; or
- The prescription does not comply with tamper-resistance industry standards or appears tampered with.

The DEA will hold accountable prescribers who issue prescriptions outside of legitimate medical use. The DEA also expects a pharmacist to exercise a corresponding responsibility to question prescriptions that do not appear to have been issued for a legitimate medical use.[24] Pharmacists should report their suspicions. Agencies that may be notified include:

- Local law enforcement;
- U.S. DEA;
- State Medicaid Fraud Control Unit; and
- State licensing board if a health care professional is involved.



Or contact:

U.S. Department of Health and Human Services, Office of Inspector General

ATTN: Hotline

P.O. Box 23489

Washington, DC 20026

Phone: 1-800-HHS-TIPS (1-800-447-8477)

TTY: 1-800-377-4950

Fax: 1-800-223-8164

Email: HHSTips@oig.hhs.gov

Website: <https://forms.oig.hhs.gov/hotlineoperations/>

44. Talk to pharmacy staff members about overrides at the point of sale (POS).

- Submit claims with vacation supply override codes only if the patient is on vacation; and
- Submit claims with known prior authorization (PA) override codes only if the patient meets the PA criteria.

Consider the risk for fraud, waste, or abuse if pharmacy staff members use override codes to adjudicate claims without appropriate substantiation. Inappropriate overrides for vacation supplies or PA at the POS are another potential source of risk for fraud. Recently, CareMed, a specialty pharmacy in New York, agreed to pay \$9.5 million in fees to the Federal government and roughly \$450,000 to the State of New York for falsifying PA information to process claims for Medicare and Medicaid beneficiaries. Pharmacy employees, with knowledge of the criteria at various insurance companies, would provide clinical information to the insurance representatives so the patient would “meet” the necessary requirements to have the medication covered.[25] Talk to staff members about when overrides are appropriate.

45. Talk to pharmacy staff members about prescription origin codes.

- Do not alter prescription origin codes; and
- Verify the prescriber DEA number and office telephone number for all controlled substance prescriptions received by telephone. If the caller or prescriber is unknown, confirm the contact information with a



secondary source. If the contact information differs, call the prescriber’s office at a published telephone number to confirm the prescription.

Prescription Origin Codes[26]

Code	Appropriate Use
1	Written—Prescription is presented to the pharmacy on a paper prescription pad.
2	Telephone—Prescription is conveyed to the pharmacy verbally by telephone call, voicemail, or other electronically recorded verbal message.
3	Electronic—Prescription is transmitted to the pharmacy by the National Council for Prescription Drug Programs’ SCRIPT Standard or Health Level 7 (HL7) Standard transactions.
4	Facsimile—Prescription is transmitted to the pharmacy by facsimile machine.
5	Pharmacy—A prescription origin code value of 5 is used when a pharmacy staff member must create a new prescription number from an existing prescription. This may occur due to prescription transfer between pharmacies, prescription transfer between pharmacies in the same parent organization, sale of prescription records from one pharmacy to another, or changes in pharmacy software requirements. A prescription code value of 5 is also appropriate when a pharmacist has prescriptive authority and dispenses a pharmacist-prescribed product, such as emergency contraceptives or Controlled Substances Act Schedule V cough preparations.

Consider the risk for fraud, waste, or abuse if pharmacy staff members adjudicate a claim with an origin code that does not apply. A prescription origin code identifies the method by which a pharmacy receives a prescription. It is important to note any changes made to the original prescription do not change the origin code.[27] Prescriptions received via phone may be particularly vulnerable given the capability to misrepresent a physician’s office and provide a callback number that does not belong to the physician.[28] In one case

involving the New York Medicaid program, 69 of 172 prescriptions indicated as phoned-in from an initial sample audit were found to be improper.[29]

46. Talk to pharmacy staff members about product selection (dispense as written—DAW) codes.
- Only use the DAW 1 product selection code when the prescriber has indicated product substitution is not allowed on the prescription; and
 - Only use the DAW 2 product selection code when the patient has requested to receive the brand name drug rather than the generic equivalent.

Prescription Selection Codes[30]

DAW Code	Appropriate Use
0	Appropriate when the prescriber indicates product substitution is allowed or when the prescriber does not include a product selection code on the written prescription. The pharmacy provider may dispense multi-source and single-source generic drugs or single-source brand name drugs using this product selection code.
1	Appropriate only when the prescriber indicates verbally or on the written prescription that substitution is not allowed— “substitution is not allowed,” “dispense as written,” or “brand name medically necessary.” The pharmacy provider may only dispense the brand name version of the drug prescribed using this product selection code.
2	Appropriate only when the patient indicates he or she requests the brand name version of the drug prescribed. The pharmacy provider may dispense only the brand name version of the drug prescribed using this product selection code and may do so even though the prescriber did not indicate substitution is not allowed.
3	Appropriate if a generic drug is available, but the pharmacist opted to dispense the brand name drug even though the generic drug was in stock.
4	Appropriate if a generic drug is available, but the pharmacist opted to dispense the brand name drug because the generic drug was not in stock.
5	Appropriate if a generic drug is available, but the pharmacist opted to dispense the brand name drug and elected to be reimbursed for the generic drug.
6	Appropriate when an override DAW code is required.
7	Appropriate when substitution is not allowed because the brand name drug is required to be dispensed by State law. This may occur if State law requires drug testing of generic drugs that has not yet been completed.
8	Appropriate when the generic drug is not available. This may occur if the generic drug has been approved by the FDA but not yet manufactured and distributed.
9	Appropriate when the prescriber indicates product substitution is allowed, but the beneficiary’s prescription drug plan requires the pharmacy to dispense the brand name product.[31] For example, the SMA may require the pharmacy to dispense the brand name product to meet the requirements of a statutorily defined manufacturer rebate agreement.



Consider the risk for fraud, waste, or abuse if pharmacy staff members adjudicate claims with inaccurate product selection codes. The DAW product selection code designation references the reason a particular brand is dispensed based upon direction from the prescriber.[32] Excessive use of certain DAW codes may raise red flags from an audit perspective, especially the use of DAW 1 on multi-source products. Review acceptable use of DAW 1 and DAW 9 codes with staff and emphasize appropriate documentation procedures. Proper documentation on prescriptions, especially those received via phone, is critical to withstand audit scrutiny and avoid fraudulent accusations of modifying the prescription to increase revenue. The phrases “brand name medically necessary” or “dispense as written” are needed in the cases of DAW 1 prescriptions. In some situations, SMAs may request a brand instead of generic substitution. In these instances with proper documentation, DAW 9 is appropriate.

47. Talk to pharmacy staff members about partial fill procedures.

- Adjudicate partial fills appropriately. Do not “owe” patients any drug quantity if the full quantity to be dispensed has already been billed;
- Only use the partial fill functionality of the billing system when unable to fill the full quantity to be dispensed;
- Do not bill the payer for the full amount of a partial refill; and
- Do not bill the payer for a second dispensing fee when completing a partial refill.

Consider the risk for fraud, waste, or abuse if pharmacy staff members bill for the entire prescribed quantity but dispense a partial supply while waiting for additional stock to be delivered. A partial fill occurs when a pharmacy does not dispense the total quantity of the medication indicated on the prescription. Potential fraud exists because the pharmacy may receive reimbursement to which it was not entitled. If the pharmacy bills and receives reimbursement for a complete fill and “owes” the beneficiary the remainder of the fill, the beneficiary may not pick up the owed portion, or the pharmacy may not be able to obtain additional supply of the medication. When the medication is returned to stock, the pharmacy inventory is inaccurate, and Medicaid has overpaid the pharmacy. This topic was the subject of an OIG investigation related to \$25 million in overpayments by Medicare Part D for Schedule II prescriptions partial fill completions billed as refills.[33] In addition, pharmacies may create partial fill claims as a means to generate a second dispensing fee. As is

the case with other potential audit red flags, an excess of partial fills has the potential to trigger an audit. Implement a sound partial-fill protocol, including proper documentation, to avoid accusations of partially filling prescriptions in an effort to generate dispensing fee revenue.

48. Talk to pharmacy staff members about how they select package sizes when more than one size is available.
- Select the smallest commercially available package size to address the prescription requirements;
 - Ensure the NDC dispensed matches the NDC billed, particularly for generic and compounded medications;
 - Adhere to State-specific Medicaid compound prescription billing requirements;
 - Bill accurate quantities of medications used in compounded medications; and
 - Confirm that commercially available equivalents do not exist and that the compounded medications are treating a medically necessary indication.

Consider the risk for fraud, waste, or abuse if pharmacy staff members select a package size larger than is necessary. Areas that are particularly vulnerable to audit findings include topical preparations, reconstituted products, and compounds. Review with staff the importance of selecting the smallest commercially available package size, and in cases where this does not occur, document the reason for the larger package size on the prescription (for example: affected area for topical preparations). Staff must ensure the NDC dispensed matches the NDC billed. For compounded medication in particular, if a staff member bills for the entire contents of a package to create a compound when a smaller volume would have been adequate to create the compound, potential for fraud, waste, or abuse exists. In addition, pharmacy staff members may inappropriately flag non-compound products as compounds to increase revenue. A pharmacy owner in West Virginia recently pleaded guilty to defrauding Medicare and Medicaid for dispensing compounded generic medications and billing for the brand. Medicare and West Virginia Medicaid will recover \$1.1 million from a settlement with the pharmacy.[34] Review compound prescription billing procedures with staff to ensure the correct package size and NDC are selected and billed appropriately and to prevent future audit recovery.

49. Talk to pharmacy staff members about how they document beneficiary receipt of prescriptions.
- Always obtain signatures from patients or their agents at the time of prescription pickup.

Consider the risk for fraud, waste, or abuse if pharmacy staff members do not document proof of delivery. Routine examination of signature logs is worthwhile to prepare for potential audits or to uncover fraud in the form of forged signatures. The potential for fraud exists when no records demonstrate proof of delivery because pharmacy employees may forge a beneficiary's signature for a prescription that never reaches the beneficiary.[35]

50. If a Medicaid overpayment is identified, take one of the following steps:
- Reverse any claim within the last year;
 - Send a check and an explanation for any older claim; or
 - Self-disclose the overpayments to your SMA or the OIG.

Pharmacies must report the overpayment within 60 days from the date the overpayment is identified.[36] Overpayments usually include the following situations:[37]

- At the time of the service, the individual receiving the service was not eligible for Medicare or Medicaid;
- Medicare or Medicaid mistakenly paid as primary where another third-party payer was properly primary;
- The payment amount was miscalculated and excessive;

- The service did not fall within one of the statutory benefits or was subject to a statutory exclusion; or
- The service was not medically necessary.

The FCA contains a whistleblower provision allowing an individual, known as a “relator,” to file a lawsuit on behalf of the Federal government against a person or business based on evidence of fraud against Federal programs or contracts. The whistleblower is entitled to a portion of any monies recovered.[38] The FCA includes a treble damages provision (a tripling of actual and compensatory damage) for persons who have “actual knowledge, deliberate ignorance of the truth or falsity of the information, or reckless disregard of the truth or falsity of the information.”[39] In addition, persons may be found to have violated the FCA in reverse—not by receiving money to which the person is not entitled, but by avoiding payment of monies due the Federal government.[40] In addition, a pharmacy may be terminated as a Medicaid provider for cause because the pharmacy has engaged in fraud for abusing billing privileges (for example: billing for services that were not provided or failing to repay a Medicaid overpayment).[41] Identifying and reporting overpayments in a timely manner will prevent negative consequences and offers the pharmacy the opportunity to provide staff training to prevent future overpayments.

Conclusion

CMS is committed to educating pharmacy providers about potential fraud, waste, and abuse related to pharmacy services. The four Pharmacy Self-Auditing booklets in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” Toolkit provide self-audit steps to identify potential audit triggers in a pharmacy practice. The booklets address areas prone to potential fraud, waste, and abuse related to pharmacy services, and provide instruction on how to report suspected fraud, waste, and abuse. Pharmacy providers can use audit findings to identify areas of practice that require further scrutiny as well as use these tools to educate pharmacy personnel about potential fraud, waste, and abuse.

This booklet discusses how evaluating billing practices can be incorporated into a pharmacy self-audit. The booklet contains 15 of the 50 steps to conduct a pharmacy self-audit and examines common quantity and days’ supply billing errors. In addition, inappropriate refill practices, overrides, partial fill procedures, and package size selection are discussed. A thorough review of these steps as they pertain to pharmacy practice will help pharmacies preserve State Medicaid program integrity and improve the quality of patient care for State Medicaid beneficiaries.

To review any of the three additional booklets in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” Toolkit (Booklet 1—Prescribing Practices, Booklet 2—Controlled Substances Management, and Booklet 3—Invoice Management), with audit questions and detailed information regarding each step, visit <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html> on the CMS website. The steps in the four booklets correspond to the steps in the document titled “Pharmacy Auditing and Dispensing: The Self-Audit Control Practices to Improve Medicaid Program Integrity and Quality Patient Care Checklist.”

To see the electronic version of this booklet and the other products included in the “Pharmacy Self-Auditing: Control Practices to Improve Medicaid Program Integrity and Quality” Toolkit, visit the Medicaid Program Integrity Education page at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html> on the CMS website.

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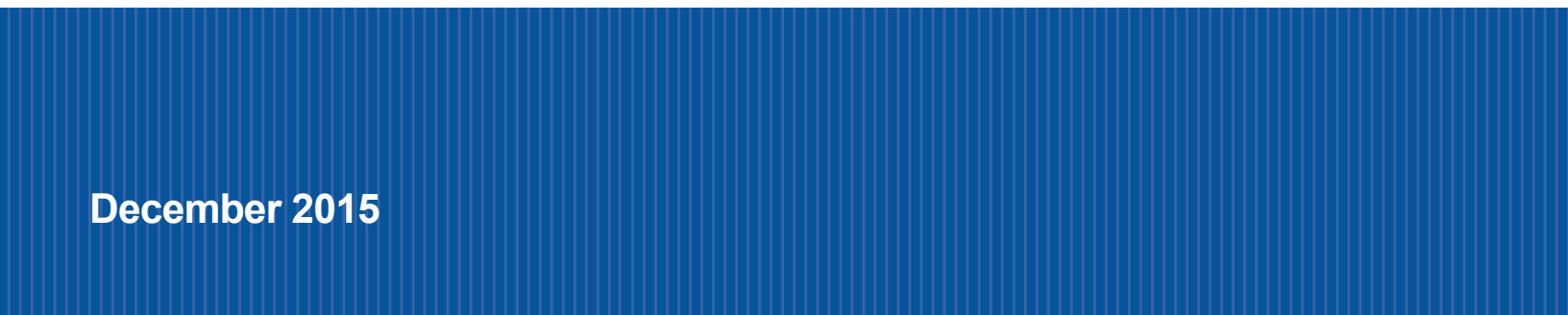
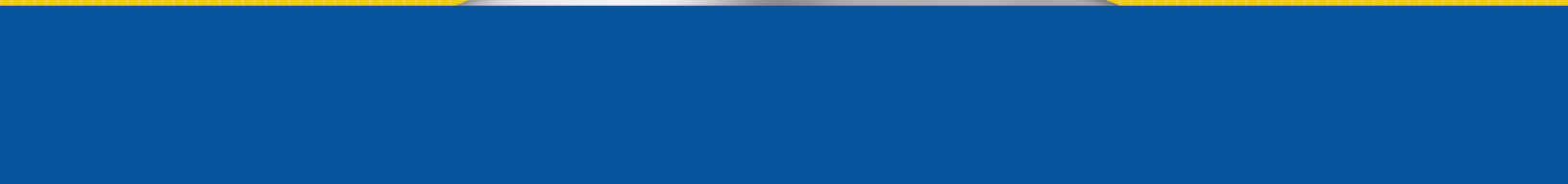
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This booklet was current at the time it was published or uploaded onto the web. Medicaid and Medicare policies change frequently so links to the source documents have been provided within the document for your reference.

This booklet was prepared as a service to the public and is not intended to grant rights or impose obligations. This booklet may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. Use of this material is voluntary. Inclusion of a link does not constitute CMS endorsement of the material. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

December 2015



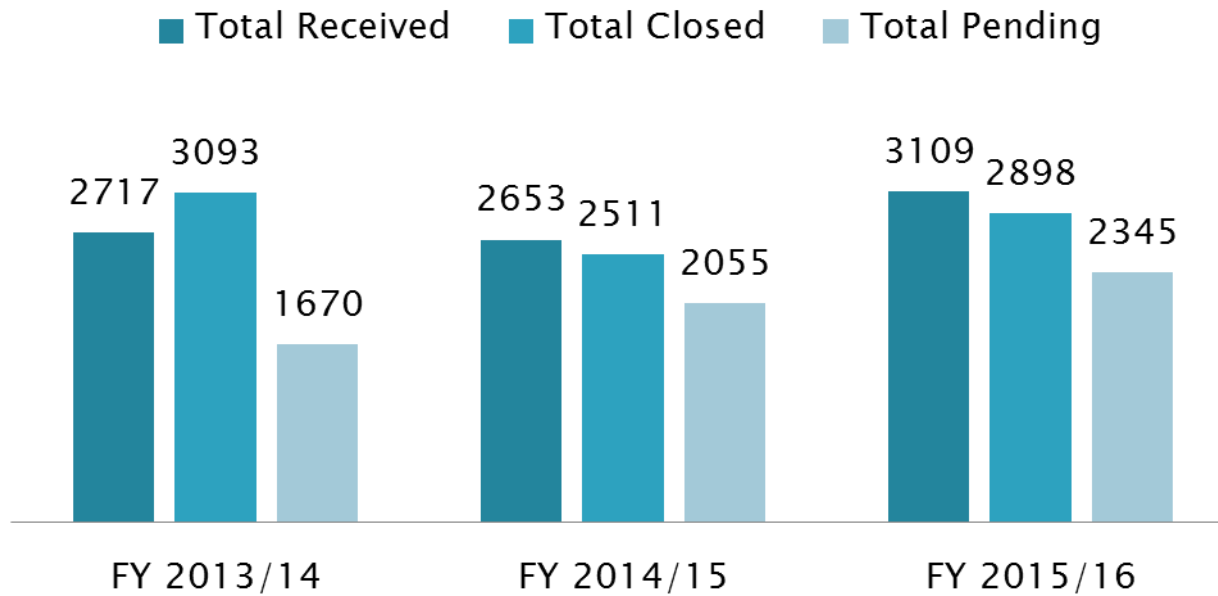
December 2015

Attachment 4

Enforcement Committee Meeting Citation and Fine Presentation California State Board of Pharmacy

Julia G. Ansel
Chief of Enforcement
August 31, 2016

Total COMPLAINTS



Total FINES ASSESSED

	FY13/14	FY 14/15	FY 15/16
Total Citations Issued	1985	1180	1976
Total Fines Assessed	\$13,011,000	\$1,694,080	\$2,264,285
Total Med Error Citations Issued*	638	377	578
<small>*One citation may include more than one med error violation.</small>			
Total Med Error Fines Assessed	\$286,750	\$202,600	\$394,450

Total CITATIONS ISSUED BY LICENSE TYPE

	FY 2015/16
Pharmacist with Citation and Fine	718
Pharmacist with Citation and no Fine	85
Pharmacy with Citation and Fine	381
Pharmacy with Citation and no Fine	252
Technician with Citation and Fine	319
Technician with Citation and no Fine	2
Wholesalers	23
Designated Representative	17
Clinics	5
Drug Room	1
Hospital or Pharmacy - Government Owned	12
Hospital	18
Miscellaneous (Intern, Correctional Facility, Non-Resident Pharmacy and Vet Retailers)	113
Unlicensed Activity	30
Total Citations FY 2015/16	1976

Closed

WITH CITATION AND FINE

	FY 13/14	FY14/15	FY 15/16
Pharmacist	339	224	352
PIC	363	196	366
Pharmacy	375	186	381
Total Closed with Citation and Fine	1077	606	1099

T OP TEN VIOLATIONS BY PHARMACIST Fiscal Year 2015/16

Violation	Percentage
CCR 1716 Variation from Prescription	43%
CCR 1714(d) Operational Standards and Security; pharmacist responsible for pharmacy security	17%
CCR 1764 / Civil Code 56.10 (a) Unauthorized Disclosure of Prescription Medical Information	7%
CCR 1707.2(b)(1)(A) In addition to obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not been previously disclosed to the patient	6%
CCR 1707.3 Duty to review drug therapy	5%
BPC 4301 (h) Unprofessional Conduct; the administering to oneself, of any controlled substance, or use and any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	5%
CCR 1714 (b) Operational Standards and Security; pharmacy responsible for pharmacy security	4%
BPC 4301(l) Unprofessional Conduct; conviction of a crime substantially related to the practice of pharmacy	4%
CCR 1711(d) Quality Assurance program finding shall be used to develop systems to prevent medication errors	4%
BPC 4231d)/ CCR1732.5 Failure to provide documentation substantiating completion of continuing education/ renewal requirements for pharmacist	4%

T OP TEN VIOLATIONS BY PHARMACIES

Fiscal Year 2015/16

Violation	Percentage
CCR 1716 Variation from Prescription	39%
CCR 1714 (b) Operational Standards and Security; pharmacy responsible for pharmacy security	21%
BPC 4113(d) Every pharmacy shall notify the board in writing within 30 days of the date of a change in PIC	10%
BPC 4113(a) PIC: Notification to the board; responsibilities, every pharmacy shall designate a PIC within 30days in writing of the identity of the license number of that pharmacist	7%
CCR 1764 / Civil Code 56.10 (a) Unauthorized Disclosure of Prescription Medical Information	6%
CCR 1707.3 Duty to review drug therapy	4%
CCR 1707.2(b)(1)(A) In addition to obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not been previously disclosed to the patient	4%
CCR 1711(d) Quality Assurance program finding shall be used to develop systems to prevent medication errors	3%
BPC 4081 (a) records of dangerous drugs and devices kept open for inspection; maintenance of records, current inventory	3%
BPC 4305 (b) Disciplinary grounds: failure of pharmacy or pharmacist to notify of termination of PIC; continuing to operate without pharmacist; operation of pharmacy for more than 30 days without supervision or management by PIC	3%

T OP TEN VIOLATIONS BY PIC

Fiscal Year 2015/16

Violation	Percentage
CCR 1714(d) Operational Standards and Security; pharmacist responsible for pharmacy security	33%
CCR 1716 Variation from Prescription	25%
CCR 1764 / Civil Code 56.10 (a) Unauthorized Disclosure of Prescription Medical Information	7%
BPC 4081 (a) records of dangerous drugs and devices kept open for inspection; maintenance of records, current inventory	7%
CCR 1714 (b) Operational Standards and Security; pharmacy responsible for pharmacy security	6%
CCR 1707.2(b)(1)(A) In addition to obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not been previously disclosed to the patient	5%
CCR 1714 (c) Operational standards and security; the pharmacy must be maintained in a sanitary condition	5%
CCR 1711(d) Quality Assurance program finding shall be used to develop systems to prevent medication errors	5%
CCR 1735.2(j) Compounding requirements – PIC shall complete a compounding self assessment prior to any sterile injectable compounding is performed in pharmacy	5%
BPC 4081 (a) / CCR 1718 Records of dangerous drugs and devices kept open for inspection; maintenance of records, current inventory/ current inventory defined	4%

P RESCRIPTION ERRORS VIOLATION DATA

Fiscal Year 2015-16

Fine Amount	Number	Percent of total Violations
\$0	264	41%
\$100 - \$999	192	29%
\$1,000 - \$2,000	161	25%
\$2,500 - \$5,000	32	5%
Total Number of Med Error Violations	649	100%

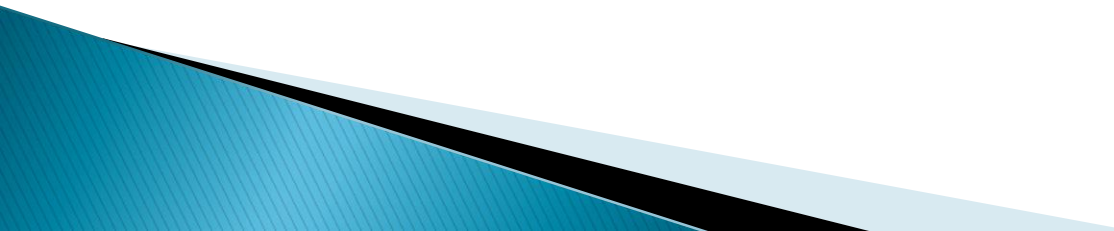
MEDICATION ERROR DATA

Fiscal Year 2015/16

Look-alike / Sound-alike Errors		Lipitor	Lexapro
Clonazepam	Lorazepam	L-Thyroxine	Liothyronine
Clomid	Clomipramine	Lovaza	Lorazepam
Clomiphene	Clomipramine	Metformin	Metoprolol
Clomiphene	Clonazepam	Methadone	Metadate
Duricef	Fioricet	Methotrexate	Metolazone
Hydralazine	Hydroxyzine	Risperidone	Ropinirole
Hydrochlorothiazide	Hydroxyzine	Rocaltrol	Ropinirole
Ketorolac	Ketoconazole	Subocone	Suboxone
Labetalol	Lamotrigine	Tramadol	Trazodone

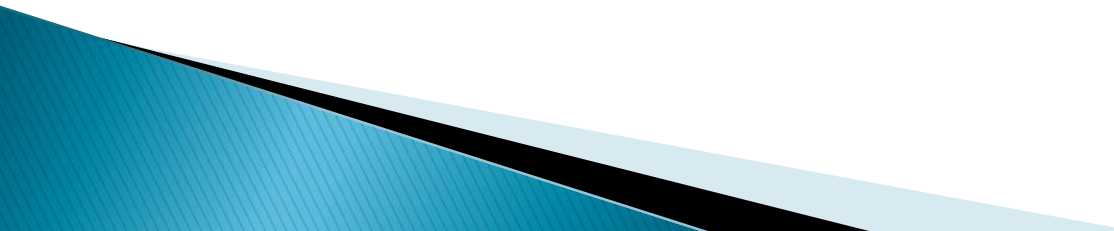
P RESCRIPTION ERROR CASES FY 2015/16

\$500 Fine

- # **Case 1:** A pharmacist-in-charge dispensed Clonidine .1mg to a patient instead of Trihexyphenidyl 2mg tablets. Patient ingested wrong medication.
 - # **Case 2:** A pharmacy dispensed a dry powder for Amoxicillin 125mg/5ml bottle, without mixing with water. Oral suspension for a child was given to patient in a powder form.
 - # **Case 3:** A pharmacy dispensed Boost Kid Essentials .03-1 gram-kcal/ml liquid instead of Pediasure .06-1.5 gram-kcal/ml liquid.
- 

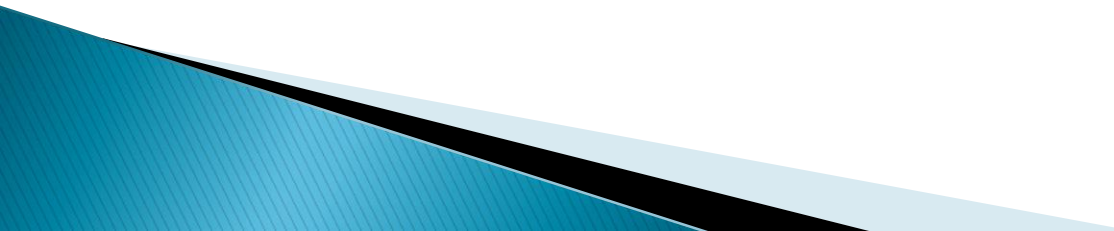
P RESCRIPTION ERROR CASES FY 2015/16

\$750 Fine

- # **Case 1:** A pharmacist dispensed a prescription written for Xanax 1mg but filled it with Lorazepam 1mg tablets.
 - # **Case 2:** A pharmacist verified a prescription for Diethylpropion 75mg tablets labeled with directions for use of 1 tablet in the morning, despite being prescribed with direction for use of ½ to 1 tablet in the morning.
 - # **Case 3:** A pharmacist incorrectly dispensed one 5ml box of Erythromycin eye drops instead of the prescribed Gentamicin eye drops.
- 

P RESCRIPTION ERROR CASES FY 2015/16

\$1,000 Fine

- # **Case 1:** A pharmacy dispensed Montelukast 4mg tablets which had some Montelukast 5mg tablets co-mingled in the same bottle.
 - # **Case 2:** A pharmacy dispensed Picato .05% gel instead of prescribed Picato .015% gel.
 - # **Case 3:** A pharmacist dispensed Fioricet with codeine instead of the prescribed Fioricet plain.
- 

P RESCRIPTION ERROR CASES FY 2015/16

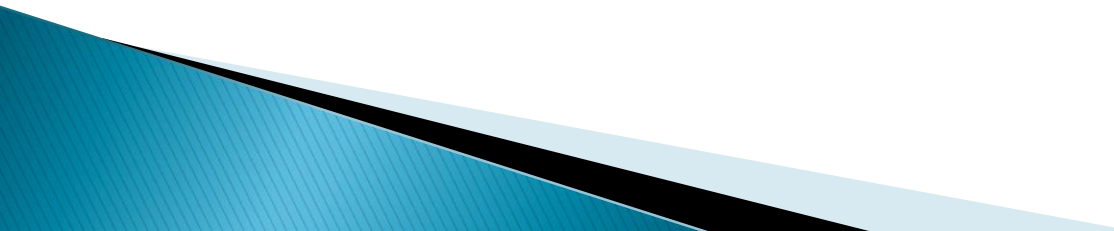
\$1,500 Fine

Case 1: Patient "Ira T." was dispensed medication meant for patient "Irma T".

Case 2: A pharmacy dispensed Cephalexin 500mg versus the prescribed Amoxicillin 500mg. Quality Assurance Review was not completed.

\$2,500 Fine

Case 1: A pharmacy allowed the compounding of drug products but failed to maintain a compounding log for each of the compounded drug products.



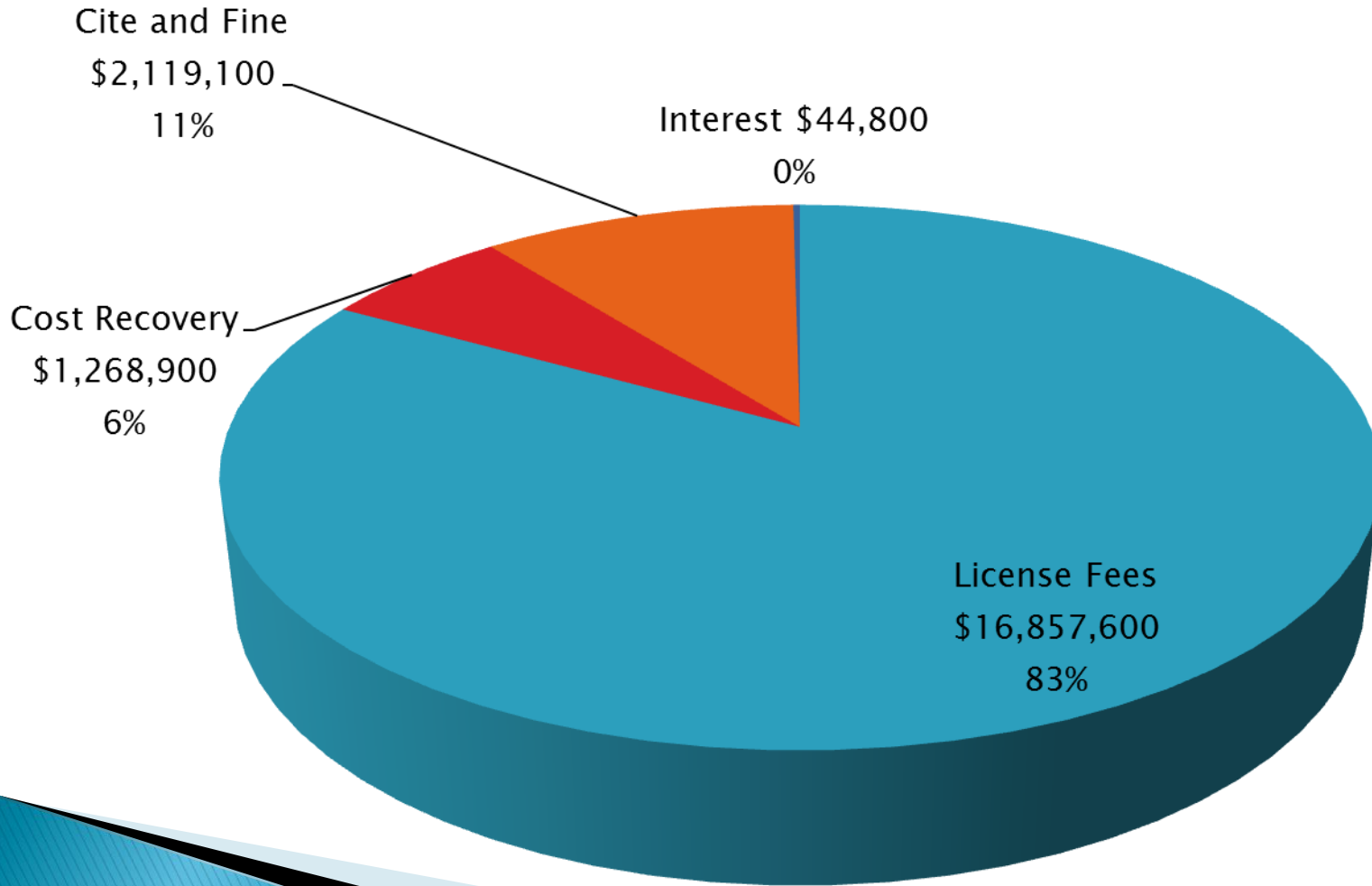
P RESCRIPTION ERROR CASES FY 2015/16

\$5,000 Fine

- # **Case 1:** A pharmacy dispensed clomipramine capsules instead of clomiphene tablets to a patient. Consumer ingested medication and became sick for two days. Patient was dispensed clomipramine capsules without oral consultation.
- # **Case 2:** A pharmacist dispensed a prescription for Metformin 1000mg, two tablets, twice a day versus prescribed Metformin 500mg, two tablets, twice a day. Pharmacists at this location failed to provide consultation to patients. Also failed to document medication errors.

Total Revenue

Fiscal Year 2015/16 FM 12



Attachment 5

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				792
Closed	790				790
4301 letters	4				4
Pending (at the end of quarter)	2441				2441

Cases Assigned & Pending (by Team) at end of quarter*

Compliance / Routine Team	1063				1063
Drug Diversion/Fraud	450				450
RX Abuse	171				171
Compounding	126				126
Probation/PRP	75				75
Mediation/Enforcement **	252				252
Criminal Conviction	304				304

Application Investigations

Received	154				154
Closed					
Approved	110				110
Denied	10				10
Total ***	147				147
Pending (at the end of quarter)	111				111

Letter of Admonishment (LOA) / Citation & Fine

LOAs Issued	114				114
Citations Issued	588				588
Total Fines Collected ****	\$450,174.15				\$450,174.15

* 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 9/30/2016 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				105
Accusations Filed	73				73
Statement of Issues Filed	5				5
Petitions to Revoke Filed	4				4
Pending					
Pre-accusation	255				255
Post Accusation	278				278
Total*	573				573

Closed

Revocation					
Pharmacist	4				4
Intern Pharmacist	1				1
Pharmacy Technician	37				37
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	4				4

Revocation, stayed; suspension/probation					
Pharmacist	1				1
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	0				0

Revocation, stayed; probation					
Pharmacist	8				8
Intern Pharmacist	0				0
Pharmacy Technician	4				4
Designated Representative	0				0
Wholesaler	1				1
Sterile Compounding	0				0
Pharmacy	5				5

Surrender/Voluntary Surrender					
Pharmacist	7				7
Intern Pharmacist	0				0
Pharmacy Technician	10				10
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	3				3

Board of Pharmacy Enforcement Statistics Fiscal Year 2016/2017

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 16/17**

Public Reprival/Reprimand

Pharmacist	5				5
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	0				0

Licenses Granted

Pharmacist	0				0
Intern Pharmacist	0				0
Pharmacy Technician	1				1
Designated Representative	1				1
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	0				0

Licenses Denied

Pharmacist	0				0
Intern Pharmacist	0				0
Pharmacy Technician	3				3
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	0				0

Cost Recovery Requested**	\$307,270.00				\$307,270.00
Cost Recovery Collected**	\$132,381.11				\$132,381.11

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions

Interim Suspension Order	0				0
Automatic Suspension / Based on Conviction	0				0
Penal Code 23 Restriction	2				2
Cease & Desist - Sterile Compounding	0				0

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				176
Intern Pharmacist	3				3
Pharmacy Technician	37				37
Designated Representative	1				1
Pharmacy	54				54
Sterile Compounding	10				10
Wholesaler	5				5
Probation Office Conferences	15				15
Probation Site Inspections	141				141
Successful Completion	5				5
Probationers Referred to AG for non-compliance	0				0

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 September 30, 2016.

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					
PRP Under Investigation	3				3
PRP In Lieu Of					
Total Number of PRP Intakes	3				3
New Probationers					
Pharmacists	2				2
Interns					
Technicians	2				2
Total New Probationers	4				4
PRP Participants and Contracts					
Total PRP Participants	53				N/A
Contracts Reviewed	50				50
Probationers and Inspections					
Total Probationers	81				N/A
Inspections Completed	141				141
PRP Referrals to Treatment					
Referrals to Treatment	2				2
Drug Tests					
Drug Test Ordered	911				911
Drug Tests Conducted	895				895
Relapse					
Relapsed	1				1
Major Violation Actions					
Cease Practice/Suspension	4				4
Termination - PRP	2				2
Referral for Discipline					
Exit from PRP or Probation					
Successful Completion	4				4
Termination - Probation	1				1
Voluntary Surrender	3				3
Surrender as a result of PTR	1				1
Public Risk	2				2
Non-compliance	19				19
Other					
Patients Harmed					
Number of Patients Harmed	None	None	None	None	None

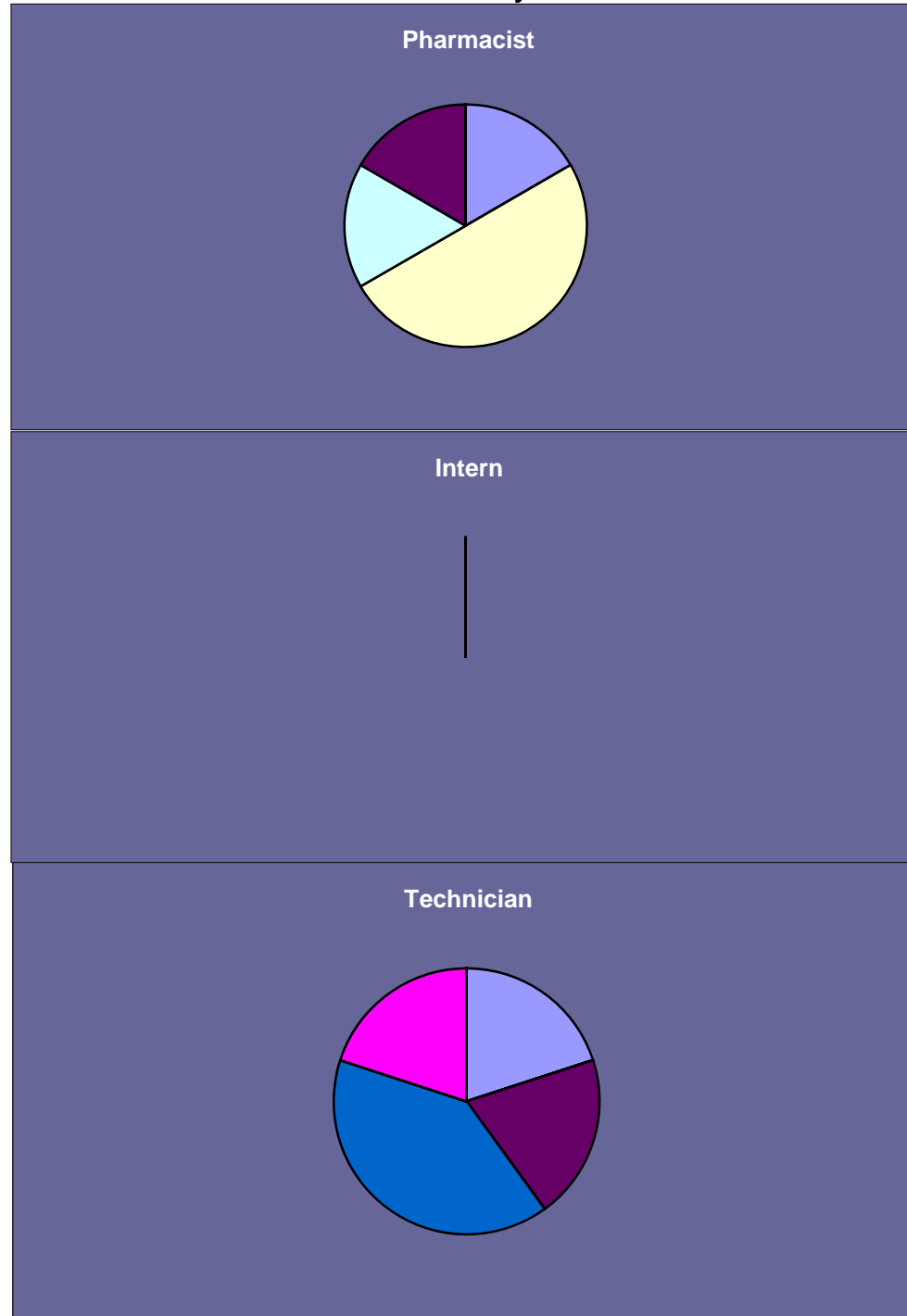
SB 1441 – Program Statistics

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				1
Ambien					
Opiates	3				3
Hydrocodone	1				1
Oxycodone	1				1
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 16/17
Alcohol					
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				1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines	1				1
Barbiturates					
Marijuana	2				2
Heroin					
Cocaine					
Methamphetamine	1				1
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

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

- 1 Alcohol
- 2 Opiates
- 3 Hydrocodone
- 4 Oxycodone
- 5 Benzodiazepines
- 6 Barbiturates
- 7 Marijuana
- 8 Heroin
- 9 Cocaine
- 10 Methamphetamine
- 11 Pharmaceutical Amphetamine



**Board of Pharmacy Citation and Fine Statistics
July 1, 2016 - September 30, 2016**

Citation Breakdown by License Type

Total Issued	RPH with Fine	RPH no Fine	PHY with Fine	PHY no Fine	PIC with Fine**	PIC no Fine**	TCH with Fine	TCH no Fine
598	167	38	117	74	89	113	70	0

Citation Breakdown by Miscellaneous License Type

Wholesalers	Exemptee's	Clinics	Drug Room	Exempt Hosp.	Hosp. Pharmacy	Misc.*	Unlicensed Premises	Unlicensed person
14	7	2	1	4	58	28	13	5

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

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

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	27%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	32%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	37%
1716 - Variation from prescription	25%	1716 - Variation from prescription	18%	4169(a)(1) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity...	25%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	9%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	14%	1716 - Variation from prescription	8%
4231(d)/1732.5 - Failure to provide documentation substantiating completion of continuing education/Renewal Requirements for Pharmacist	7%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that phar	8%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	7%
4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	7%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	7%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	5%
11165(d)(2) - Pharmacy shall provide the following information the Department of Justice: prescriber's category of licensure and license number; federal controlled substance registration number ...	6%	4305(b) - Disciplinary Grounds: Failure of Pharmacy or Pharmacist to Notify Board of Termination of Pharmacist-in-Charge; Continuing to Operate Without Pharmacist; Operation of a pharmacy for more tha	7%	1718/4081(a) - Current inventory defined/Records of dangerous drugs kept open for inspection	4%
11200(b) - No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply...	5%	11165(d)(2) - Pharmacy shall provide the following information the Department of Justice: prescriber's category of licensure and license number; federal controlled substance registration number ...	5%	1707.1(a)(1)(B)(2) - Duty to maintain medication profiles; a patient medication profile shall be maintained... for each prescription dispensed by the pharmacy-Prescribers name, license number, DEA regis	3%
1761 - Erroneous or uncertain prescriptions	5%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	4%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	3%
4301(h) - Unprofessional Conduct – The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	4%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law	3%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	3%
1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	4%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice...	2%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law	3%

Attachment 5.5



Guidance on Applying for Compliance Delays During Construction In Pharmacies that Compound

Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver of such compliance for a period of time to permit the required physical changes. See also related provisions in CCR section 1751.4.

Application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated for such waiver.

For hospitals, please see *Guidance on Applying for Compliance Delays During Construction in Hospital Pharmacies that Compound*, to request an exemption.

Please submit your request via email to: Compounding.waivers@dca.ca.gov

Or mail to: Compounding Construction Waiver Request
 CA State Board of Pharmacy
 1625 N Market Boulevard, Suite N-219
 Sacramento, CA 95834

Please retain a copy of your submitted request and make available for review at the licensed location.

Below is an example of the requested information in a format that you may submit to the board to request a waiver. It is in a fillable PDF format that you can complete online, printout, have signed and then return to the board along with any attachments. This document and form are available at www.pharmacy.ca.gov.

Pharmacy Name:

License Number: PHY/PHE

Please provide sterile compounding licenses associated with the above license: LSC/LSE

Name of the Individual Submitting this Request:

Title:

Email:

Phone Number:

The provisions of the regulation for which a compliance delay for construction is needed:

(Note: CA Code of Regulations section 1735.6(f) requires the identification of code sections requiring physical construction, alteration or improvement that are the reason for the waiver request)

1735.6, list subsections

1751.4 list subsections

Please list if other sections

A description of the physical changes that must be made for compliance *(Attach additional page if necessary):*

Please provide the timeframe for construction to completion:

Have building plans been developed? Yes _____ No _____

Has a building permit been secured? If yes, please provide number:

Please provide a written description of how the pharmacy will perform compounding while the compliance delay is in effect.

Reviewed by:

Pharmacy Pharmacist-in-Charge _____

Please Print

Signature: _____ Date: _____

Please do not send architectural drawings or structural plans as they will not be reviewed.



Guidance on Applying for Compliance Delays During Construction In Hospital Pharmacies that Compound

Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver of such compliance for a period of time to permit the required physical changes. See also related provisions in CCR section 1751.4.

Application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated for such waiver.

For non-hospitals, please see *Guidance on Applying for Compliance Delays During Construction in Pharmacies that Compound*, to request an exemption.

Please submit your request via email to: Compounding.waivers@dca.ca.gov

Or mail to: Compounding Construction Waiver Request
 CA State Board of Pharmacy
 1625 N Market Boulevard, Suite N-219
 Sacramento, CA 95834

Please retain a copy of your submitted request and make available for review at the licensed location.

Below is an example of the requested information in a format that you may submit to the board to request a waiver. It is in a fillable PDF format that you can complete online, printout, have signed and then return to the board along with any attachments. This form is available at www.pharmacy.ca.gov.

Hospital Pharmacy Name:

License Number: HSP/HPE

Provide all sterile compounding license numbers associated with the above license that require modification as part of this request:

LSC LSC LSC LSC LSC LSC

Name of the Individual Submitting this Request:

Title:

Email:

Phone Number:

OSHPD Project Number for this modification (if applicable):

OSHPD Facility Identification (if applicable):

OSHPD Hospital Building Number (if applicable):

Please attach a copy of the Project Completion Timeline, including a specific timeline for construction for EACH compounding pharmacy location that needs modification and is included under this Project Number.

The provisions of the regulation for which a compliance delay for construction is needed:

(Note: CA Code of Regulations section 1735.6(f) requires the identification of code sections requiring physical construction, alteration or improvement that are the reason for the waiver request.)

1735.6, list subsections

1751.4 list subsections

Please list if other sections

A description of the physical changes that must be made for compliance (*Attach additional page if necessary*):

Have building plans been developed? Yes No

Has a building permit been secured? If yes, please provide number:

Please provide a written description of how the pharmacy will perform compounding while the compliance delay is in effect. Identify how compounding will take place after 1/1/17 until construction starts, during construction, and the transition into the newly remodeled location. (Please note if a new or temporary location is needed, a new permit may be required with the Board of Pharmacy and notification may be required to the California Department of Public Health. Additionally inspections are likely to be required before the use of any sterile compounding location begins operation. Please plan and communicate accordingly.)

Reviewed by:

Hospital Chief Executive Officer, Hospital Chief Operating Officer or Executive Director:

Please Print Name and Title

Signature: _____ Date: _____

Please do not send architectural drawings or structural plans as they will not be reviewed.

Waiver

Requests

Received



RECEIVED BY CALL CENTER
BOARD OF PHARMACY
2016 SEP 30 PM 2:21

Shideh Ataii, Pharm.D
Director of Pharmacy Services
Tracy E. Feng, Pharm.D.
Pharmacist In Charge
Contra Costa Regional Medical Center and Clinics
2500 Alhambra Ave
Martinez, CA 94553

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834-1924

September 27, 2016

To Whom It May Concern:

This letter is to request in writing for a waiver from the structural requirements in Title 16 California Code of Regulations, 1735 et seq., and 1751 et seq for the sterile compounding license **LSE 100556 at Contra Costa Regional Medical Center Outpatient Pharmacy** located at 2500 Alhambra Ave, Building 1, Martinez, CA 94553.

The specific sections of the Title 16 California Code of Regulations that will require structural modifications at our pharmacy are:

- **1735.6. Compounding Facilities and Equipment.**

(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.

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

b) (2) 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).

- **1751.4. Facility and Equipment Standards for Sterile Compounding.**

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.1 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).



Shideh Ataii, Pharm.D.
Director of Pharmacy Services
Tracy E. Feng, Pharm.D.
Pharmacist In Charge
Contra Costa Regional Medical Center and Clinics
2500 Alhambra Ave
Martinez, CA 94553

(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.

The construction process in order to meet the language of the requirements is described in the attached documents from the Architect of Record, Kava Massih Architects.

- 1) Attachment 1: Document describing the construction process and time frame for completion of project
- 2) Attachment 2: Detailed recommendations from engineers
- 3) Attachment 3: Drawing of external ventilation ducting routes
- 4) Attachment 4: Drawing of final construction plans

The pharmacy will continue to perform compounding and dispensing functions while the construction waiver is in effect. That process is described in the attached document (Attachment 5) from the Contra Costa Facilities Manager, Dave Duet.

For any questions regarding this waiver request, please contact the pharmacist-in-charge, Tracy E. Feng, Pharm.D. by email at tracy.feng@hsd.cccounty.us or telephone at (925) 370-5668 or the Director of Pharmacy Services, Shideh Ataii, Pharm.D. by email at sataii@hsd.cccounty.us or telephone at (925) 370-5601.

Sincerely,

A handwritten signature in blue ink, appearing to read "Shideh Ataii".

Shideh Ataii, Pharm.D.
Director of Pharmacy Services
Contra Costa Regional Medical Center and Clinics
2500 Alhambra Avenue
Martinez, CA 94553
Phone: 925-370-5601
Fax: 925-370-5251
e-mail: sataii@hsd.cccounty.us

A handwritten signature in blue ink, appearing to read "Tracy E. Feng".

Tracy E. Feng, Pharm.D.
Pharmacist-in-Charge
Contra Costa Regional Medical Center
2500 Alhambra Ave
Martinez, CA 94553
Phone: (925) 370-5668
Fax: (925) 370-5269
e-mail: tracy.feng@hsd.cccounty.us



Contra Costa Regional Medical Center | Martinez
Outpatient Pharmacy

16 September 2016

To Whom It May Concern:

The construction process for this project will begin after the Construction Documents are complete, reviewed by the Contra Costa County building department and bid to qualified General Contractors. The Outpatient Pharmacy is in a building that is licensed under the adjacent Acute Care Hospital. The building was constructed to OSHPD 3 requirements and will be reviewed to those standards by the County Building Department.

Plan review by OSHPD in Sacramento is not required.

The schematic design phase and evaluation of existing systems have been completed. The building can accommodate the proposed Pharmacy renovation. There are no proposed structural modifications to the building.

The Architect of Record is Kava Massih Architects who will design and administer the contract for construction. Since only Schematic Design has been completed, the building permit is still months away from being secured.

Proposed Schedule

Design Development	09/30/16 – 11/24/16
Construction Documents	11/25/16 – 02/23/17
Plan Review	03/02/17 – 04/12/17
Bidding	04/18/17 – 07/10/17
Contracting	07/17/17 – 07/28/17
Construction	08/02/17 – 12/05/17
Occupancy	12/10/17

Recommendation

Mechanical

Hazardous Compounding Pharmacy Room

The following is a brief list of requirements to meet USP 800/797 Engineering controls using the proposed plan layout to optimize the containment cabinets (CAI/CACI) location, changing it from non-classified C-SCA room to a classified ISO-7 cleanroom.

- Directly exhaust the ISO-7 cleanroom and containment cabinet to the exterior of the building.
- Provide 30 air changes per hour of supply to the space.
- Provide differential pressure sensors between the ISO-7 cleanroom, and the ante area as well as between the ante area and the Pharmacy lounge/office area with a visual and audible alarm. The Hazardous Compounding Pharmacy room must maintain a negative pressurization of 0.01” to 0.03” W.C.

Non-Hazardous Compounding Pharmacy Room

- Directly exhaust the ISO-7 cleanroom and containment cabinet to the exterior of the building.
- Provide 30 air changes per hour of supply to the space.
- Provide differential pressure sensors as described above.

Each of the following rooms needs to be exhausted at the higher of 30 air changes per hour (ACPH) or the hood exhaust air quantity, as noted below:

Room Name	Floor Area Square Feet	Exhaust Air - CFM		
		At 30 ACH	Hood Exhaust	Required Exhaust
Hazardous Compounding Pharmacy	160	720	850	850
Non-Haz Compounding Pharmacy	135	610	425	610
Ante Room	90	405	--	405
Total Exhaust		1,735	1,275	1,865

A total of 1,865 cfm of exhaust air is required.

Two separate exhaust ducts will be provided from the renovated area to the roof, per Figure 1, below. Two 14” dia ducts will be provided: one duct for the Hazardous Compounding Pharmacy Room and another for the Non-Hazardous Compounding Pharmacy and Ante Room. The ducts will be routed northwards and then extended to the roof at building exterior wall. There will be a separate exhaust fans for each system, with the Hazardous Compounding Pharmacy exhaust fan, purposely built for the containment cabinet(s) exhaust, such as the Greenheck Vektor Lab Exhaust Fan with high plume discharge.

Makeup air for this 1,865 exhaust air will be provided by a packaged rooftop unit, with supply air ductwork routed adjacent to the exhaust air ductwork at the exterior of the building. Supply air ductwork will be fitted with HEPA filters at the roof, and a booster fan, if required.

The existing mechanical unit in the Hazardous Compounding Pharmacy Room does not conform to USP requirements and will be removed.

Plumbing

Hazardous Compounding Pharmacy Room

Only recommendation is to remove the existing sink within the existing pharmacy segregated compounding area. Sinks and emergency eyewash stations are to be located in the Ante room and Receiving rooms.

Electrical

Power System

1st Floor:

The existing circuits being fed from the Normal Branch Panel 'L1B' shall be re-used. Spare breakers are available if additional circuits are required.

2nd Floor:

The existing circuits being fed from the Emergency Branch Panel 'EL2D' shall be re-used. Spare breakers are available if additional circuits are required.

3rd Floor:

Based on record drawings, the existing Emergency Branch Panel 'EL3B' has available spare breakers to accommodate new loads. This panel shall be utilized to serve new HVAC units on the roof to serving the renovated pharmacy suite. Verification shall be conducted prior to commencement.

Wiring Devices

1st Floor:

New receptacles will be provided in the new Non-Hazardous Compounding Pharmacy 2 room, receiving, and ante room. These receptacles shall be connected to the emergency branch Panel 'EL2D'. In the Outpatient Office/Work room, existing dual channel surface mounted raceway will be re-used and modified to fit the new smaller office space. New controlled receptacles shall be provided in the office and kitchen per Title 24 requirement for plug load controls. Receptacles on normal circuits shall be fed from the normal branch Panel 'L1B'.

Lighting System

As part of the renovation, new 2'x4' recessed LED luminaires will be provided throughout the pharmacy space. For the Compounding Pharmacy 1 & 2, Ante room, and Receiving, recessed LED luminaires rated for cleanrooms will be utilized. Lighting controls shall consist of manual toggle switches and ceiling mounted occupancy sensors. Lighting will be connected to existing lighting circuit serving the pharmacy space.

Roof:

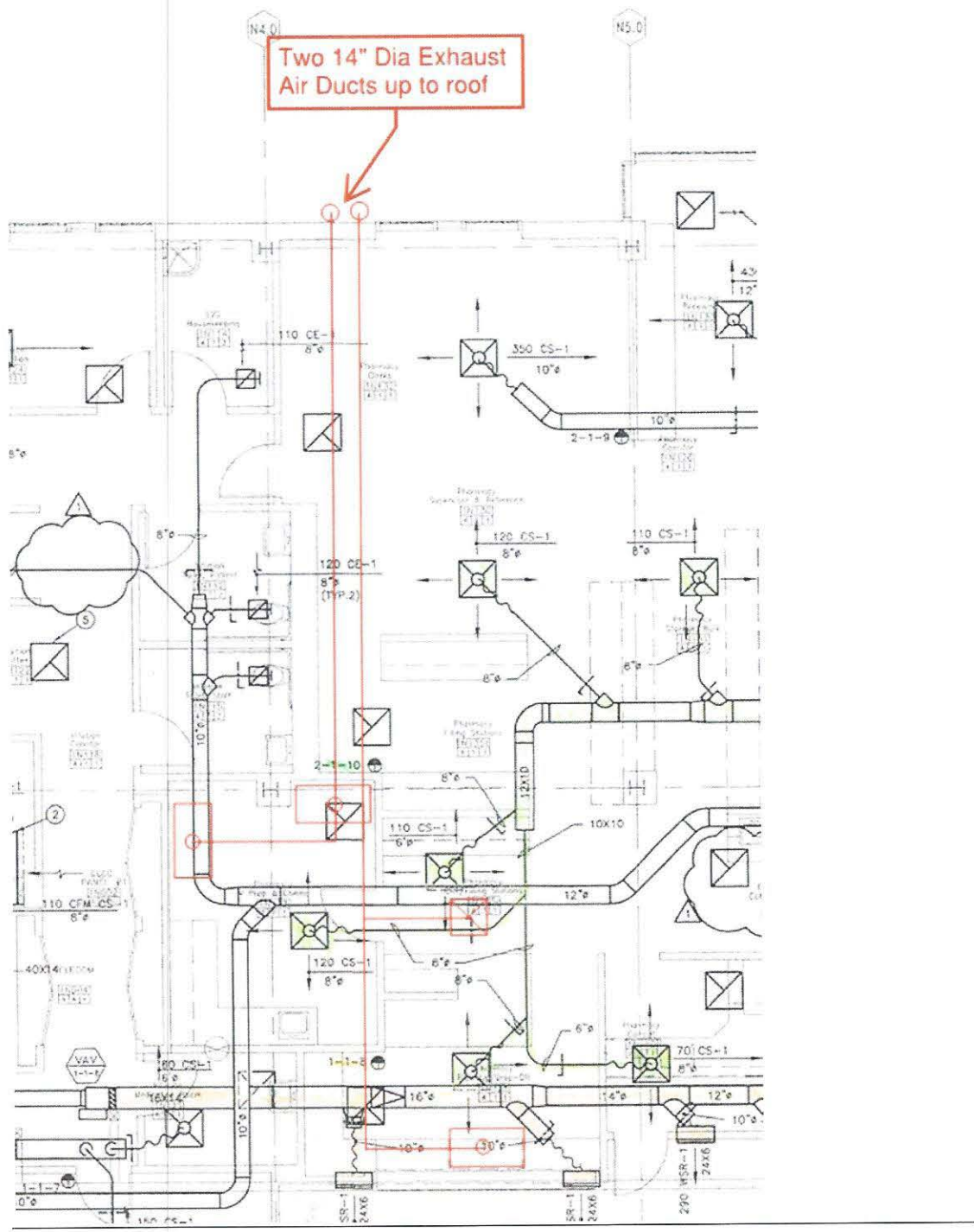
The existing Normal Branch Panel 'HRB' and Panel 'L3B' both have available spare breakers to accommodate new loads. No modifications are required.

Mechanical Systems

As part of the remodel, new HVAC units on the roof will be provided. The exhaust fan will be rated at 120/208 volt power and shall be fed from Emergency Branch Panel 'EL3B' on the 3rd floor. Provide a new weatherproof receptacle outlet within 25 feet of the exhaust fan for maintenance if it is not within 25 feet of the existing outlet, as required by CEC 210.63. Disconnect switch shall be provided for the new exhaust fan as required for shutoff means. The receptacle outlet and disconnect switch shall also be fed from the 120/208 volt Panel 'L3B'.

ATTACHMENT 3

Hazardous Compounding Pharmacy and Non-Hazardous Compounding Pharmacy/Ante Room Exhaust Air Duct Route



Room Area Schedule

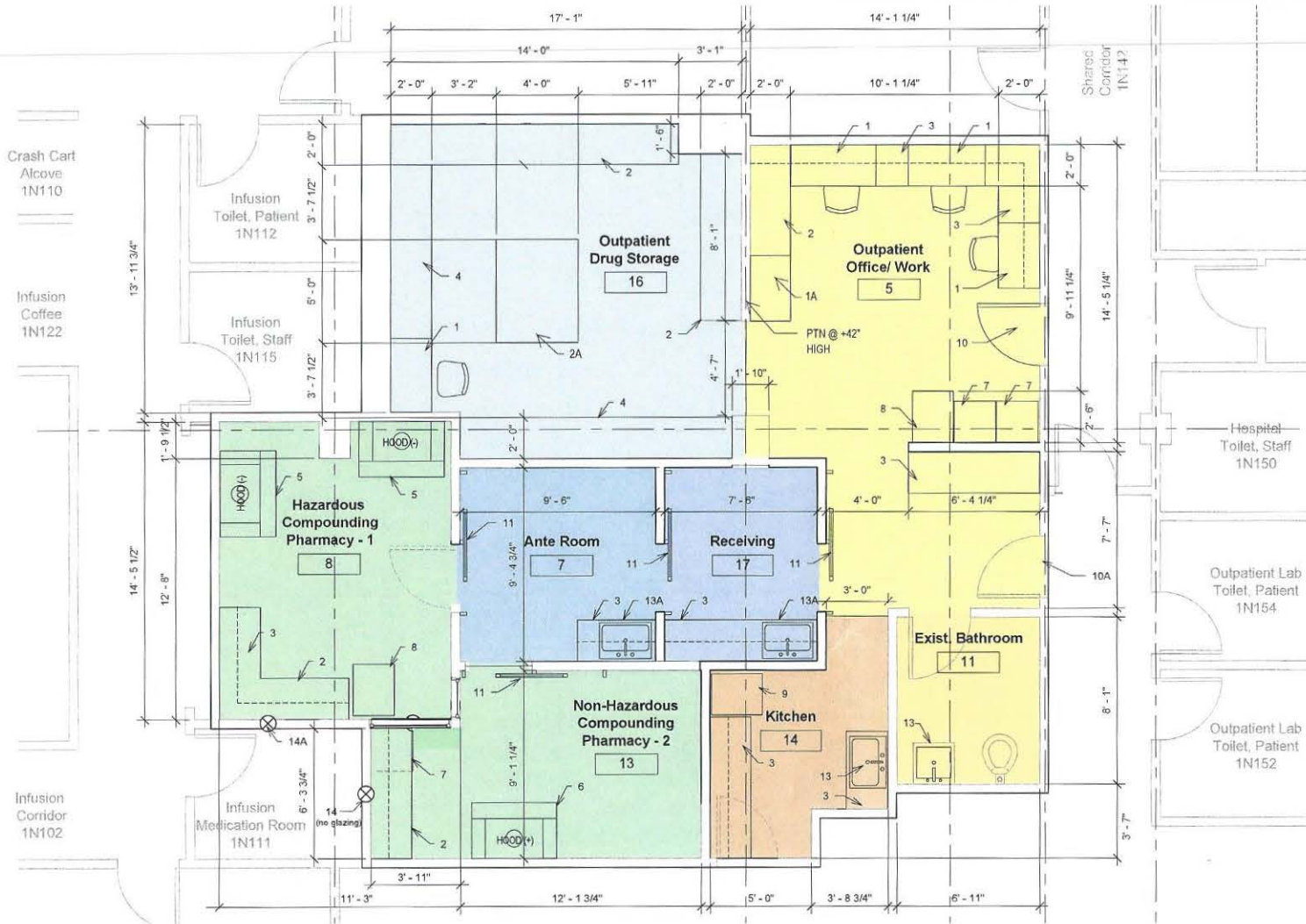
NAME	AREA	AIR BALANCE	HVAC/ CLEAN RM
Office/Work	290 SF	Neutral	n/a n/a
Receiving	70 SF	Neutral	n/a n/a
Ante Room	90 SF	+	30 ACPH ISO7
Pharmacy -1	160 SF	-	30 ACPH ISO7
Pharmacy -2	135 SF	++	30 ACPH ISO7
Drug Storage	270 SF	Neutral	n/a n/a
Kitchen	80 SF	Neutral	n/a n/a
Existing Bathroom	55 SF	Neutral	n/a n/a

KAVA MASSIH ARCHITECTS
 920 Grayson Street | Berkeley, CA 94710
 95 Federal | San Francisco, CA 94107

CCCRMC, Building 1
 Pharmacy Remodel
 Concept Plan
 June 15, 2016

KEY

- 1 DESK / 1A SIT STAND DESK
- 2 COUNTER W/ STORAGE BELOW
- 2A ISLAND WORK COUNTER W/ STORAGE BELOW
- 3 COUNTER W/ OVERHEAD AND UNDER COUNTER STORAGE
- 4 FLOOR TO CEILING SHELVING
- 5 HOOD WITH DEDICATED EXHAUST
- 6 HOOD WITH DUCTED EXHAUST
- 7 EXISTING UNDERCOUNTER REFRIGERATOR
- 8 EXISTING FULL HEIGHT REFRIGERATOR
- 9 EXISTING FULL HEIGHT REFRIGERATOR FOR KITCHEN USE
- 10 NEW DOOR
- 10A EXISTING DOOR
- 11 NEW SLIDING DOOR
- 12 COUNTER HEIGHT WALL
- 13 SINK
- 13A SINK W/ EYE WASH STATION
- 14 PASS-THRU WINDOW
- 14A EXISTING PASS-THRU WINDOW



Attachment 5



Facilities Department: ***Temporary Relocation of Pharmacy Staff***

Issue Name: Temporary Relocation of Pharmacy Staff During Bldg1 BOP Required Construction. Estimated Start Date 1 st Quarter of 2017	Project Leaders: Dave Duet and Tim Friend- Facilities, Bill Perry and Jerry Casey- Public Works
---	---

SITUATION:

USP 800 is a new law that pertains to hazardous drugs and the safety of personnel. Part of the requirements of the new law is the venting of compounding areas and containment cabinets to the outside. This new law will require physical modification of the infusion pharmacy as well as the surrounding areas in the Martinez Outpatient Pharmacy. Completion of work is required by July of 2018. In addition, California State Board of Pharmacy has modified regulations regarding compounding regulations that have been approved as of September 15, 2016. The new regulations will take effect January 1, 2017.

BACKGROUND:

To complete the requirements of USP800 and California State Board of Pharmacy compounding regulations, alteration of the existing Martinez Outpatient Pharmacy space is needed. To that end, it will be necessary to temporarily relocate Pharmacy Staff while construction takes place. Additionally, the construction in the existing space will need to be phased to allow the work to continue uninterrupted during construction.

ASSESSMENT:

Temporary Staff Relocation

Room 54 in E Ward will be used as the "swing space". Pharmacy staff will be relocated to this swing space for the duration of the construction. Access to the space is controlled by a door lock keypad. The code will be unique and specified by Pharmacy management. Adequate temperature controlled space will be provided to staff along with the required office furniture, phones, IT equipment, etc. Included in the access controlled space is a separate bathroom including a toilet and handwashing sink. Additionally, a portable handwashing sink will be provided. (The specifications for the portable sink are attached). This will be a single basin handwashing sink with a temperature controlled water temperature output of up to 107F+/-3F. It is powered by 110v ac power and has 2 - 5gal tanks (one potable water tank and one grey water tank). These tanks will be refilled and emptied daily by CCRMC Engineering staff. A portable eyewash station will be provided as well. Facilities staff will be available for any additional needs.

Attachment 5



Facilities Department: Temporary Relocation of Pharmacy Staff

Phasing

The renovation of the Outpatient Pharmacy space will be carried out in 2 phases. Refer to Attachment 4 drawing "Pharmacy Remodel Concept Plan." The staff currently housed in areas 16 and 5 (phase 1) on the drawing will be moved to Room 54 first. Construction will take place in this phase 1 area. Adequate barriers will be installed between the 2 phased areas. Additionally, infection protocols will be followed and an interim life safety plan will be enacted. Once construction is complete in phase 1, staff will be moved back from Room 54 and occupy the newly constructed space. Consequently, staff from rooms 8, 7, 17, 13, and 14 will then be moved to Room 54 (phase 2). Once staff is relocated, construction will commence in the phase 2 area. Once the phase 2 construction is complete, staff will move back into their new space and the project will be complete.

RECOMMENDATIONS:

Have this swing space available for use by the start of construction in the Martinez Outpatient Pharmacy. Carry out the phasing of construction and the movement of staff. Complete construction and licensing by the July 2018 deadline. Move staff to the new Pharmacy space once licensing is complete.



Indoor Hot Water Portable Hand Wash Sink

Product Application

Ozark River Portable Sinks® are designed to assist individuals and businesses comply with hand-washing codes and regulations by placing hand-washing at the point of contact. Add them conveniently to any area.

The Elite Pro offers durable construction and factory installed dispensers making it a perfect match for these indoor compliance applications:

- Outdoor Tent Food Vendors
- Covered Patio Food and Beverage Serving
- Catering Events
- Waitress Stations
- Hospitality
- Residential Covered Decks and Garages
- Mobile Trailers
- Classrooms and Covered Playgrounds
- Trade Shows, etc.



ESLSWB-SS-SS3N

ESLSWB-SS-SS1N

Standard Features

- Instant Hot Water System
- Stainless Cabinet Countertop and Basin
- White Laminate with Black 3mm PVC Edged Doors
- 3" Swivel Casters (Front Locking)
- Locking Cabinet
- ADA Compliant Faucet Handles
- GFCI Outlet Protection
- Water Tanks: 5 Gal. Fresh and 6 Gal. Waste
- Exclusive Quick-Connect Tank System

Standard Door Color



White/Black (WB)

Color Options on Laminate Doors with 3mm PVC Edging

Eleven Optional Door Colors to choose from at no additional charge. Custom colors upon request. (price and lead time may vary)

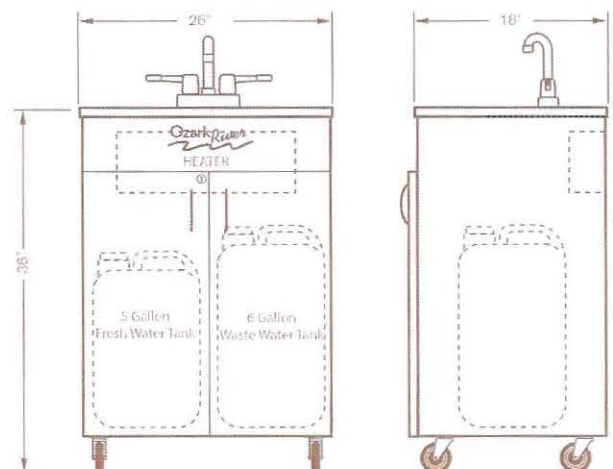


Exclusive Quick Connect Tank System



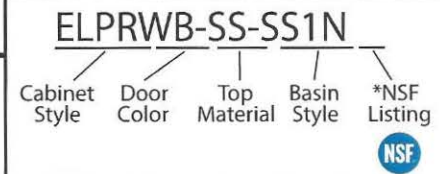
Standard Operating Requirements

- Each sink must have grounded, dedicated 110V, 20A circuit breaker
- Dry, level surface
- If extension cord is used, cord must be 12/3, rated at 20A or higher
- Water must meet EPA Standards with PH between 7.0 and 9.0



Quick Guide

How Our Model Numbers Work



* If "N" is not included in the Model Number, the product is not NSF Certified.

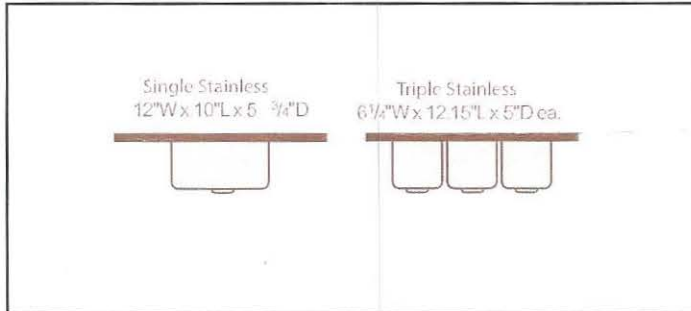
Elite Pro

Indoor Hot Water Portable Hand Wash Sink

Model Number	ESLSWB-SS-SS1N
Model Name	Elite LS 1
Number of Basins	Single
Basin Material	Stainless Steel
Basin Dimensions	12" W x 10" L x 5.75" D
Top Material	Stainless Steel
Cabinet Dimensions	26" W x 18" D x 36" H
Cabinet Material	Stainless Steel
Doors Material	White Laminate with 3mm Edgebanding
Product Weight	72 lbs.
NSF Certified	Yes
GPM	0.50
Fresh Water Tank	5 Gallon
Waste Water Tank	6 Gallon
Approx Hand Washings	40 qty. 15 second hand washings
Electrical Requirements	110V, 20A Dedicated Outlet and Breaker
Warranty	Two Years

Model Number	ESLSWB-SS-SS3N
Model Name	Elite LS 3
Number of Basins	Triple
Basin Material	Stainless Steel
Basin Dimensions	6.25" W x 12.15" L x 5" D (each basin)
Top Material	Stainless Steel
Cabinet Dimensions	26" W x 18" D x 36" H
Cabinet Material	Stainless Steel
Doors Material	White Laminate with 3mm Edgebanding
Product Weight	72 lbs.
NSF Certified	Yes
GPM	0.50
Fresh Water Tank	5 Gallon
Waste Water Tank	6 Gallon
Approx Hand Washings	40 qty. 15 second hand washings
Electrical Requirements	110V, 20A Dedicated Outlet and Breaker
Warranty	One Year

Basin Compartment Dimensions



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 Office: 62.630.3700
 Fax: 562.630.3800

Pharmacy Name: Pine Pharmacy

License Number: PHY/PHE NRP1330

Please provide sterile compounding licenses associated with the above license: LSC/LSE NSC99844

Name of the Individual Submitting this Request: Joseph Catanese

Title: Supervising Pharmacist

Email: jcatanese@pinepharmacy.com

Phone Number: 716-332-2288

The provisions of the regulation for which a compliance delay for construction is needed:

(Note: CA Code of Regulations section 1735.6(f) requires the identification of code sections requiring physical construction, alteration or improvement that are the reason for the waiver request)

- 1735.6, list subsections
- 1751.4 list subsections
- Please list if other sections

A description of the physical changes that must be made for compliance *(Attach additional page if necessary):*

Currently, our cleanroom facility contains both an ISO 5 LAFW and an ISO BSC in the buffer room. With the setup and size the way it currently is, a separate, negative pressure hazardous room cannot simply be added on. Potentially, an entirely new clean room facility, complete with separate negative pressure hazard room, must be built in a separate location in the pharmacy, temporarily eliminating non-sterile compounding space until facility is completed and non-sterile compounding can be relocated to the old clean room space.

Please provide the timeframe for construction to completion:

Late 2017 to mid 2018. We are currently in the process of determining best options to make our facility compliant with USP <800>, USP <797> and California Code of Regulations, along with vetting contractors to complete work

Have building plans been developed? Yes No

Has a building permit been secured? If yes, please provide number: No

Please provide a written description of how the pharmacy will perform compounding while the compliance delay is in effect.

Since only a small percentage of sterile compounds produced are hazardous, we would continue to compound those in the ISO 5 BSC. Closed System Drug Transfer Devices would be used when possible. Hazardous chemicals would be physically segregated away from non-sterile stock. Any non-sterile steps involving hazardous drug weighing, mixing, etc would be performed under powder containment, and the operator would be required to, at a minimum, wear n95 respirator, sterile chemo gown, and double glove with sterile chemo rated gloves (in addition to all USP <797> requirements).

Reviewed by:

Pharmacy Pharmacist-in-Charge Joseph Catanese

Please Print

Signature: 

Date: 10/11/2016

Please do not send architectural drawings or structural plans as they will not be reviewed.



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

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

Guidance on Applying for Compliance Delays During Construction In Pharmacies that Compound

Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver of such compliance for a period of time to permit the required physical changes. See also related provisions in CCR section 1751.4.

Application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated for such waiver.

For hospitals, please see *Guidance on Applying for Compliance Delays During Construction in Hospital Pharmacies that Compound*, to request an exemption.

Please submit your request via email to: Compounding.waivers@dca.ca.gov

Or mail to: Compounding Construction Waiver Request
 CA State Board of Pharmacy
 1625 N Market Boulevard, Suite N-219
 Sacramento, CA 95834

Please retain a copy of your submitted request and make available for review at the licensed location.

Below is an example of the requested information in a format that you may submit to the board to request a waiver. It is in a fillable PDF format that you can complete online, printout, have signed and then return to the board along with any attachments. This document and form are available at www.pharmacy.ca.gov.

Pharmacy Name: Professional Village Pharmacy, INC.

License Number: PHY/PHE 46997

Please provide sterile compounding licenses associated with the above license: LSC/LSE N/A

Name of the Individual Submitting this Request: John C. Richards IV

Title: President/Pharmacist-In-Charge

Email: JCRPharmD@gmail.com

Phone Number: 916-483-3455

The provisions of the regulation for which a compliance delay for construction is needed:

(Note: CA Code of Regulations section 1735.6(f) requires the identification of code sections requiring physical construction, alteration or improvement that are the reason for the waiver request)

1735.6, list subsections (E SUBSECTION)

1751.4 list subsections

Please list if other sections

A description of the physical changes that must be made for compliance *(Attach additional page if necessary)*: Professional Village Pharmacy is working with QleanAir to install a negative pressure room. I am waiting an answer from the California State Board of Pharmacy to see if one of our propped ideas will need a seperate license. I have left messages and spoken to both an inspector and the person in charge of licenses. They are checking with each other and as of yet not returned my call with an answer. Our other option is to put a negative pressure externally vented compounding room into the area that we now use for our office. Our building is 58 years old and we are trying to get something that will work inside our existing building. We will need to build and externally vent with all appropriate mechanical work in either site. We are trying to get this taken care of ASAP.

Please provide the timeframe for construction to completion:

ASAP. Realistically I have been told 6 months with all physical, mechanical improvements and the permitting process that goes along with it.

Have building plans been developed? Yes No

Has a building permit been secured? If yes, please provide number: NO

Please provide a written description of how the pharmacy will perform compounding while the compliance delay is in effect.

As we have in the past. We have an area that we use as a separated compounding area with 2 Powder Safe hoods. We are clinical preceptors for UCSF, UOP and California Northstate University College of Pharmacy. All have made sure that we follow proper compounding guidelines. We recently had a State Board of Pharmacy inspector in our pharmacy and he looked at our compounding and gave his approval. We also hold a certificate as an Exemplary Provider in compounding pharmacy from The Compliance Team.

Reviewed by:

Pharmacy Pharmacist-in-Charge John C. Richards IV

Please Print

Signature: 

Date: 10/11/16

Please do not send architectural drawings or structural plans as they will not be reviewed.

From: San Diego Compounding Pharmacy [mailto:sdcprx@gmail.com]
Sent: Monday, October 10, 2016 8:13 AM
To: DCA, Compounding Waivers@DCA
Subject: Waiver Application 2017

Regarding: 10-9-2016

San Diego Compounding Pharmacy
5395 Ruffin Road #104
San Diego, CA 92123
PHY: 47015
LSC: 99276

Jerry Greene, PIC and owner.
Phone: [858-277-8884](tel:858-277-8884)
Fax: [858-277-8889](tel:858-277-8889)
Email: sdcprx@gmail.com

I am requesting a delay in compliance and a waiver regarding California Code of Regulations 1735.6., subsections E-1, 2, & 3.

We have several issues going on.

First, my current lease expires in mid-2018 and my landlord is not renewing. Therefore I am going to be moving to a new location and thus building a new facility which will include a Sterile Positive Pressure room as well as a newly designed Negative Pressure Room.

Secondly, if I were to construct a negative pressure room at my current location (I've been here since 2005), my landlord has denied me venting to the outside of the building. USP 800 guide lines or not, he refuses to allow this.

I have spoken at great lengths with both Simplex as well as Terra Universal about the construction of this negative pressure room, buffer room and ante-room. I have spoken with, and have a commitment from, an HVAC company to install a separate air-conditioning unit for this room and include hepa-filters in the ceiling as well as forced ventilation out of the building as described provision 1735.6 subsection E-1, 2, and 3.

All three have come up with plans for this room, but it must be constructed at my new facility in 2018.

Therefore, I have no current city permits, or a time frame to have the project completed until I get closer to moving.

In the meantime, all of our Non-Sterile compounding will continue to be performed as we always have. All of my staff are trained in gowning, gloving and masking up prior to working. The staff wears rubber soled shoes ONLY inside the pharmacy and store their shoes in the storage closet at

the end of the day. If anyone leaves the suite, but remain in the building, they don booties, and if they leave the building, they change into "street shoes."

All of our weighing is performed under Airclean 700 Series powder hoods, and all equipment is sprayed with alcohol prior to being removed from under the hood and hepa-filters. Capsules, creams, gels etc...are and have always been weighed and compounded under the 700 Series powder hood.

All HD's used in sterile compounding are weighed and solubilized in a Class 8 ante-room and then taken directly into the Class 5 Airclean 4000, or Airclean 600 laminar flow hood for filtration.

All of our sterile products are sent out for Sterility and Endotoxin Testing and our non-sterile products are rotated quarterly for potency testing from each compounding technician at random. Our hoods and the CleanRoom are certified twice a year which include airflow pressure and viable testing.

I have been a compounding pharmacist since 1988 and have always been in compliance with BOP regulations. I am just running into some small delays regarding the new regulations and hope that I will be allowed more time in order to keep my doors open, and my staff working.

If you should have any questions, please feel free to contact me at the pharmacy during business hours.

Thank you for your consideration-

Jerry Greene, R.Ph., FACA
San Diego Compounding Pharmacy
5395 Ruffin Road #104
San Diego, CA 92123
P) [858-277-8884](tel:858-277-8884)
F) [858-277-8889](tel:858-277-8889)
www.sdcprx.com



From:
Sent:
To:
Cc:
Subject:

Good Morning,

Key Compounding Pharmacy, is a California licensed sterile and non-sterile Non-Resident compounding pharmacy, our license numbers are NRP1536 & NSC100631.

We would like to request a facility waiver, we understand that it is a delay only and not an exemption. Are there further steps in the process to obtain a delay waiver or is this email sufficient?

Thank you in advance for your assistance.

Best Regards,

Rachael Vardeman, PhT
Regulatory Affairs

As part of our continuous improvement efforts, we invite you to complete a survey about your recent experience with Key Compounding Pharmacy. [Click here to start the survey.](#)



Phone: 800-878-1322 Ext.101
Fax: 888-878-1118
Federal Way, WA 98003
www.keycompounding.com



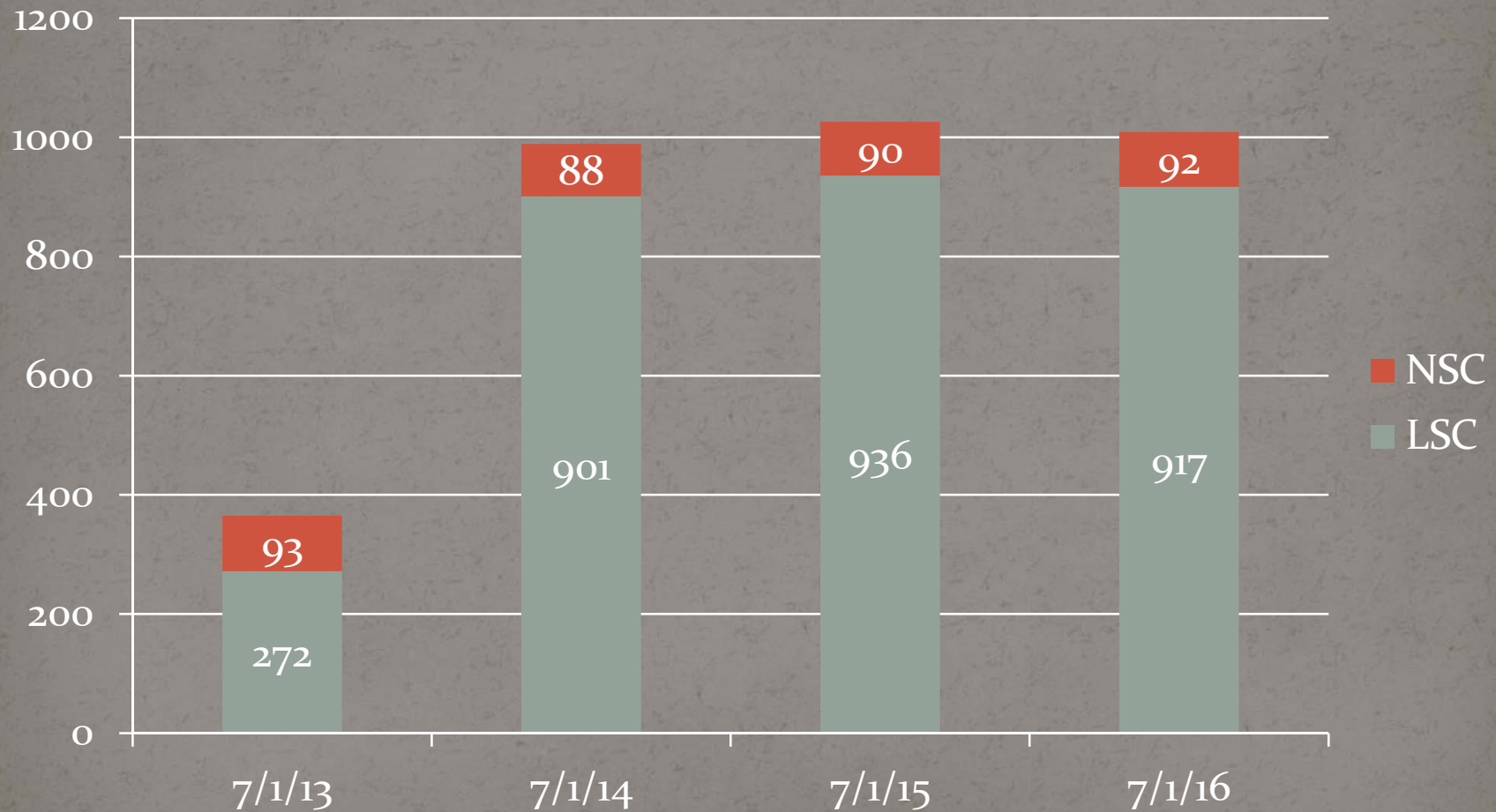
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Attachment 6

Sterile Compounding Inspections Overview

Presented on 8/31/16
Enforcement & Compounding Committee
By Christine Acosta PharmD.

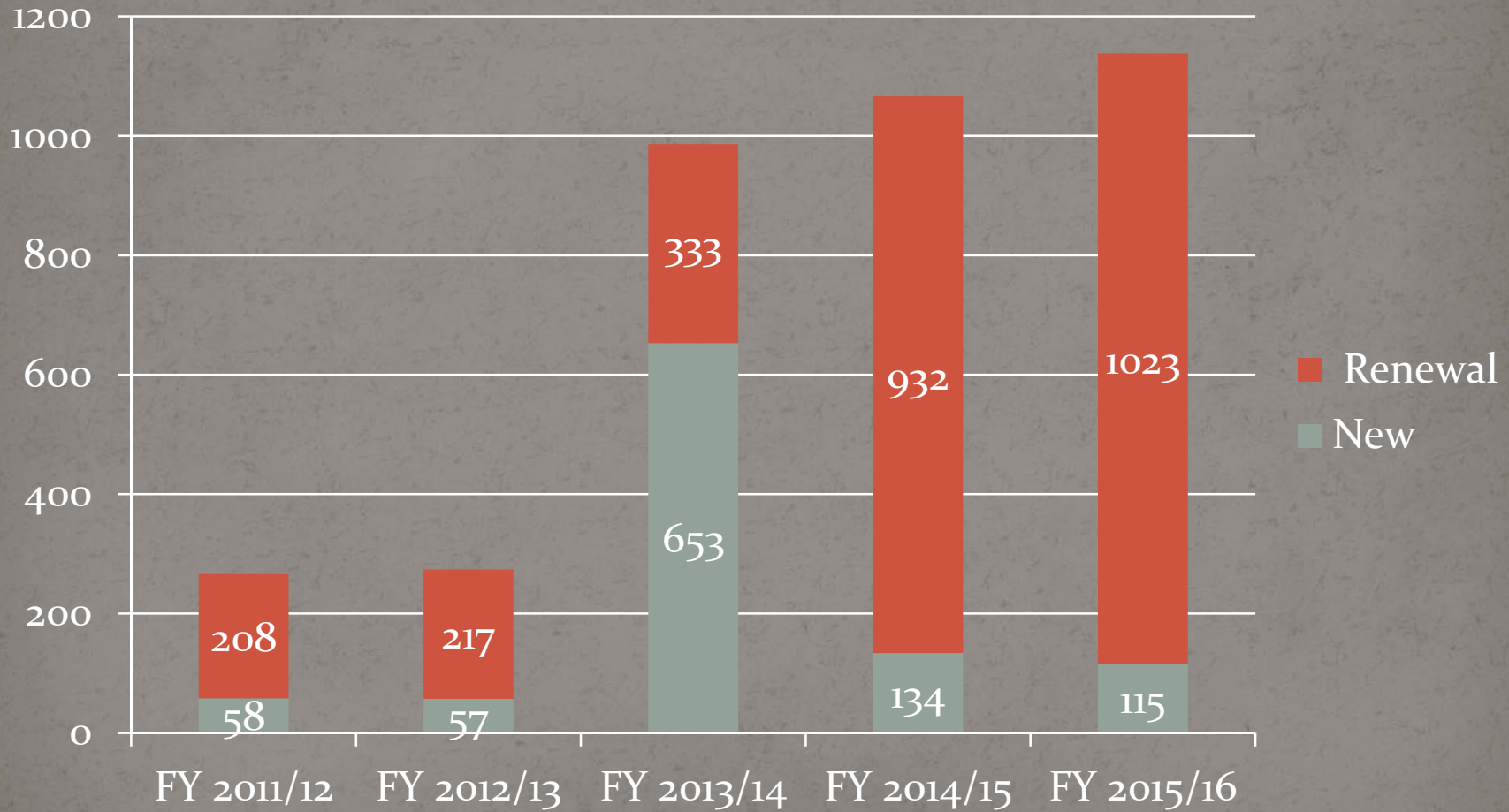
Total NSC and LSC Licenses By Year 2013-2016



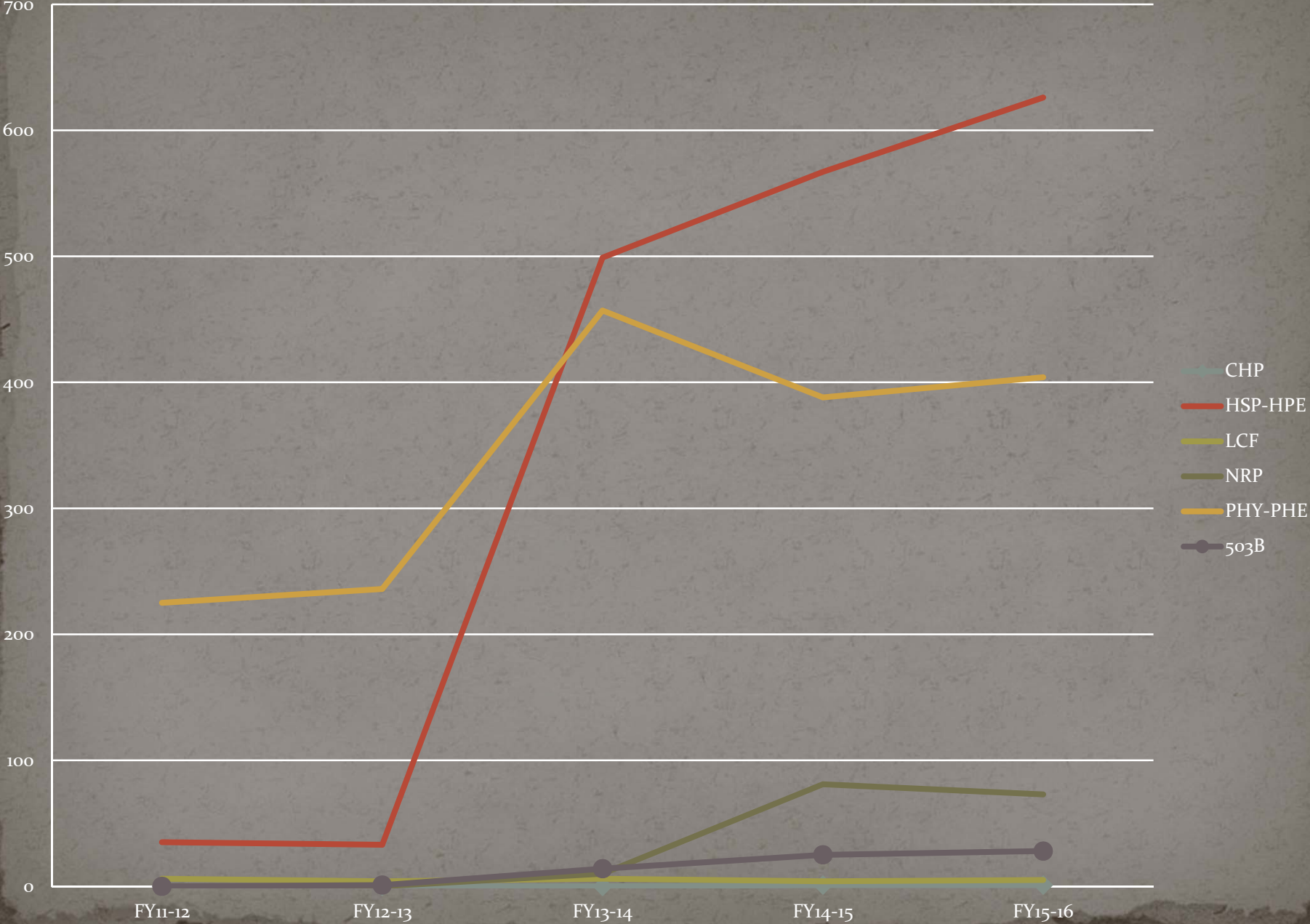
Number of LSC issued



Total LSC Inspections Performed FY 2012/13 to FY 2015/16

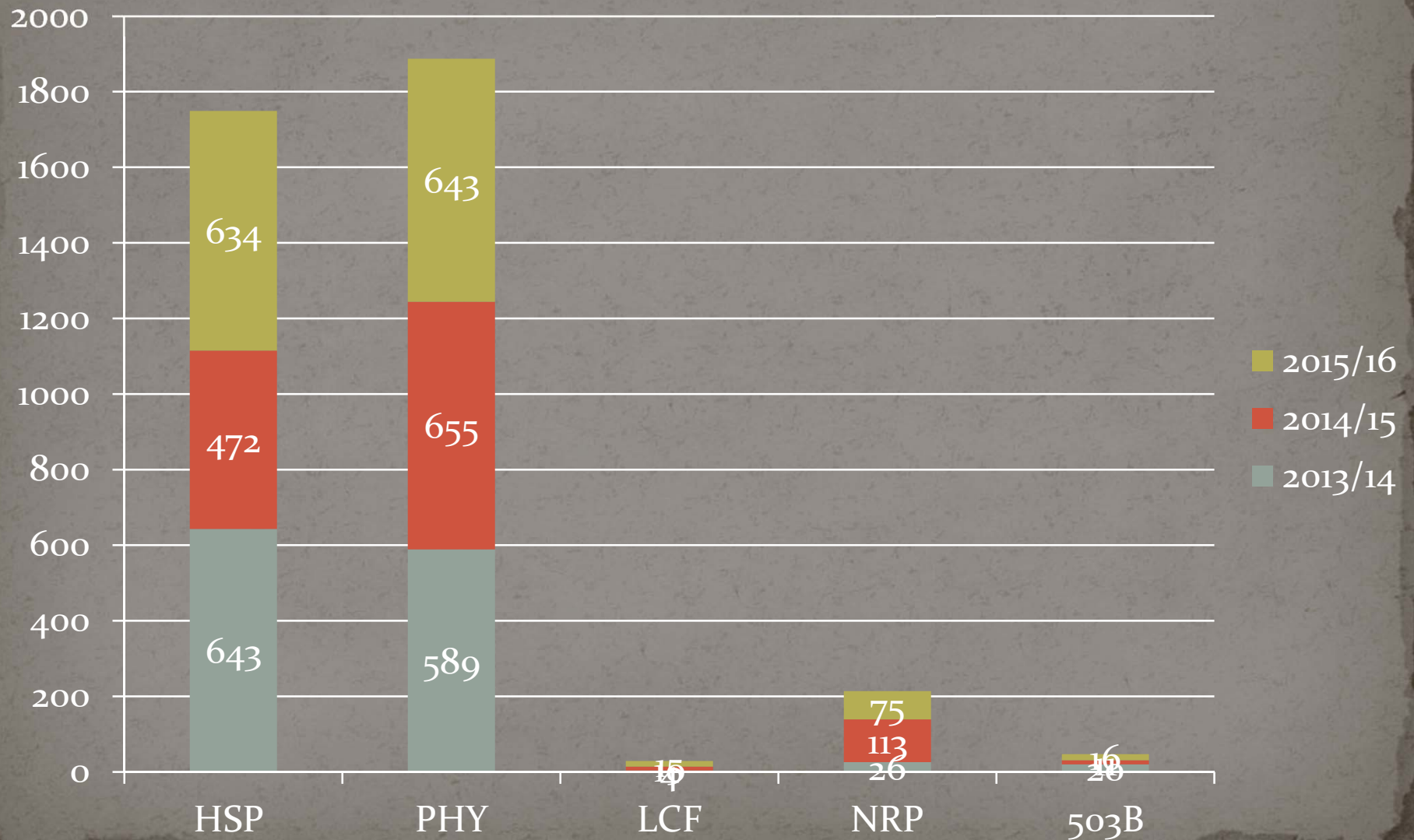


Sterile Compounding Inspections by License Type



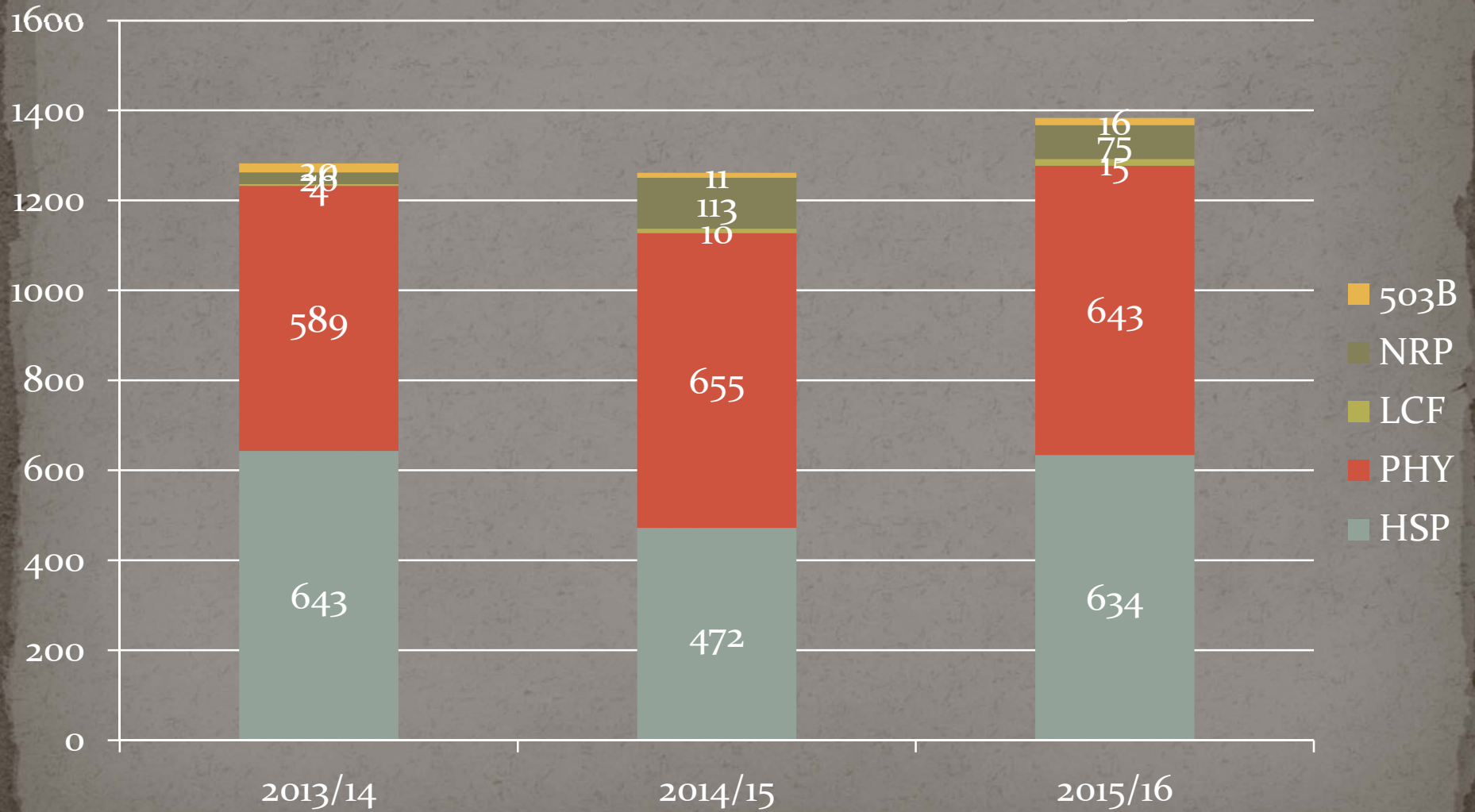
Violations by License Type

FY 2013/14, 2014/15, 2015/16

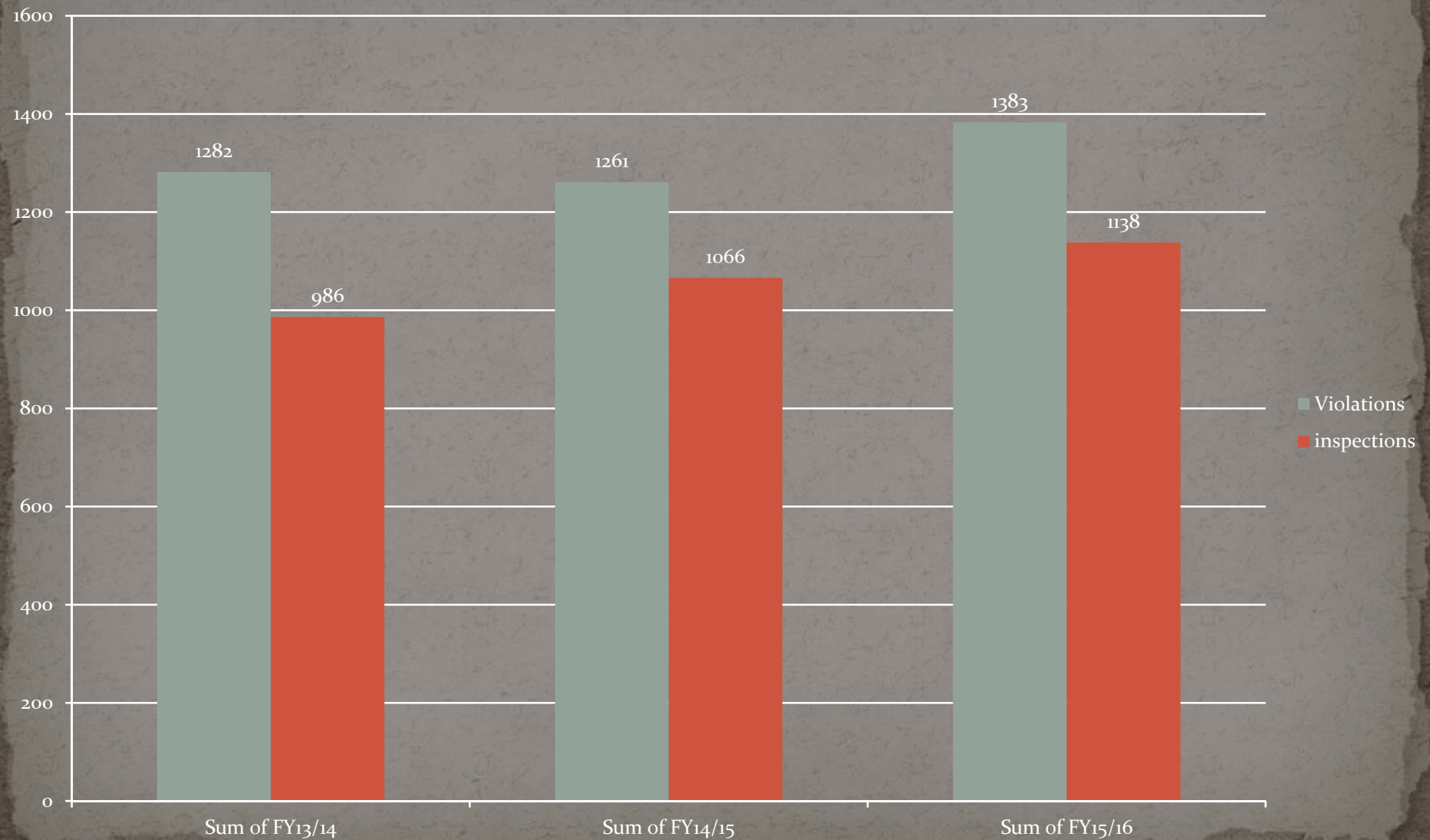


Total Violations by Year

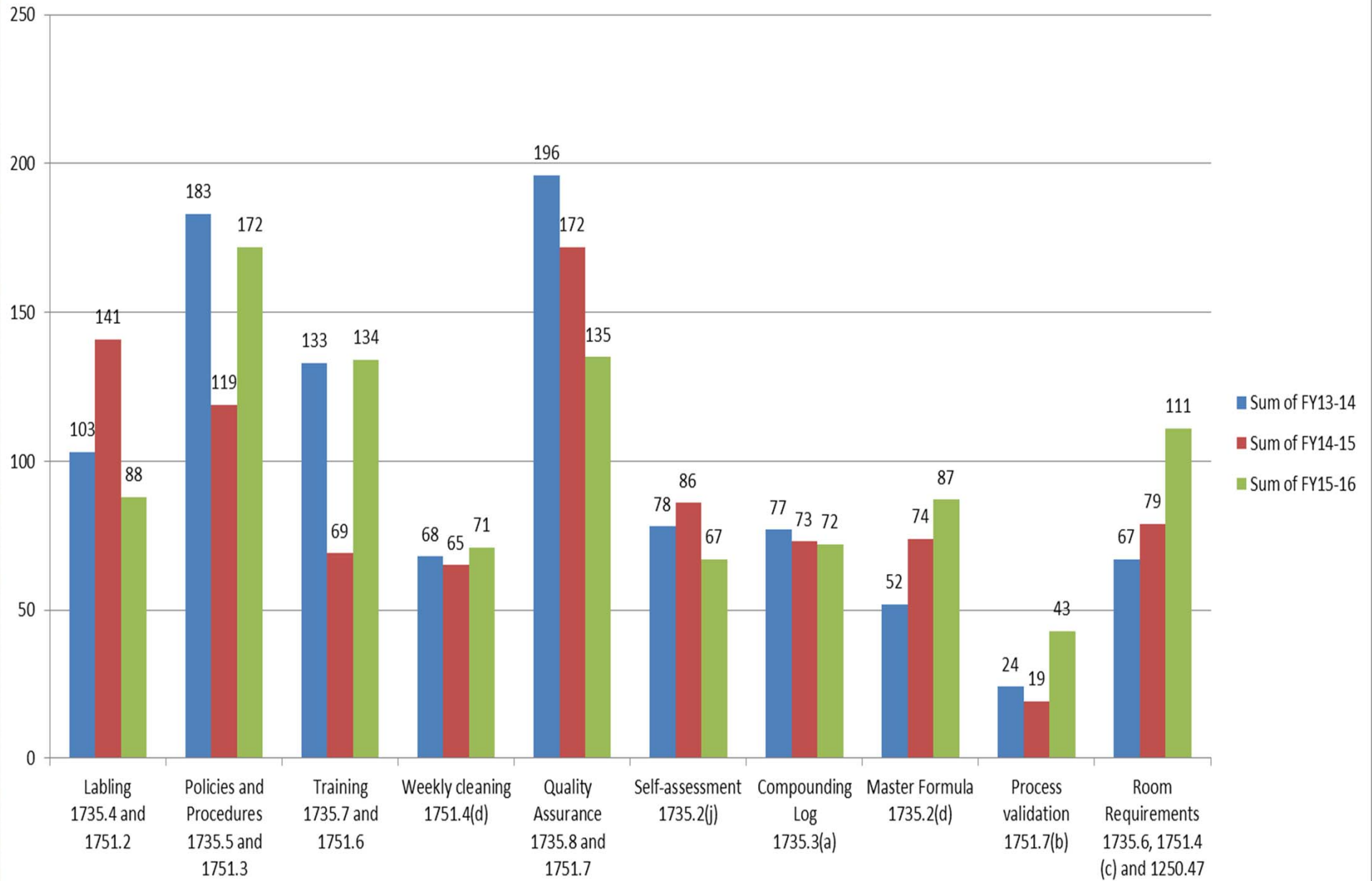
FY 2013/14, 2014/15 and 2015/16



number of violations by related to the number of inspection done



Top Violations



Number of LSC on probation on 7/1

	FY13/14	FY14/15	FY15/16
• PHY	2	5	9
• HSP	0	0	0
• NRP	1	1	0

Number of LSCs with actions during each FY

	FY13/14	FY14/15	FY15/16
• Revocation	0	0	0
• Probation	4	0	1
• Voluntary Surrender	2	3	1
• Public Reprimand	0	0	2

Number of LSCs referred to the AG

	FY13/14	FY14/15	FY15/16
• LSC	2	1	0
• NSC	0	1	1

Education: Master Formulas

CCR 1735.2(d)

- A drug product shall not be compounded until the pharmacy has first prepared a written **master formula record** that includes at least the following elements:
 - (1) Active ingredients to be used.
 - (2) Equipment to be used.
 - (3) Expiration dating requirements.
 - (4) Inactive ingredients to be used.
 - (5) Process and/or procedure 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.

Education: Recordkeeping for Compounded Drug Preparations

CCR 1735.3 (a) For each compounded drug product, the pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.

Education: Recordkeeping for Compounded Drug Preparations

CCR 1735.3 (a) For each compounded drug product, the pharmacy records shall include:

- (6) The manufacturer and lot number of each component.
 - Exemption: one-time basis for administration with 72hrs to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
- (7) A pharmacy assigned reference or lot number for the compounded drug product.
- (8) The expiration date of the final compounded drug product.
- (9) The quantity or amount of drug product compounded.

Sterile Compounding Inspections: Overview

THE END

Attachment 7

Compounding Regulations Q&A for the pending changes to Title 16 CCR 1735 and CCR 1751

Based on the Second Modified text dated November 17, 2015.

Guidance not meant to be a substitute for legal counsel.

1. When referring to a compounding aseptic isolator, what is meant by “not be recirculated nor turbulent” in CCR 1735.1(f) and CCR 1735.1(g)?

Please see CETA: Compounding Isolator Testing Guide document CAG-002-2006 (revised 12/08/08) for a clearer understanding of certification requirements.

2. When referring to a commercially available product, what is “essentially a copy”?

See CCR 1735.1 (k) for definition.

Please note nothing in this section is intended to limit the compounding or reconstitution of commercially available products per the manufacture’s FDA approved prescribing information.

3. What is meant by a “clinically significant difference” between a compounded preparation and the comparable commercially available drug product?

This is to be determined by a prescribing practitioner; please see CCR 1735.1(k)

4. Where is sterile compounding required to be done?

See CCR 1735.6 for Compounding Facilities and Equipment requirements and CCR 1751.4 for Facility and Equipment Standards for Sterile Compounding. The requirements outlined in CCR 1735.6 and CCR 1751.4 must **BOTH** be met when sterile compounding is done.

5. What does “evaluated for sterility” mean in CCR 1735.1(u) with regards to a “media-fill test?”

“Evaluated for sterility” means the growth-based media is, according to the media’s manufacturer guidelines, correctly stored, monitored, and reviewed for the presence of growth or lack thereof.

6. What is meant by “most complex compounding procedures” in CCR 1735.1(u) ?

Please see CCR 1751.7(b) for the full requirements for process validation.

7. Why do the BOP regulations conflict with the FDA's enforcement and guidance of 503A practice under FD&C act, as related to "office use" of compounded drug products?

The BOP is tasked with protecting of the public of California by enforcing the California regulations and statutes. The FDA does not enforce the same set of regulations or statutes as the BOP and there will be occasional conflicts.

8. Under CCR 1735.2(d) why is the BOP preventing hospitals from compounding and requiring them to use commercially available ready for administration sterile products?

See CCR 1735.1 (k) for definition of "essentially a copy." Please note nothing in this section is intended to limit the compounding or reconstitution of commercially available products per the manufactures FDA approved prescribing information.

9. Do the requirements for the assignment of beyond use dates (BUD) apply to both sterile and non-sterile compounds?

See CCR 1735.2(i)(1) for the requirement of assignment of the BUD of a non-sterile compounded drug product. See CCR 1735.2(i)(2) and CCR 1751.8 for the requirement of assignment of the BUD of a sterile compounded drug product.

10. What is meant by "container closure integrity test" under CCR 1735.2(i)(3)(B)?

Please see USP <1207> STERILE PRODUCT PACKAGING—INTEGRITY EVALUATION.

11. What is meant by "stability studies" under CCR 1735.2(i)(3)(C)?

Please see USP <1150> PHARMACEUTICAL STABILITY.

12. Do you really expect a master formula, as defined in CCR 1735.2(e), for all compounded products made for an inpatient in a licensed health care facility?

Yes, a compliant master formula shall be prepared prior to the compounding of any product with the exception as defined in CCR 1735.2(f). Nothing in this regulation is meant to require a paper or printed version of a master formula, as long as the compliant electronic master formula is readily retrievable.

13. Do you really expect the compounding log to be a single document as defined in 1735.3(a)(2)

Yes, the compounding log shall be a single document which may be more than one page. Nothing in this regulation is meant to require a paper or printed version of a compounding log, as long as the compliant electronic compounding log document is readily retrievable.

14. What are the expectations of the BOP with regards to the training of environmental services staff (i.e. EVS)?

As required by CCR 1735.7(a), the EVS or any staff cleaning the compounding area must have the skills and training required to properly and accurately perform their assigned responsibility and there must be documentation demonstrating this training.

15. What is the value to randomly testing one product per year for qualitative and quantitative analysis as required by CCR 1735.8(c)?

The testing of one product per year for qualitative and quantitative analysis, as required by CCR 1735.8(c), is the minimum requirement set forth to validate the internal processes of a facility. The BOP allows discretion by the pharmacist-in-charge in determining if a greater quantity or a more frequent sampling of preparations is more representative of the actual practice setting and, therefore, of more value to the evaluation of the internal processes of a facility.

16. Why are continuous monitoring or recording devices not allowed for air pressure differentials under CCR 1751.1(a)(8) ?

Nothing in this section disallows the use of continuous monitoring or recording devices for the measuring of air pressure differentials. California Code of Regulations 1751.8(a)(8) requires the air pressure differentials to be documented daily but does not state how that document is to be made or kept.

17. Why is the BOP requiring me to stop compounding my lot of drugs to disinfect per 1751.4(e)?

Nothing in the regulations requires the compounder to stop compounding to disinfect.

18. Why is the BOP requiring the use of a sterile agent to disinfect in CCR 1751.4(e)?

The EPA defines disinfection and sterilization to have two distinct meanings. The regulation is requiring disinfection with an agent that is sterile. CCR 1751.4(e) only addresses disinfection.

19. Why is the BOP not allowing my CACI to be used outside an ISO Class 7 environment?

California Code of Regulations 1751.4(f) provides for the use of properly certified isolators outside the ISO Class 7 environment.

20. Can you please tell me what type of make-up is allowed in the clean room under the pending regulations?

California Code of Regulations 1751.5(a)(6) disallows all cosmetics in the ISO Class 5 and ISO Class 7 compounding areas.

21. What training is required for a pharmacist who is overseeing compounding?

California Code of Regulations 1751.6(e) defines the training requirement for all pharmacies which compound sterile drug preparations. The pharmacist's requirements is specifically addressed in CCR 1751.6(e)(2).

22. Who does the CCR 1751.8(e) labeling requirement apply to? How can the BOP require a registered nurse or medical doctor to label an immediate use IV preparation?

Under CCR 1735, compounding is defined as occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist. The BOP has no jurisdiction over nursing or medical practice. CCR 1751.8(e) is related only to immediate use compounds made by pharmacy staff in a licensed pharmacy.

23. What specific areas do compounders (sterile and non-sterile) need to prepare for once the compounding regulations are finalized/implemented?

There are many areas in the pending regulations which have changes compared to the current regulations. The BOP would suggest each PIC read the pending regulations and complete the new self-assessment and then make the determination as to what the most critical changes are for their practice.

24. What does the BOP plan to do after the new revised USP <797> publishes?

The BOP has plans to readdress our regulations once the USP committee has completed their revisions.

25. Why is the BOP planning to enforce USP <800> before the USP implementation date of mid-2018?

The BOP is tasked with protecting of the public of California by enforcing California regulations and statutes. The BOP does not enforce the minimum practice standards set forth by the USP committee. However, the BOP does understand the cost and time associated with a remodel and/or construction can be significant. Therefore, we have a system in place to allow for facilities to apply for a waiver to allow a defined amount of time to become compliant. See CCR 1735.6(f) for full details.

26. Can our inpatient pharmacy make IV's for our outpatient pharmacy to use for our subacute unit?

Under B&PC 4123 one licensed pharmacy can compound patient specific sterile preparation for a second licensed pharmacy after notification to the BOP. Also, please refer to B&PC 4029, B&PC 4380 and CCR 1710 for the allowance of such activity.

27. Would an inspector expect the walls behind the hood to be cleaned even though hoods are hard to move or cannot be moved due to earthquake brackets?

California Code of Regulations 1751.4(d)(2) specifically addresses the cleaning of the walls within a cleanroom.

28. Why would only a resident pharmacy be required under BPC 4127.9(a)(2) to report a recalled sterile compounded preparation to the BOP within 12 hours. Why is a non-resident pharmacy not held to the same standard?

Under BPC 4127.2(e)(3), all nonresident sterile compounding have the same reporting requirement.

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

See CCR 1735.2(i) for the requirements of assigning a BUD for a compounded drug preparation. Specifically, review CCR 1735.2(i)(2) and (3) for the requirements of extending of a BUD.

30. Does PATT2™ testing (media fill testing for training and competency) need to be done per licensed LSC location?

Per CCR 1751.7(b)(1), the same personnel, procedures, equipment, and materials are part of the process to demonstrate competency on aseptic technique and aseptic area practices.

31. In CCR 1735.1(a) what does “high-particulate-generating activities” mean? Specifically, how does it relate to B&PC 4127.7 and USP <797> requirements for presterilization of non-sterile to sterile compounding?

There is no formal definition of high-particulate-generating activities as this is very dependent on the pharmacy’s specific practice.

There is no specific relationship between high-particulate-generating activities and the requirements of B&PC section 4127.7 and Title 24 CCR section 1250.4(5): both of which require all compounding of non-sterile to sterile injectables to be conducted in one of the following environments: 1) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas. 2) An ISO class 5 cleanroom. 3) A barrier isolator that provides an ISO class 5 environment for compounding.

The 2014 version of USP <797> states in Appendix 1 that “presterilization procedures for high-risk level CSP, such as weighting and mixing, shall be completed in no worse than an ISO Class 8 environment” again there is no relationship specific requirement.

32. Can a Pharmacy Technician, Registered Nurse (RN), Physician (MD/DO), medical assistant (MA) compound in a medical office?

Compounding is defined in CCR 1735(a) as 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. There is currently no allowance for compounding outside a licensed pharmacy under the supervision of a licensed pharmacist.

33. When labeling a large volume IV solution do I need to have the exact volume label or does the 10% rule apply. (Example: D5W 1000 ml with 20ml of drug added can it be labeled 1,000mls or must it be labeled 1,020ml?)

All IV solutions need to be labeled compliant with at least CCR 1751.2, CCR 1735.4 and B&PC 4076. Please keep in mind there is overfill in each premade manufactured bag so even if you labeled the example bag from above with 1,020ml it would likely be incorrect unless the bag was compounded into an empty sterile bag.

34. I do not understand the exemption under CCR 1735.3(a)(1)(F)(i). What do I not need to log and under what instances? Please explain.

The exemption is for a single lot (see definitions in 1735.1(t)) which will be administered within 72hrs in an appropriately licensed facility. These products do not require the logging of the manufacturer, expiration date and lot number of each component; however, all other requirements in CCR 1735.3(a) must be documented.

35. How long will we have to get in compliance with the new building requirements for hazardous compounding?

The current draft of the regulation will go into effect 1/1/2017.

36. If the new regulations are going to require monthly (instead of the current weekly) cleaning in compounding area, can we start that practice now?

California Code of Regulations 1751.4(d) requires exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination. This will be the active and enforceable regulation until 1/1/17.

37. My hospital pharmacy is in the basement and there are challenges to venting hoods to outside and ceiling air filter/exchanges. What exemptions are available?

There are no exemptions available. If a facility anticipates they will not be compliant with the physical requirements by the effective of 1/1/17, a waiver may be requested to allow additional time for the necessary structural changes to be made (see CCR 1735.6(f)).

38. Is the Board going to adopt USP <800>?

No.

39. If the FDA is inspecting 503B facilities, why does the BOP need to?

The BOP is mandated to protect the public of California and, under BPC 4127.1(c) and 4127.2(c), the BOP cannot issue or review a license to compound sterile drug products until the facility has been inspected and found in compliance with regulations adopted by the BOP.

40. Can you look at the architect's plans and provide comments? Can the BOP?

Neither the BOP's inspectors nor the BOP will review or approve any construction projects.

41. Why do I need to label my hormones as "hazardous" when the manufactured products do not require this type of labeling?

All compounded hazardous drugs as defined by CCR 1735.1(r) need to be labeled compliant with at least CCR 1751.2, CCR 1735.4 and B&PC 4076. You may want to consider reviewing USP <800> for the difference in types of exposure, dosage forms, and the assessment of risk that is required while compiling your facility's list of hazardous drugs.

42. Under CCR 1735.1(l), "daily" is defined as "occurring every day the pharmacy is operating." What happens when the compounding area is not open on a day the retail area of the pharmacy is open?

If the pharmacy is open, then activities requiring daily monitoring or maintenance are required. There are no exemptions for any activity if the compounding area(s) is/are not in use but the pharmacy is open. A refrigerator and freezer need to be monitored at least every 24hrs to ensure they are storing the dangerous drugs at the correct temperature. Please see required policies and procedures under CCR 1735.5(c)(9).

43. What drugs does the BOP require to be treated as "hazardous drugs?"

As defined in CCR 1735.1(r), all anti-neoplastic agents identified by NIOSH as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge. As also required in USP <800>, each entity or each PIC must create and maintain a list of hazardous drug that the entity handles. The BOP is asking the PIC to determine what drugs and dosage forms are handled or manipulated in their facility and to define and document the selected drugs and dosage forms as "hazardous."

44. Our scales are brand new and have internal calibration. We record performance of the daily calibration by recording our initials on an online form. Is this acceptable under CCR 1735.6(c)?

If the calibration is done prior to use, per manufacturer's specification and the documentation online is retrievable and not alterable for 3 years, there is nothing to prevent this type of calibration.

45. California Code of Regulations 1735.6(e) is conflicting with USP <800> when it comes to the ACPH required for non-sterile compounding. Which do we follow?

Currently, CCR 1735.6(e)(1) requires 30 ACPH for all rooms where hazardous compounding is done regardless if it is sterile compounding or not and 12 ACPH are allowed for segregated compounding area (CCR 1735.1(af)). USP <800> has an allowance for a non-sterile hazardous compounding room (C-SEC) with only 12ACPH. On 1/1/17, the BOP's regulations will go into effect requiring all rooms where hazardous compounding takes place to have 30 ACPH.

46. I was told I have to keep a copy of my master formula, my compounding log and my potency result stapled all together. May these be immediately available? For example, the master formula document is online (e.g. PK Software), the compounding log is filed, and the potency and sterility results are stored online. Is this acceptable?

The current wording in CCR 1735.8(c) states: "All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula." However, the pending regulations in CCR 1735.8 (c) states: "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." These records must be kept in a readily retrievable form for at least 3 years as required by CCR 1735.3 (d) and CCR 1751.1(c).

47. Why under CCR 1751.1(a)(5) are smoke studies required for all ISO certified spaces?

Smoke studies are required for all ISO certified spaces. This will be updated in the next revision.

48. Under CCR 1751.3(a)(1), what action levels for levels for colony-forming units (CFUs) should the pharmacy be following? Internal levels or USP <797>?

The action level needs to be defined by the PIC and noted in a P&P as well as what plan of action will be taken if they are exceeded.

49. Under CCR 1751.3(a)(15) what is meant by a “sterilization method suitability test?”

There must be documentation to show the method used to sterilize a preparation is capable of repeatable sterilization of said preparation. For example: it would not be acceptable to use an autoclave as the method of sterilization for a drug in oil or it would not be acceptable to use a filter for sterilization without completing and documenting the filter integrity test (bubble test).

50. Under CCR 1751.4 (j), what does “qualified individual” mean? I’ve have purchased a microbial air sampler and have been trained using the video and instructions from the manufacturer. Is it acceptable?

The PIC will need to deem who is qualified and what training is required to ensure all equipment use is stored, used, maintained and cleaned in accordance with the manufacturer’s specification. Training and qualification documents need to be made and retained (CCR 1735.3 (d) and CCR 1751.1(c)) to show the individual is qualified. See CCR 1735.7 and 1751.6 for training requirements.

51. Under CCR 1751.7(c) for the initial three times gloved fingertip sampling what is the expectation?

For initial gloved fingertip sampling: this should be conducted on three separate entries into the clean room just after sterile gloves are donned but before gloves are sprayed with sterile alcohol. Each of the three separate entries **MUST** yield zero CFUs to be considered passing for the individual to be allowed to compound sterile drug preparations.

52. Is it required to have each Biological Safety Cabinet (BSC) and Compounding Aseptic Containment Isolator (CACI) external vented?

Yes, please see CCR 1735.6(e)

53. Is it required to each Biological Safety Cabinet (BSC) and Compounding Aseptic Containment Isolator (CACI) to have a dedicated external vent?

No, see CCR 1735.1(c) and CCR 1735.1(f) where it states this external venting **should** be dedicated to one BSC or CACI.

Acronyms:

ACPH: air changes per hour

B&PC: Business and Professions Code

BOP: The California State Board of Pharmacy

BUD: beyond use date

CCR: California Code of Regulations.

CETA: Controlled Environment Testing Association

CFUs: colony-forming units

CSP: Compounded Sterile Preparations

EPA: Environmental Protection Agency

FD&C act: Food Drug and Cosmetic act

FDA: Food and Drug Administration

NIOSH: National Institute for Occupational Safety and Health

P&P: policy and procedure

PIC: Pharmacist- in-Charge

USP <1150>: United States Pharmacopeia Chapter 1150

USP <1207>: United States Pharmacopeia Chapter 1207

USP <797>: United States Pharmacopeia Chapter 797

USP <800>: United States Pharmacopeia Chapter 800

Attachment 8

Fraud concerns grow as spending on handmade 'compounded' drugs soars

By Julie Appleby July 17

Kaiser Health News

Government spending has skyrocketed on “compounded” drugs that retail pharmacists custom make, drawing federal investigators’ attention for potential fraud and overbilling.

Spending on these medications in Medicare’s Part D program rose 56 percent last year, with topical creams and gels, among the costliest products, now priced at hundreds or thousands of dollars per tube. And over just four years, the federal workers’ compensation program saw its spending on compounded medications spike from \$2.35 million to \$214 million.

The increases, along with a sharp jump in the number of patients getting compounded drugs, “may indicate an emerging fraud trend,” said Miriam Anderson, who helped oversee a June [report](#) on Medicare spending by the inspector general at the Health and Human Services Department.

Some prescriptions may not have been medically necessary and others not even dispensed, according to the report.

The practice of compounding, which is done by mixing drugs in pharmacies or special compounding centers, is as old as the pharmacy profession itself. The specifically tailored medications are aimed at patients who cannot take commercially prepared treatments. Patients who cannot swallow pills can get liquid formulations, for example, or those allergic to certain dyes can get products made without them.

But use among Medicare beneficiaries and federal employees in workers’ comp insurance plans has recently soared, according to Anderson’s report and a separate Postal Service inspector general’s [study](#) released in March. Similar run-ups in use and spending also have been noted by private-sector benefit managers.

In the Part D drug program, the number of beneficiaries getting compounded drugs has grown 281 percent since 2006 to nearly 280,000 in 2015. Spending on such drugs reached \$509 million — up 625 percent since 2006, the HHS inspector general report noted, although that amount remained a tiny fraction of the Part D’s total drug spending.

Topical creams and gels, which are often used for pain, are among the fastest-growing category of compounded drugs. Part D spending on those rose 3,466 percent over the decade; the average cost per prescription hit \$331, up from \$40 in 2006.

New rules from the Labor Department went into effect July 1, aimed at slowing spending increases for the federal workers' comp program. Among other changes, the agency will limit initial prescriptions to 90 days.

While legitimately prescribed compounded drugs “can dramatically improve a patient’s quality of life,” it is important to have “proper controls around billing,” John Voliva, executive vice president of the International Academy of Compounding Pharmacists, said Monday in a statement. The HHS inspector general’s report demonstrated that such controls “are not in place,” he said.

The scrutiny itself has been increasing since a 2012 meningitis outbreak linked to a Massachusetts compounding pharmacy that sold tainted injectable medications. Sixty-four people died.

In the wake of that case, some states tightened their oversight of the industry, particularly of pharmacies making products that must be sterile. Those drugs are not considered approved by the Food and Drug Administration, although the agency does get involved when it is concerned that a site might not be making medications properly or has started to mass-produce treatments rather than preparing them for individual patients.

At times, compounded drugs can be more cost-effective. When Turing Pharmaceuticals last year raised the price of a drug used for patients with compromised immune systems from \$13.50 a pill to \$750, Express Scripts, one of the nation’s largest pharmacy benefit managers, partnered with a compounding pharmacy to produce its own version for \$1 a pill.

“Some compounding we should be happy for,” said Glen Stettin, senior vice president for clinical, research and new solutions at Express Scripts.

Still, sharp increases in spending prompted Express Scripts to crack down on what pharmacy-made products it will cover — which cut about 1,000 ingredients from the list. The company has since seen its clients’ spending on pharmacy-made drugs fall sharply. It also has been targeted by two antitrust lawsuits filed by compounding pharmacies in federal court.

Nationally since 2012, pharmacies have been required to report all ingredients they use to make a compounded drug. The idea was to provide insurers with more information about what they were being billed for and ensure there were no hidden elements.

The effect on drug prices is up for debate. Stettin and others said a few unscrupulous pharmacies began adding more ingredients so they could charge more.

“They are [creating] combinations of things that have never been tested together,” he said. “We saw a diaper cream that was billed at \$1,000, where a patient could get one over the counter for \$2.50.”

In California, federal investigators say a marketer for one pharmacy paid doctors to write prescriptions for compounded pain creams formulated to include a “five-pack” of the most expensive ingredients. Then the pharmacy could bill the state worker’s compensation program \$3,000 per tube for creams that cost about \$20 to make, according to a federal indictment filed in June.

Also last month, federal prosecutors in Florida unsealed an indictment against a doctor who allegedly was given kickbacks — including a \$72,000 BMW — for sending prescriptions to a particular pharmacy, which then billed Medicare, the military program Tricare and other government health programs for compounded creams. Prices ranged from about \$900 to \$21,000 for a one-month supply, according to court documents.

Medicare has not detailed the actions it might take. The HHS inspector general’s report does not make any recommendations, although investigators expect to issue a follow-up report that will.

Kaiser Health News is a national health policy news service that is part of the nonpartisan Henry J. Kaiser Family Foundation.

Attachment 9



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: August 31, 2016

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1747 North Market Blvd
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: 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

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, PharmD, Supervising Inspector
Christine Acosta, PharmD, Supervising Inspector
Laura Freedman, DCA Staff Counsel
Veronica Wogec, Staff Services Manager II
Rob Buckner, Criminal Conviction Unit Manager
Kelli Williams, Complaint Unit Manager
Debbie Damoth, Administration Unit Manager
Laura Hendricks, Administrative Analyst

I. Call to Order and Establishment of Quorum

Doctor Amy Gutierrez, chair of the committee, called the meeting to order at 10:17 a.m. by welcoming those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

Note: This meeting was not webcast.

II. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Dr. Gutierrez asked if there was any public comment on items not on the agenda or agenda items for a future meeting. Mr. Weisser commented on drugs, such as the Epipen, Naloxon and end-of-life drugs that have increased in price to the point where they are cost prohibitive for the average consumer. He inquired if the board should take a position on this issue. Dr. Gutierrez suggested that we agendize this issue for a future meeting.

III. ENFORCEMENT MATTERS

a. University of California, San Diego's Pilot Program to Permit Patients to Access Medications From an Automated Storage Device Not Immediately Adjacent to the Pharmacy -- Update and Discussion and Consideration of Modifications to the Pilot Program, if Necessary.

Dr. Gutierrez reported that at the board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated storage device for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first time fills.

Dr. Gutierrez explained that at the June 2016 Enforcement and Compounding meeting, Dr. Hirsch delivered a presentation via telephone on the progress of the implementation and reported that the program launched on January 20, 2016.

The kiosk has about 200 users, which is approximately 4 percent of the 4,800 Sharp employees. Additionally, the kiosk has 24-hour video surveillance and on-site monitoring.

Dr. Hirsch's statistics indicated there had been 534 total pickups at the kiosk and 334 of those pickups have been during normal business hours. Additionally, 191 were identified as new prescriptions, 99 were refill prescriptions, and 234 were for over-the-counter (OTC) medications.

Dr. Hirsch stated they need to average 140 prescription pickups per month to reach the study target of 820; however, at the current rate of only 80 pickups per month, the project will fall short of that goal based on the current length of the study. Dr. Hirsch requested an extension to continue collecting data through December 2016 and proposed reporting back to the board in March 2017.

After a discussion, the committee decided to recommend allowing more time for the collection of data and reporting of the study's findings. The committee recommended to the board to:

- 1) allow UCSD to collect data through the first quarter of 2017,
- 2) allow UCSD to report the findings of the study at the May 2017 Board Meeting, and

- 3) allow UCSD to continue operating the kiosk until a decision is made at the May 2017 board meeting

The board approved these modifications to the study at the July 2016 Board Meeting.

Discussion and Comment

Dr. Hirsch provided an update of the study via telephone and responded to questions from the committee. A copy of the presentation is provided at the back of these minutes.

Sara Lake, a representative from Asteres, clarified that as prescriptions are approved and loaded into the kiosk, patients receive a text to alert them that their medication is available for pick-up. New prescriptions are placed on hold until a telephone consultation has been completed. Consultations are available 24 hours per day, seven days a week. Upon request, consultations are available for refill prescriptions and OTC medications. If a pharmacist wishes to discuss a prescription with a patient, the pharmacist can place a hold on the medication.

One of the committee members expressed concern that a kiosk may not be inviting to walk up to for a consultation. Ms. Lake remarked that Dr. Hirsch completed a study in 2005/06 to research the quality of counseling for refill medications. The original regulation for California Code of Regulation section 1713 was written based on the study results and allows for refill prescriptions from an automated refill delivery device immediately adjacent to the pharmacy. In that study, there was no significant difference between counseling sessions done via phone or in person. She remarked that the issue is about access to prescriptions, and now they have 24 hour access to the prescription and can also speak with a pharmacist. She also remarked that they have found that employees that pick up prescriptions from the pharmacy often decline a consultation for refill prescriptions and that they don't necessarily want to talk face-to-face to a pharmacy employee when they are employed at the hospital where the pharmacy is located. Ms. Lake agreed to forward a copy of the study to President Gutierrez and Executive Officer Virginia Herold. Dr. Hirsch clarified that the current study is not designed to study after hours counseling. Ms. Herold inquired if the board would like more information on patient counseling and offered to obtain more data on patient counseling from UCSD.

Reports on this study will continue to be provided at each quarterly Enforcement and Compounding Committee meeting while the study is underway.

b. CURES 2.0 Prescription Monitoring Program and Use of CURES by Pharmacists – Update and Discussion and Consideration of Next Steps, if Necessary.

Dr. Gutierrez reported that as of July 1, 2016, California law requires that all pharmacists with active licenses apply with the California Department of Justice (DOJ) to access CURES. The board has made considerable efforts to ensure pharmacists with active licenses were advised of this requirement. These efforts included a postcard mailing to all pharmacists in February 2016 and a letter sent exclusively to pharmacists

who did not have their names listed in CURES at the end of May 2016. The letter triggered more than 2,000 inquiries to the board from pharmacists seeking to become registered or with questions on various issues. The board worked diligently with the DOJ over the following weeks to resolve every issue.

On August 25, 2016, the DOJ reported that there were 38,259 dispensers registered for CURES 2.0. This number excludes pharmacists who were approved under CURES 1.0 and have not yet logged in to CURES 2.0 to update their profiles and indicate their board and licensee type. Board staff believes that there are 2,280 active pharmacists who may not have registered to access CURES.

Discussion and Comment

Ms. Herold confirmed that five percent of registered pharmacists have not signed up for CURES. This fall, board staff will make another attempt to identify and reach out to pharmacists with active licenses who have not applied for access to CURES. A lot of retired pharmacists still hold active licenses. She commented that some of these pharmacists may not have computer access and/or computer knowledge and may find the registration process difficult. The board has created an alert system to notify new pharmacists that they must sign up for CURES. As board inspectors complete pharmacy inspections, they confirm that the pharmacists are registered for CURES.

Dr. Gutierrez commented that patient activity report data reflects that there are three to four times more prescribers than dispensers, yet the dispensers are running a significant number of the patient activity reports. Both pharmacists and doctors are actively using CURES. Ms. Herold clarified that “accessed” CURES means that they have logged into the CURES system, whereas patient activity report data reflects the actual use of CURES.

There has been considerable growth since January 2016 in the number of pharmacist registrants and especially in the number of patient profile reports requested by pharmacists and physicians each month.

Ms. Herold stated that about four million controlled substance prescriptions are issued each month. Because patient names are not entered into the CURES system in the same manner each time, the actual number of patients being dispensed controlled substances cannot be readily determined.

Dr. Gutierrez reported that, as approved by the board in the July Board Meeting, researchers at University California Davis will be surveying pharmacists who renew their licenses in November to learn about their use and opinion of CURES 2.0. Physicians will participate in a related survey at the same time. Both survey results will be shared with the board. Dr. Gutierrez reported that at some point we will discuss how we will link the CURES 2.0 reporting system with other states. Ms. Herold stated that all but three states are moving toward a single reporting system.

c. Discussion and Consideration of Consumer Enrollment in Automated Refill Programs for

Prescription Medications.

Dr. Gutierrez reported that traditionally pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs ("auto-refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications.

The argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

In 2012, the *Los Angeles Times* and other media outlets reported that some of these programs actually had adverse consequences for the public in that they contributed to medication errors, waste and fraudulent billing practices. There were allegations pharmacy staff enrolled patients in auto-refill programs without their knowledge or consent because pharmacists were working under work quotas that directed or rewarded patient enrollment in these programs. From late 2012 through 2013, the board received over 100 complaints directly related to auto refill programs due to the media attention. Many of the complaints were from patients who received prescriptions they did not request and who had difficulty returning the prescriptions for a refund. Other patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued by their prescriber. Some of these events resulted in patient harm.

In response to the large number of complaints, Executive Officer Herold and other staff worked with the various agencies to address these concerns and explore possible violations of pharmacy laws and regulations.

In 2013, the Federal Centers for Medicare & Medicaid Services (CMS) proposed new regulations which resulted in additional rules for auto-refill programs for Medicare patients receiving prescriptions from mail order pharmacies.

Since 2013, the number of auto-refill complaints received by the board has decreased; however, the board continues to receive complaints related to these programs.

At this meeting the committee discussed developing requirements for pharmacies to retain signed documentation that patients have "opted in" to a pharmacy's auto-refill program. Most pharmacies contend patients are asked whether or not they wish to enroll in the auto-refill program prior to enrollment. Enrollment is then documented in the computer; however, there is no written documentation or signed consent from the patient. Instead, enrollment in these programs is based on verbal consent. The board continues to receive complaints which allege patients are enrolled into auto-refill programs without consent. President Gutierrez reported that this committee may also

wish to consider how often signed consent should be obtained (e.g., annually) and whether signed consent should be obtained separately for each prescription placed on auto-refill.

With regard to pharmacies in the community practice setting, Dr. Gutierrez said the committee may wish to consider additional requirements for pharmacies to notify patients upon pick up, both verbally and in writing (on the receipt), if the prescription was refilled automatically. Many consumers, especially the elderly, assume that if the pharmacy refilled a prescription, then the prescriber must have authorized it and wanted them to continue taking the medication. This is not always the case and can cause confusion for consumers. Notifying the patient that the prescription was refilled because it was on auto-refill might help to eliminate some of the confusion, or at least open a dialogue with the pharmacist to prevent potential harm to the patient from unwanted refills. Dr. Gutierrez also reported that the committee may also wish to consider whether the above requirement for notification should be documented in writing by the pharmacy.

With respect to both community pharmacies and mail order pharmacies, she reported that the committee may wish to consider requirements for written policies and procedures related to auto-refill. The policies and procedures might include procedures to ensure discontinued medications are removed from the auto-refill program and drug therapy reviews are conducted by the pharmacist to prevent duplicate therapies.

Discussion and comments

Supervising Inspector, Doctor Anne Hunt reported that complaints have decreased, yet continue. Many patients indicate they have not provided consent to be enrolled in the auto-refill program. They receive medication that they did not know they were going to receive and are sometimes ingesting medication that has been discontinued by their prescriber. Additionally, when they try to return the medication, there is pressure for them to keep it. When patients receive medications that they do not want, it increases the disposal of medication and waste.

Dr. Hunt stated that one of the main complaints is about constant robo calls to pick up medication that the patient did not want or request. She stated that there is no signed document to indicate if a person has asked to be placed on auto-refill for a particular medication; it's difficult to validate these complaints.

Ms. Herold reported that another frequent complaint is that someone other than the patient may pick up the medication for the patient. Later, they realize that they don't need the medication; however, they cannot return it to the pharmacy for a refund. Some patients found that their insurance was billed for medication that they did not authorize or pick up. This problem is compounded when the patient has multiple doctors and multiple prescriptions. Dr. Hunt stated that there does not appear to be a mechanism to address changes in drug therapy: a previous prescription may be discontinued, the strength may be changed, or the patient may be prescribed two

different drugs in the same class because one drug was not working and they switched to another.

She reported that it's difficult to adjudicate these complaints because there is no documentation to review. Dr. Gutierrez remarked that it's difficult to validate the patient's allegation because there is no requirement to document auto-refill authorization.

A committee member commented that auto-refills have resulted in an economic boom for some of the chains and that the CMS has documented this problem. It's a terrible economic impact to the consumer, who is often elderly. If the patient knows about the auto-refill and opts in, it may be good.

Committee Member Greg Lippe likes the auto-refill program and finds it convenient. Committee Member Stan Weisser stated that he would like people to opt in and require auto-refill authorizations to have expiration dates so that patients have the opportunity to reevaluate their decision.

Dr. Gutierrez asked that board staff put together a presentation for the next board meeting to discuss options with respect to authorization of auto-refill medication and pharmacy documentation. She also requested that mail order pharmacies be addressed.

Committee Recommendation:

Motion: Board staff will develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

M/S: Weisser/Lippe

Support: 6 Oppose: 0 Abstain: 0

Public Comments

Consumer Christine Bristol stated that after she purchased a new cell phone, she began receiving robo calls intended for the person who previously had her cell phone number. It took two to three calls to the pharmacy before she was able to stop the calls. This was a HIPAA violation as the messages had the patient's name and phone number. Executive Officer Herold encouraged Ms. Bristol to contact the board if this happens again.

Brian Warren from the California Pharmacists Association stated that while misfired robo calls are not ideal, pharmacies are trying to encourage patients to continue taking maintenance medication and that the auto-refill program has helped this. He remarked that auto-refill authorizations may be signed at different times of the year for multiple prescriptions. The pharmacy management system will have to track this as consumers may have multiple prescriptions that need auto-refill approval.

Board Member Stan Weisser said that he is sensitive to over regulating pharmacies. Dr. Gutierrez and Ms. Herold both suggested that the pharmacy keep a signed form in the pharmacy and that the auto-refill status be noted on the receipt to remind patients that they have signed up for auto-refill.

Steve Gray from Kaiser Permanente reported that several states have reviewed this issue and that Oregon had to put regulations on hold due to the adverse impact to patients. He suggested studying regulations from other states, such as Texas. He commented on the CMS possession ratio concept where pharmacies and health plans are penalized if they cannot prove that their patients have received medication.

Dr. Gray also commented that it's often the elderly that forget to refill their medication and also forget that they signed up for auto-refills. He asked that the communication committee review this and stated that the problems are a small percentage compared to the benefits. He also suggested that we consider something other than a wet signature to indicate authorization for the auto-refill program. Dr. Gutierrez commented that the main concern is to make sure that the patients are aware that their medications are on auto-refill

Robert Stein from KGI School of stated that the standard practice in most retail pharmacies is that the computer considers the prescription expired after one year. The prescription number is regenerated when the new prescription is renewed.

d. Discussion and Consideration of Statistics for Board-Issued Citations and Fines.

The board had asked staff to provide information about board-issued citations and fines. During this meeting, Board Chief of Enforcement Julie Ansel provided information regarding citations and fines issued by the board. A copy of the presentation is provided behind these minutes.

She noted that pharmacies, pharmacists, and technicians account for 90 percent of all fines. The remaining 10 percent of fines are spread across wholesalers, clinics, and hospitals.

Ms. Herold stated that a citation and fine or letter of admonishment is not considered formal discipline; it is more equivalent to a speeding ticket. The goal in issuing them is to get the licensee to determine what led to the violation and change their practices so that the violations do not reoccur.

Assistant Executive Officer, Anne Sodergren stated that approximately one third of the investigations opened by the board are as a result of a consumer complaint. The next biggest number of complaint investigation is internally generated and often result from notifications to the Criminal Conviction Unit related to a licensee arrest.

Board member Ricardo Sanchez left at 11:34

A lunch break was taken from 12:08 – 12:43

IV. COMPOUNDING MATTERS

a. Discussion and Consideration of Statistics on Compounding Violations Identified by the Board (2014 – 2016).

Board Supervising Inspector Christine Acosta provided the committee with an overview of compounding violations identified by the board over the last several years. A copy of this presentation is provided at the back of the minutes.

Dr. Acosta stated one of the main violations that inspectors find is that licensees are not completing the compounding self-assessment form, which allows the pharmacy to do their own gap analysis. These are not usually repeat violations; it is often a new pharmacy or a new PIC that commits this violation.

Another frequent violation is not having a master formula. The inspectors are educating licensees about the proposed new compounding regulations.

Many licensees are not compliant with regulations with respect to compounding room requirements. Supervising Inspector Acosta provided examples, such as particle board in the clean room, not cleaning behind the hood, cardboard boxes next to the laminar flow hood, and laminar flow hoods that have non-porous material beneath

Dr. Gutierrez suggested that future meetings include detailed information on common violations so that the licensees can better understand trends and take preventative measures to comply with regulations. Dr. Acosta remarked that there are several *The Script* articles in the works that will promote education and transparency. She also stated that the board is receiving more voluntary license surrenders of state compounding licenses when licensees see that the board has a strong case against them they tend to not renew their license rather than go through the license revocation process. Dr. Acosta confirmed that an inspection is required each time a permit is issued or renewed. Every two years the board is attempting to complete a full hospital inspection, which is a two to three day inspection. Ms. Herold confirmed that our goal is to inspect all pharmacies every four years. Ms. Herold remarked that sometimes sterile compounding is harder to accomplish for smaller hospitals because they do not have the resources that larger hospitals have.

b. Pending Compounding Regulations, Title 16 California Code of Regulations, 1735 et seq., and 1751 et seq.; Status Update and Discussion and Consideration of Next Steps, if Necessary.

Dr. Gutierrez reported that on May 8, 2015, the board initiated a formal rulemaking to update California's compounding regulations. The rulemaking is currently at the Office

of Administrative Law undergoing final review. The board set the effective date of the regulation as January 1, 2017. The board expects to have feedback on the outcome from Office of Administrative Law on or before September 13, 2016.

Discussion and Comment

Brian Warren with the California Pharmacists Association asked that additional time be granted to allow pharmacists to implement these substantial changes. He suggested that an extension be given to allow pharmacies a reasonable amount of time to complete a waiver and make changes to their facility. He also stated that some of the board's proposed regulations conflict with local building ordinances and gave an example of a local fire ordinance. Supervising Inspector Acosta replied that he may be referring to a pharmacy where they were asked to clean behind the hood, yet there were earthquake brackets holding the hood in place. Dr. Acosta remarked that she has also heard that there are some cities that will not allow for external ventilation. Mr. Warren agreed to provide us with the ordinance information for review.

Steve Gray and Lori Hensic from Kaiser suggested that the board consider moving back the date for enforcement of the January 2017 regulation so that they can revise their policies, procedures, workflow, and training to incorporate changes in the regulations. Dr. Acosta stated that over the last year, the Licensed Sterile Compounding inspectors have been educating licensees about the proposed compounding regulations so that there will be a smooth implementation. Ms. Herold stated that the board usually uses a degree of educational compliance when implementing a requirement; however, this regulation has a serious impact on public health and safety, any delay is potentially putting at risk the population of the state's patients that get medication from that pharmacy. Dr. Gutierrez remarked that we have been talking about the guidelines for over a year now. Dr. Acosta remarked that for the last year, pharmacies have been receiving a free gap analysis as inspectors provide information on the pending regulation during pharmacy inspections.

Dr. Jenny Partridge, an ACHC survey inspector for the Texas Board of Pharmacy provided some examples of local ordinances that may conflict with the board's pending regulations:

1. Santa Clara Fire Department requires that the hood and tables be bolted and that fire sprinklers be caulked. This means that facilities will not have smooth, impervious walls and they cannot clean behind the hood.
2. In some cases, the Environmental Protection Agency will not let a pharmacy vent their non-sterile hazardous room outside because of the size of the room.
3. The city of Beverly Hills does not want venting to put any "bad stuff" in their air.

She thinks that it will be difficult to implement the viable air testing that must now occur quarterly for non-sterile compounding, which requires that the pharmacy hire an outside firm or purchase their own viable air impaction device at a cost of roughly

\$10,000.00 to do their own testing; however, they may not be properly trained in how to use this complex equipment.

The USP 800 guidelines require 30 air changes per hour and non-sterile compounding requires 12 changes per hour; however, the California regulations require 30 changes per hour for both sterile and non-sterile compounding. Essentially, California is requiring a sterile room to conduct non-sterile hazardous compounding. She encourages a delay in the implementation of the regulations.

Dr. Acosta acknowledged that we will have many pharmacies that will not be compliant with the new regulations on 1/1/2017; she stated that the building codes that conflict with the regulation will be a work in progress. Ms. Herold stated that the Office of Statewide Health Planning and Development (OSHPD) agreed to work with us to resolve conflicts. Dr. Acosta stated that the working draft regulations were released in November of 2015. Licensees have had the opportunity to start training and working toward meeting USP 800 and that the USP 797 is a minimum practice standard and is currently in our regulations-- we are not at the national minimum practice standard for sterile compounding. Even without the hazardous regulations, we not even at the minimum practice standard. Regardless of how much training is done, there will always be a need for more training; however, we have to raise the bar in California before a catastrophic event occurs. Dr. Gutierrez remarked that she does not see anything from a non-building standpoint that should be that difficult to implement. Ms. Herold stated that the board has collectively worked over a period of years to develop these regulations, and at some point, we need to move forward. If we delay them, we are risking public health and safety and national support of pharmacies even compounding.

Dr. Moussie Hailemariam asked that the committee to clarify the definition of what hazardous is and provided an example of working with pure hormones.

B.J. Bartlson from California Hospital Association (CHA) stated that the board has done an outstanding job of working with hospitals on the sterile compounding regulations over the last three years. CHA has spent the last year doing education consisting of training, gap analysis, pharmacy matrixes, webinars, and are working closely with OSHPD. She sent over 400 member hospitals a packet of informational items.

Staff Counsel Laura Freedman commented that there is a distinction between the association and the board and agreed that she would review the materials. Dr. Gutierrez recommended that we include these tools on our website with a notation that they are CHA tools.

c. Discussion and Consideration of the Proposed Process for Pharmacies Seeking Waivers From Structural Requirements in Title 16 California Code of Regulations, 1735 et seq.,

and 1751 et seq.

Dr. Gutierrez reported that the final version of the proposed compounding regulations contain a waiver provision for some of the structural requirements to provide the pharmacy time to secure the construction modifications needed. As proposed in the regulation as subdivision 1735.6(f) and in 1751.4(l)), the waiver request shall:

1. be made in writing;
2. identify the provision(s) requiring physical construction, alteration, or improvement; *and*
3. contain a timeline for any such change.

Since the last meeting, staff has met with the OSHPD in an attempt to tap into their review and approval process as one route for the board's waiver process. Using the OSHPD review process would not be a feasible option for community compounding pharmacies which, in many instances, do not require OSHPD review. In such cases these pharmacies would be requested to provide similar information directly to the board. Executive Officer Herold provided a presentation on a proposed waiver process. A copy of this presentation is included immediately after the meeting minutes.

A PowerPoint titled *Making a Request for a Construction Waiver* clarified that waivers are for a delay in implementation so that construction can occur: not an exemption from compliance.

Public Comment

Brian Warren from the California Pharmacists Association expressed the need for consistency in the way the board reviews and approves waivers.

Paige Tally from the California Council with the Advancement of Pharmacy posed a question about a pharmacy that has leased a building where the landlord will not allow venting to the outside of the pharmacy. Staff Council Laura Freedman commented that this IS the right place to raise the issue; however, we cannot provide an answer today.

Terence Webb from Advantage Health inquired about multiple waivers for one organization. Ms. Herold advised that each waiver is specific to the building and a separate waiver will generally be required for each licensed sterile compounding facility.

Marie Cottman spoke on behalf of her independent licensed sterile compounding facility. She recommends that the board have a team of reviewers for consistency and that the team provide feedback to the inspectors so that they know what to expect for each particular license.

Steve Gray representing Kaiser wanted to know what the process will be while waivers are under review and while the project is going forward. Ms. Herold clarified that the intent of the wavier process is to determine how or if the pharmacy will perform compounding while the construction is in effect.

Marie Cottmon installed a HVAC system for 12 changes per hour in an anticipated 800 room; however, if she has to comply with 30 changes per hour, she will have to upgrade her HVAC system at a cost of \$15,000. Ms. Herold responded that the regulation is in now in final form and that she may have to comply with 30 changes per hour. At this point, the board has made a decision to keep the 30 changes per hour. Supervising Inspector Acosta commented that these issues did not come to light during the public comment period, so we moved forward with 1735.6.(e)(1).

Staff Council Laura Freedman stated that after the Office of Administrative Law approves the regulations on September 22, 2016, the board can consider initiating a new rule making. Ms. Freedman clarified that the regulation states 12 air changes per hour is acceptable for non-sterile compounding, so there may not be a problem.

Brian Warren commented that while the 12 changes per hour for non-sterile compounding are helpful, it still requires external venting. President Gutierrez commented that venting could be updated in a future rule making.

d. Compounding Self-Assessment of the Draft Compounding Self-Assessment Form to Implement the Pending Compounding Regulations.

Supervising Inspector Acosta developed a Compounding Self-Assessment form which is displayed in **Attachment 7**.

Discussion and Comment

- Dr. Gutierrez suggested that we remove the Drug Enforcement Agency (DEA) number from the Self-Assessment.
- On page 8, section 6.6; she requested that we specify that the waiver in question is from the board and asked that the waiver be attached.
- Quantitative analysis will be addressed in the FAQs.

Ms. Herold reported that our intent is to bring the self-assessment before the board in October 2016.

Public Comment

Marie Cottman recommends removal of item 2.3 from the Self-Assessment and states that this is in direct conflict with the FDA. Ms. Herold commented that there is another guidance document that acknowledges that anticipatory compounding may be done in limited quantities for up to 30 days.

e. Discussion and Consideration of Frequently Asked Questions about Sterile Compounding

Dr. Acosta developed a *draft* of frequently asked questions regarding compounding, which is provided in **Attachment 8**.

Discussion and Comment

- Question 13: The word “really” will be removed from question 13.
- Question 14: It was clarified that the PIC is responsible for making sure that each person is trained.
- Question 22: It was clarified that a hospital license designates the address of the pharmacy. There may be a main pharmacy, a lower level area where the dangerous drugs are kept, and then satellite pharmacies throughout that licensed hospital. These regulations apply when a licensed pharmacist is practicing compounding in a licensed hospital.
- Question 32: a FAQ will be added to clarify the definition of a licensed pharmacy.
- Question 35: will be modified to include the waiver process.
- Questions 41 and 43: Supervising Inspector Acosta clarified that the PIC is going to need to do some type of analysis to determine what is hazardous. This gap analysis depends on the practice setting.
- Question 42: it was clarified that the daily activities (cleaning, pressurization, temperature monitoring) in the sterile area must occur each day that the pharmacy is open, even if sterile compounding is not taking place.
- Question 46: remove the “e.g.”

Public Comments

Brian Warren from Californian Pharmacists Association reports that pharmacists have expressed concern that they were informed by board inspectors that all hormones are considered hazardous. Supervising Inspector Acosta remarked that she would not consider all hormones hazardous; however, all hormones should be reviewed because they can be hazardous depending on what the pharmacist is doing with them and how they are being handled. She stated that the board’s mission is to protect the public, USP section 800 protects the employee.

Mr. Warren recommended that the air changes per hour be revised based on the discussion that took place earlier in the meeting.

Paige Tally from the California Counsel for the Advancement of Pharmacy commented that question 43 is subjective. Ms. Acosta commented that if everything on the NIOSH list is eliminated, we essentially eliminate a lot of compounders. Also, section 800 is to protect the compounder. We are tasked with protecting the public, not the compounder. These decisions should be based on professional judgment.

Jenny Partridge commented that PCAB requires all compounding (sterile, non-sterile, hazardous, non-hazardous) to have a BSC powder containment hood for operator safety and that external venting is only required for hazardous compounding. Dr. Acosta reported that the definition of biological safety cabinet in 1735.1(c) says that when hazardous drugs are prepared, the hazardous air must vent to the outside.

f. Discussion and Consideration of Frequently Asked Questions about Venting in Compounding Pharmacies.

Dr. Gutierrez remarked that in the frequently asked questions, 37, 52, and 53 address venting issues in compounding pharmacies. The board has been asked questions several times regarding this subject.

g. Federal Food and Drug Administration's Draft Guidance Documents – Discussion and Consideration, including Whether to Submit Board Comments

Dr. Gutierrez reported that in recent months, the FDA has released multiple guidance documents regarding compounding and outsourcing duties and regulations. During this meeting, the committee will have the opportunity to discuss several of the guidance documents which contain proposed elements for FDA regulation.

The guidance documents are instructional in that they reflect enforcement priorities the FDA pursues during inspections. The board has an opportunity to provide written comments on a guidance document. Staff suggests that the first two documents be considered for possible comments. The document itself can be found in **Attachment 9**.

1. Insanitary Conditions at Compounding Facilities: Released 8/3/16

The FDA considers a drug to be adulterated “if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.” Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death. This includes both drugs produced under facilities licensed under section 503A or section 503B.

Drugs prepared, packed, or held under insanitary conditions are deemed to be adulterated. The FDA’s guidance on sterility specifically addresses pharmacies; federal facilities; physician offices (including veterinarian offices); and outsourcing facilities that compound or repackage human or animal drugs (including radiopharmaceuticals); or that mix, dilute, or repackage biological products.

FDA states that since 2012, it has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounding facilities have voluntarily recalled drug products intended to be sterile and temporarily or permanently ceased sterile operations as a result of those findings. However, FDA states that it does not inspect the vast majority of compounding facilities in the United States because they generally do not register with FDA unless they elect to become outsourcing facilities.

Public Comments

Sarah Wallick is a pharmacist specializing in 503B outsourcing facilities. She commented that it's important that the board's feedback differentiate what insanitary conditions are. She stated that the guidelines don't differentiate between having a rat in the clean room versus having one time lapse in environmental monitoring, both of which are at very different ends of the spectrum.

2. Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act -- Draft released 7/7/16

Dr. Gutierrez reported that this guidance pertains to compounding by an outsourcing facility. According to the FDA, a compounded drug product made by an outsourcing facility must not be "essentially a copy of one or more approved drug products," as well as meeting other criteria.

The guidance states that outsourcing facilities must compound under current good manufacturing conditions. Drug products compounded by outsourcing facilities are exempt from FDA drug-approval requirements and the requirement to be labeled with adequate directions for use. Because of these and other criteria governing outsourcing facilities, the FDA states that compounded drug products by outsourcing facilities should only be distributed to health care facilities or dispensed to patients to fulfill the needs of patients whose medical needs cannot be met by an FDA-approved drug, unless drug is on a shortage list.

Outsourcing facilities cannot generally compound drugs that are essentially copies of approved drugs. Outsourcing facilities may not compound unapproved over-the-counter drug products under exemptions in 503B. The guidance focuses on describing how the FDA will apply these principles to drug products compounded by outsourcing facilities.

1. A compounded drug by an outsourcer is essentially a copy of an approved drug if the compounded drug is identical or nearly identical to an approved drug UNLESS
2. The approved drug appears on the drug shortage list at the time of compounding, distribution and dispensing.

FDA intends to consider a compounded drug product to be identical or nearly identical to an approved drug if they both have the same:

1. active ingredients

2. route of administration
3. dosage form
4. dosage strength and
5. excipients

Discussion and Comment

The board agreed to consider comments. There was no public comment.

3. Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

A bulk drug substance is defined in part as a substance that “becomes an active ingredient or a finished dosage form of the drug, but does not include intermediates used in the synthesis of such substances.” The FDA is in the process of developing a “bulks list” for use in compounding and is currently evaluating the nominated items. **Attachment 11** contains information about this guidance.

Public Comment

Steve Gray representing Kaiser stated that there is a heavy requirement to document the specific need. He does not feel that this is realistic. This may deny some patients a drug because the pharmacist does not want to substantiate it.

Pharmacist Ranel Larsen commented that the guidance document addresses drugs, but not dietary supplement monographs.

4. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Dr. Gutierrez reported that this guidance updates the FDA’s policies with respect to a pharmacy’s compounding of human drug products. **Attachment 12** contains the guidance document.

A compounded drug product is exempt from sections 501(a)(2)(B), 502(f)(1) and 505 of the FD&C Act if it meets the conditions of section 503A. Specifically, the compounded drug product qualifies for the exemptions if:

1. The drug product is compounded for an identified individual patient based on the receipt of a valid prescription, or a notation, approved by a physician or other practitioner authorized to prescribe.
2. The compounding of the drug product is performed:
 - By a pharmacist in a pharmacy or federal facility or a physician,
 - By a pharmacist or physician in limited quantities before the receipt of a valid prescription order for an individual, provided:
 - The product produced is based on a history of pharmacist or

- physician received valid prescription orders for the compounding of the human drug product, and
- Those orders have been generated solely within an established relationship between the pharmacist or physician either for a patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order.
 - The drug product is compounded in compliance with USP standards regarding pharmacy compounding with bulk drug substances that comply with USP or NF monograph standards.
 - Anticipatory compounding is not done in inordinate amounts
 - The drug product is compounded in a state with a signed MOU with the FDA or ships no more than 5 percent in states without a MOU for interstate shipments

The FDA also will establish sanctions for those who violate the FDA's compounding requirements, including for violations involving producing adulterated drugs, unapproved new drug products, misbranded drugs

Discussion and Comment

The board agreed to consider comments. There were no public comments.

h. Articles in the News, Including Discussion and Consideration of "Fraud Concerns Grow as Spending on Handmade 'Compounded' Drugs Soar."

Dr. Gutierrez reported that this article, which was published in the July 17, 2016, edition of *The Washington Post*, reports that government spending on compounded drugs under Medicare's Part D rose 56 percent over the last year, with topical creams and gels among the costliest products. Over a four-year period, the federal workers' compensation program reports an increase from \$2.35 million to \$214 million.

A copy of this article is provided in **Attachment 13**.

There were no board or public comments.

The meeting adjourned at 3:45 p.m.

Making Request for a Construction Waiver to Comply with CA's Compounding Regs

Draft Procedures

August 31, 2016

16 CA Code of Regulations

As proposed in the regulation (as subdivision 1735.6(f) and in 1751.4(l)), the waiver request shall:

1. be made in writing;
2. identify the provision(s) requiring physical construction, alteration, or improvement; *and*
3. contain a timeline for any such change.

Additional Requirements

- The board or its designee may grant the waiver for construction when, in its discretion, good cause is demonstrated for the waiver.
- The waiver provision is not an exemption from compliance with the compounding structural requirements, but a delay in required compliance.

Status of the Compounding

Regulation Provisions

Once the compounding regulations have been approved (the expected decision date is about September 13), the board will begin accepting waiver requests. Information will be added to the website announcing the option and how to submit a waiver request.

However, if the regulation is not approved by the Office of Administrative Law and returned to the board for correction and future resubmittal, waiver requests will not be accepted until the regulation is approved.

Regulation Status

However, if the regulation is not approved by the Office of Administrative Law and returned to the board for correction and future resubmittal, waiver requests will not be accepted until the regulation is approved.

Process

The board expects to see in the

pharmacy's or facility's written request for a waiver to permit construction the following items:

1. The name of the pharmacy, name of the individual submitting the request, title and contact information (address, email and phone number),
2. The reason for submitting the request, including the specific sections of California's compounding requirements requiring physical construction, alteration or improvement that are the reason for the waiver request,

Process

3. A description of the status of the construction process in the pharmacy:

- Is there an architect, if so who?
- Is this a structural modification, describe
- Have building plans been developed?
- Has a building permit been secured?
- Time frame for completion of construction.

Remaining Components

4. If review by OSHPD is required, provide a copy of “Project Completion Timeline” and the “General OSHPD Project Number.”

5. A written description of how the pharmacy will perform compounding while the construction waiver is in effect.