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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 Officier
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 Manger
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. D r . 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 insterility 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.