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: September 9, 2015

LOCATION: DCA Headquarters, First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Amy Gutierrez, PharmD, Chair, Professional Member
Greg Lippe, Public Member, Vice Chair
Stan Weisser, Professional Member
Allan Schaad, Professional Member
Rosalyn Hackworth, Public Member

COMMITTEE MEMBERS NOT PRESENT:
Greg Murphy, Public Member

STAFF 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
Susan Cappello, Enforcement Manager

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:01 a.m.

Dr. Gutierrez welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

I. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comments were received.

II. ENFORCEMENT MATTERS

a. Update on the CURES 2.0 Prescription Monitoring Program

Background

The California Department of Justice (DOJ) is continuing to work on upgrading the CURES system. On June 30, the DOJ had a "soft launch" of CURES 2.0 as the new system is called. Since then the DOJ has been working to pilot test the new system and install upgrades that will permit conversion to the new, enhanced system.

Below is the update prepared in late June on the soft launch from the DOJ's press release:

CURES 2.0 Soft Launch and Phased Rollout

Update from July 1, 2015:

The Department of Justice (DOJ) and the Department of Consumer Affairs (DCA) are pleased to announce that the state's new Controlled Substance Utilization Review and Evaluation System – commonly referred to as "**CURES 2.0**" – went live on July 1, 2015. This upgraded prescription drug monitoring program features a variety of performance improvements and added functionality.
In order to ensure a smooth transition from the current system, CURES 2.0 will be rolled out to users in phases over the next several months, beginning with early adoption by a select group of users who currently use CURES and meet the CURES 2.0 security standards, including minimum browser specifications. DOJ is currently identifying prescribers and dispensers who meet these criteria and will contact and coordinate their enrollment into CURES 2.0. For all other current users, access to CURES 1.0 will not change and no action is needed at this time. For users and entities not currently enrolled in CURES, further notification will be provided in August as to the enrollment/registration process.

Practitioners and health systems should begin to prepare for universal adoption of the system by January 2016, at which point all users will be required to meet CURES 2.0's security standards. If you have any questions please contact cures@doj.ca.gov.

Thank you for your continued support of the CURES program.
Note: CURES 2.0 users will be required to use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system.

Discussion and Comment

At this meeting, Robert Sumner and Mike Small of the DOJ provided an update on the transition to the new CURES 2.0 system. They advised the committee that CURES 2.0 should be available to all users by January 2016 and explained some of the barriers in transitioning to CURES 2.0. Mr. Sumner explained that there are 18,487 pharmacists registered with CURES, which is less than 50% of all licensed California pharmacists.

Steven Gray representing Kaiser requested that the DOJ attend the California Society Hospital Pharmacists (CSHP) seminar to conduct CURES enrollment. Mr. Gray was asked to submit details of the meeting for consideration. Ms. Herold offered to help with CURES enrollment at this meeting.

There were no additional comments from the committee or public.

b. Update by the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medication from an Automated Storage Device not Immediately Adjacent to a Pharmacy

Background

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy involving use of an automated storage device for prescription medication for which staff and their families of a Sharp Hospital in San Diego, who opt in, may pick up their outpatient medications from this device located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication can be dispensed to a patient.

This study was planned to start in June or July, 2015. However, in scheduling items for this committee meeting, we learned that the project is running a bit behind.

Discussion and Comment

At this meeting, via telephone, Dr. Hirsch delivered a presentation on the implementation of this program, which she anticipates will start in December 2015.

There were no comments from the public or committee.

A copy of this presentation can be found at the end of this document.

c. Discussion Regarding the Board's Proposed Regulations for the Take Back of Prescription Medication

Background

Since the July board meeting, work has continued to refine the board's proposed requirements for drug take back programs.

Meanwhile, additional counties have established requirements to permit or require take back of unwanted pharmaceuticals from the public. This often involves pharmacies.

On September 26, the Drug Enforcement Administration (DEA) will conduct another national Drug Take Back day. The board has released a subscriber alert and posted information about this collection day on the board's web site.

Board staff agreed to incorporate comments from this meeting into a draft and bring it to the October Board Meeting.

Board staff respectfully suggested a motion from this meeting for a recommendation that staff complete work on the proposed regulation, including incorporating comments made at this meeting, and bring the draft to the board meeting with a recommendation for the board to initiate a rulemaking by releasing the requirements for the 45-days of public comment.

Discussion and Comment

Ms. Freedman, board counsel, suggested that the committee focus on policy of the regulation and allow the board to tweak the language.

Heidi Sanborn, representing the California Product Stewardship Council, thanked the committee and reminded everyone that this regulation does not provide any funding mechanism for any of this to happen so thee problem will still not be solved. She expressed concern about the requiring a sharps collection bin in addition to drug bin as currently required in the draft regulations because there is no funding and this added expense would ensure there would be no program. She suggested the requirement to provide sharps collection be removed to allow flexibility to pharmacies who want to voluntarily host drug bins and/or local governments attempting to set up medicine collection programs

The San Mateo Department of Public Health expressed concerns with the sharps requirement and stated that this requirement may hinder pharmacies participation.

Mr. Weisser inquired into the cost of sharps disposal.

Jen Jackson from San Francisco County voiced concern about the cost of sharps disposal. While she agreed sharps collection, she said that requiring sharps collection alongside meds collection would unnecessarily burden passage of local producer responsibility legislation. She also asked for clarification as to how existing pharmacies that do not take back controlled drugs would register.

The proposed regulations require pharmacies to register with the DEA. Ms. Jackson offered to provide the committee with information about the Health and Safety Code that allows for the co-mingling of sharps and drugs.

Mr. Weisser asked that a future agenda item include the manufacturer responsibility of drug take back.

A representative of the City of Santa Rosa agreed with comments made by previous speakers and requested clarification on several items including why inhalers are excluded. He requested that the committee remain cognizant of the impact the regulations may have on existing programs. Ms. Herold responded that pharmacies are DEA registrants and must comply with the DEA requirements irrespective of what the board does. The representative

of Santa Rosa requested that the committee consider maximum flexibility and questioned about how the use of a common or contract carrier can ensure the chain of custody. He also asked if the language can reference "liners" instead of "bags".

It was noted that the committee should consider is if there is value in the board creating a standardized sign for all drug take back.

Dr. Gutierrez discussed the need to educate pharmacies about the DEA requirements to register as a collector.

Brian Ward of CSHP thanked the committee for moving forward with these regulations. He informed the committee that the Environmental Protection Agency (EPA) just released information about their requirements for drug take back. He encouraged the committee to ensure that the board's regulations are consistent with EPA requirements.

Dr. Gutierrez sought clarification from counsel on whether the board's regulation indicated that drug take back is not required in our regulation but is required by a local ordinance, which one supersedes the other. Counsel indicated she would research the issue.

Dr. Gutierrez recessed for a break at 11:17 a.m.

The meeting reconvened at 11:27 a.m.

Dr. Gray representing Kaiser made several suggestions:

- He stated that the term "tampering" is ambiguous and suggested that the committee provide a definition of this term.
- He suggested that the regulation require that the liner material be made of antineoplastic material.
- He suggested that the board clarify the definition of controlled substances to include the state and federal schedules.
- He asked for the purpose of the signage requirement and whether this posting provides safe harbor if a consumer places a prohibited item in the bin.
- He requested that the board pursue legislation to create the safe harbor.
- He asked for clarification on the placement of the bin and stated that it is ambiguous.
- He suggested that the board clarify the documentation requirement when the mail back option is provided to the consumer.

<u>Committee Policy Discussion</u>
Question: Should we assume that all medications being brought in are controlled substance?
Answer: Yes.

Question: Do we want to differentiate between sharps vs. other mail bins?
Answer: The committee recommended removing the sharps requirement.

The committee stated that pharmacies shall not be required to participate in drug take back programs and that pharmacies on probation is prohibited from participating in this program.

The committee stated that pharmacies participating in drug take back programs should not be prohibited from receiving reimbursement.

It was noted that the committee should focus on where the bins can be located and find other ways to prevent a consumer from dropping off medications when a pharmacy is closed. It was also noted that bins should be lockable when the pharmacy is closed.

The committee questioned whether there should be common signage and agreed that the board should develop a sign for posting.

Public Comment on Committee Policy

Heidi Sanborn expressed concern that some collection capacity could be lost if the board requires all pharmacies providing medicine take back to collect controlled substance medicines because some pharmacies do not want to handle controlled substances.

Brian Warren sought clarification as to whether counsel will be researching drug take back, sharps take back or vs. both. Counsel advised that the current draft calls for both.

The Marin County Pharmacist Association recommended that the committee keep the focus on getting drugs out of the home to prevent drug abuse and overdose.

The City of Santa Rosa concurred with comments by Heidi Sanborn and expressed concern about the cost.

Tim James from the California Grocers Association is trying to determine how all of the different pieces will work together, including the technical aspects of the regulations. They are concerned that this program could compromise food safety. His association will provide written comments in the next few days.

Committee Recommendation:

Motion: Recommend that staff complete work on the proposed regulation, including the policy comments, and bring the proposed regulation to the board for possible initiation of a rulemaking.

M/S: Weisser/Lippe
Support: 5 Oppose: 0 Abstain: 0

There were no additional comments or questions.

Dr. Gutierrez recessed for a 30-minute lunch break at 12:24 p.m.
The meeting reconvened at 1:02 p.m.

d. Discussion on Enforcement Options for Patient Consultation Violations

Background:
Nearly 25 years ago, the Board of Pharmacy promulgated regulations to require pharmacists to consult with patients when receiving a medication for the first time. The board included in the regulation additional occasions where a pharmacist must consult a patient, such as when the patient has questions or the pharmacist believes the medication warrants consultation.

California's requirements are sometimes confused with national requirements enacted about the same time by CMS for Medicare patients in what was known as "OBRA 90." However, California's requirements were actually adopted before OBRA 90's requirements. The OBRA 90 requirements require that Medicare patients be offered consultation when they receive medication for the first time. California's requirement that the pharmacist initiate consultation is stronger and broader than the OBRA 90 requirement in that it pertains to all patients, not just those whose medications were paid for by Medicare. This established one standard of care for all patients in California.

After approval of California's patient consultation requirements, the board also delayed implementation of patient consultation at the request of the profession because pharmacists stated they could not provide consultation without the aid of pharmacy technicians. So the approved patient-consultation regulation was delayed so that the board could secure statutory authority and then promulgate regulations to establish the licensure of pharmacy technicians to "free" the pharmacist to provide consultation.

California's requirement is that the pharmacist consult the patient – not to offer to consult. When creating the consultation rulemaking, the board emphasized that consultation was to be initiated by the pharmacist and that denial of the consultation must be made directly to the pharmacist. Other staff (e.g., pharmacy technicians or ancillary staff) are not to screen for consultation by asking if the patient wanted to speak to the pharmacist or have questions about the medication. Consultation is required when the patient or the patient's agent is present in the pharmacy to receive consultation.

Over the years, the board has added other enhancements to help ensure patients receive meaningful consultation, including a Notice to Consumers poster that must be posted in the pharmacy. This poster states the pharmacist must consult with each patient about his or her new medication, and lists the five questions a patient should understand before taking a prescription medication.

More recently, in promulgating the requirements for patient-centered labels, the board required that oral consultation services be available in 12 languages to aid limited-English speaking patients in better understanding how to take their prescription medication.

Over the years, the board has enforced the patient consultation requirement in various ways. Initially, it was one of the first violations for which the board used its citation and fine authority. In recent years, the board typically assesses fines of approximately $1,000 when it observes failure to consult during an inspection. If a medication error has occurred and a consultation was not provided, the board generally issues a higher fine.

In 2011, board staff began working on a project with three California District Attorney's (DA's) offices to aid in the board's enforcement of patient consultation. Using the state's Unfair Business Practices statute in Business and Professions Code section 17200, the DA was able to assess higher fines for failure to consult. Additionally, the DA's used undercover investigators to pass prescriptions, which is an action the board has not done.

The DA's investigations resulted in substantial fines to three pharmacy chains: CVS (2013, $658,500); Rite Aid (2014, $498,250); and recently Walgreens (2015, $502,000).

At the July board meeting, the board heard a report summarizing the results of a short Survey Monkey questionnaire conducted by the board involving patient consultation.

Discussion and Comment

The committee heard testimony from Anna Guerrero, representing Fred Meyer, as well as the president of the Marin County Pharmacists Association, Natalia Mazina, and the Alameda County Pharmacists Association.

Members of the Marin County Pharmacists Association asked the board to slow down the workflow of pharmacists. As this issue was not previously included in the agenda, they requested a future agenda item to discuss workflow issues.

The board received a comment that while the pharmacists want to consult, they are not given the opportunity to consult.

Dr. Gutierrez noted that providing patient consultation provides an opportunity to catch errors.

Dr. Gutierrez requested that the Communication and Public Education committee focus on consumer education and why patient consultation is important.

Some comments and/or questions received from the public included if the board can prohibit the use of a system that requires a patient to accept or decline patient consultation in advance of payment or dispensing of a prescription and if putting a cap on the number of prescriptions filled in a day could be enforced by the board. In addition citations should be issued to the business and as part of the order of abatement, require a pharmacy to take certain steps to ensure patient consultation is provided.

Dr. Gutierrez noted that mail order pharmacies should be addressed as well and requested that an agenda item be added to revise title 16 California Code of Regulations section 1707.6 and point of sale devices.

Public Comment

Robert Stein from the KGI School of Pharmacy stated that by checking the box it was clear that no patient consultation occurred. He stated that the pharmacist should document that patient consultation was provided or refused.

There were no additional comments.

e. Discussion of the Proposed Regulation for Pharmacies and Clinics Aimed at Reducing Losses of Controlled Substances

Background

At the July board meeting, the board approved initiation of a rulemaking to establish inventory requirements of controlled drugs for pharmacies and clinics. This regulation will be noticed before the October board meeting.

The regulation requires perpetual inventories of all federal Schedule II drugs, with a physical count every 90 days. Additionally, the board will establish a list of one or several additional controlled drugs from Schedules III – V that are reported as frequently stolen to the board and/or DEA.

Provided below is a list of the top non-Schedule III-V drugs reported lost or stolen to the board in the last year. For ease of comparison, all drugs listed have been converted into administration dosage units (i.e., liquids have been converted into 5 mL teaspoons to identify a dose). On the basis of this list, the board would require the inventory monitoring of alprazolam and promethazine with codeine.

Top Ten: FY 2014 – 2015 CS Schedules III-V Losses by Quantity

Drug	Quantity In Actual Dosage Equivalents
Alprazolam	160,169
Promethazine/Codeine	77,862*
Carisoprodol	38,579
Tramadol Hydrochloride	34,801
Acetaminophen/Codeine	27,903
Lorazepam	26,864
Zolpidem Tartrate	18,657
Diazepam	17,139
Clonazepam	14,628
Phentermine	10,820

*mLs converted into 5mL dosage units

The board's staff also developed the following list of Schedule II controlled drugs reported lost or stolen within the last year.

Top Ten: FY 2014 – 2015 CS Schedule II Losses by Quantity

Drugs	Quantity In Actual Dosage Equivalents
Hydrocodone and Combos	402,377*
Oxycodone and Combos	73,756*
Amphetamine/Salts/Methamphetamine	26,368
Hydromorphone/Oxymorphone	20,885
Dex/Methylphenidate	19,212
Methadone	9,817
Fentanyl Citrate	6,822
Diphenoxylate/Atropine	4,130
Tapentadol Hydrochloride	2,062
Meperidine HCl	831

*total dosages (mLs converted into 5mL dosage units and added to solids)

Dr. Gutierrez provided an overview of the above charts.

There were no comments from the committee or the public.

f. Tracking of Automated Drug Delivery Devices in Use in California

Background

Pharmacies are able to operate automated dispensing machines or devices in various settings away from the licensed pharmacy. This includes:

- Skilled nursing homes and other health care facilities licensed under Health and Safety Code section 1250 (c), (d) or (k) (the devices are authorized under section 1261.6 of the Health and Safety Code, authority for pharmacies to do this in specific locations is specified in Business and Professions Code section 4119.1)
- Clinics licensed under section 4180 of the Business and Professions Code (the devices are authorized under section 4186) – these include licensed, nonprofit community or free clinics defined under Health and Safety Code 1204(a)(1), a clinic operated by a federally recognized Indian tribe or tribal organization referred to in Health and Safety Code section 1206(b), a clinic operated by a primary care community or free clinic operated on a separate premises from a licensed clinic and that is open no more than 20 hours per week as referred to in Health and Safety Code section 1206(h), a student health center clinic operated by a public institution of higher education such as college health center as referred to in Health and Safety Code section 1206(j).
- Hospitals may use Pyxis or Pyxis-type machines throughout a hospital to store medication under application of provisions in Title 22 that allow drugs to be stored in

nursing stations. The Pyxis and like devices are considered secured storage units for drugs.

The board does not know how many of these devices are in use, where they are in use, or which pharmacies are responsible for the machines.

The demand for additional use of these devices is growing. As reported earlier at this meeting a pilot study is underway that, if proven valuable, would allow patients to pick up medication from devices not located in a pharmacy.

Board staff suggests that a simple registration be established for pharmacies that operate these devices to identify their locations and consider this action to be a beneficial step in board oversight and enforcement. Pharmacies that add, move, or remove a device could report changes to the board via the submission of a form. This registration could operate much like the off-site storage waivers for records waivers. At annual renewal of the pharmacy license, the pharmacy would update or confirm the list of devices it operates and where each one is located.

A regulation or statutory amendment may be needed to establish this requirement.

Discussion and Comment
Dr. Gray spoke in support of having device locations in outpatient and retail settings, but not require it in hospitals. He suggested that the board should differentiate between the two.

Dr. Gutierrez commented that board should consider a separate proposal to require licensure of drug delivery devices.

There were no additional comments.

III. COMPOUNDING MATTERS

a. Discussion on Medicare's Pharmacy Practice Expectations for Critical Access Hospitals

Background
Time was set aside for a discussion of these practice guidelines for hospital pharmacies. This item is for discussion and information purposes.

Various excerpts from the ASHP article are provided below:

> The "CMS document officially establishes United States Pharmacopeia (USP) Chapter 795 as the minimum standard for practices related to nonsterile compounding and USP chapter 797 for compounded sterile products."

"USP chapter 795 has been an enforceable standard since 2001, meaning that state boards of pharmacy and other organizations can use it as the basis for fines and other adverse actions against noncompliant regulated entities. Chapter 797 has been enforceable since 2004."

The article later goes on to quote ASHP as stating: "'only by a pharmacist or other personnel authorized in accordance with State and Federal law' may pose compliance problems for sparsely staffed critical access hospitals."

"According to the CMS document, critical access hospitals that contract for compounding activities must have access to the vendor's quality assurance data to verify compliance with USP chapters 795 and 797. Each hospital must document that it obtains and reviews the data. CMS also expects vendors to demonstrably follow state laws and meet the requirements of 503A of the Food, Drug and Cosmetic Act that relate to the compounding of human drug products."

The article then goes on to discuss outsourcing facilities and their potential future role in providing compounded drugs for hospitals. It notes that CMS' policy acknowledges the Food and Drug Administration's preference for hospitals to use official outsourcing facilities to obtain compounded sterile products. But then the article notes that outsourcing facilities are not meeting FDA's expectations when information from the FDA's Web site is reviewed. The FDA Web site lists all licensed outsourcing facilities and the number of FDA inspection report findings (on form 483) and 12 warning letters issued by the FDA to outsourcers. As of late January, only 1 of the 42-registered outsourcing facilities that had been inspected by the FDA had "no significant objectionable conditions" identified by the FDA.

There were no comments from the committee or the public.

b. Warnings about Becton-Dickinson Syringes and Loss of Medication Potency from the Federal Food and Drug Administration and Institute for Safe Medication Practices

Background

Several weeks ago, the FDA and Institute for Safe Medication Practices released warnings about the loss of potency detected for certain medications stored in 3mL, 5mL, and larger Becton–Dickinson syringes.

This item was added to the agenda so that the committee can discuss the situation and make a determination as to whether the board needs to initiate additional actions or warnings to clinicians. The board is aware of one recall initiated following release of these warnings. The executive officer has also learned that several outsourcers may have identified this loss in potency prior to these releases and took steps to notify their customers.

A proposed additional warning is:

> The California State Board of Pharmacy is resending the following subscriber alert that was recently sent involving IV medications stored in BD syringes in the interests of ensuring that all pharmacy practitioners are aware of this potential public safety issue. Please review this cautionary information carefully. The issue seems to be isolated to 3 and 5 mL BD syringes at this time, although the FDA has concerns with larger syringes. Pharmacists need to make certain all of their clinicians are aware of this situation so they can report any therapy failures/nonresponses to drug therapy when administering drugs that have been stored in syringes to the pharmacy and to FDA's MedWatch.

William Stewart recommends that the board be cautious in its actions because he believes there has not been sufficient research.

There were no additional comments or questions.

c. Discussion on Compounding for Prescriber Office Use

Background

Section 4052(a)(1) of the California Business and Professions Code provides that: Notwithstanding any other law, a pharmacist may furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

This "reasonable quantity" of compounded drug product has been defined in 16 California Code of Regulations section 1735.2(c) as:

> (c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of a compounded drug product that:
> (1) Is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
> (2) Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
> (3) For any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

The recent proposed modifications to the compounding regulation take out the 72-hour supply for that could be distributed to patient. Other changes have also been made to this section which as currently proposed reads:

> (c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section

4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber's agent and paid for by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

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

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

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

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

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

If the proposed compounding regulation changes take effect, pharmacies will be able to compound for prescriber office use, but not in quantities for prescribers to dispense to a patient.

There were no comments from the committee.

Public Comment

Marie Cottman remarked that this is in direct conflict with the federal 503A. She was advised that the board is moving towards making its requirements consistent with the FDA.

There were no additional comments or questions.

d. Comments on the Food and Drug Administration's Guidance Document #230 on Compounding Animal Drugs from Bulk Drug Substances

Background

The Board of Pharmacy has previously expressed interest in submitting comments on the FDA's Guidance Document 230, *"Compounding Animal Drugs from Bulk Substances."*

The committee discussed this document and the comments it wishs to submit to the FDA.

The following provides an overview and summary of the guidance provided in the FDA's document. The guidance supports and reinforces the regulatory framework developed by FDA for pharmacies and outsourcers who compound human drugs with several exceptions.

- For pharmacies that compound medications for animal use, the FDA guidance states that a veterinarian's prescription is required for the specific animal. The prescription must contain the standard information required on all prescriptions but also must include:
  1. The name and species of the animal
  2. A statement that the animal is not a food-producing animal
  3. If a manufactured drug exists, a statement that the compounded product would make a clinical difference from the manufactured product

  The guidance provides that pharmacies that compound such drugs must do so pursuant to USP 795 and 797 standards, by or under the supervision of a pharmacist, and such compounded products may not be distributed by wholesalers.
  Finally, the guidance allows a pharmacy to compound for future furnishing but is limited to the maximum quantity of that drug dispensed in a 14-day period within the last six months.

- For outsourcing facilities that compound animal drugs from bulk substances, the FDA is developing a list (which is not yet completed) of approved drug substances that an outsourcing facility must use when compounding for animals, linked to the species and the condition.

  The compounding must be done in accordance with cGMP standards by or under the supervision of a pharmacist. Outsourcing facility-compounded drugs may not be used on or in food producing animals, and must be expressly labeled to state this prohibition.

  The veterinarian must note on the order or prescription that the veterinary drug is intended to treat a specific condition and specific species, and this must match the listing on the FDA's bulk drug substances list. The guidance specifies labeling requirements and a

statement on the label that the product is not for resale. The guidance also requires that any drugs compounded by an outsourcing facility must be reported on the biannual lists of products compounded that must be sent to the FDA, with a notation of the products intended for animals.

The guidance also permits compounding by a veterinarian.

Public Comment
Jeremy Schmidt stated that the list for bulk powders changes on daily basis. Ms. Herold suggested that he provide his comments to the FDA.

Ms. Herold recommended that the board support the FDA's direction with respect to the guidance document.

Committee Recommendation:
Motion: Recommend that Ms. Herold draft comments that the board supports the direction of the guidance document and bring to the September 30, 2015 board meeting.

M/S: Lippe/Weisser
Support: 5 Oppose: 0 Abstain: 0

There were no additional comments or questions.

e. Discussion on the Compounding Services provided by Sterile Compounding Pharmacies and Outsourcing Facilities

Background
The November 2013 enactment of the DQSA created a new type of entity authorized to compound medications – the outsourcing facility. These generally large-scale production facilities are authorized to compound large quantities of medications for use by other entities. The medications must be prepared under current good manufacturing practices (or cGPMs), which are more stringent than compounding requirements for pharmacies, since many patients in multiple locations can receive these medication that are not usually linked to a patient-specific prescription.

The legislation essentially creates a new entity, with the results that there are three types of drug producers.

1. Manufacturers who are regulated by the FDA, and for facilities located in a specific state, often by a unit of the state's Department of Health (this occurs in CA). Manufacturers are required to perform extensive drug testing trials before receiving authorization to market a drug. Their physical plants are inspected by the FDA and must comply with rigorous cGMPs.

2. Outsourcers are regulated more like drug manufacturers and are regulated under cGMPs, but outsourcing facilities are exempted from performing drug approval testing like manufacturers must do for their products. In the future, the FDA has stated they plan on developing specific cGMP requirements for outsourcing facilities, but these specialized requirements are not yet available.

3. Pharmacies, which are authorized to compound pursuant to a patient-specific prescription, are regulated by state boards of pharmacy. Because pharmacies generally do not compound drugs in quantities the size of those produced by outsourcing facilities or manufacturers, pharmacies are regulated under lesser standards. Sterile compounding pharmacies, however, are generally regulated at a level closer to that of manufacturers and outsourcers because of heightened concerns about sterility, integrity, potency and quality of the compounded medication.

For a number of years, the board and other agencies have grappled with the issue of at what point does a pharmacy compounding medications in large quantities in anticipation of receiving a prescription, actually become a manufacturer because the pharmacy is compounding so much medication, or compounding not specific to received prescriptions. The board, the CA Department of Public Health and the FDA have all studied and discussed this issue in CA over the years, and similar discussions have gone on in other states and federally.

With the advent of outsourcing facilities, the issue is simplified;

- An outsourcing facility (aka a 503B facility) licensed by the FDA (and in the future by the CA Board of Pharmacy if located or shipping into the state), shall function under the supervision of a pharmacist and operate according to cGMPs, to produce compounded drug products for multiple entities without a prescription.
- A pharmacy (aka a 503A facility) may compound a medication pursuant to patient-specific prescription order or in very limited quantities based on normal dispensing patterns in anticipation of a prescription, and dispense pursuant to a patient-specific prescription.
- A specially licensed sterile compounding pharmacy may compound a sterile medication pursuant to a patient-specific prescription or in limited quantities based on normal dispensing patterns in anticipation of a patient-specific prescription, but dispense pursuant to a patient-specific prescription.
- A pharmacy may compound medication or sterile medication for administration in a physician's office (but after implementation of California's new compounding requirements, not for dispensing to patient in 72-hour quantities).

<u>Discussion and Comment</u>

It was asked if compounding hospital pharmacies should be required to be licensed as a 503B to comply with federal law.

Dr. Gray asked what will happen in the next few months.

Dr. Gutierrez requested that discussion of 503B's be added to the next agenda.

There were no further comments from the public.

f. Review of Sterile Compounding Statistics Identified by the Board

Supervising Inspector Dr. Acosta provided an overview of statistics compiled by the board from inspections and investigations of California-licensed compounding pharmacies from March 2015 to September 2015.

Discussion and Comment
Dr. Gutierrez requested that compounding statistics be posted on the boards website. Dr. Gutierrez also requested that board staff create FAQ's regarding compounding.

It was recommended by staff counsel that the board create a link to view the statistics rather than attach the presentation to the minutes since it's a snapshot in time.

Dr. Gray representing Kaiser, inquired about possible problems with completing sterile compounding inspections timely for those pharmacies with a November 1, renewal date.

There were no further comments from the public.

Dr. Acosta's presentation can be found at the end of this document.

IV. FUTURE MEETING DATES

- December 14, 2015
- March 2, 2016
- June 1, 2016
- August 31, 2016

Dr. Gutierrez adjourned the meeting at 3:11 p.m.