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: June 1, 2016

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
Allen Schaad, Professional Member

COMMITTEE MEMBERS NOT PRESENT:
Greg Murphy, Public Member
Stan Weisser, Professional 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
Veronica Wogec, Staff Manager II
Rob Buckner, Investigations Manager
Kelli Williams, Complaint Unit Manager
Debbie Damoth, Administration Unit Manger
Laura Hendricks, Administrative Analyst

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 9:00 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.

II. ENFORCEMENT MATTERS

a. 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 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 the initial dose.

This study was planned to start in June or July 2015; however, at the September 9, 2015 Enforcement Committee meeting, Dr. Jan Hirsch, BS Pharm, PhD, spoke via telephone and anticipated the pilot study would not begin until December.

At the December 14, 2015 Enforcement Committee meeting, Dr. Hirsch, reported that they would launch the device, enroll patients and refine data collection tools and processes during the first and second quarters of 2016, collect and review the data during the third quarter of 2016, and report back to the board with their results during the last quarter of 2016.

Also at the December meeting, the committee recommended that the board ask UCSD to collect drug classification data as part of the study. The board approved this recommendation at the February 2016 board meeting.

At the March 2, 2016 Enforcement Committee meeting, Dr. Hirsch reported that the study had launched on January 20, 2016 and 120 patients had enrolled to use the automated device. The committee recommended that the board ask UCSD for the number of employees and the work hours of those who utilize the device. At the April 28, 2016 board meeting, the board approved the recommendation.

Discussion and Comment

At this meeting, via telephone, Dr. Hirsch delivered a presentation on the progress of the implementation and reported that the program launched on January 20, 2016. Dr. Hirsh indicated that, because the kiosk was originally located near a fire exit, the location of the kiosk was moved from the employee entrance to an alcove on the first floor lobby on May 28, 2016. The kiosk still has 24-hour video surveillance and on-site monitoring.

The kiosk has about 200 users, which is approximately 4 percent of the 4,800 Scripps employees. Dr. Gutierrez asked whether the over-the-counter (OTC) medications described in the data were under a prescription, or whether they were just OTCs like Tylenol. Dr. Hirsch confirmed that the kiosk was being used, in part, to provide OTC medications.

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

Committee Recommendation:
Motion: Recommend that the board:

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

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

There were no public questions or comments.

b. Update on the CURES 2.0 Prescription Monitoring Program

Background
The Department of Justice (DOJ) announced that beginning January 8, 2016, the upgraded prescription drug monitoring program, CURES, was available and all current registrants would need to update their registration in the new 2.0 environment to ensure access to the upgraded system.

According to DOJ, CURES 2.0 is available to all registrants that use Microsoft Internet Explorer Version 11.0 or greater, or the latest versions of Mozilla FireFox, Google Chrome, or Apple's Safari when accessing the system. Registrants that do not currently have access to one of those specified internet browsers will be able to continue to access the prior version of CURES until the legacy system's retirement, at which time an updated browser must be used.

The board has worked with DOJ to develop "Frequently Asked Questions" to assist registrants with understanding CURES 2.0.

On February 8, 2016, the board sent post cards to all licensed California pharmacists as a reminder that California law requires all individuals holding an active California pharmacist license register with CURES by July 1, 2016.

In June 2016, according to reports generated by the CURES system, 30,544 pharmacists have registered for CURES 2.0, an increase of 22 percent from the March Enforcement Committee Meeting when 25,132 pharmacists had registered. Additionally, over 344,000 Patient Activity Reports were run in the last 30 days by pharmacists, indicating pharmacists are using CURES.

Discussion and Comment

At this meeting, Ms. Herold, who sits on the DOJ/DCA Change Control Board for CURES, provided an update on CURES 2.0 program. There are 14,330 active pharmacists who are not registered to access CURES. Of these pharmacists, 8,143 have California addresses of record, 5,985 have other U.S. addresses of record and 202 have foreign addresses of record. The board is currently mailing a reminder letter to all of these pharmacists of their obligation to apply for registration in CURES by July 1, 2016. Ms. Herold stated that the board recently sent letters to active pharmacists who are not registered to access CURES informing them of their duty to register. The letters also gave them information about how to become registered, including links to "how-to" videos on DOJ's website. The board also encouraged pharmacists to join the board's subscriber alert system to receive email updates.

Dr. Gutierrez noted that prescribers are not allowed to review CURES reports for the prescriptions they write to identify potential misuse. Dr. Gutierrez stated that the board should think about sponsoring legislation to allow prescribers to access to their own CURES records. Ms. Herold stated legislation in that area would be better left to the Medical Board.

Dr. Gutierrez asked whether the board could add a "countdown to compliance" clock with the CURES registration requirement on the board's website. Ms. Herold answered that a "countdown" would be possible.

Dr. Gutierrez also asked what would happen to pharmacists who were still not compliant as of July 1st. The committee discussed its options and decided to recommend sending a final letter to unregistered pharmacists. The letter would notify non-compliant pharmacists of their non-compliance and warn them that future sanctions would follow if they failed to comply.

Committee Recommendation:

Motion: Recommend that the board:

1) Continue outreach to promote CURES registration
2) Work with DOJ to identify those who are not registered
3) Report to the board at the July meeting on the status of compliance and discuss possible progressive adverse action for non-compliant pharmacists

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

There were no public comments or questions.

At this point, because someone had wanted to make a statement but was not present when the meeting began, Dr. Gutierrez allowed a public suggestion for a future agenda item. Brian Warren, of the California Pharmacists Association, urged the board to continue discussing ways of allowing pharmacies to use alternative testing methodologies for sterility testing of compounded sterile products.

Mandy Lee, representing Pharmedium, also requested to have the item added to a future agenda.

c. Consideration of the Proposed Regulation Relating to Reconciliation and Inventory Reports of Controlled Substances (Currently, to Add Title 16 California Code of Regulations Section 1715.65)

Background

At the July 2015 Board Meeting, the board approved initiation of a rulemaking to establish inventory requirements for controlled drugs for pharmacies and clinics. The regulation would require perpetual inventories of all federal Schedule II drugs, with a physical count every 90 days. Additionally, the board would 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 the Drug Enforcement Agency (DEA).

The regulation was released for the required 45-day public comment period between October 16, 2015 and November 30, 2015. At the February 2016 Board Meeting, the board referred the regulation back to the Enforcement Committee for review and consideration of the comments submitted.

Discussion and Comment

To focus the discussion, Dr. Gutierrez and Ms. Herold reviewed all the public comments and developed a new draft of the regulation. Dr. Gutierrez stated the revised draft would require a quarterly inventory and reconciliation, not just an inventory. Hospitals would be required to complete an inventory and reconciliation every 90 days for only drugs stored in the pharmacy.

For drugs stored in automated delivery devices, the pharmacist-in-charge would be responsible, in part, for ensuring the drugs are accounted for and the device is secure. The draft removes any requirement to physically count drugs stored in a device as the regulation would require an active on-going reconciliation process.

At this point, the committee saw a 7-minute news report from Colorado regarding hospital drug diversion and losses.

When the meeting resumed, the committee members agreed the revised regulation language had been improved.

Christine Versichele, representing Dynalabs, commented that Dynalabs is seeing an increase in the number of samples they are receiving from across the country to test for diversion at the hospital level.

Rita Shane, Cedars-Sinai Medical Center, asked whether hospitals that utilize a perpetual inventory system would need to complete a quarterly inventory and reconciliation. Dr. Gutierrez stated that the hospital would just need to take a snapshot every 90 days to meet the requirement.

Dr. Shane asked whether the inventory and reconciliation should include all Schedule II drugs or just opioids and whether high volume drugs should be rotated and reconciled more often. Dr. Gutierrez stated the proposed regulation would require an inventory and reconciliation at least quarterly, so facilities could perform an inventory earlier at their discretion.

Laura Freedman, DCA staff counsel, asked for permission to work on non-substantive changes to the proposed language prior to the next board meeting.

Committee Recommendation:
Motion: Recommend that the board withdraw the old rulemaking and initiate a new rulemaking using the revised proposed language dated May 25, 2016.

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

There were no additional comments or questions.

d. Consideration of the Department of Consumer Affairs Contract and Audit of the DCA Diversion Program Provided by Maximus Health Services

Background
The California Business and Professions Code provides that various healthcare licensing boards, under the auspices of the Department of Consumer Affairs (DCA), may establish a program to identify and rehabilitate licensees whose competency might be impaired due to substance abuse or mental illness. The board is one of several DCA boards that have implemented such programs; however, the board's program differs from those of other DCA

boards in that it does not divert licensees from discipline -- it uses the program as a monitoring program for its participants before, during, and after discipline has been secured.

In 2003, DCA began contracting with Maximus Health Services, Inc., to provide what DCA calls "Diversion Program Services." In October 2015, an audit of Maximus was conducted for the contract period January 1, 2010 through December 31, 2014. This report was referenced in the board's 2015 Sunset Report, but never shared with the board specifically.

Discussion and Comment
At this meeting, Ms. Herold explained the program's importance and process.

Mr. Lippe asked whether anyone is asking the board to use the program in lieu of discipline. Ms. Herold answered that no one has asked the board to change the way it uses the program.

Dr. Gutierrez noted a 50 percent success rate.

Ms. Sodergren provided information about the board's costs to run the program. She stated that the participants pay $100 per month and the board subsidizes the remaining administrative cost. Participants also incur various other costs such as inpatient treatment which can be more expensive. The board asks the case manager to work with participants to find other sources of funding if private insurance won't cover the cost of the program. The board tries to address the participant's financial concerns to ensure the cost of the program does not prevent anyone from using the program.

Ms. Sodergren stated that the average length of time participants spend in the program is three to five years, depending on the person and the underlying issue. Further, Ms. Sodergren indicated that the board's program is in compliance with the standards set forth in SB 1441.

Ms. Herold clarified that pharmacy technicians are not part of the program and can sometimes get help through programs offered by their employers.

There were no additional questions or comments.

e. Consideration of the Food and Drug Administration's Required Class-Wide Safety Labeling Changes for Opioid Pain Medications

Background
On March 22, 2016, the U.S. Food and Drug Administration (FDA) announced required class-wide safety labeling changes for immediate-release opioid pain medications. Among the changes, the FDA is requiring a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The FDA is also now requiring a warning that chronic maternal use of opioids during pregnancy can result in neonatal opioid withdrawal syndrome

(NOWS), which can be life-threatening. Provided below is a sample of how the new black box warning label might appear:

ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME

Addiction, Abuse, and Misuse
[TRADENAME] exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing [TRADENAME], and monitor all patients regularly for the development of these behaviors or conditions *[see Warnings and Precautions (5.X)]*.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of [TRADENAME]. Monitor for respiratory depression, especially during initiation of [TRADENAME] or following a dose increase *[see Warnings and Precautions (5.X)]*.

Accidental Ingestion
Accidental ingestion of even one dose of [TRADENAME], especially by children, can result in a fatal overdose of [active moiety] *[see Warnings and Precautions (5.X)]*.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of [TRADENAME] during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available *[see Warnings and Precautions (5.X)]*.

In addition, the FDA is requiring several safety labeling changes across all prescription opioid products to include additional information on the risks of these medications.

There were no questions or comments.

f. Consideration of the Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain

Background
On March 15, 2016, the Centers for Disease Control and Prevention (CDC) released 12 recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.

The recommendations are grouped into three areas:

- Determining when to initiate or continue opioids for chronic pain
- Opioid selection, dosage, duration, follow-up, and discontinuation
- Assessing risk and addressing harms of opioid use

The categorization of the recommendations was based on the following:

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least one year later
- Extensive evidence shows the possible harm of opioids (including opioid use disorder, overdose, and motor vehicle injury)
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm

This guidance is in addition to guidance provided by other agencies on opioid prescribing. In November 2014, the Medical Board of California produced its *Guidelines for Prescribing Controlled Substances for Pain*. According to the Medical Board's executive director, the Medical Board is in the process of comparing its guidelines with those of the CDC. Board staff will continue to monitor this review and its outcome. The Medical Board's guidelines are available from its website at www.mbc.ca.gov.

At this meeting
Ms. Herold stated that the California Medical Board has reviewed the CDC guidelines and might be adding some of the specific language to its own guidelines to create a consistent policy recommendation.

There were no additional questions or comments.

g. Proposal to Add Statutory Authority Relating to the Registration with the Board of Automated Delivery Systems for Dispensing of Medication

Background
At the February 2016 Board Meeting, the board considered a draft proposal to establish a registration requirement for pharmacies that operate automated delivery systems. During the meeting, the board discussed creating inventory requirements for the devices and the need to clarify some of the terminology used in the draft language. The board also heard public comment in which the board was asked to modify the requirements for hospitals that use the automated delivery systems. The board asked staff to modify the language and bring it back to the committee for further discussion. Subsequent to that meeting, staff worked with the board president and vice-president to refine the language (provided below).

Proposal to Add Section 4105.5

(a) *For purposes of this section, an automated drug delivery system includes a device as defined in Health and Safety Code Section 1261.6(a)(1).*

(b) *Every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall provide the board in writing with the location of each device within 30 days of installation of such a device, and on an annual basis as part of the license renewal. The pharmacy shall also advise the board in writing*

within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) Every pharmacy that uses such a system may only do so if all of the following conditions are satisfied.

1. *Use of the device is consistent with legal requirements.*
2. *Policies and procedures include appropriate security measures and monitoring of the inventory to prevent thefts and diversion. <u>The inventory shall be done at least quarterly.</u>*
3. *Drug losses from the device are reported to the board as required by law.*
4. *The pharmacy license is in good standing with the board.*
5. *<u>The device is located within a seventy-five mile radius of the pharmacy</u>.*

(d) The board may prohibit a pharmacy from using a system if it determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal such a decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) <u>A device used in a licensed hospital for doses administered in the hospital is exempt from subdivision (b).</u>

At the April 27-28 Board Meeting, the board discussed the proposed language, and asked questions regarding the level of security that the board should require for the locations of the machines, especially if the machine would be located 75 miles from the pharmacy.

Supervising Inspector, Janice Dang, explained how the automated drug delivery systems are used in skilled nursing facilities and noted that in rural areas the machines may actually be located farther than 75 miles from the pharmacy.

The board determined that requiring the registration of the automated drug delivery systems would provide the board with important information regarding the use of the machines; however, they elected to send the proposed language back to the Enforcement Committee so that sections (c) and (d) (which detail the specific requirements for the use of the machines) could be further vetted.

<u>At this meeting</u>

The committee reviewed and discussed subdivisions (c) and (d) of the proposed regulation language.

Mr. Lippe inquired as to whether a 75-mile radius was actually necessary. When the committee began leaning towards eliminating the distance requirement, the discussion then moved to whether the board should specifically limit the locations within California and whether pharmacies could provide drugs to other states without obtaining a license in the other state. Supervising Inspector Dang clarified that even though two pharmacies might be

close in proximity (near the border of two states, for example), they could not ship across state lines without obtaining a license in the other state.

The committee heard public comment in support of eliminating the 75-mile radius limit.

Committee Recommendation:
Motion: Recommend that the board eliminate the 75-mile radius limit and remove subdivision (c)(5) from the proposed regulation.

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

Ms. Freedman suggested clarifying "good standing" as written in subdivision (c)(4) of the proposed language. After discussion, the committee settled on new language.

There were no public questions or comments.

Committee Recommendation:
Motion: Recommend that the board amend subdivision (c)(4) of the proposed regulation to replace "good standing" with "unexpired and not subject to any disciplinary conditions."

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

Ms. Freedman suggested amending subdivision (e) to specify that a hospital would be exempt from the registration requirements in subdivision (b). Dr. Gutierrez also believed "device" should be replaced with "system" to be consistent with subdivision (a).

There were no public questions or comments.

Committee Recommendation:
Motion: Recommend that the board amend subdivision (e) of the proposed regulation to read, "A system used in a licensed hospital for doses administered in the hospital is exempt from the registration requirement in subdivision (b)."

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

The committee then made a motion to forward the entire amended language to the board for review and approval.

Doug O'Brien and Lori Hensic of Kaiser Permanente questioned the definition of "inventory" as used in subdivision (e) of the proposed language. He asked whether "inventory" means physical count or a report you can generate from the automated device. He also questioned the definition of "hospital" as used in the subdivision because the term could refer to the CDPH consolidated hospital license as well as areas accredited by other agencies.

Mr. O'Brien also raised a question regarding devices in doctor's offices wherein the drug inventory is owned by a physician. Ms. Herold responded that the board is not interested in devices owned by a physician.

Lynn Paulsen suggested that the regulation include all automated devices on the consolidated CDPH license and that any additional devices, owned by the pharmacy but not on the consolidated pharmacy license, be registered in a different manner.

Mr. O'Brien additionally asked whether the hospitals, which are exempt from the registration requirement, would also be exempt from the inventory requirement. Ms. Herold answered that they would not be exempt and would need to perform an inventory every 90 days. Mr. O'Brien then wanted clarification because the earlier regulation had exempted in-patient devices from controlled substance inventories.

Dr. Gutierrez proposed using language from the inventory portion of the previous regulation.

Ms. Hensic encouraged the board to mirror the previous regulation language as much as possible as it would be easiest and least confusing. She also suggested the board consider creating a task force and include larger organizations which deal with more complex matters, to provide some feedback into the confusion surrounding the consolidated hospital licenses.

Jeff Nehira of Mercy General Hospital spoke in favor of using the language from the previous regulation.

Dr. Gutierrez stated she wanted to work with staff counsel on the inventory language. Ms. Freedman thought the language could be revised simply by just stating that the inventory shall be done consistent with the board's regulations.

Ms. Herold warned that the board's sunset bill would have to go into the Assembly without the registration provision if the board chose to work through and include the inventory language. Dr. Gutierrez asked whether removing the inventory language from subdivision (c)(2) and addressing the inventory requirement at another time would allow the sunset bill to move forward this year with the registration requirement. Ms. Herold believed removing the inventory language would solve the problem.

Ms. Freedman indicated there could be an opportunity for the board to conduct a special meeting in conjunction with the regular board meeting to review the registration regulation.

She believed there was an exemption to the 10-day requirement for the Open Meeting Act if the meeting deals with legislation.

Committee Recommendation:
Motion: Recommend that the board:

1) Remove the underscored portion of subdivision (c)(2) of the proposed regulation
2) Forward the final revised proposal to the board

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

There were no additional questions or comments.

Below is the revised language that will be brought to the next board meeting for review:

Proposal to Add Section 4105.5

(a) *For purposes of this section, an automated drug delivery system includes a device as defined in Health and Safety Code Section 1261.6(a)(1).*

(b) *Every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall provide the board in writing with the location of each device within 30 days of installation of such a device, and on an annual basis as part of the license renewal. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.*

(c) *Every pharmacy that uses such a system may only do so if all of the following conditions are satisfied.*

1. *Use of the device is consistent with legal requirements.*
2. *Policies and procedures include appropriate security measures and monitoring of the inventory to prevent thefts and diversion.*
3. *Drug losses from the device are reported to the board as required by law.*
4. *The pharmacy license is unexpired and not subject to disciplinary conditions.*

(d) *The board may prohibit a pharmacy from using a system if it determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal such a decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.*

(e) *A system used in a licensed hospital for doses administered in the hospital is exempt from the registration requirements in subdivision (b).*

Dr. Gutierrez recessed for a break at 11:27 p.m.
The meeting reconvened at 11:41 p.m.

h. Consideration of a Proposal to Conduct Inspections of All Pharmacies every Four Years

Background

The board's charge to regulate the pharmacy profession necessitates routine inspections of licensed facilities to confirm adherence to or identify failures in adherence to the requirements of pharmacy law. Failure to perform such inspections makes the board's enforcement program reactive rather than proactive because inspections are currently done when the board is investigating potential violations of pharmacy law from a complaint or other information that would trigger an investigation.

For a number of years, the board's policy has sought to inspect all facilities every three or four years. The board has been unable to complete these routine inspections of all facilities with any regularity, and in recent years has had to substantially reduce such inspections because the board's first priority is investigation of complaints and performance of mandated annual sterile compounding inspections. While thousands of inspections are completed, inspections occur generally as part of the investigative process, prior to issuance or renewal of a sterile compounding license, or as part of probation monitoring.

All Inspections FY11-12 thru FY14-15 by Visit Type

Number of Inspections Inspection Type	FY11-12	FY12-13	FY13-14	FY14-15	Total
Routine	1730	1010	287	342	3369
Investigation	743	896	875	926	3440
Probation/PRP	258	228	139	227	852
Sterile Compounding	268	276	996	1067	2607
Other	34	39	32	26	131
Grand Total	**3033**	**2449**	**2329**	**2588**	**10399**

Mandatory inspections on a routine but random basis would enable the board to perform compliance inspections to educate licensees about pharmacy law as well as identify problems early to prevent more serious consumer issues from developing. Like all inspections, such inspections would be unannounced.

Compliance inspections provide an opportunity for board staff to answer questions about pharmacy law and complete follow up inspections to confirm compliance of facilities previously issued either citations or letters of admonishment.

Establishing a policy of mandatory inspections of each pharmacy every four years would supplement our current practice of conducting inspections principally to investigate problems (or inspect sterile compounders).

The board currently has 6,614 community pharmacies licensed in California. Some of these pharmacies have never been inspected by the board. The creation of a policy directing the board to perform inspections of all pharmacies every four years would require approximately 1,650 routine inspections annually. Over the last two years, the board completed an average of 1,215 inspections annually (routine plus investigation inspections).

At the December 14, 2015 Enforcement Committee meeting, the committee recommended creating a statutory mandate to complete random, unannounced routine inspections of resident pharmacies once every four years.

At the February 24-25, 2016, Board Meeting, the board referred the matter to the Enforcement Committee for additional discussion about ways to ensure more compliance inspections are performed.

<u>At this meeting</u>
Dr. Gutierrez pointed out that the board is conducting annual sterile compounding inspections at hospitals, so hospital pharmacies are being inspected but community pharmacies are not.

Ms. Herold indicated the focus of the visits would be aimed at compliance and education. Ms. Herold clarified that the board could create a policy and would not need legislation to require inspections every four years.

Dr. Gutierrez asked whether board staff had noticed any trends regarding a link between investigations and the period of time since the last pharmacy inspection. Ms. Herold stated board staff had looked for trends but had not found any.

Ms. Herold indicated the board expects each inspector will have to complete 12 additional inspections per year if current statistics remain constant. The additional inspections would be done without additional funding.

Mr. Schaad asked how often the self-assessment form is modified. Ms. Herold responded the forms were developed approximately 10 years ago and are modified every two years to reflect when laws and regulations are created and/or revised. Ms. Herold explained that, in part because the board lacked the resources to inspect every year, the self-assessment was

created to allow pharmacies to assess their own operations as if they were being inspected by the board.

There were no additional questions or comments.

III. COMPOUNDING MATTERS

a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations Sections 1735 et seq., and 1751 et seq.

Background

On May 8, 2015, the board initiated a formal rulemaking to update California's compounding regulations. The chronological timeline for the regulation is:

Board approved proposed the text for rulemaking:	April 21, 2015
45-day comment period:	May 8 – June 22, 2015
Regulation Hearing:	June 25, 2015
15-day comment period:	July 31 – August 15, 2015
15-day comment period:	November 20 – December 5, 2015
Board approved the final text:	January 19, 2016
File submitted to DCA for review:	March 10, 2016

The board set the effective date of the regulation as January 1, 2017. The file is currently being reviewed by DCA.

At this meeting

Ms. Herold explained that the board received a 90-day extension to allow time for the DCA director and administration to review the file.

Ms. Freedman stated some modifications had been made to the regulation package by staff, but that no changes had been made to the language.

Dr. Gutierrez was concerned that the board had set the effective date of the regulation as January 1, 2017, but that the review and approval process might not leave enough time for pharmacies to review the regulation prior to implementation. Discussion revealed that the regulation could possibly not be approved until October or November 2016.

Ms. Herold suggested reviewing the status of the rulemaking file at the July Board Meeting before determining whether to delay the effective date beyond January 1, 2017.

Committee Recommendation:
Motion: Update the board on the status of the rulemaking at the July Board Meeting with the possibility of extending the effective date.

M/S: Lippe/Schaad
Support: 3 Oppose: 0 Abstain: 0

There were no public questions or comments.

b. Presentation by the Office of Statewide Health Planning and Development Regarding its Process for Reviewing Structural Modifications Needed in Healthcare Facilities

At this meeting
Glenn Gall, Supervisor in the Facilities Development Division of the Office of Statewide Health Planning and Development (OSHPD), made a presentation on the process for reviewing structural modifications in healthcare facilities.

Dr. Gutierrez explained that as part of the sterile compounding regulation, there will be some requirements for structural modifications to pharmacies that compound hazardous materials. Before the board begins considering waivers, it wanted to get information from OSHPD regarding timelines, requirements, and the OSHPD building process.

Mr. Gall provided an overview of OSHPD's statutory authority, design process, and involvement in hospital alteration projects. OSHPD's timeline for plan review tries to focus on one initial review and two subsequent back checks with the initial review taking place within 60 days and the subsequent checks being completed within 30 days each. Subsequent follow ups can continue indefinitely until the plan meets OSHPD's requirements.

OSHPD requires hospitals to meet the standards listed in USP 797, but doesn't need to enforce much as the pharmacy designers typically have the expertise to know how to design to meet standards. Mr. Gall referred to California Building Code section 1224.19 (title 24, part 2, chapter 12) as being the specific pharmacy requirements. Other relevant codes include the California Electrical Code (Part 3), the California Mechanical Code (part 4), and the California Plumbing Code (part 5).

During the permit phase of any project, OSHPD first approves the specifications and drawings before a building permit is issued. There are also requirements for testing, inspection, and observation which list required tests specific to the type of construction. An inspector of record, hired by the facility as required by law, is always involved; OSHPD provides oversight and quality assurance of facility's inspection program. Other members of the inspection team include the OSHPD Compliance Officer, the OSHPD Fire and Life Safety Officer, the architect of record, a structural engineer, and mechanical engineer, and an electrical engineer.

Dr. Gutierrez asked Mr. Gall the process for updating the codes with revisions to building standards. Mr. Gall explained that OSHPD has quarterly meetings with the California Hospital Association and its members to discuss OSHPD's regulations as well as CDPH's regulations, the board's regulations and any others that affect building. Additionally, OSHPD assists in writing national building codes for health facilities. Mr. Gall indicated the process to revise the building is a 18 to 36 month cycle. If the board wants to change anything in the Building Code, Mr. Gall is the point of contact for getting it completed.

Dr. Gutierrez asked how the process works when the board has certain requirements in regulation but OSHPD doesn't have the same requirement's in its codes. Mr. Gall answered that builders need to comply with the board's requirements. OSHPD doesn't prescribe the requirements because they're not keeping up with the board and haven't looked at the details as closely as the board. Mr. Gall believes the board's new regulations might be most appropriately located in the mechanical code so designers and engineers know what to do without having to look in too many places.

Mr. Gall explained the building codes are revised on a triennial cycle based on changes to the international building code; the state is mandated to adopt the new edition every three years. New code proposals are made during the supplemental 18-month cycle. Mr. Gall also explained the process to obtain an emergency authorization on a much shorter timeline. Provided an agency can provide evidence that meets the standard of an emergency relative to public safety, it can propose a regulation change to the building standards commission and have it approved immediately. During the following 180 days, the agency would proceed with the public process, take comments, and possibly revise the regulation based on feedback. At the end of the 180 days, the regulation would become permanent but the regulation would have been in effect the entire time.

Mr. Gall indicated that the code change cycle was just beginning. The 2016 revisions will be published July 1, 2016 and will then be enforceable beginning January 1, 2017.

Dr. Gutierrez asked Mr. Gall about the timeline he would recommend for waivers from the board's new regulation. Mr. Gall suggested not calling the delay in compliance a "waiver" because the licensees are still expected to comply eventually. He believed 180 days would be a reasonable period of time to allot for the design and review phase. Regarding the construction phase, Mr. Gall thought an additional 180 days might not be enough depending on the scope and complexity of each project.

Supervising Inspector Christine Acosta asked whether the OSHPD process includes estimated dates for the beginning and end of the construction phase. Mr. Gall responded that the builder has one year to get the permit following approval, so there are no mandated beginning and end dates.

Dr. Gutierrez asked whether OSHPD would be willing to lend its expertise to help the board review waiver requests and determine whether the requests appear realistic. Mr. Gall indicated OSHPD would be willing to help.

Dr. Gutierrez asked Mr. Gall about the type of information the board should request as part of its waiver review process. Mr. Gall thought the following elements would be important:

- Definitive dates
- Purpose
- Scope of the project
- Project plan
- Structural modifications vs non-structural modifications (remodel)
- Cost
- Design professionals involved (including the architect of record and the inspector of record)

Mr. Gall suggested it might be beneficial to the board and the facilities to set a definitive date for project completion. Mr. Gall did not believe it would take more than two years for a facility to complete its project.

Mr. Gall believed it would be a good idea to include the California Hospital Association in the process and solicit their input.

Lori Hensic, Kaiser Permanente, questioned Mr. Gall's two year estimate for completing the projects and indicated it sometimes takes a significant length of time to identify funding for projects. Mr. Gall clarified that his estimate included only the project review, approval and construction.

Supervising Inspector Acosta suggested it would make more sense for the board to require OSHPD's approval as part of the board's waiver process. She reasoned that because the board doesn't have the expertise to review project plans, the board could streamline the waiver process by having OSHPD review and approve the plans first. Ms. Freedman stated that the waiver language in the board's regulation only requires the facility to identify the provision requiring physical construction or alteration and the timeline for the changes. Ms. Freedman also cautioned the committee to not add anymore requirements that would then necessitate another regulation. Dr. Acosta shared her concern that facilities submitting their waiver requests to the board will view the board's waiver approval as an approval of the project. Mr. Gall indicated the first person the facility would hire in planning a construction project would typically be the architect of record.

Dr. Gutierrez recessed for lunch at 1:11 p.m.
The meeting reconvened at 1:45 p.m.

c. Consideration of the Process for Pharmacies Seeking Waivers in Anticipation of the New Requirements in Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.

Background

The final version of the proposed regulations contains a waiver provision for some of the structural requirements. 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
3. contain a timeline for any such change

At this meeting

Staff developed a proposed process for pharmacies to request waivers. The committee reviewed a proposed waiver application form and discussed the proposed process.

Based on previous testimony from Mr. Gall from OSHPD, the committee decided to not discuss the waiver process at the meeting. Ms. Herold indicated she could develop a waiver application and process to bring to the board meeting in July. Dr. Gutierrez believed it would be good to develop a subcommittee to review waiver requests with technical assistance from OSHPD.

John Richards, owner of a community non-sterile compounding pharmacy, commented that his pharmacy is located in an older building and he's had two construction companies tell him they would not be able to build anything to meet the new regulation's requirements. He further stated he had signed a three-year lease six months prior to the regulation notice and would not be able to move. He questioned whether the board would grant him a waiver until he could move into a new building upon his lease's expiration. Ms. Herold wondered whether the board would grant an exemption in his current location for over two years. She wasn't sure whether there might be a way Mr. Richards could comply with the regulations short of a structural modification. Supervising Inspector Acosta stated that Mr. Richards would definitely not be the only person in his situation. Dr. Gutierrez told Mr. Richards that the regulation's effective date hadn't even been set yet, so that would give him more time. Ms. Herold indicated the board would look into developing options.

There were no additional questions or comments.

At this point, Dr. Gutierrez skipped ahead in the agenda to item (f).

f) Overview of Compounding Inspections Performed and Violations Noted

At this meeting

Supervising Inspector Christine Acosta presented data compiled from board inspections of licensed (sterile and non-sterile) compounding pharmacies from July 1, 2015 through May 13, 2016. Dr. Acosta indicated the board had 1,025 licensed sterile and non-sterile compounding facilities and 1,021 had been inspected. Of those inspected, the majority were hospitals (564) and pharmacies (360). She informed the committee that 1,162 violations had been issued, with most being issued for not having a master formula, not cleaning on the correct schedule, having an inadequate master formula or compounding log, not having a written quality assurance plan, and not having nonporous and cleanable surfaces. The inspections led to three Cease and Desist orders and 18 cases being forwarded to the Attorney General's office for formal discipline. Seven facilities are currently on probation.

Dr. Acosta provided instruction regarding the most frequent violation. She referred to California Code of Regulations section 1735.2 (d) which states that "a drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at the 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 the preparation of the drug
7) Post-compounding process or procedures required, if any"

Dr. Gutierrez asked what equipment needs to be listed to comply with (2). Dr. Acosta responded she would, at minimum, need to know which hood was used and whether any specialty equipment was used (a repeater pump or an automated mixer, for example).

Dr. Acosta sees most violations occur for inadequate preparation procedures, quality reviews, and post-compounding procedures. Specific, detailed volumes, directions, and notes must be included in the procedures and must be followed by staff every time to ensure a high level of control and consistency in the pharmacy. Inspectors should be able to walk into any pharmacy and make the drug based on the master formula.

Christine Versichele, representing Dynalabs, commented that Dynalabs requires master formula worksheets when it does testing. She asked for an example of a master formula worksheet that they could use. Ms. Herold indicated the board doesn't have a worksheet but that the elements in 1735.2(d) are what the board expects to see.

Lynn Paulsen questioned Dr. Acosta about her earlier statement that inspectors need to know which hood is used for each drug. She stated that the current regulation language doesn't require identifying the specific hood. Dr. Acosta agreed that the language is not specific in

that area, but responded that it's to the pharmacy's benefit to identify the hood at which something is compounded because if a hood is turned off, for example, every drug must be recalled if the hood at which the drugs were compounded can't be identified. Dr. Acosta stressed that the hood at which a drug was made needs to be trackable. Dr. Gutierrez suggested the board would need to do more education in this area. Dr. Acosta agreed to prepare an educational article for an upcoming issue of the *Script*.

The committee also heard a public question regarding porous and damaged surfaces. Dr. Acosta explained that many times problems arise from lack of maintenance where surfaces (Formica, for example) are chipped, cracked, or broken and have not been repaired to the manufacturers' specifications. Dr. Acosta reiterated surfaces must be non-porous and cleanable. Supervising Inspector Dang added that she has observed situations in which the top of a surface is laminated but the bottom is exposed particle board. Surfaces manufactured in that manner are unacceptable.

There were no additional questions or comments.

d. Consideration of The Pew Charitable Trust Reports: "Best Practices For State Oversight of Drug Compounding" and "National Assessment of State Oversight of Sterile Drug Compounding"

Background

Recently, the Pew Charitable Trust published reports on the best practices for drug compounding. The goal of these reports is to establish a baseline describing state policies today, and promote best practices in order to ensure that patients are safeguarded regardless of the state in which they receive treatment.

- ***Best Practices for State Oversight of Drug Compounding*** proposes best practices that are most meaningful to patient safety and the most achievable -- while recognizing that state funding may place limits on oversight systems
- ***National Assessment of State Oversight of Sterile Drug Compounding*** looks at the compounding landscape across the states to see how regulation and oversight vary in a number of categories (e.g., inspection, tracking, licensing)

Executive Officer Herold served on this task force representing this board and California.

At this meeting

Ms. Herold stated the process for the reports began in 2014 before there was much direction on outsourcing. The Pew Charitable Trust is now taking on outsourcing on a national level and is looking to the larger states for leadership.

Marie Cottman commented that the report was fabulous and asked whether colleagues in other professions were going to be held to the same high standards as pharmacists are in the

practice of pharmacy. Ms. Herold responded that it those decisions would have to be made by the FDA and other boards.

e. Consideration of the Food and Drug Administration's Guidance Documents on Standards for Compounding Drugs Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

In April 2016, the FDA released three draft guidance documents for public comment involving compounding or outsourcing of human drugs. Each of these documents is listed below for discussion at this meeting. The board may choose to submit comments, which would be due by mid-July, on some or all of these guidance documents as the FDA develops policy for compounding and outsourcing facilities in the USA.

1) Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Background

According to this guidance document, the guidance in this document addresses:

- Compounding AFTER the receipt of a prescription for an identified, individual patient,
- Compounding BEFORE the receipt of a prescription for an identified individual patient (anticipatory compounding), and
- Compounding for office use.

This guidance document states the value of compounding for individual patients by pharmacies, outsourcing facilities and physician offices when clinically necessary for a patient. The FDA states that when a product is compounded by a pharmacy or physician for an individual patient, the compounding entity is usually not registered with the FDA, and that the FDA is not usually aware of problems with compounded drug products unless it receives a report of a serious adverse event or visible contamination.

The FDA also states it has identified many pharmacies that compound drug products under insanitary conditions that ship numerous products, sometimes in large amounts, across the country. "The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm."

As such, the FDA states that compounding by 503A facilities (pharmacies) necessitate the following tenants:

1. Compounding is for an identified individual patient (after a patient-specific prescription is received)

2. Drugs compounded in advance of receiving prescriptions are compounded only in limited amounts (anticipatory compounding)
3. Drugs are distributed pursuant to a patient-specific prescription

The guidance document encourages the use of the following statement when a prescriber is prescribing a compounded drug product for a patient:

Per [type of communication] with [name of prescriber] on [date], [name of prescriber] has advised that compounded [name of drug] is necessary for the treatment of [name of patient].

The guidance states that unless anticipatory compounding is done for a limited quantity of compounded products, a prescription for a specific patient is first required before compounding occurs.

Anticipatory compounding may occur:

- Based on a history of the licensed pharmacy receiving a valid prescription order,
- If the orders have been generated solely within an established relationship between the pharmacist and prescriber,
- The compounder holds for distribution no more than a 30-day supply,
- The amount of supply is based on the number of valid prescriptions received by the compounder for identified individual patients in a 30-day period over the past year

The guidance draws a distinction in the activities performed by an outsourcer versus a pharmacy in that because the outsourcer is held to a higher standard of facility requirements and reporting obligations for adverse events and other factors, "outsourcing facilities can compound and distribute sterile and non-sterile non-patient-specific drug products to hospitals, clinics, and health care practitioners for office use."

<u>At this meeting</u>

Dr. Gutierrez observed the guidance looked much like the board's office compounding guidelines. Ms. Herold commented that the 30-day limit is more restrictive than California's which is more open-ended. She stressed that the guidance leans towards not dispensing without a prescription in hand for 503As. Dr. Acosta said she has seen the FDA inspect 503As. She commented that as soon as FDA inspectors observe any office use, they consider the facility to be a 503B and hold it to CGMP standards. It is her understanding that the FDA doesn't want to see any office use in a 503A. In her opinion, the FDA wants to put all non-patient specific compounding or outsourcing on 503Bs where there is stricter regulation.

Sarah Wallick commented that she had been in compounding for a long time and had recently spent the past three years at a 503B facility. She said she had witnessed 503As receive warning letters for not having patient specific prescriptions and any type of non-office use. She asked whether pharmacies should follow California law or the FDA guidance. Ms. Herold advised her to review her business plan and decide.

Marie Cottman asked whether the board intended to comment on the draft guidance. Dr. Gutierrez indicated that there were currently no plans to provide comment. Ms. Cottman stated that it's in the best interest of the patient as well as the pharmacy to be able to make more than a 30-day supply in appropriate instances, but that this guidance does not allow for the pharmacist to use professional judgment.

There were no further questions or comments on this guidance.

2) Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Background

This guidance document was developed for entities registered or considering registering as outsourcing facilities, and whether the "at one address means" whether multiple suites used for compounding constitute separate locations.

According to the guidance, outsourcing facilities may or may not receive a prescription for a compounded drug product, and are not subject to interstate distribution restrictions as are 503A facilities, but are required to compound all products under Current Good Manufacturing Practices (CGMPs), label all products as compounded, and be subject to adverse event reporting.

The FDA goes on to discuss that any product compounded in an outsourcing facility must be compounded pursuant to CGMP conditions, and not those of a pharmacy. Thus the FDA concludes that there can be no comingling of products (those compounded under 503A conditions and those compounded under 503B outsourcing conditions) in the same facility. All compounding in such facilities must be done under outsourcing facility requirements.

If implemented, this policy would require California licensed sterile compounding pharmacies that produce large quantities of non-patient specific compounded product to be generally regulated as outsourcers, not as pharmacies. As such, the guidance supports enactment of the board's SB 1193 to permit separate regulation of outsourcers and pharmacies.

The guidance also addresses the co-location of a manufacturer and an outsourcing facility and concludes:

> *"When a facility both manufactures conventional drug products and compounds drug products under section 503B, the policies described in this guidance would apply to the facility's compounded drug products except with respect to CGMP requirements that must be implemented throughout a manufacturing facility and cannot be applied differently to different drug products in the same facility, such as environmental monitoring and pressure differential monitoring requirements."*

The guidance states that approved drug products manufactured by a manufacturer would be easily differentiated from the outsourcing-produced products due to the differing labeling requirements between outsourcing facility-produced drugs and manufactured drugs.

At this meeting
Ms. Herold commented that this guidance was consistent with California's provisions.

Robert Nichol commented that he was starting a 503B facility which will be licensed as a retail pharmacy then will register as a 503B. He asked guidance regarding the standards his facility should maintain. Dr. Acosta told him if his facility maintained 503B (CGMP) standards, it would be far more compliant than California regulations require.

Sarah Wallick expressed concern that patients might not see the benefits of CGMPs because pharmacies might choose to form as a 503A to avoid the more stringent requirements of a 503B.

Ms. Herold commented that the board prohibits outsourcing facilities from being simultaneously licensed as a sterile compounding pharmacy because it wanted pharmacies to focus on serving patients and outsourcers to continue to focus on manufacturing.

There were no further questions or comments on this guidance.

3) Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

Background
This guidance states that outsourcing facilities are not required to be licensed as pharmacies, they may compound products in large quantities, they will be inspected by the FDA on a risk-based assessment, and they may compound with or without having a patient-specific prescription.

The FDA notes that compounding in hospitals can occur under various forms: some hospitals compound only those products the hospital needs for its patients (e.g., inpatients and emergency department), while other hospitals compound for other facilities within their health system (clinics, infusion centers, long-term care) for administration or dispensing.

According to this guidance document, hospitals can compound pursuant to a patient-specific prescription as well perform anticipatory compounding for future use. Hospitals can also buy compounded products from outsourcers for use within their facilities. Additionally, some hospitals have registered as outsourcing facilities.

The FDA goes on to repeat messages from the other two proposed guidance documents that it does not routinely regulate compounding by pharmacists or physicians, and thus is not aware of substandard compounding practices until an adverse event occurs. If compounding is done in an outsourcing facility, then because the FDA has regulatory oversight and the facility must adhere to CGMPS, higher production of compounded products can occur with longer beyond use dates without the risks inherent in compounding pharmacies. The FDA further states that compounded products should be used only when commercial products will not fit the medical needs of a patient.

The guidance states that in hospital pharmacies, compounding must be done in accordance with all provisions of regulations governing 503A pharmacies, and such pharmacies may be subject to regulatory action for violations of new drug approval, adequate directions for use and CGMP requirements.

The guidance goes on to state that in a hospital or health system, compounding may occur after receipt of a valid order for an identified, individual patient, or be done in limited quantities in advance of receipt for an identified, individual patient.

The FDA indicates that it does not intend to take action when a hospital pharmacy distributes compounded drug products without first receiving a patient-specified drug order if:

1. The drug products are distributed only to healthcare facilities that are under common ownership of the hospital pharmacy and that are located within a 1-mile radius of the compounding pharmacy;
2. The drug products are only administered within healthcare facilities to patients within the healthcare facilities, pursuant to a patient specific prescription or order; and
3. The drug products are compounded in accordance with all other provisions of section 503A, and any other applicable requirements of the FD&C Act and FDA regulations (e.g., the drug products are not made under insanitary conditions or misbranded).

The FDA states that the 1-mile radius is necessary because a health system pharmacy that compounds drug products without patient-specific prescriptions for facilities within its health system across a broader geographic area could function as a large manufacturing operation, but without the necessary standards to assure drug quality. If such a pharmacy contaminates or otherwise adulterates or misbrands a compounded drug, the drug has the potential to harm many patients.

The FDA instead offers that outsourcing facilities, which are subject to CGMP requirements and other conditions that help to assure drug quality, can compound and distribute drug products to healthcare facilities nationwide without first receiving prescriptions for identified individual patients.

The FDA states that a hospital compounding pharmacy can register as an outsourcing facility if it intends to provide compounded drugs to facilities such as other hospitals or

clinics outside the 1-mile radius of the pharmacy in which the drug is compounded without first obtaining a prescription for an identified individual patient.

Noted: This guidance conflicts with the regulatory provisions enacted under Business and Professions Code section 4128 et seq. under which the board licenses centralized hospital packaging pharmacies. Centralized packaging pharmacies allow hospitals under common ownership to secure unit-dose packaged medications from a centralized pharmacy if the pharmacies are located within 75 miles of the licensed packaging pharmacies.

At this meeting

Dr. Gutierrez asked whether the guidance affects all packaging. Ms. Herold responded that the guidance doesn't allow compounding, but is silent on the repackaging piece. Dr. Gutierrez questioned whether centralized hospital repackaging pharmacies which exceed the 1-mile radius noted in the guidance would have to apply for a 503B. Ms. Herold agreed with Dr. Gutierrez's understanding and added that the pharmacies would also have to apply for a manufacturing license so they could repackage the drugs.

Dr. Acosta shared that central hospital pharmacies need to be aware that they are going to have to transition to a 503B and that current legislation will forbid them from performing patient-specific compounding or doing TPNs.

Robert Eastin of Scripps Health commented that Scripps has a centralized hospital pharmacy and is preparing to transition to a 503B based on the FDA guidance.

Ms. Herold stated that she didn't know when the guidance would be finalized but that comments were due in July.

Lynn Paulsen commented that the FDA should focus volume instead of an arbitrary 1 mile radius.

Ms. Herold told the committee that she spoke to one of the authors and informed her that California consolidated hospital licenses may cover 30 miles, compounding product and shipping daily back and forth. According to the guidance, the hospital pharmacy will need to become licensed as an outsourcing facility. Under the FDA's construct, the pharmacy won't be able to serve the hospital. Ms. Herold believed California hospitals will need to push back strongly against the FDA regardless of what the board decides.

There were no additional questions or comments.

IV. MEETING DATES FOR 2016

The Enforcement Committee will meet on the following dates during 2016:

- August 31, 2016

Dr. Gutierrez adjourned the meeting at 3:13 p.m.