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

DATE: January 4, 2017

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Amy Gutierrez, PharmD, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Julia Ansel, Chief of Enforcement
Laura Freedman, DCA Staff Counsel
Christine Acosta, PharmD, Supervising Inspector
Kelli Williams, Complaint Unit Manager

Note: The webcast of this meeting can be found on the board's website.

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Gutierrez called the meeting to order at 9:00 a.m. Roll call was taken and the following members were present: Amy Gutierrez, Greg Lippe, Stan Weiser, Allen Schaad, and Ricardo Sanchez.

II. Public Comments on Items Not on the Agenda/Proposed Agenda Items for Future Meetings

Jeremy Schmidt from Roadrunner Pharmacy in Arizona read the following prepared statement concerning non-sterile compounding:

"With the passage by the board of new restrictive Testing/Beyond Use Dating requirements that became effective two days ago, the compounding pharmacy and veterinary community has been negatively impacted for patient care.
The primary reason that veterinarians require longer BUD dating is because they practice differently. The board responded appropriately earlier when new office use and dispensing regulations were adopted to accommodate veterinary practice. We all know that when you take

your pet in to see the veterinarian, one expects to leave with the appropriate medication. This happens from compounded office stock on an on-going basis.

The new testing requirements for additional stability for products that have been sold for years will result in an added financial burden to every pet owner in California. Many pharmacies, like our own, have up to 300 lines of non-sterile medications that practices need daily to treat these pets when they walk in. The newly required testing can add as much as $30,000 annually per medication to meet the new board requirements. The veterinary medication market is so small that these added costs over so few products will drive pet owners away from the veterinarians. The other option of 14 days dating does not work. Many medications made in our pharmacy are routinely tested before release, leaving only a few days for the veterinary practice to use the product. They also will only purchase a tiny amount, yet shipping and testing must be spread over the company's costs inflating the price of these medications substantially.

We ask that veterinary medications be exempted from these added testing requirements. Pets are not people and our pharmacy has demonstrated over a 20 year period that our potency/stability testing has been effective and adequate for a national pet population. Reducing medications to treat your pet in California by reducing availability and/or driving up price 2 to 4 times for pet owners is not the answer.

At a minimum, we request that the board place this item of concern on the agenda for your next meeting so that we can address these challenges with the veterinary community input. Given the "service-on-demand" nature of veterinary medicine, the office use requirements are unable to give an accurate assessment of realistic office use needs. Again, we ask for your consideration of an exemption for veterinary practices."

The committee agreed to add this item to the next Enforcement and Compounding Committee Meeting agenda.

III. Enforcement Matters

a. CURES 2.0 Prescription Drug Monitoring Program

Background

The Controlled Substances Utilization Review and Evaluation System (CURES) / Prescription Drug Monitoring Program (PDMP) is a computer system that stores Schedule II, III and IV prescription data reported by dispensers.

1. Presentation by the California Department of Justice, including Features for Pharmacists

Discussion and Comment

The committee heard a presentation from Mike Small from the California DOJ. As part of the presentation Mr. Small announced that the decommission date for CURES 1.0 is March 5, 2017. He noted that fewer than 10% of users (roughly 13,000) have not migrated to new CURES 2.0. Mr. Small advised that committee that when users sign in to CURES 1.0, they receive instructions to sign on to CURES 2.0 using an appropriate browser.

As part of his presentation, Mr. Small noted that that by law

Pharmacies and direct dispensers are required to report at least weekly into CURES all Scheduled II-IV drugs they dispense and advised the committee that CURES typically receives about one million prescription reports per week, and, data in the system reflects dispensing information exactly as it is reported.

Mr. Small indicated that one of the benefits of CURES is that it registered prescribers and dispensers can access patient activity reports (PARs) that have up to one year of patient-specific prescription history. He noted that this information assists health practitioners in safely prescribing medications and in identifying patients at risk for addiction.

Mr. Small highlighted changes the law relating to the CURES system including that that all active California licensed pharmacists and California licensed prescribers who are authorized to prescribe scheduled drugs were required to register to access CURES by July 1, 2016 or upon licensure. Mr. Small noted that last year, Senate Bill 482 (Lara, Chapter 708, Statutes of 2016) added H&S section 11165.4 requiring prescribers under specified conditions to consult with the CURES database prior to first-time prescribing a Schedule II, III, or IV controlled substance and at least every four months thereafter if the medication remains part of the treatment of the patient.

Mr. Small provided an overview of some of the benefits of the expanded CURES 2.0 system including a more robust system that allows for better identification of potential doctor shoppers, better monitoring of at-risk prescribing threshold, and better peer to peer communication through features like the ability to denote if a treatment contract is in place between a prescriber and patient or if a prescriber has placed a limitation on a patient seeking controlled substance prescriptions from other prescribers

Mr. Small advised the committee that CURES 2.0 features a fully automated registration process, provides the ability to a used to assign a delegate the authority to initiation PAR requests (the delegate cannot receive the report), and provides daily alerts to prescribers on patient who reach system identified prescribing thresholds

Mr. Small discussed the improvements in the system that ensure a more comprehensive patient history and the ability to provide de-identified data to researched and public health officials as allowed under the law.

2. Discussion and Consideration of CURES System Components

The committee discussed the reporting time period for dispensers which is currently seven days and the resulting lag in information sharing. The committee discussed if it would appropriate to reduce the reporting period to allow for closer to real time information. Mr. Small advised the committee that he believes the system would be capable of accepting data on a real-time basis and could turn the data around in 24 hours making accessible to registered users.

The committee discussed some of the concerns heard from pharmacists using the system including a limitation with the patient activity report which does not currently reflect the days' supply of the medication. The committee discussed that this information is very important for a dispenser. The committee was advised by Mr. Small that sometimes pharmacists just receive a list of NDC numbers which results from the incorrect NDC being entered at a pharmacy and noted such an error can make the NDC number difficult to match.

The committee discussed the alert features of the system. Executive Officer Herold commented that 250,000 alerts a day are difficult to manage and suggested a higher, more meaningful threshold may be appropriate. Mr. Small agreed to work with Ms. Herold and board inspectors to determine if the system can be modified to provide more meaningful alert information, particularly to pharmacists.

Board member Muñoz arrived at 9:26 a.m.

As part of its discussion, the committee considered if schedule V prescriptions should be reported to CURES. Mr. Small confirmed that the CURES system can support reports of Schedule V drugs; however, the statute does not currently require that these drugs be reported to CURES.

Chairperson Gutierrez reported that she has received feedback that providers want to know what has been dispensed under their DEA numbers. The committee noted that other states' PDMP programs offer this information to prescribers. Mr. Small stated that some states that have provided this information in the past and have found that some prescribers illicitly modify their records based on this information; however, he is open to further discussion. Dr. Gutierrez commented that there are diversion cases where providers are unaware that their prescription pads have been stolen and have no idea that unauthorized prescriptions are being written under their DEA number. Dr. Gutierrez commented that prescribers do not have a method to reconcile their prescription pads and should have a right to this information as it is under the prescriber's DEA number. Mr. Small commented that the current statute does not require prescription pads to have a uniform look and feel; it only requires a list of features. Mr. Small noted that this makes it difficult for investigators to determine if a prescription is legitimate. He also stated that one prescription pad can be worth up to $1.5 million to a drug diverter. Ms. Herold suggested that the committee consider following New York's lead where, with the exception of emergency room prescribing, most controlled substances are e-prescribed.

Public Comments

The board heard public comment on the CURES system and then discussed shortening the time that dispensers have to report to CURES. Ms. Herold remarked that reporting requirements used to be once a month and were reduced to once a week as Schedule III and IV drugs were added to the CURES. Mr. Small stated that changing the reporting requirement to 24 hours would seem possible.

Public comment was provided that 24 hour reporting may be difficult to meet due to workflow and technological issues and asked that the board consider 72 hours.

MOTION: Recommend to the board changes to the CURES system to include the days' supply of medication in the PAR as well as the ability for prescribers to have access to the prescriptions written by them. Recommend to the board that it pursue a statutory change to change the reporting requirement for dispensing information to include schedule V prescriptions and require reporting within 48 hours of dispensing.

M/S: Lippe / Weisser
Support: 6 Oppose: 0 Abstain: 0

b. Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications From an Automated Drug Delivery System Not Immediately Adjacent to the Pharmacy

Background

At the 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 drug delivery systems (ADDS) for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first time fills.

The committee has received quarterly updates on the study, including usage of the system.

Discussion and Comment

Dr. Hirsch delivered a presentation via telephone on the progress of the study. She reported that the ADDS was implemented on January 20, 2016 and that data collection continued through December 2016. Data analysis will be completed during the first quarter of 2017 and a report will be made to the board at the May 2017 Board Meeting.

Dr. Hirsch reported the following activity from January 20, 2016 through November 30, 2016 7% of campus employees (338 users) utilized the ADDS and that an average of 88 prescriptions were dispensed per month. Dr. Hirsch noted that in the beginning months, the data reflects that there were a higher number of new prescriptions which is due to a higher number of prescription transfers. Dr. Hirsch continued to state that many of these prescriptions turned into refills during the course of the study and noted that the majority of new and refill prescription pickups and over-the-counter medication pickups occurred during normal pharmacy hours. As part of the presentation Dr. Hirsch indicated that Sharp Memorial Hospital has not receive any complaints from user of the ADDS and has received testimonials about the convenience.

Kim Allen from Sharp Memorial Hospital was present at the committee meeting and reported that employees of Sharp do not have a closed health benefit system noting that employees have multiple health plans to choose from.

Ms. Allen also indicated that the original research proposal was to conduct the study at the corporate office where usage may have been higher based on the population. Ms. Allen reported that it was a challenge to inform employees about the ADDS and that the availability of the ADDS was communicated during rounds with different nursing units, informational tables in the cafeteria, electronic publications, and discussed during meetings. Ms. Allen noted that because Sharp employees may work at five different locations she could not conclude that most Sharp employees are aware of the ADDS and indicated that enrollment was not as high as desired.

Ms. Allen remarked that a lot of employees were using the ADDS after a change in work shifts and that offering over-the-counter medication in the ADDS has been beneficial in helping people get familiar with how to use the ADDS.

As part of its discussion, the committee reviewed a prior study that was completed on patient consultation. Board Member Weisser discussed the value of in-person consultation for patients and provided examples of new mothers with sick children and the elderly. Mr. Weisser cautioned against drawing conclusions based on a small sample size of the patient consultation study.

The committee did not take action on this item.

c. Disposal of Sharps in Pharmacy-Operated Drug Take Back Programs: Discussion and Consideration of Statutory and Regulatory Framework and Possible Changes

Background

Since late 2014, the board has been working on drug take-back regulations for pharmacies. The rulemaking file to implement the board's regulation requirements was submitted to the Department of Consumer Affairs (DCA) in December 2016. Hopes are for the regulation to go into effect toward the end of the first quarter of 2017.

The committee has previously discussed how to address the return of sharps by the public to a pharmacy collection of household pharmaceutical waste at a pharmacy. Of particular concern is the increasing widespread distribution and availability of EpiPens to respond to various emergencies in locations such as schools and restaurants.

The board's pending drug take-back regulation provides requirements that signage for collection receptacles contain the following prohibition: "Medical sharps and needles (e.g., insulin syringes) shall not be deposited." This is consistent with pharmacy law. Towards the end of the board's efforts to develop the take-back regulations, there were requests that collection receptacles also accept the return of sharps. In order to proceed with the rulemaking, the board decided to consider the issue of sharps, which includes such items as needles, syringes, lancets and EpiPens as a separate piece.

Discussion and Comment

As part of the committee's discussion, Executive Officer Herold explained that sharps are handled separately from pharmaceutical waste for a number of reasons including the Department of Transportation's (DOT) transport requirements. Ms. Herold explained that under the board's drug take back regulations pharmaceutical waste is placed in a liner that is similar to a trash bag. Ms. Herold continued that once full, the liner is removed from the holder and then placed in a rigid, impenetrable container for transport. Ms. Herold noted that as the liner is removed from the holder, the contents settle, similar to removing a trash bag at home and indicated that since the liner is not rigid, there is the possibility that sharps can poke through. She reported that California has a mandatory requirement for separate sharps take-back for any entity that provides a needle exchange program. According to Ms. Herold, in Sacramento County, any pharmacy that sells sharps must also provide a means for the public to dispose of used sharps.

Public Comments

Kelvin Yamada, Chief of the Environmental Branch of the California Department of Public Health (CDPH), commented that his agency regulates the generation, transport and disposal of medical waste from clinical facilities. Mr. Yamada commented that disposing of sharps in a liner creates a very hazardous situation for a pharmacist or staff member who may be removing the liner and then transporting it to a receptacle. Mr. Yamada noted that once sharps reach the landfill, they are run over by trucks and other heavy equipment and indicated that just because the sharps were originally in a rigid container does not mean that they will stay in one. He noted that CDPH considers an EpiPen that is encapsulated to be a sharp.

Chairperson Gutierrez commented that DEA regulations permit drug waste to be collected in a pharmacy; however, sharps can be collected in many authorized locations. Mr. Yamada pointed out that it is helpful to separate sharps waste from pharmaceutical waste because they are both disposed of differently: sharps are disposed of in an autoclave and pharmaceuticals are incinerated.

Ms. Herold pointed out that the DEA regulations require that pharmaceutical waste be disposed of in a lined container. However, the DOT requires that such waste be transported in rigid containers.

Chairperson Gutierrez commented that broader regulations that allow disposal of sharps in multiple public areas, such as airports, seem to be the best protection for the community.

Staff Counsel Laura Freedman commented that traditionally the sharps container only contained the sharp itself and not the drug. Even though regulations address the ability to have a separate container, to meet both the conditions for pharmaceutical waste and sharps waste a "super container" that meets all of the requirements of the sharps container and the medical waste container may be necessary which would require a statutory change. Ms. Herold pointed out that the situation is complicated because there is the federal overlay as well as transportation across state lines. Ms. Herold noted that people have been doing something for years and may not be flexible in moving forward with a different solution. Ms. Freedman stated that Business and Professions Code section 4145.5 does not clarify how sharps that contain medication should be disposed of.

A representative of Californians Against Medical Waste asked that the committee to consider a separate statewide policy for the disposal of sharps stating that when sharps are disposed of improperly, waste workers at landfills and recycling lines are endangered and that the public is being endangered because hypodermic needles are washing up on beaches.

Doug Kobold, Program Manager for Business Development and Special Waste, stated that his agency runs a landfill, a transfer station, and collects household hazardous waste. He commented that the rigid mail back sharps containers are a great savings to the local government and indicated that it costs $0.40 per pound to get rid of sharps in a rigid container while the cost to get rid of sharps that are not in an approved container is $8.00 per pound.

Mr. Kobold noted that while they take measures to protect staff, waste management maintenance and mechanical staff are at risk of sharp punctures when they clean out and repair equipment, such as compactors and bulldozers as the workers are not able to see sharps that have been pulled into the equipment. He continued stating that if an employee is poked, they do not know if the needle has been autoclaved. Mr. Kobold indicated that they would like to see a mandatory approved container requirement for every sharps sold.

Jorden Wells with the California Product Stewardship Council (CPSC) commented that they appreciate the board taking up this discussion as the safe disposal of sharps is critically important for Californians. Ms. Wells noted that needles are found at beaches, parks, and even public offices. Ms. Wells commented that as the primary distributor of sharps, pharmacies should take an active role in the safe and separate collection of sharps and noted that consumer convenience is the key to safe disposal. CPSC recommends that the board sponsor workshops to educate the public on the safe disposal of sharps.

Chairperson Gutierrez commented that the board has moved forward with the drug take back regulations. Ms. Herold stated that the existing regulation does not need modification right now because it does not allow for sharps to be comingled with pharmaceutical waste.

The committee agreed to keep this issue with the Enforcement Committee until a solution is identified and that the Enforcement Committee will work with other agencies, such as CalRecycle and Sacramento County to find a solution.

Motion: Recommend to the board that the committee continue to work with stakeholders to find a solution for the disposal of sharps.

M/S: Lippe / Weisser
Support: 6 Oppose: 0 Abstain: 0

A break was taken from 9:45 a.m. to 10:55 a.m.

d. Automated Drug Delivery Systems (ADDS)

1. Presentation(s) Regarding Options and Features Currently Available

Discussion and Comment
The board heard brief presentations from ADDS vendors and agreed that there needs to be more discussion as to how to embrace new technology when it conflicts with existing laws. The committee received a request to install ADDS in satellite clinics to be remotely operated by a pharmacist. Chairperson Gutierrez and Laura Freedman both commented that the committee does not have delegated authority to authorize this and that the issue has not been agendized for this meeting. Ms. Herold reported that the committee is not in a position to waive an existing law.

2. Discussion and Consideration of Refilling of ADDS in Skilled Nursing Facilities

Background
In skilled nursing facilities, ADDS are sometimes installed to permit furnishing of emergency medications or to start initial doses of medications to patients receiving care in the facilities. The board's staff believes that California law directs that drug stock maintained in the ADDS are stock of the pharmacy and that the pharmacy is responsible for restocking the device). However, board staff has been advised that some skilled nursing facilities have begun using nursing staff or perhaps other employees to refill the ADDS.

The California Department of Public Health's consultants and board inspectors note that the refilling of an ADDS is similar to the restocking of the emergency kits in SNFs, which after medication is removed from a kit, the kit is returned to the pharmacy for inventory, restocking and recordkeeping functions.

Discussion and Comment
The committee heard public comment from Robert Menet from the California Department of Public Health, Licensing and Certification Program. His program oversees licensing and certification of facilities such as acute care facilities, intermediate care facilities, skilled nursing facilities, and general acute care hospitals. Mr. Menet remarked that his organization is not aware of any regulation that allows anyone other than pharmacy personnel to restock ADDS.

He commented that Health and Safety Code section 1261.6 was enacted in 2009 and that technology has evolved significantly since the statute was put into place. Mr. Menet noted that the section is confusing, awkwardly worded, and subject to interpretation, however in the opinion of CDPH, any

medication that is not patient specific— that has not been dispensed by the pharmacy-- remains the pharmacy's inventory and should be under control of the pharmacy. Mr. Menet continued to state that he believes that section (g) is referring to the integrity of the drug distribution system and that CDPH would defer to the board's interpretation of this statute and will enforce accordingly.

3. Discussion and Consideration of Next Steps by the Committee or Board

The committee directed board staff to establish a one-day board meeting within the next 60 days to hear presentations on ADDS, particularly for ADDS intended for locations away from the pharmacy, and discussion of relevant laws relevant laws. The board's discussion will be framed around a series of questions, such as how ADDS will be controlled, how vendors ensure that drugs are matched with the correct patient, security features, and who can stock the ADDS. The board will send a subscriber alert with details about the forum.

Steve Gray, Kaiser Permanente, requested that as part of the meeting the board make a clear distinction between ADDS type devices that are used in conjunction with a skilled nursing or long-term care facility vs. a clinic where the patient takes the medication home. Dr. Gray noted that the law was recently changed to allow a registered nurse, who is working in a licensed clinic, to do the dispensing instead of a physician or pharmacist. He recommends that the board consider determining when a pharmacist will be involved and suggested reaching out to Washington State to discuss their recent changes.

e. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications

Background

Traditionally, pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs ("auto-refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications. The argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

From late 2012 through 2013, the board received over 100 complaints directly related to auto-refill programs due to the media attention. Many of the complaints were from patients who received prescriptions they did not request and who had difficulty returning the prescriptions for a refund. Other patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued by their prescriber. Some of these events resulted in patient harm.

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

At the October 2016 Board Meeting, staff was asked to develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

Discussion and Comment
The committee discussed the draft policy on automated refill programs:

Public Comment
The committee received public comments about Texas' auto-refill rules. The presenter stated that the auto refill program has provided pharmacists with more time to spend on consultations and that these programs have evolved significantly over the last six years. As part of Mr. McAllister's comments he noted that Texas recognizes that some Schedule IV and V medications are maintenance medications and have included them in the rule. He noted that Texas feels that the annual review is unnecessary because the patient is in charge of enrolling or disenrolling and that requiring patient approval of auto-refill medications for maintenance medications may result in a delay in therapy and inconvenience to the patient.

Ms. Herold commented that part of the purpose of the annual review is to make sure that the therapy has not changed and noted that absent a trigger to re-review medication, especially if the patient is seeing multiple prescribers, something that either duplicates the therapy or contraindicates the therapy could occur. Ms. Herold noted that some of the complaints that the board received in the past were about duplicate therapy from different pharmacies.

Mark Johnson from CVS Health offered to provide studies that show the benefit of auto-refill programs and recommended that the board review Oregon's progress in this area.

Julie Ansel, Chief of Enforcement for the board, advised the committee that regulations for Oregon and Texas and comments from CMS were taken into consideration when developing the draft policy. Ms. Herold confirmed that this document is intended to be a guideline, and from the guidelines, a regulation would be drafted and brought before the board.

Motion: Recommend to the board to approve the draft policy as amended by the committee of automated refill programs, and direct staff to use the policy to draft regulations. (The draft policy is provided below as approved by the committee)

California State Board of Pharmacy
DRAFT Policy on Automated Refill Programs:

A retail or mail order pharmacy may use a program that automatically refills prescriptions that have existing refills available, in order to improve patient compliance and are consistent with the patient's current medication therapy when all of the following conditions are met:

(1) Written notice or disclaimer of the availability of an auto-refill program shall be given to the patient or patient's agent. The patient or patient's agent must affirmatively indicate they wish to enroll in such a program and the pharmacy shall maintain documentation of such indication. Notice shall have language that references instructions on how a patient can discontinue participation in the auto-refill program.

(a) A pharmacy patient or the patient's agent shall consent to participation in an auto-refill program with a "wet" signature or an e-signature. If the pharmacy has an online consent option, the patient may enroll in the auto-refill program through that method. The pharmacy shall keep this acknowledgement on file. If the retail pharmacy has an online consent option, the patient or patient's agent can register in that manner

and the pharmacy shall keep said acknowledgment on file for one year from date of dispensing.

(b) A mail order pharmacy patient or the patient's agent shall consent to participation auto-refill program through the mail order pharmacy's website. The pharmacy shall keep this acknowledgment on file. If the mail order pharmacy does not have an online consent option, the pharmacy shall obtain a signature or email confirmation from the patient or patient's agent consenting to the auto- refill program. Acknowledgement of consent to participate in the auto-refill program shall be kept on file by the mail order pharmacy for one year from date of dispensing.

(2) The Pharmacy shall have written policies and procedures in place that ensure only medications that are eligible for the auto-refill program are enrolled in the program.

(3) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient's agent in a timely manner.

(4) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

(5) The retail or mail order pharmacy must reaffirm annually each prescription to be enrolled in the auto-refill program.

(6) Upon a receipt of a new prescription from a provider, the patient or patient's agent shall identify if the prescription is to be included in the auto-refill program, even if the new prescription is a continuation of existing therapy.

(7) Each time a prescription is refilled a reminder notification will be provided to the patient or patient's agent, affirming that the prescription is enrolled in the auto-refill program.

(8) Pharmacies that use an auto refill program will have policies and procedures in place that address the auto-fill program. These policies and procedures will be available for inspection upon request of the board.

(9) The pharmacy shall provide a full refund to the patient or the patient's agent and the payer for an auto-refill prescription that is reported as unneeded or unnecessary if the patient or patient's agent can provide evidence or documentation that they did not register for the auto-refill program or the patient notified the pharmacy of disenrollment.

M/S: Weisser/Lippe Approve: 6 Oppose: 0 Abstain: 0

f. Discussion and Consideration of the National Council of State Boards of Nursing (NCSBN) Nursys® e-Notify system

Background

The Enforcement and Compounding Committee expressed interest during a prior meeting about

learning about the e-Notify system.

The National Council of State Boards of Nursing (NCSBN)® e-Notify system is a nurse licensure notification system that provides employers of registered nurses, and licensed practical/vocational nurses, with real-time email notifications about nurses they employ. The e-Notify system alerts subscribers when changes are made to a nurse's record, including changes to: license status, license expiration, pending license renewal, and public disciplinary action, resolution and alerts.

Discussion and Comment
As part of the discussion, Ms. Herold advised members that the National Practitioner Data Bank (Data Bank) is a central national repository for disciplinary actions taken against licensees. Ms. Herold noted that while the board would like to obtain reports from the Data Bank on all licensees; it is cost prohibitive. Ms. Herold indicated that board relies on reports for licensees that are arrested or convicted in California from the Department of Justice and reminded members that as part of an individual's license renewal licensees certify under penalty of perjury that they have no arrests or convictions since the last license renewal.

There were no public comments.

g. Discussion and Consideration of Possible Revision to Title 16 California Code of Regulations Section 1707, Off-Site Storage Waivers, to Address Licensees With Previous Records Violations

Background
Existing board regulations require that pharmacies retain records of all acquisitions and dispositions of drugs for at least three years. Some pharmacies lack sufficient space within the licensed premises to store these records. Board regulations also authorize the off-site storage of pharmacy acquisition and disposition records for records older than one year for dangerous drugs and two years for controlled drugs if a board-issued waiver is secured for off-site storage. These requirements are specified in CCR section 1707.

When the regulation permitting off-site storage of records was promulgated, only licensees that had no records violations were eligible for an off-site storage waiver. In 2015/16, the board issued 178 off-site records storage waivers and denied approximately 10.

In recent months, the board has identified several pharmacies that requested off-site storage waivers but were ineligible for waivers because they had been cited for storing records off-site without an approved waiver. Their attempt to get a waiver was generated by the citation, and a desire to come into compliance, however, the regulation's provisions provide no option for the board to grant such a request for five years after the violation occurred.

Staff requested that the committee reconsider the full prohibition and authorize discretion in the award of off-site waivers.

Discussion and Comment
As part of the discussion Ms. Herold clarified a waiver would be denied if records had been falsified. Ms. Herold advised the committee of inspections conducted by staff where, as part of the inspection it was determined that the pharmacy had moved the records off site. Ms. Herold noted that the end result was that records had to be moved back into the pharmacy because a waiver could not be

granted.

Public Comments
Steve Gray, Kaiser Permanente, suggested that the board also clarify the term "off-site" used in the regulation versus premises. Ms. Herold clarified "premises" means licensed area

Based on public comment the committee changed the language to "outside of the licensed area of the pharmacy" instead of "off-site."

The committee also heard public comment from Tony Park about independent pharmacies that close their doors for good and don't know what to do with their records. The committee discussed that waivers can only be obtained by a licensed business. Ms. Herold commented that part of the board's discontinuance of business requirement records have to be stored at a licensed location for a period of three years following the pharmacy's closure and noted that a business owner will have to find another licensee to store the records for them. Ms. Herold noted that records should not be sent to a records storage facility or stored in someone's garage where these confidential health records may not be protected. Ms. Herold indicated that records sent to a storage vault may not be appropriately protected because if the person leasing the storage vault dies or stops paying the rent, the confidential health records can be sold at public auction.

Board Member Lippe pointed out that Business and Professions Code section 4333 details records retention requirements.

Motion Recommend to the board approval of recommended changes in CCR section 1707 as discussed and amended by the committee.

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside of the licensed pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code~~.

M/S: Weisser/Lippe Approve: 6 Oppose: 0 Abstain: 0

h. Discussion and Consideration of a Possible Amendment to New Business and Professions Code 4316 Regarding Cease and Desist Orders

Background
Last year, one provision contained in the board's sunset bill, SB 1193 (Hill), provided the board with the ability to issue a cease and desist order to an unlicensed entity operating within the board's regulatory jurisdiction without a license where one is required. However, following enactment of SB 1193, staff identified items in this provision needing clarification.

Discussion and Comment
As part of its discussion, counsel recommended that the committee consider replacing the words "obtaining such" in paragraph (a) with "appropriate licensure" to clarify that the licensee must have a license versus being in the process of obtaining a license.

Motion: Recommend that the board seek legislation to correct Business and Professions Code section 4316 as proposed including incorporating the revisions suggested by Ms. Freedman.

Amend Business and Professions Code Section 4316

(a) The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure without appropriate licensure.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the ~~pharmacy~~ facility pursuant to Section 1094.5 of the Code of Civil Procedure.

M/S: Lippe/Weisser Approve: 6 Oppose: 0 Abstain: 0

i. Discussion and Consideration of U.S. Department of Health and Human Services Food and Drug Administration's Article, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry

Board of Pharmacy Supervising Inspector Michael Ignacio provided a presentation to the committee on components provided in this guidance document concerning suspect product found in the pharmaceutical supply chain and addressed by the Drug Supply Chain Security Act.

Dr. Ignacio reminded members that on November 27, 2013, the Drug Supply Chain Security Act (Title II of Public Law 113-54) was signed into law and as part of the law the Food and Drug Administration (FDA) was required to issue guidance to aid trading partners in identifying a suspect product and terminating notifications. Dr. Ignacio reviewed the definition of a suspect product is defined as product for which there is reason to believe it is potentially counterfeit, diverted, or stolen; is potentially intentionally adulterated, such that the product would result in serious adverse health consequences or death to humans; is potentially the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Dr. Ignacio indicated that in December 2016, the FDA published a guidance document titled *Drug*

Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry to clarify when manufacturers and other trading partners should notify the FDA if there is a high risk that a product is illegitimate. He noted that the FDA is seeking comments and suggestions regarding this document and that the comment period ends February 7, 2017.

Dr. Ignacio stated that the guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify a product and determine whether a product is a suspect product as soon as practicable; and sets forth the process by which trading partners should notify FDA of illegitimate product or products with a high risk of illegitimacy, and how they must terminate the notifications, in consultation with FDA.

After discussion the committee determined that the board does not need to provide comments on the draft guidance. The committee was advised that the board's next *The Script* will include information on this guidance.

Public comment received suggested that the information should also be shared with the Medical Board and Dental Board.

j. Discussion and Consideration of Beyond Use Labels in Institutional Settings

Background

At the board's December 14 meeting in Glendale, the board received a request for a modification of the expiration date used on prescription labels from "exp" to "do not start after." The request came from Providence Hospital and stated the following:

> "Providence Health & Services in Southern California shares the same inpatient medication label template in our EMR system.
>
> The DOPs (covering 6 inpatient, acute-care facilities) met and discussed replacing the current "**Exp:**" field on the med label with "**Do Not Start after:**".
>
> Part of that decision had to do with using terminology that nursing staff can easily speak to (vs. using the term BUD). The group felt that using language that nurses can articulate will help with compliance.
>
> The behind-the-scenes EMR work is extensive and we wanted to solicit feedback from the Board of Pharmacy before making any changes to our medication labels. I have attached the image of the mock-up. Would you mind giving us some feedback as to the acceptability of using this language on our med labels? If you have any other suggestions, we would appreciate your guidance.
>
> With respect to existing law, Title 16 California Code of Regulations section 1735.1(b) effective 1/1/17 provides that:
>
> (c) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes)."

Discussion and Comment
Ms. Herold commented that as long as the licensee meets the minimum label requirements, they can add additional information. The additional information in this case provides clearer direction as to what is appropriate for this medication. The committee members agreed that additional information on the label that is intended to clarify the directions is beneficial to the patient. This issue may be addressed in a future news article letter of *The Script*.

IV. Compounding Matters

a. Discussion and Consideration of Statistics for Board-issued Citations and Fines for Compounding Violations

Discussion and Comment
Board Member Schaad reviewed the compounding citations and fines issued by the board between January 1, 2016 and December 16, 2016. Mr. Schaad noted that most compounding institutions cited had both sterile and non-sterile compounding citations and that 75 pharmacies had non-sterile compounding infractions and 38 had sterile compounding infractions. Mr. Schaad indicated that out of the 1,100 sterile compounding pharmacies that were inspected during the year, only 38 received citations.

The committee discussed which license(s) may be issued a citation for a violation. Ms. Herold commented that the violations are cited against the pharmacist-in-charge (PIC) at the time that the violation occurred; this may not necessarily be the PIC at the time of the inspection. She also clarified that five months can lapse between the investigation and the issuance of the citation and fine. Ms. Herold provided the committee with a brief overview of the process noting that after an inspection is completed and violations identified, a report has to be written which is then reviewed by a supervising inspector and one senior staff before the citation and fine will be issued.

Mr. Schaad also noted that there were two cases where pharmacies compounded commercially available products and were cited for this, as well as citations issued for lack of a master formula.

The committee discussed the appeal process that a licensee may request in response to a citation and heard public comment about some variances in inspector findings that are noted during an inspection.

Board member Ricardo Sanchez returned from break at 1:41.

b. Update and Discussion of Compounding Construction Waivers for New Requirements in Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.

Discussion and Comment
Supervising Inspector Christina Acosta provided an update on compounding construction waivers. Dr. Acosta reminded the committee that she and Board Member Schaad, Chairperson Gutierrez, Executive Officer Herold, Chief Enforcement Officer Julie Ansel have been reviewing these construction waivers requests consistent with the board's direction. Dr. Acosta provided an overview of the waivers received and the number of requests pending. Specifically, Dr. Acosta advised the committee that as of January 2, 2017, the board has received 493 waiver requests and processed 214 requests (43%). Of the 214 requests processed, about 50 (23%) did not have a licensed sterile

compounding license, so the waiver was not related to sterile compounding. Ms. Acosta stated that of those processed, 70 have been approved and 2 have been denied. Ms. Acosta indicated that of 214 requests reviewed, 112 (52%) were for a pharmacy and 102 (48%) were for a hospital. Dr. Acosta indicated that she working with several waiver applicants to obtain additional information so that the request can be brought forward to the committee. Dr. Acosta has provided the committee with information on the additional waiver requests that 280 waivers have not been processed noting that, including 70 which were received on December 29, 2016.

Dr. Acosta advised the committee that many of the waivers are not complete and that some waiver requests are asking that all construction requirements be waived instead of a waiver only for specific items to be updated. She noted that the applicant needs to provide the specific section of 1735.6 and 1751.4 to be waived along with the subsection and provide information detailing their attempts to comply with the regulation and when they expect to be compliant. She noted that waivers for non-construction requirements, such as not cleaning the facility or complying with policies and procedures, cannot be granted. The committee was advised that waiver requests and email communication should be sent to Compounding.waivers@dca.ca.gov.

Ms. Herold stated that board inspectors focused on doing educational compliance during inspections and board staff have provided education at specially convened public forums.

Public Comments

B.J. Bartelson from the California Hospital Association (CHA) suggested that the board partner with the CHA to complete educational webinars for hospitals. Chairperson Gutierrez suggested that the board consider this option for big issues.

As part of public comment, the committee heard a request for a template of what the ideal waiver package might look like. In response, Dr. Gutierrez explained that the application is designed to provide the information that the board will need to make a decision. Dr. Acosta explained that each practice is unique and as such a single one example for all applicants to use is not possible. The committee was reminded that, at a minimum, the request needs to include the specific regulation and subsection that applies, the specific construction required, the construction start and projected end date as well as the pharmacy's plan during the transition period

The committee noted that a sample waiver package was provided at the October 26-27, 2016 Board Meeting and could be found on the board's website in the meeting materials section in pages 82 - 108. The link to the meeting materials is:
http://www.pharmacy.ca.gov/meetings/agendas/2016/16_oct_bd_mat_enf.pdf

Kaiser representatives stated that they are committed to meeting the regulations and submitted 59 waivers on December 13, 2016. The representative noted that their two most frequent waiver requests are based on sections 1735.6(e)1, which is related to having a physically separate room, and 1735.6(e)2, which is related to having appropriate negative pressure noting that their main concern is space available in some of the older facilities, may not accommodate the template that they have developed for adding a negative pressure room. The committee was advised that Kaiser is exploring all options, including mobile clean rooms and modular clean rooms and heard that some of their challenges include relocating pharmacies or clean rooms. Commenters noted that renovations in an operating hospital takes care and time as it involves disrupting water, power, medical gasses, and air supply.

Ms. Herold reiterated that the board is currently focused on educational compliance, but noted that if staff encounters an egregious situation, action will be taken as the board's underlying core is public protection. Ms. Herold noted that pharmacies and hospitals have other options including purchasing product from somewhere else or using a shorter the beyond use date (administering the product before it has a chance to grow anything). Ms. Herold reiterated that the goal is to get licensees into compliance as quickly as possible.

A representative from Dignity Hospital commented that to lower the beyond use date, the hospital has to essentially compound one product at a time which has a significant impact on their workload.

The committee also received comments from a non-sterile compounding pharmacist asking about waivers that have been submitted, but not yet approved. Chairperson Gutierrez recommended that the pharmacy keep a copy of the waiver request at their pharmacy to show the inspector in the event of a pharmacy inspection. Dr. Acosta reiterated that the focus is educational compliance and that with the inspections conducted recently, with one exception, all inspections have resulted in education and correction only.

c. Discussion and Consideration of the United States Government Accountability Office (GAO) Report to Congressional Committees, *Drug Compounding, FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges*

Background
In mid-November 2016, the GAO released a report on the regulation of compounding by states following the 2012 New England Compounding Center public health emergency.

Discussion and Comment
Chairperson Gutierrez remarked that she noticed that other boards of pharmacy are now looking at sterile compounding in non-pharmacy areas, such as physicians' offices. Dr. Gutierrez noted that the board does not have jurisdiction over these other areas where compounding occurs and that the FDA has issued draft guidance to address this gap.

As part of public comment, clarification was requested an outsourcers ability to compound patient specific products. In response, Ms. Herold advised the committee and public that California law is different and under provisions in California law, an outsourcer cannot compound patient specific medication.

d. Review and Discussion of California Law Governing Compounding and Conflicts with USP Section 800

Background
Staff has been made aware of possible conflicts between our new compounding regulation and USP 800 and other regulatory requirements. .

Additional discussion is also needed regarding California Business and Professions Code section 4127.7 as it relates to USP 800 and our new regulations requirements for hazardous drugs.

Discussion and Comment

Dr. Acosta provided a summary of the areas of conflict between board regulations and USP 800. Dr. Acosta noted that the biggest difference is the allowance by USP for the use of a double HEPA filter for the nonsterile hazardous products which is not allowed in board's newly enacted regulations. Dr. Acosta suggested that the board may want to reconsider how it defines biological safety cabinet versus how it is defined elsewhere. Dr. Acosta noted that Business and Professions Code section 4127.7 is inconsistent Title 24 building codes.

Dr. Acosta briefly discussed the factors to consider when determining if an allowance should be made for the double HEPA filter. Dr. Acosta highlighted some of the challenges with certifying the system but suggested that it may be offset by the setting in which it is used. Chairperson Gutierrez commented that concerns have been expressed about the ability to vent the hood which is what the board's regulation currently required. The committee discussed if this requirement was appropriate for compounding such as preparing a topical preparation in a hood.

Public Comments

Rick Rhoads with University Compounding Pharmacy (UCP) noted that UCP has run into issues with the HVAC requirements as the demand of the HVAC goes up exponentially when you have to vent out the hood. UCP advised the committee that to comply with the board's current requirement a significant amount of air must leave the room that must be replaced. UCP indicated that to comply with the current regulations their pharmacy would need an air conditioner the size of a parking space to accommodate this regulation in its current form.

The committee discussed the need to create an option to allow for either the venting of the hood or the use of a double HEPA filter.

A compounding pharmacist commented that the USP 800 people are experts and that they believe that double filtration is acceptable for level 2 and 3. A representative from California Pharmacist Association also stated that they agree that the double filtration system is acceptable.

Dr. Acosta also recommended that the board reconsider its definition of "biological safety cabinet" (BSC) noting that a BSC can also be used for nonsterile drug compounding and suggested that an amendment to 1735.1(c) to remove the word "sterile."

MOTION: Recommend that the board to modify its requirements to allow the use of a double filtration system in lieu of external venting and amend CCR section 1735.1 (c) to remove the word "sterile" from the definition of a BSC.

M/S: Weisser/Lipper Approve: 5 Oppose: 0 Abstain: 1

Dr. Acosta commented that USP 800 as well as the board's new regulations create a conflict with B&P 4127.7 relating to the use of ISO 5 laminar hood. Dr. Acosta noted that the board's statute also conflicts with Current Good Manufacturing Practices (cGMPs). Dr. Acosta continued to indicate that CCR section 1751 includes reference to title 24 building codes which may also require modifications.

The committee discussed the issue and decided to focus on the most urgent issues and then have a more robust discussion about additional issues with the board's regulation in the future. The committee requested that in the future draft regulation language be provided to the committee for consideration as part of the discussion.

MOTION: Recommend to the board repeal of BPC section 4127.7.
M/S: Weisser/Lipper Approve: 6 Oppose: 0 Abstain: 0

e. Presentation on Requirements for Sterile Compounding Master Formulas

Dr. Acosta provided a presentation on compounding master formula requirements.

f. Discussion and Consideration of the Proposed Food and Drug Administration Rule, "List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act"

Background
On December 16, 2016, the Food and Drug Administration proposed rule, List of Bulk Drug Substances that can be used to Compound Drug Products, addressing six bulk drug substances the agency has evaluated and is proposing for inclusion on a list of bulk drug substances that can be used in compounding under section 503A of the Food, Drug, and Cosmetic Act. The proposed rule also proposes that four other bulk drug substances that FDA evaluated not be included on the 503A bulks list.

If the proposed rule is finalized, the six bulk drug substances proposed for inclusion will be the first ones included on the 503A bulks list.

The public comment period on the proposed rule closes on March 16, 2017.

Discussion and Comment
Dr. Acosta and Chairperson Gutierrez agreed that this topic warrants further discussion at the next committee meeting.

V. Enforcement Statistics

The committee was directed to the following statistics:

a. Citations and Fines
b. Medication Errors
c. Other Enforcement Statistics

A copy of these statistics is provided on the board's website.

There were no board member or public comments.

Meeting Dates for 2017

The committee noted meeting dates for the remainder of the year.

- April 18, 2017
- July 12, 2017
- October 17, 2017

The meeting was adjourned at 3:31 p.m.