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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:	December 14, 2015
LOCATION:	DCA Headquarters, First Floor Hearing Room 1625 North Market Blvd. Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Amy Gutierrez, PharmD, Chair, Professional Member Greg Lippe, Public Member, Vice Chair Allan Schaad, Professional Member Rosalyn Hackworth, Public 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 Laura Freedman, DCA Staff Counsel Rob Buckner, Investigations Manager Laura Hendricks, Administrative Analyst

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:15 a.m.

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

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

Holly Strom, representing the Institute for Community Pharmacy and the Los Angeles County Safe Opioid Prescribing Coalition, requested that the committee add an agenda item to a future committee meeting to discuss the Sternberg case and its relevance and the implications relating to the role of the Pharmacist in Charge (PIC). She also suggested that various scenarios be discussed to aid PICs in understanding their role.

Steve Gray, representing the Institute for Community Pharmacy, expressed concern that the Sternberg case was being touted as a strict liability case. He stated that the board's interpretation could create problems in recruiting and retaining PICs.

Bill Maguire, representing Omnicell, requested that the board consider allowing automated delivery devices in post-acute care settings and provide clarity on the locations where the devices can be used.

Megan Maddox, representing the California Pharmacists Association, requested that the board add an agenda item to a future meeting to discuss the topic of compounding pellets in an ISO 5 as a possible hazard.

II. ENFORCEMENT MATTERS

a. Presentation by the California Department of Health Care Services on California's Drug Utilization Review Program and the Medi-Cal DUR Educational Bulletin on "Morphine Equivalent Daily Dose to Prevent Opioid Overdose"

Background

There is housed in the California Department of Health Care Services a Drug Utilization Review Committee that supports the state's Medi-Cal program in creating drug benefits. Board Member Allen Schaad has asked that this program provide an overview of its duties and functions to the board's Enforcement and Compounding Committee, this will occur during this meeting. There will be three presentations as part of this segment.

- Pauline Chan, R.Ph., MBA, California Department of Health Care Services
- Shal Lynch, PharmD, CGP,Health Sciences Associate Clinical Professor
  UCSF Department of Clinical Pharmacy, School of Pharmacy
- Randall S. Stafford, MD, PhD, Medi-Cal DUR Board Member, Professor of Medicine, Stanford University

Each day in the United States, 46 people die from an overdose of prescription opioid or narcotic pain relievers. Recent studies demonstrate that a patient's cumulative MEDD is an indicator of potential dose-related risk for adverse drug reactions to opioids, including overdose. As a result, many state Medicaid Drug Utilization Review (DUR) programs have established recommendations for MEDD or opioid dose limitation.

Discussion and Comment

At this meeting, Pauline Chan of the California Department of Health Care Services provided an overview of the Medi-Cal DUR program, and discussed the Medi-Cal DUR educational bulletin "Morphine Equivalent Daily Dose to Prevent Opioid Overdose." The committee also heard a second presentation from Shal Lynch of the University of California, San Francisco regarding the evaluation of morphine equivalent daily dose (MEDD) in patient care.

Ms. Herold mentioned that one of the red flags for opioid misuse is cash payments. She asked Ms. Lynch whether there is any plan to match fee for service data to the CURES data in order to track transactions in which a patient uses Medi-Cal to pay for one prescription then uses cash to pay for others. Ms. Chan answered they are looking into integrating CURES data.

Dr. Gutierrez asked whether health plans are required to track MEDD. Ms. Chan stated some health plans had asked for MEDD information that they could use but that tracking MEDD is not required.

Dr. Gutierrez also asked whether Medi-Cal takes any action if a patient exceeds the California MEDD limit of 80mg. Ms. Chan and Ms. Lynch stated that the 80mg cutoff acts as a warning trigger but that no action is currently taken when a patient exceeds the MEDD.

There were no public comments.

Committee Recommendation:

Motion: Add the MEDD educational bulletin to the board's website.

M/S: Lippe/Hackworth
Support: 4 Oppose: 0 Abstain: 0

b. Legislative Proposal for the Board of Pharmacy to Establish a List of Synthetic Cannabinoids that Would be Illegal for Use in California

Background

Spice (synthetic cannabinoids) and *bath salts* (synthetic cathinones) refer to two groups of designer drugs that have increased in popularity in recent years. These substances are created with *analogs* of commonly used illicit drugs. An analog is one of a group of chemical compounds that are similar in structure and pharmacology.

A form of synthetic cannabinoids, commonly referred to as "Spice" or "K2," is designed to affect the body in a manner similar to marijuana, but is not derived from the marijuana plant. These substances began appearing across the U.S. in 2008, and their popularity grew over the following years mainly because they could be sold legally and not detected in urinalysis drug tests.

These substances contain different ingredients that have been reported to cause a number of physical reactions including agitation, anxiety, nausea, vomiting, tachycardia, elevated blood pressure, tremors, seizures, hallucinations, paranoid behavior, and no responsiveness. Synthetic cannabinoids are not currently identified using routine screening tests, and the creation of new products of this type makes it difficult to detect these chemicals or regulate products that contain these substances.

Although these substances were made illegal nationally in 2012, synthetic cannabinoids and cathinones remain available, generally through black market internet sites, indicating a need for continued education, prevention, and enforcement.

Young adults and youth are often the buyers.

California's Health and Safety Code as amended effective 1/1/16 provides the following:

11375.5. [Stimulants]

(a) Every person who sells, dispenses, distributes, furnishes, administers, or gives, or offers to sell, dispense, distribute, furnish, administer, or give, any synthetic stimulant compound specified in subdivision (c), or any synthetic stimulant derivative, to any person, or who possesses that compound or derivative for sale, is guilty of a misdemeanor, punishable by imprisonment in a county jail not to exceed six months, or by a fine not to exceed one thousand dollars ($1,000), or by both that fine and imprisonment.

(b) Every person who uses or possesses any synthetic stimulant compound specified in subdivision (c), or any synthetic stimulant derivative, is guilty of-*an infraction, punishable by a fine not to exceed two hundred fifty dollars ($250).*

(c) Unless specifically excepted, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, or unless listed in another schedule, subdivisions (a) and (b) apply to any material, compound, mixture, or preparation which contains any quantity of a substance, including its salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers whenever the existence of such salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers is possible, that is structurally derived from 2-amino-1-phenyl-1-propanone by modification in one of the following ways:

(1) By substitution in the phenyl ring to any extent with alkyl, alkoxy, alkylenedioxy, haloalkyl, or halide substituents, whether or not further substituted in the phenyl ring by one or more other univalent substituents.

(2) By substitution at the 3-position with an alkyl substituent.

(3) By substitution at the nitrogen atom with alkyl or dialkyl groups, or by inclusion of the nitrogen atom in a cyclic structure.

(d) This section shall not prohibit prosecution under any other provision of law.

And

11357.5. [Synthetic Cannabinoids}

(a) Every person who sells, dispenses, distributes, furnishes, administers, or gives, or offers to sell, dispense, distribute, furnish, administer, or give, or possesses for sale any synthetic cannabinoid compound, or any synthetic cannabinoid derivative, to any person, is guilty of a misdemeanor, punishable by imprisonment in a county jail not to exceed six months, or by a fine not to exceed one thousand dollars ($1,000), or by both that fine and imprisonment.

(b) Every person who uses or possesses any synthetic cannabinoid compound, or any synthetic cannabinoid derivative, is guilty of an infraction, punishable by a fine not to exceed two hundred fifty dollars ($250).

(c) As used in this section, the term "synthetic cannabinoid compound" refers to any of the following substances:

(1) Adamantoylindoles or adamantoylindazoles, which includes adamantyl carboxamide indoles and adamantyl carboxamide indazoles, or any compound structurally derived from 3-(1-adamantoyl)indole, 3-(1-adamantoyl)indazole, 3-(2-adamantoyl)indole, N-(1-adamantyl)-1H-indole-3-carboxamide, or N-(1-adamantyl)-1H-indazole-3-carboxamide by substitution at the nitrogen atom of the indole or indazole ring with alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, or 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group, whether or not further substituted in the indole or indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent, including, but not limited to, 2NE1, 5F-AKB-48, AB-001, AKB-48, AM-1248, JWH-018 adamantyl carboxamide, STS-135.

(2) Benzoylindoles, which includes any compound structurally derived from a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring with alkyl, haloalkyl, cyanoalkyl, hydroxyalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, or 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent, including, but not limited to, AM-630, AM-661, AM-679, AM-694, AM-1241, AM-2233, RCS-4, WIN 48,098 (Pravadoline).

(3) Cyclohexylphenols, which includes any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, haloalkyl, cyanoalkyl, hydroxyalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, or 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or (tetrahydropyran-4-yl)methyl group, whether or not further substituted in the cyclohexyl ring to any extent, including, but not limited to, CP 47,497, CP 55,490, CP 55,940, CP 56,667, cannabicyclohexanol.

And more of this follows in the section.

Discussion and Comment

At this meeting, the committee reviewed and discussed a legislative concept that would be authored as 2016 legislation by Senator Hernandez to have the Board of Pharmacy establish a list of synthetic cannabinoids and stimulants that would be illegal for use in California until incorporated formally as statutory modifications into Health and Safety Code sections 11375.5 and 11357.5. Currently the Senator's office is working on the language.

Ms. Herold explained that the Controlled Substances Act is very specific. Because it is so specific about the type of substances that are illegal, one molecule of the substance can be changed and the substance becomes legal. The process to address the new substance and make it illegal by adding it to statute is long and complicated. Therefore, Senator Hernandez wants to find a way by which the board could provide an interim step, perhaps by emergency, short term regulations. This would allow law enforcement to use the board's regulation to arrest and prosecute vendors while the Department of Justice seeks revisions to the permanent statute.

The board heard comments from an individual who provided an article on Synthetic Marijuana Linked to Major Birth Defects and also asked how a pharmacist is supposed to provide patient consultation to an individual who is also taking medical marijuana. Dr. Gutierrez indicated that the item was not on the agenda and asked the commenter to keep her comments focused on cannabinoids or pending legislation. The commenter indicated she is in favor of the board working with Senator Hernandez's office.

Committee Recommendation:

Motion: Work with Senator Hernandez to develop the legislative concept.

M/S: Lippe/Hackworth
Support: 4 Oppose: 0 Abstain: 0

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

Background

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

This study was planned to start in June or July, 2015; however, 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.

Discussion and Comment

At this meeting, Dr. Hirsch provided an update via telephone and stated that the study would go live on December 15, 2015. She provided a timetable which indicated that UCSD began a pre-kiosk 6-month data collection during the last quarter of 2015. They will implement the device, enroll patients and refine data collection tools and processes during the first quarter 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.

Sharp will be marketing the kiosk to its employees and encouraging them to use it.

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

Steve Gray, representing Kaiser, asked if the data would be comparable given the study design and the seasonal timeframe for the data collection. He also asked whether UCSD would report at a drug-specific level and whether the study would be able to compensate for seasonal fluctuations (e.g., cold/flu season). Dr. Hirsch answered that the study will look at the return to stock rate for the pharmacy vs. the kiosk.

Dr. Gutierrez asked whether the drug class would be included in the data. Dr. Hirsch stated she thought they should have thought about collecting data at the drug class level and would be open to adding that data.

Committee Recommendation:

Motion: Request the collection of drug classifications as part of the study.

M/S: Lippe/Hackworth
Support: 4 Oppose: 0 Abstain: 0

d. Sunset Review Proposals

The board's 2016 Sunset Report was submitted to the Legislature when it was due on December 1, 2015. Below are several issues highlighted in the report.

1. Regulation of Outsourcing Facilities by the Board

Background

In 2012, medication contaminated by fungal material that was compounded by a Massachusetts pharmacy killed 65 and injured approximately 700 individuals in various

states. In response, the California Board of Pharmacy initiated a review of its then sterile injectable compounding requirements that had been enacted in 2001. Among other actions, the board sponsored legislation in 2013 to increase licensure requirements for sterile compounding pharmacies (SB 294, Chapter 565, Emmerson). The legislation expanded the definition of sterile compounding to include injectable medications, inhalation products and medication applied in the eyes. The law also eliminated accreditation by outside agencies as an alternative to licensure with annual board inspections, and the board began a massive upgrading of its sterile compounding regulations, a process that is nearing completion in late 2015.

The November 2013 enactment of the federal Drug Quality and Security Act (DQSA) responded to the 2012 compounding tragedy in a new way: this legislation created a new type of entity authorized to compound medications – the outsourcing facility. These generally large-scale production facilities are authorized to compound large quantities of medications for use by other entities, whereas a pharmacy generally compounds pursuant to a patient-specific prescription. Medications prepared by outsourcing facilities must be done under current good manufacturing practices (or cGMPs), which are more stringent than compounding requirements for sterile compounding pharmacies, since many patients in multiple locations can receive these medications that are not usually linked to patient-specific prescriptions.

Currently California is licensing as sterile compounding pharmacies federally licensed outsourcing facilities located within or shipping medication into California. This is increasingly losing its viability as a regulatory solution. First, it does not recognize the federal outsourcing requirements that permit large scale compounding. Second multiple states are moving to establish regulatory frameworks to license outsourcing facilities as separate entities, and some bar licensure of these facilities in their home states as sterile compounding pharmacies. This is currently an issue in Mississippi, and will be an issue in July in New Jersey. Several other states have pending legislation in this area as well.

In 2015, the board sponsored legislation (SB 619, Morrell) to license outsourcing facilities as separate entities both within and outside California to ship into the state. This bill was held in suspense by the Senate Appropriations Committee. In 2016, the board seeks to resume pursuing regulation of outsourcing facilities as separate entities. The Senate Business and Professions Committee will evaluate outsourcing facilities as part of its evaluation of the impact of the DQSA during our sunset review. A legislative solution is likely to come as part of this review.

Discussion and Comment

At this meeting, Ms. Herold explained that the sunset review committee staff has indicated that establishing a licensing program for outsourcing facilities located within and outside California will be a sunset issue for the board to address. Ms. Herold foresees the board working with the committee staff to find a solution.

Steve Gray, representing Kaiser Permanente, suggested that any proposed legislation be specific when defining the provisions for a pharmacy and an outsourcing facility to do business at the same location.

Ms. Herold clarified that the board does not allow two licenses to share the same premises. Some rare exceptions include a 3PL and a wholesaler as well as a wholesaler and a veterinary retailer. Two different licensees need to have a hard wall between them, must have separate ingress and egress, and must maintain separate records.

2. Registration of Automated Delivery Devices in Use

Background

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

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

The board has no idea how many of these machines are in use, where they are in use, or which pharmacy is responsible for any machine.

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

At the September 9, 2015, Enforcement Committee meeting, staff suggested that a simple registration be established for pharmacies that operate each of these machines that identifies their locations, as a beneficial step in board oversight and enforcement. The list

could be updated as needed via form submission to the board by a pharmacy adding, moving or removing a machine. This registration could operate much like the off-site storage waivers for records waivers. Then at annual renewal of the pharmacy, the pharmacy would update or confirm the list of machines it operates and where each is located. Staff noted that a regulation or statutory amendment is likely needed to establish this requirement.

Discussion and Comment

At this meeting, Dr. Gutierrez provided an overview of the background and Ms. Herold indicated that this proposal was one of the board's three recommendations in the sunset report.

There were no questions or comments.

e. Proposal for Routine Inspections of 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 means that the board's enforcement program is reactive rather than proactive and relies solely on being advised of a potential violation of pharmacy law via a complaint or other information that would trigger an investigation.

For a number of years the board has wanted 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. While 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

# 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 to complete follow up inspections of facilities previously issued either citations or letters of admonishment to confirm compliance.

Mandatory inspections once every four years would be an alternative to our current practice of conducting inspections principally to investigate problems (or inspect sterile compounders).

The board currently has 6,572 community pharmacies licensed in California. Some of these pharmacies have never been inspected by the board. The creation of a statutory mandate directing the board to perform inspections of all pharmacies every four years would require approximately 1650 routine inspections annually. Over the last two years, the board completed an average of 1,215 inspections annually (routine plus investigation inspections).

Discussion and Comment

At this meeting, Dr. Gutierrez provided an overview of the proposal. Ms. Herold advised that the board needs to commit to performing the proposed inspections. The inspections would allow the board inspectors to work proactively as a resource for pharmacies instead of initiating inspections reactively based on complaints.

Committee Recommendation:

Motion: Motion to create a statutory mandate to complete random, unannounced routine inspections of pharmacies once every four years.

Steve Gray, representing Kaiser Permanente, inquired whether the motion was intended to include all facilities the board licenses or just pharmacies. Second, he asked whether the motion was intended to include nonresident pharmacies.

Ms. Herold clarified that the motion was intended to include resident pharmacies and non-resident sterile facilities only. Ms. Herold stated that the National Association of Boards of Pharmacy is conducting inspections on nonresident pharmacies and that the board has staff in place to review the reports if the pharmacy is licensed in California. The board wants to complete the inspections without increasing the inspector staff or raising fees.

Committee Recommendation:

Amended Motion: Create a statutory mandate to complete random, unannounced routine inspections of resident pharmacies once every four years.

M/S: Lippe/Hackworth
Support: 4 Oppose: 0 Abstain: 0

f. Discussion on Items in the News:

1. "Preventing Diversion in the ED" from www.pppmag.com, November 2015

Background
An article was added to the agenda by Board President and Committee Chair Gutierrez. In the article, the author asserted that drug diversion by health care workers is quite common. The article reviewed the techniques health care workers use to divert drugs and suggested multifaceted approaches for preventing and identifying diversion.

This item was informational only. There were no questions or comments.

2. Settlement Agreement Between the Drug Enforcement Administration and Massachusetts General Hospital for Drug Diversion

Background
Earlier this fall, the U.S. Drug Enforcement Administration alleged that Massachusetts General Hospital failed to make and keep records required by the Controlled Substances Act, and failed to provide effective controls and procedures to guard against theft and loss of controlled substances from October 4, 2011 through April 1, 2015. On September 28, 2015, Massachusetts General Hospital agreed to pay a settlement amount of $2,300,000.

This item was informational only. There were no questions or comments.

g. Review of Controlled Substances Losses Reported to the Board

Background
Board discussions in recent meetings have included drug thefts from automated drug dispensing machines. Board staff was recently asked to tabulate how many controlled substances losses have been reported to the board from automated dispensing machines.

While there is no category listed on the DEA 106 report to capture this specific type of data, board staff reviewed all loss reports since January 1, 2015 and identified the following losses that had been identified in automated dispensing machines. When reviewing the data keep in mind that:

1. The amount of controlled substances reported lost is usually lower than the actual amount of loss determined at the end of an investigation, and

2. Without a reporting category for this type of loss, some losses from automated dispensing machines could be reported under other categories.

Reports of Losses Related to Automatic Dispensing Machines (ADMs: Pyxis, Omnicell, Acudose, etc.) January 1, 2015 - November 30, 2015	Total # Reports	ADM Losses - Percent of Total Reports	Total Dosage Units Lost
180	2,267	8%	6,714

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

Board of Pharmacy License Type for ADM Losses	# of Reports
Hospitals	177
Pharmacies	3
Total	**180**

Type of loss	# of Reports
Pilferage/Possible Pilferage or Not following proper procedures by nurse(s)	97
Unknown cause	78
Lost in transit to/from Automatic Dispensing Machine	2
Automatic Dispensing Machine error	1
Possible Pilferage by Pharmacy Technician	1
Possible Theft by patient	1
Total	**180**

The board will begin reporting all controlled substances losses reported to the board at each Enforcement and Compounding Committee Meeting.

Discussion and Comment

At this meeting, Dr. Gutierrez provided an overview and asked Ms. Sodergren to provide an analysis of the data. Ms. Sodergren explained that the Total Dosage Units Lost data was skewed by one large loss of over 4,600 units. If the one large loss is removed, the average loss is actually about 11 dosage units.

Regarding types of loss, Ms. Sodergren clarified that losses where the type of loss was unknown were very small. The highest loss was 25 dosage units, but the majority of losses were 5 dosage units or fewer. It doesn't appear that there are significant losses where pharmacies are unable to identify the cause.

Lynn Paulsen, speaking for herself, stated she believed there is an opportunity to improve controls with automated delivery devices. Currently, each facility decides how to best monitor the devices. She suggested that there be a "safe harbor" wherein a PIC would not be disciplined if they could prove they followed established guidelines/best practices for detecting drug diversion.

Dr. Gutierrez recommended that the board review the Mayo Clinic process for identifying potential diversion.

Bill Maguire, representing Omnicell, stated he believes establishing a best practices guideline for pharmacies, both manual and automated, would be a good idea.

Dr. Gutierrez asked why vendors do not do a better job of educating their customers about the systems and best practices. Mr. Maguire answered that some vendors provide education, but some customers might become overwhelmed. He indicated that canned reports are available, but staff has to review them and decide which best fit their needs.

Committee Recommendation:
Motion: Invite vendors to come to the next enforcement and compounding committee meeting to discuss reports/best practices for diversion detection.

M/S: Lippe/Hackworth
Support: 4 Oppose: 0 Abstain: 0

h. Update on the CURES 2.0 Prescription Monitoring Program

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

At the September 9, 2015, Enforcement Committee Meeting, staff from the California Department of Justice provided an update on the transition to the new CURES 2.0 system and advised the committee that CURES 2.0 should be available to users by January 2016. It was stated that 18,487 pharmacists, less than 50 percent of California's licensed pharmacists, had registered for CURES 2.0.

Meanwhile, the board continues to register pharmacists at continuing education events it hosts.

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. Ms. Herold stated that pharmacies will have until July 2016 to update their browsers to meet DOJ's security standards. Users must upgrade to Internet Explorer 11.0 or greater, or the most recent versions of Firefox, Chrome, and Safari. The Department of Justice will support CURES 1.0 until July 2016, but may only support CURES 2.0 afterward.

Ms. Herold believes online user registration will be available in January 2016. She indicated that DOJ is preparing an updated press release that should be available within the next few weeks. Once DOJ releases their update, the board will issue a new subscriber alert. Dr. Gutierrez asked that the board also include an article about CURES 2.0 enrollment in the next *The Script* newsletter.

Steve Gray, representing Kaiser Permanente, inquired whether other boards have indicated how or if they are going to confirm their licensees are enrolled as required. Dr. Gray suggested that the board send out its press release to national associations as well as state associations to account for licensed pharmacists living in other states or countries.

Angie Manetti, representing the California Retailers Association, was encouraged to hear that the deadline has been extended to July 1, 2016 as many of her members were in the process of completing complicated and expensive updates to their entire computer systems.

i. Enforcement Options for Patient Consultation Violations

Background

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

Sometimes California's requirements are confused with national requirements enacted about the same time by CMS for Medicare patients in what was known as "OBRA 90." However, California's requirements were actually adopted before OBRA 90's requirements. The OBRA 90 requirements provided that Medicare patients be offered consultation when they receive medication for the first time. So California's requirements, requiring the pharmacist to initiate consultation, were stronger and broader than the OBRA 90 requirements in that they

pertained to all patients, not just those whose medications were paid for by Medicare, establishing one standard of care for all patients in California.

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

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

Over the years, the board has added other enhancements to help ensure patients receive meaningful consultation, including a "Notice to Consumers" poster that must be posted in a pharmacy that specifically states the pharmacist must consult with each patient about his or her new medication, and lists the 5 questions a patient should understand before taking a prescription medication.

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

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

In 2011, board staff began working on a project with three California district attorneys' offices to aid in the board's enforcement of patient consultation. Using the state's unfair business practices statute in Business and Professions Code section 17200, the DAs' offices were able to assess higher fines for failure to consult. Additionally, the DAs' offices used undercover investigators to pass prescriptions, an action the board has not done.

The DAs' investigations have resulted in more substantial fines to three pharmacy chains where investigations have been completed – CVS (2013, $658,500), Rite Aid (2014, $498,250) and recently Walgreens (2015, $502,000).

At the September 9, 2015, committee meeting, the committee heard questions and comments from the public regarding whether the board can prohibit the use of a system that requires a patient to accept or decline patient consultation in advance of payment. The committee requested that the Communication and Public Education committee focus on consumer education and why patient consultation is important.

Discussion and Comment
This item was added to the agenda in the event the committee wished to discuss sanctions for failure to consult, or to wait for the Communication and Public Education Committee to complete its work on reviewing consultation matters before discussing sanctions.

Dr. Gutierrez indicated that it was her understanding that this item would be deferred to the Communication and Public Education Committee for follow up.

Ms. Herold verified that the Communication and Public Education Committee was given general responsibility for uncovering the reasons why consultations aren't being performed. She believed it was appropriate to wait until the Communication and Public Education Committee finishes its work before the Enforcement and Compounding Committee proceeds any further.

j. Discussion and Update to the Board's Emergency Response Policy

Background
On September 15, 2015, the board held an Emergency Board Meeting in response to the wildfires in Lake and Napa counties. In light of the recent use of the policy it is being brought to the board for evaluation and assessment to determine if changes to the policy are necessary.

At the October 28-29, 2015 board meeting, this item was referred to the enforcement committee for discussion.

Discussion and Comment
At this meeting, Ms. Freedman provided some background and discussed some of the challenges of the current policy. The current policy suggests that a meeting wouldn't need to be held pursuant to the open meeting act. She advised amending the opening statement to specify that if the board is not able to establish a quorum, three members would be able to exercise the board's authority pursuant to Business and Professions Code section 4062.

Ms. Freedman also stated that the board has other options including delegating the authority to a specific board member, perhaps the board president. She recommended that if the board chose that option, that it limit the authority to 14-30 days.

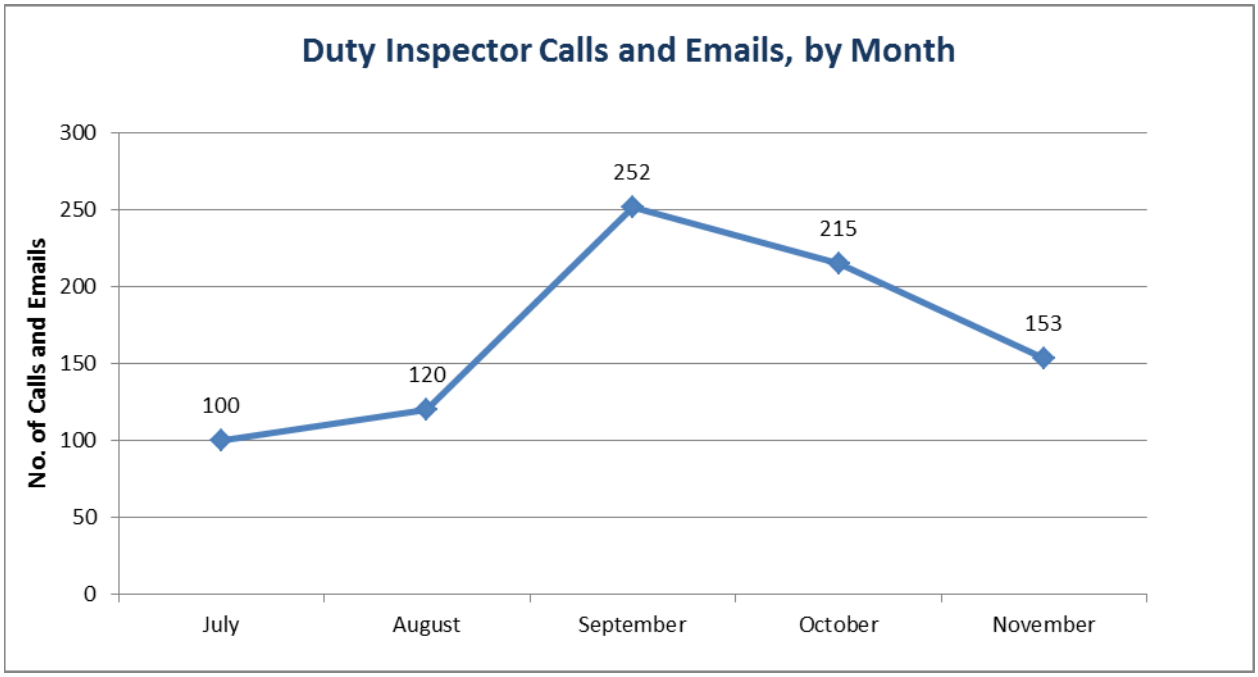
Committee Recommendation:
Motion: Modify board policy to delegate its authority pursuant to Business and Professions Code section 4062 to the board president for a period of 30 days.

M/S: Lippe/Hackworth
Support: 4 Oppose: 0 Abstain: 0

k. Review of Duty Inspector Activities

Background
Since July 1, 2015, Pharmacy Board inspectors have responded to 840 calls, an average of 168 calls each month. The board's highest month was September, with 252 calls. July was the lowest month, with 100 calls.

Chart: All Inspector Calls, Trends by Month



In September, the board expanded its inspector answer program in two ways. First, the board tripled the hours inspectors take phone calls from six hours each week to 16 hours. Second, the board added the "Ask.Inspector" email box. Board inspectors respond to emails five days a week. Additionally, in September, licensees were sent a Subscriber Alert to let them know of the board's expanded inspector hours.

The addition of the added call hours and the email box has resulted in a significant increase in activity. In September, inspector requests more than doubled from August. There were 120

calls in August and 252 in September, an increase of 115 percent. In September and October, inspectors handled more than 200 calls each month. In October and November, the number of calls declined but not yet back to the August levels.

The September spike in inspector calls may be temporary, but it is too soon to be certain. The board's office was closed for three days in November for holiday observances. It is possible these closures contributed to the declines.

We will continue to provide these statistics at future meetings.

The board's new public information officer is beginning to work to establish an online resource directory FAQ. The goal is to put many questions and answers online so individuals may find their own answers. The public information officer is just beginning training to do this.

Discussion and Comment
Dr. Gutierrez reviewed duty inspector activity statistics.

Ms. Herold indicated that the new Public Information Officer is working on an online FAQ directory. She estimated the FAQ's would be available in 30-90 days.

There were no questions or comments.

III. COMPOUNDING MATTERS

a. 2015 FDA Intergovernmental Meeting on Drug Compounding and Drug Supply Chain Security Held in November 2015

Background
On November 16 and 17, the FDA convened the 2015 Intergovernmental Working Meeting on Drug Compounding and Supply Chain Security. This meeting had representatives from about 45 states and was intended to exchange information with states as the 2013 Drug Quality Security Act is being implemented.

Executive Officer Herold and a deputy director from the California Department of Public Health were California's attendees.

The purpose of the meeting was to update states on emerging FDA policy regarding sterile compounding, outsourcing facilities and supply chain security requirements (the latter are the provisions that preempted California's e-pedigree requirements).

Most of the meeting focused on compounding/outsourcing requirements, with the last quarter of the meeting focusing on the licensing requirements for wholesalers and third-party logistics providers. Executive Officer Herold provided presentations during both segments.

Below is an overview of the agenda:
1. Compounding Regulatory Policy Update
2. Draft Standard Memorandum of Understanding between FDA and the States
3. Information Sharing and Disclosures (between state agencies and FDA)
4. A Comparison of US Pharmacopeial Convention General Chapter 797 to the Current Good Manufacturing Practice Regulations Enforced by DEA
5. Inspections of Sterile compounding Facilities and Enforcement
6. State Handling of Outsourcing Facilities
7. Overview of DSCSA Implementation
8. Wholesaler Distributor and 3PL Provider Licensing
9. FDA and State Collaboration

Discussion and Comment

At this meeting, Ms. Herold discussed and highlighted information from the FDA meeting. Specifically, Ms. Herold indicated that the FDA is inspecting pharmacies and notifying the state boards of pharmacy when follow-up is needed. Additionally, Ms. Herold stated that some states are inspecting outsourcing facilities using USP 797 (including California) although the FDA is regulating outsourcing facilities using Current Good Manufacturing Practices (CGMPs). The board has a bill that will become a sunset issue regarding the future regulation of outsourcing facilities.

Ms. Herold noted that many states are attempting to catch up to the new federal requirements and many don't have requirements to fingerprint their applicants. This highlights this disparity in regulation and oversight when shipping across state lines.

The FDA was to have some documents on wholesaler and 3PL licensure available on November 27, 2015, but the documents are still in the draft and review phase and are not yet ready for release.

Dr. Gutierrez asked for clarification on USP 797. Ms. Herold stated that 797 is a guideline that the FDA allows to be enforceable. Years ago, the board asked if the state could require 797 by itself, but the board's attorneys determined that the germane parts of 797 would have to be placed into law. The board is almost finished adding those germane parts of 797 to state law.

There were no public comments.

b. Development of a Waiver Process from Building Standards Requirements Contained in Proposed Title 16 California Code of Regulations Sections 1751 et seq.

Background

During the October 2015 board meeting, the board discussed and took action on proposed changes to compounding requirements. As part of this discussion, the board discussed the need to establish a waiver requirement for some of the structural requirements. Suggested components to facilitate such a process were included in the most recent modifications to the proposed regulation (where the comment period ended December 5). 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

Consistent with the proposed language which was noticed for comment, board staff will work on development of a specific format upon adoption of the language by the board. Board review of the last proposed modifications to the compounding regulation will be scheduled for the next board meeting.

This item was informational only. There were no questions or comments.

c. Review of "USP <800>: Key Considerations and Changes for Health Systems," Hospital Pharmacy 2015; 501(1):941-949

Background

This topic was added to the agenda by President Gutierrez.

On March 28, 2014, the United States Pharmacopeia and the National Formulary (USP-NF) published USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings, as open for public comment in the USP Pharmacopeial Forum (PF) 40(3). USP <800> serves as a new standard to guide the handling of hazardous drugs in order to protect patients, health care personnel, and the environment. USP <800> describes hazardous drug handling related to the receipt, storage, compounding, dispensing, and administration and disposal of both sterile and nonsterile products and preparations. According to this review, "Although complying with USP <800> may seem to be a daunting task, it can be manageable if approached in a systematic organized way. "

The final version of the chapter will be published on Feb 1, 2016 and USP states it will become enforceable on July 1, 2018.

This item was informational only. There were no questions or comments.

IV. MEETING DATES FOR 2016

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

- March 2, 2016
- June 1, 2016
- August 31, 2016

Dr. Gutierrez adjourned the meeting at 12:53 p.m.