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

DATE: July 12, 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
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
Thomas Lenox, Chief of Enforcement
Laura Freedman, DCA Staff Counsel
Christine Acosta, PharmD, Supervising Inspector
Peg Panella-Spangler, PharmD, Supervising Inspector
Veronica Wogec, Staff Services Manager II
Laura Hendricks, Executive Assistant

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

Chairperson Gutierrez called the meeting to order at 9:36 a.m. Roll call was taken and a quorum was established with the following members present: Ricardo Sanchez, Valerie Munoz, Greg Lippe, Amy Gutierrez, and Allen Schaad.

Note: This meeting was not webcast.

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

Chairperson Gutierrez asked if there was any public comment on the items not on the agenda or for agenda items for future meetings.

There was no public comment.

III. Enforcement Matters

a. Discussion and Consideration of Reporting Drug Losses Under State and Federal Laws.

Background
CCR Section 1715.6 establishes the requirement for the owner to report any loss of controlled substances within 30 days to the board.

CFR Section 1301.76(b) established a requirement for reporting of a significant drug loss to be reported to the Drug Enforcement Administration.

At prior meetings, the committee discussed the federal and state requirements for the reporting of lost controlled substances under federal and state law. California Code of Regulations, Title 16, section 1715.6, Reporting Drug Loss, states;

"The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

Federal regulations require that registrants notify the Drug Enforcement Agency (DEA) Field Division Office in their area, in writing, of the theft or "significant" loss of any controlled substance within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in their area, DEA Form 106, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss. Below is Title 21, Chapter II, Code of Federal Regulations, 1301.76 (b).

Ms. Freedman indicated at a prior meeting that the addition of the word "significant" would create lack of clarity in what licensees are required to do under regulations, as it is a subjective term.

Discussion and Comment
Chairperson Gutierrez explained that California uses a broader term and uses "any loss" of controlled substances. The committee noted that "significant" to a large pharmacy may have a different meaning to a small pharmacy. Ms. Herold stated the regulation providing a requirement for quarterly inventory reconciliation counts of all federal Schedule II drugs will be going back to the board at the July board meeting. If the board adopts it without changes it will go forward to the outside administrative agencies. Staff commented it could be beneficial to review drug loss data after the reconciliation regulations go into effect to allow for analysis of the pre and post data, and to see if there is a difference in the reporting of smaller losses opposed to larger losses that we are seeing now.

The committee discussed whether it is going to make changes to CCR 1715.6 and to consider directing staff to continue provide the drug loss reporting under CCR 1715.6 and monitor what impact the pending amended regulations have on drug losses.

The committee reviewed the drug loss statistical reports which covered fiscal year (FY) 2012/13 through FY 2016/17(ending May 2017) and noted that the reports were very informative. The top drug group loss in the last fiscal years reported was Hydrocodone, at 42% of the overall total of losses. Hydrocodone was also the top reported drug loss, by drug name, at over 38%. Chairperson Gutierrez asked if the staff knew if this was a result of hydrocodone becoming a Schedule II drug. Ms. Herold recalled there was a 20% drop in California and it was similar across other states.

The report revealed that dosage units per loss type was high and the committee requested staff to drill down in the data on a few categories, such as the loss types "other" and "unknown." Mr. Schaad asked for the mean and a distribution per number of losses for the 4,000 and 6,000 loss reports.

The report revealed that losses are on the rise. The table for FY 2015/16 showed a total of over one million and a half dosage units lost compared to FY 2016/17 (through May) with over 2 million dosage units lost. The data exhibited large amounts of theft and night break-ins. Board staff mentioned they have heard from pharmacies that robberies and night break-ins are on the rise.

Chairperson Gutierrez recommended for clarity that staff break down by pharmacy types what is included in the "chain stores" with respect to dosage unit losses. The committee requested losses for Southern California and Northern California be broken down and to include a denominator. There may be twice as many pharmacies in Southern California, therefore twice as many losses. Ms. Herold stated we need to know how to track it over time because it will provide us with meaningful data for future policy meetings. Chairperson Gutierrez suggested that the committee take the drug data subject off line to be able to put together a packet the data elements and denominators needed. The committee agreed to meet in the future regarding the specifics needed in tracking the data and future reporting.

The committee continued the discussion on whether or not to add the word "significant" to any of the regulations. Dr. Gutierrez asked when the board receives a drug loss report, with the word "any", does the staff review those and do they stratify what the actions are to determine what is high risk. The committee discussed what the benefit would be in adding the word "significant." Ms. Sodergren explained that from the staff perspective it is not believed that the word "significant" should not be added in because one unit of fentanyl may be different than not one unit of hydrocodone. Staff not only looks at a single loss but also looks at an aggregation over time for that facility. Once staff is able to look at the data pre-inventory reconciliation and then the post-inventory reconciliation the board will have two sets of data for comparison to better analyze the issue.

Ms. Herold explained that early on there were pharmacies that were required by the DEA to do total counts and report single losses. At first there were complaints but when they report the one, two and three pill losses, it shows accountability that they would not have had. Public Member Greg Lippe commented pharmacies that are doing 100,000 prescriptions a year may be different than the one that is doing minimal prescriptions per year. The losses are on the rise and it was agreed upon again to wait for the results on the reconciliation regulations, and not add the word "significant."

Drug loss statistics were provided to the committee.

Public Comment

Tim Lopez, Pharmacy Manager, Community Regional Medical Center, commented on the proposed language for CCR 1715.65, regarding reconciliation. Chairperson Gutierrez explained that CCR 1715.65 was not on the agenda and we could not discuss this item. This will be discussed at the July board meeting.

b. Discussion and Consideration on Drug Diversion by Employees and Proposal to Mandate Reporting to Law Enforcement.

Background

Business and Professions Code (BPC) 4104 in part, establishes the requirements for a pharmacy to notify the board within 14 days of specified information including theft, diversion or self-use of

dangerous drugs. A copy of BPC 4104 was provided to the committee.

During the May Board Meeting, Board Member Albert Wong asked that the board agendize a discussion on the mandatory reporting of drug diversion and/or theft to the appropriate law enforcement agency. There is currently no requirement to report drug diversion and/or theft to law enforcement agencies although the board has encouraged pharmacies to contact law enforcement agencies when employees admit drug thefts or work under the influence. Based on reports to the board under BPC 4104, the board has opened 112 case investigations.

Discussion and Comment

The committee discussed adding mandatory reporting language regarding drug diversion and or/theft to the regulations. Staff recommended the following language to amend BPC 4104:
"(f) Every pharmacy shall contact local law enforcement within 24 hours when an employee admits to drug theft or being chemically, mentally, or physically impaired as provided in this section. A copy of the report shall be retained for three years."

Chairperson Gutierrez explained that if and when we identify there is a theft that a police report be filed immediately. This would positive for the board to allow the board to identify when theft occurs and who the individuals are.

Ms. Herold explained that if we get the arrest report earlier, we can initiate action to remove the individual from practice, even on the allegations and ask the court to take away their license. As it stands now, an individual can get caught stealing from their employer, get fired and still obtain another job at another pharmacy. It may be two years before discipline is finalized even on that mandatory report received from the pharmacy, but if the individual gets arrested the board would have the ability to have them removed or restrict the license in a way that keeps them out of the pharmacy, while the board goes through the disciplinary process.

Mr. Sanchez voiced that typically in the legal system it is important to wait for adjudication before putting a label on an individual.

Ms. Sodergren stated she assumed the authorities would not make an arrest just based on a report from a pharmacy but rather there is an investigation or an admission to back up the allegation. Some pharmacies notify law enforcement and often there is no subsequent arrest. When a licensee is arrested, the board has the ability to request practice restrictions in criminal court.

The committee discussed the issue and considered language offered that could be used to facilitate implementation of the requirement. The committee agreed that the requirement, if pursued should only apply to drug thefts.

The committee did not take action on this item but requested that staff collect data on drug losses reported to police versus those not reported as well as the case outcomes. This item will be brought back to the committee for further discussion after the data is available.

c. Update on the Development of the Joint Training from the Board and the DEA on CURES and Prescription Drug Abuse.

Background
In March 2017, the board, DEA and the University of California, San Diego (UCSD) provided a day-long conference on prescription drug abuse, corresponding responsibility and preventing drug losses from a pharmacy. There were 200 attendees who earned 6 hours of continuing education (CE) credits, and another 132 attendees earned one additional hour of continuing education to secure the training needed to provide naloxone under California's protocol. Since March, Executive Officer Virginia Herold and Enforcement Chief Tom Lenox have been working on additional joint training sessions on opioid abuse for 2017. The tentative training schedule is below:

- August 26 - One full day training session at Cal Northstate University, College of Pharmacy in Elk Grove (7 units).
- October 21 - One full day training session at Keck Graduate Institute in Claremont (7 units).
- November 7 - One 3-hour training session from 6-9pm at the Catamaran Hotel in San Diego, this session will be a part of the California Opioid Summit hosted by a variety of organizations including the California Department of Public Health (3 units).

Motion: The board recommended to award continuing education credit for individuals attending the training sessions.

M/S: Lippe/ Munoz Approve: 5 Oppose: 0 Abstain 0

d. Safe Medication Transitions for Patients Being Discharged.

A handout titled The *Safe Medication Transitions: Evidence-Based Solutions Infographic* was provided.

Background
A significant number of errors are found on patients' computer hosted medication lists which results in errors during hospital admissions and adverse outcomes post-discharge, including emergency department visits and readmissions. Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

Discussion and Comment
During the meeting the committee heard a presentation from Dr. Rita Shane on The *Safe Medication Transitions: Evidence-Based Solutions Infographic.* The presentation highlighted the benefits to patients when pharmacists and training technicians are involved in medication reconciliation as part of the admission and discharge of a patient from a hospital. As part of the presentation, Dr. Shane shared her recommendations for pharmacy staff to ensure the accuracy of the medication lists at admission and discharge for high risk patients. The committee discussed the findings of the study and the benefits to patient outcomes.

Listed below are some of the highlights of Dr. Shane's presentation:

- Top 3 concerns of hospital executives: 1. Inconsistent practices across departments, disciplines and shifts (59.7%) 2. Patients being discharged with an incorrect medication list (47.9%) 3. Difficulty importing external medication history, including home medications (46.2%)
- Medication discrepancies occur in up to 70% of patients at hospital admission or discharge.
- 67% of patients have medication errors on their medication lists upon admission.

- 82% of patients >65 years old have at least 1 discrepancy on their medication list.
- 7.4 errors per medication list in high risk patients.
- During hospitalization, medication errors occur in up to 50% of adult and 75% of pediatric patients.
- Over one third of hospitalized patients had medication order errors - 85% originated with the medication history. Up to 59% of medication history errors can cause harm.
- Up to 80% of patients have at least one medication list discrepancy upon leaving the hospital.
- A May 2017 Wall Street Journal article highlighted that to make hospitals less deadly, bring in pharmacists. The article stated 94% of harmful errors were intercepted by pharmacists.
- Discharge medication lists completed by pharmacists resulted in an absolute risk reduction of 46.5% when compared to usual care.
- Post-discharge pharmacist follow-up with discharge education reduced readmissions and ED visits vs usual care (39% to 24.8%).
- Post-discharge pharmacist reconciliation and education reduced readmissions and ED visits vs usual care (0% vs 40.5%).
- Post-discharge pharmacist follow up can reduce readmission from skilled nursing facility by 25%.
- In the ED, a pre-post study found that pharmacy technicians created an accurate medication history 88% of the time compared to 57% of the time when nurses completed the history ($p<0.0001$).

In summary, Dr. Shane recommended that for high risk patients, pharmacy staff will ensure the accuracy of the mediation list at admission and discharge.

Ms. Herold commented this is an educational opportunity to educate patients on the importance of knowing their medication lists. Ms. Sodergren stated there may be an opportunity in our law to recognize that some of these duties be handled by pharmacy technicians and could be a topic discussed within the licensing committee.

Public Comments

Art Whitney, Pacific West Pharmacy, commented discharge paperwork can be 20 pages long per patient. If you increase the technician ratio, the pharmacists could spend more time on this issue.

LoriAnne DeMartini, CEO, California Society of Health-System Pharmacists, agreed with Dr. Shane's recommendation. CSHSP is launching a certificate program in conjunction with Cedars Sinai, regarding transitions in care. She encouraged discussion on this issue with CDPH, as sometimes Title 22, CFR 42, pertaining to hospitals and nursing homes is in conflict with the board's laws and regulations.

The board recommended referring a portion of this issue to the Communication and Public Education Committee to develop consumer education materials highlighting the importance of maintaining and conveying medication history to health care providers in a hospital and the importance of understanding how medication lists change at discharge. Further, refer the role a pharmacy technician can play to the Licensing Committee to consider what, if any changes should be made to the functions a pharmacy technician may perform in a hospital.

e. Discussion and Consideration of Recalls of Drug Manufacturers at the Patient Level.

Background

At the board's request, staff reviewed all subscriber alerts involving recalls that were sent from the board from May 2014 through May 2017 at the patient or pharmacy level. A list of drug manufacturer recalls was provided. There were 785 recalls issued and the greatest number of recalls from any manufacturer was 67. The data lists the top 20 manufacturers that had recalls. It should be noted that

some of the manufacturers could be subsidiaries to other manufacturers but are listed according to how the recall and manufacturer's name was submitted.

Discussion and Comment
The committee discussed the information provided and requested that staff further separate the data to identify what recalls were at the patient level versus the pharmacy level for the last year.

The committee did not take action on this item.

f. Discussion and Consideration on Request for Wholesalers to Report Suspicious Drug Sales.

Background
Current California law on wholesalers furnishing controlled substances states that no wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer in California shall furnish controlled substances for other than legitimate medical purposes. Violations shall be punishable by imprisonment or fine, or both, fine and imprisonment. California Health and Safety Code, Section 11153.5 was provided to the committee.

Federal law under the Code of Federal Regulations, Title 21, Part 1301, section 1301.74 (a) (b) was provided to the committee. In summary this section provides the following:

Before distributing a controlled substance the registrant shall make a good faith inquiry either with the Administration or with the appropriate state controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance. If the registrant is suspicious that they are not registered, they shall inform the Field Division Office of the Administration. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Earlier this year two large drug wholesale distributers agreed to pay millions of dollars in civil penalties for alleged violations of the Controlled Substance Act (CSA). The distributors allegedly failed to notify the DEA of suspicious orders for controlled substances. McKesson Corporation agreed to pay a record penalty of $150 million and suspended their sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida for multiple years. McKesson also agreed to compliance terms for the next five years that includes specific, rigorous staffing and organizational improvements. Cardinal Health has agreed to pay $44 million in fines for allegations that it failed to alert the DEA of suspicious orders of powerful narcotics by pharmacies in Florida, Maryland and New York.

Committee Discussion
The committee discussed action taken by the Oregon Board of Pharmacy wholesale distributors to report "suspicious orders" to its board. The rule went into effect on July 1, 2017.

The committee reviewed the language adopted by Oregon:
"A wholesale distributor must notify the Board in writing of suspicious orders of controlled substances to be distributed in Oregon upon discovery. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." OAR 855-065-0010. (This notification must be in writing, which means a written letter, email or fax copy of what is submitted to the DEA)

As part of its discussion, the committee considered if California should pursue a similar mandatory reporting requirement and considered possible language that could be used to implement such a

requirement, which is provided below:

Upon discovery, a wholesale distributor must notify the board in writing by letter, email or fax, of suspicious orders of controlled substances to be distributed in California upon discovery. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Chairperson Gutierrez requested this item be added to the next board meeting agenda. Ms. Herold commented that while there are no requirements for wholesalers to report excessive or suspicious orders to the board, there have been several such reports made in the last few years.

Public Comment
Danny Martinez, CPhA, voiced concerns regarding the manner in which the notification must be provided. Chairperson Gutierrez suggested Mr. Martinez to provide the board with recommendations regarding the optimal method of communication of notification for consideration at the next board meeting.

Motion: The board recommended pursuing a mandatory reporting requirement for wholesalers either through statute or regulation. Staff to draft proposed language for next board meeting.

M/S: Lippe/ Munoz Approve: 5 Oppose: 0 Abstain 0

g. Discussion and Consideration of the California State Auditor Report on Home-Generated Sharps and Pharmaceutical Waste.

Background
Over a year ago, the Legislature requested that an audit of home-generated sharps and pharmaceutical waste services be conducted by the State Auditor Agency. The audit report was recently released; below is a summary of the report's recommendations as well as comments made by the State Auditor Agency. This report is provided for information to the community.
On June 6, 2017, the board's take-back regulations took effect.

Committee Discussion
The report concluded the Legislature should provide CalRecycle statutory oversight responsibility for home‑generated sharps and pharmaceutical waste disposal, and provide CalRecycle additional resources to the extent it can justify the need. This responsibility should include:

- Developing and implementing a public education campaign about home‑generated sharps and pharmaceutical waste. CalRecycle should coordinate this campaign with local, state, and, to the extent possible, federal agencies to ensure consumers receive consistent guidance regarding proper disposal methods.
- Maintaining an up‑to‑date, well‑publicized, and accessible statewide list of free sharps and pharmaceutical waste collection sites.
- Increasing consumer access to proper disposal sites in underserved areas.

To increase in-state options for processing California's home-generated pharmaceutical waste, the Legislature should consider expressly authorizing municipal solid waste incinerators to burn limited quantities of home‑generated pharmaceutical waste, but only after considering environmental impacts. To ensure consistency throughout the state, the Legislature should adopt standard requirements for counties to follow when implementing Extended Producer Responsibility (EPR) programs. These

requirements should limit any additional costs the programs may impose on consumers.

The State Auditor Agency commented that although it recommended that CalRecycle be the lead state agency over the disposal of sharps and pharmaceutical waste, CalRecycle took issue with certain information in its report and expressed significant reluctance in taking on this leadership role.

California State Auditor Summary of Report Number 2016-127 was provided. The full report may be found at: http://www.auditor.ca.gov/pdfs/reports/2016-127.pdf.

Ms. Herold commented that we have regulations that establish requirements for pharmacies with respect to collection receptacles. The board's regulations follow very closely what the DEA has authorized with respect to controlled drugs. It seems this structure within CalRecycle will run parallel with the board's requirements. There are two bills in the legislature that could be amended to take authority over from the board which would put the board as the second regulator in this space. Ms. Herold state she believes the board will have some participation in the regulation of Home-Generated Sharps and Pharmaceutical Waste.

The committee did not take action on this item.

IV. Compounding Matters

a. Review and Discussion of the Board's Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq., and Relevant Chapters of US Pharmacopeia Relating to Compounding.

Relevant Law
CCR Section 1735 et seq., and CCR section 1751 et seq., establishes the requirements for compounding drug preparation.

Business and Professions Code section 4127.1 requires the board to adopt regulations to establish policies, guidelines and procedures to implement Article 7.5, Sterile Drug Products, and further requires the board to review any formal revisions to General Chapter 797 of the United States Pharmacopeia and the National Formulary (USP-NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official.

Background
In April 2015, the board formally initiated a rulemaking to promulgate the board's compounding regulations. The final version of the regulation language was adopted by the board on January 19, 2016, and approved by the Office of Administrative Law on September 13, 2016. The effective date of the regulations was January 1, 2017.

Since adoption, both the committee and board have received public comment regarding the impact of the regulations on patient populations principally for oral compounded preparations, including animals.

In response to the public comments, the committee held a special meeting on June 2, 2017 that focused solely on the board's compounding regulations. As part of the meeting, the committee reviewed written comments and recommendations from board staff and members of the regulated public as well as heard public comments during the meeting. At its conclusion, the committee approved the recommendations offered by staff. The committee also requested that members of the public provide examples of compounded preparations that would provide additional context to support

requested changes. Furthermore the committee requested that staff evaluate comments received from the public and provide recommendations.

Since that time, board staff reviewed the comments provided, reviewed the examples submitted and conferred with internal and external experts. A grid was provided detailing the requested amendments to various sections of the compounding regulations, staff's recommendation, and a brief statement supporting the recommendation. Supplemental information submitted by stakeholders and the draft minutes from the June 2, 2017 compounding meeting were also provided.

b. Discussion and Consideration of Possible Recommended Changes to Board Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq.

Committee Discussion

As part of its discussion the committee considered possible changes to the regulations being requested by members of the regulated public as well as board staffs' recommendations to each of those changes.

After discussion and consideration of both written and public comment, the committee provided guidance to staff in several areas. The committee noted in several areas, that changes were not necessary as the underlining principle of the board's regulation is that a pharmacist use professional judgement.

Staff drafted proposed language that could be used to implement the recommended changes. Below is a list of each of the sections where amendments are being suggested.

CCR 1735.1

- CCR 1735.1 (c) & (f): This change was approved by the board during the January 2017 Board meeting.

- CCR 1735.1 (l): Staff recommended rejecting to amend the definition of "daily" to specify that electronic monitoring of temperatures be allowed. Additional guidance will be developed through FAQs.

- CCR 1735.1(n): Staff recommended rejecting to amend the definition of "dosage unit" to be one prescription but offer amendments in other areas. Recommended language was provided by staff under CCR 1751.7(e) and e(2)(c).

- CCR 1735 (r): Staff recommended to agree to update the definition of hazardous to mirror USP <800) by July 1, 2018. A copy of a USP <800> reference document was provided to staff and board members during the meeting. Staff recommended not to include this amendment in the emergency regulations and to be given the opportunity to better vet the issue for a future amendment. Board requested staff to provide suggested language on this regulation for the next enforcement committee meeting.

- CCR 1735.1: Staff recommended rejecting the addition of the definition of "sterility" and "stability". Additional guidance will be developed under FAQs.

Public Comments

Danny Martinez ,CPhA, commented on CCR 1735.1(l) concerning electronic monitoring and providing clarification in a FAQ versus a regulation with respect to how it will be applied consistently by inspectors in the field. Ms. Herold stated in any instance where there are inconsistencies, individuals to should contact a Supervising Inspector at the Board or Ms. Herold directly to voice their concerns and decrease

inconsistencies. Specifically, with respect to "sterility" and "stability" Mr. Martinez had concerns about these being referenced in an FAQ for consistent application.

Paige Talley, California Council for the Advancement of Pharmacy, CCR 1735.1(e)(1) stated USP <797> only states the minimum required air pressure differential and, there is no maximum in the USP chapter. Ms. Sodergren replied that Board staff received these comments late yesterday and will need time to review the information before a response can be provided.

Committee Discussion

- CCR 1735.2(a): Staff recommended rejecting to remove the requirement to document prescriber authorization to compound a product. The committee requested additional research is evaluated by board staff for consideration at a future meeting.

- CCR 1735.2 (c): Staff recommended rejecting to expand prescriber office use provisions and change in the definition of "reasonable" quantity. If the federal government makes changes in this area, it may be appropriate to re-evaluate.

- CCR 1735.2(d): Staff recommended rejecting to change regulation to indicate that prohibitions to compounding only apply to human drugs. Under both USP <795> and <797> and California law, the compounding of veterinary products must meet the same standards and preparation as humans.

- CCR 1735.2(i): Staff recommended accepting to clarify the board's interpretation of "identical". Additional guidance will be developed through FAQs or possibly through a definition in regulation for both nonsterile and sterile.

- CCR 1735.2(i)(1): Staff recommended accepting to clarify the conditions under which a BUD can be extended for a non-sterile compounded preparation. The Board recommended pursuing a regulatory amendment which requires emergency adoption procedures. (See board motion at the end of this section.)

- CCR 1735.2(i)(2-4): Staff recommended accepting in part the requirements to extend a BUD on sterile products. The committee requested that additional research be evaluated by board staff for consideration of assignment of a BUD for sterile products at a future meeting.

- CCR 1735.2(i)(5): Staff recommended rejecting the concern with the conditions for establishing a shorter BUD. This provision was included in CCR 1735.2(h).

- CCR 1735.2: Staff recommended accepting in part to make stability, container closure, sterility and testing frequency consistent with USP standards. This provision will be addressed a future meeting.

- CCR 1735.2(3): Staff recommended rejecting that potency over time studies can be used to validate stability of a preparation and assign extended beyond use dates.

- CCR 1735(4): The committee requested additional research on the possible exemption from the definition of compounding the mixing of ingredients from an FDA kit.

Public Comments

Public comment was made urging the board not to adopt emergency regulations as the public was just viewing the information that morning. Ms. Gutierrez stated the enforcement committee cannot act independently and there will be plenty of time to comment regarding the emergency regulations as any recommendation made by the committee must go to the full board for a vote. If the Board doesn't adopt emergency regulations the current BUDs will stay in effect and a regular rulemaking process will be need to be undertaken which can take over a year. The Board did not recommend putting all amendments through an emergency rulemaking process, just a specific portion.

Rachelle Taggs, Precision Pharmacy, commented on the reasons to compound a product. CCR 1735.2(d) states no pharmacy shall compound a drug that is classified as withdrawn or removed from the market or is a copy or essentially a copy of a commercially available drug product, unless the drug appears on an ASHP or FDA list that it is in short supply. These lists only apply to human products. Vets often refer to their wholesalers on whether a drug is available or whether they have access to it.

Art Whitney, Advantage Pharmacy, commented that when one compounds a product, one may need to use a buffering or a carrying agent. In a recent inspection the inspector said the BUD cannot exceed any of the ingredients. Mr. Whitney stated the buffering agent or a stabilizer has no bearing on the product. Board staff will research this issue.

Marie Cottman, commented that buffers may not be stable on their own, but when applied to another product or mixed with other ingredients, the final product is actually more stable than the buffer on its own.

Lauren Forsythe, UC Davis Teaching Hospital, commented on the interpretation of "identical" in the Boards regulations. Ms. Forsythe asked for clarification whether this interpretation applies to just sterile compounds and not non-sterile compounds. Ms. Sodergren stated the Board hopes to clarify this in a FAQ.

Eric Tosh, Vice President Board of Directors for ICP, commented regarding potency over time versus stability indicating studies for BUDs. He suggested that the board take into consideration newer technology that may likely provide less expensive choices that may provide the robustness in testing and studies the Board's is looking for. He cautioned that the Board not narrow the specificity of the studies allowable, as to not narrow the scope.

Dr. Shane, Cedars Sinai, commented that in a hospital setting the physician expects a prescription to be compounded if that is what is required to deliver the medicine to the patient in a timely fashion. In some cases care would be delayed if prescriber authorization were necessary prior to compounding. The medical staff has the expectation that pharmacists are not required to contact the prescriber prior to compounding.

Carla Kutz, Director Quality Assurance, DynaLabs, 1735.2(i)(G)(v) commented that the word "expected" is nebulous. Ms. Sodergren commented that the intent was to mirror USP <795>.
In addition, with respect to buffering agents, she would categorize these as "processing aides". They have no active or inactive interference with a formulation. They are there to aide and adjust and are not considered an ingredient and should not be treated as such with respect to a BUD. Identical should be identical at the molecular level, effective and pure, regardless of sterile or non-sterile.

David Perkin, Diamond Back Drugs, commented on CCR 1735.2(c). Reasonable quantity is a difficult thing for a veterinarian to predict because they don't know if they will be treating a six pound animal

that day or a 150 pound animal. A veterinarian cannot predict how soon they will be using the medication and in what quantity due to the type of patients they treat in their practice. Day's supply is very difficult to predict and will always be a major guessing game. Mr. Perkin is trying to understand what "reasonable quantity" means.

Franco Franca, Dollar Drug, Santa Rosa commented on 1735.2(i)(1)(G) and asked if "identical" applies to sterile or nonsterile. Chairperson Gutierrez commented that "identical" is applicable for both sterile and nonsterile. For nonsterile, Mr. Franca, wanted to know what type of a study is acceptable for extension of a BUD. Chairperson Gutierrez mentioned the intent of the extension of the BUD is not to do testing but to allow for the professional judgment of the pharmacist, to utilize evidence to support the extension of the BUD, whether it is through Trissels, a journal article or another reference.

Marie Cottman, Pacific Compounding Pharmacy, commented on 1735.2(a) requirement to document prescriber authorization to compound a product. She stated this can delay therapy. She suggested that the regulation be amended when it is an unexpected compound, for example, when the commercially available product is not available. Ms. Cottman agreed it is important to let prescriber's know that something must be compounded due to something unexpected when the prescriber was not anticipating a compound be necessary for a particular prescription.

Jenny Partridge, contracted inspector/surveyor, commented on the issue of staff rejecting potency over time, she said no one from the board contacted PCAP or NABP. She stated potency over time is accepted if it is done with stability indicating methodology. Ms. Sodergren stated potency over time does not always include stability indicating methodology but the converse is true. Stability indicating methodology does include potency over time, which is why the board is recommending stability over time because it will include both factors. Ms. Sodergren also noted board staffs relied on published documents from PCAP and NAPB verse a one on one phone call.

Carla Kutz, Dynalabs, stated there are cases when potency over time is useful and valid, however, the first step in determining this is for the pharmacist to evaluate, in their professional judgment, by identifying the critical components, which may include multiple things. When testing is done the most important question a professional must ask themselves is 'is this stability indicating data'. Potency over time is only part of the entire picture.

A member of the public commented he does not want to spend $50,000 to justify work he has been doing for many years. He commented everyone present wants to provide effective products for their patients. He was confused and intimidated about what these emergency regulations are all about. Chairperson Gutierrez stated that the emergency regulations are being discussed to make the process faster and because they board understand the impact to patients. The board is doing their best to correct the situation.

Ranelle Larson, PCCA, commented on prepackaged kits under CCR 1735. She commented whether the language should read "FDA registered kit versus FDA registered manufactured kit." There is a difference with respect to what is required. She suggested the board look at this in greater depth. The committee agreed to go back and look at this issue regarding a possible exemption from the definition of compounding the mixing of ingredients from an FDA kit.

Motion: The board recommended pursuing regulatory amendment to CCR section 1735.2(i)(1) to establish beyond use dates for nonsterile drug preparations requiring emergency adoption procedures as discussed by the committee as an emergency regulation.

M/S: Lippe/ Munoz Approve: 5 Oppose: 0 Abstain 0

Committee Discussion

- CCR 1735.6(e)(3): Staff recommended rejecting to create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastic. This may be addressed in part when board staff addresses the definition of "hazardous". Board staff will look at the need for risk assessment. Note: This change was approved by the board during the January 2017 Board meeting.

- CCR 1735.1 & 1735.8: Staff recommended rejecting to add definition for "simple compounding", "moderate compounding" and "complex compounding" with additional modification to CCR 1735.8 quality assurance requirements applying to sterile or nonsterile.

- CCR 1735.8(c): Staff recommended rejecting the development of a list of compounds and dosage forms that would be specifically subject to analytical testing. Additional Guidance will be provided in FAQs. This refers to the QA plan that the pharmacy needs to establish internally.

Public Comment

Paige Talley, California Council on the Advancement of Pharmacy, suggested adding the language "BSC or CACI" under CCR 1735.6(e)(3).

Mark Johnson, CVS and Laura Wolmsky, Walgreens, asked for an exemption on annual testing under CCR 1735.8 for simple compounds, such as magic mouthwash. Mr. Johnson stated it was too cost probative for his company to allow all their stores to continue to compounding if there were required to test 1 product from each store every year. Mr. Johnson stated they would be forced to stop compounding at some stores which would limit patient's access to compounded medications.

Christine Versichele, Dynalabs, commented on costs of testing. If a compound is difficult to test, the test may cost more, but if the compound is simple, potency over time test is relatively inexpensive. She quoted an approximate price of $130.

Committee Discussion

CCR 1751

CCR 1751.1 (a)(5): Staff recommended accepting to clarify where the smoke studies must be done and establish a frequency. Language provided refers to "Bi-annual video smoke studies in all ISO class 5 certified spaces." The definition of biannual is twice in one year. The committee identified this section as requiring an amendment but does not meet the threshold for emergency adoption. The committee agreed to take this amendment to the board for consideration and discussion to pursue regular rulemaking.

- CCR 1751.3: Staff recommended rejecting to clarify what environments require a sampling plan.

- CCR 1751.3(c): Staff recommended rejecting to provide detailed description of what the SOPs need to include for sterilization and depyrogenation process.

- CCR 1751.4: Staff recommended rejecting that cleaning must be done when hazardous drugs are being compounded as well as what environment must be cleaning.

- CCR 1751.4(d): Staff recommended accepting in part to add a definition of germicidal to allow the use

of a ready-to-use germicidal detergent including sterile water. The committee requested board staff evaluate additional research regarding where decontamination needs to occur and bring it back for consideration a future meeting.

- CCR 1751.4 (d) & (d)(1-2): Staff recommended accepting in part that cleaning need not happen daily but rather every day the facility is used to prepare sterile drug products. The committee requested board staff evaluate additional research and bring this back for consideration at a future meeting.

- CCR 1751.4(g)(1): Staff recommended rejecting to create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastic. Staff will review USP <800> risk assessment recommendations. The committee requested board staff to evaluate and bring this back for consideration at a future meeting.

- CCR 1751.4 (k): Staff recommended accepting to remove the minimum room temperature.
The committee identified this section as requiring an amendment but does not meet the threshold for emergency adoption. The committee agreed to take this amendment to the board for consideration and discussion to pursue regular rulemaking.

- CCR 1751.8(g)(1): Staff recommended rejecting to add a requirement for two pairs of standard gloves for all hazardous compounding. This is consistent with USP <797> at this time.

- CCR 1751.6(e)(2): Staff recommended rejecting to provide alternative training requirements for staff only involved on the supervision of personnel compounding but not compounding themselves. Additional guidance will be provided in FAQs.

- CCR 1751.7(e)(1): Staff recommended accepting in part to allow for an alternative method of testing as those described in USP <71> to perform end product testing and also exempt irrigations from pyrogen testing. Draft language will allow for alternative testing, specifically RMM. The committee requested board staff to evaluate additional research and bring this back for consideration at a future meeting.

<u>Public Comment</u>
Danny Martinez, CPhA, asked for clarification of the definition of bi-annual under CCR 1751.1 (a)(5). Bi-annual means twice in one year.

Marie Cottman, commented on CCR 1751.4(d)(1). She stated cleaning every 48 hours is very limiting to community practices. Right now she cleans daily but not on the weekends when her facility is not open. She commented she should not be getting into her sterile garb and then mop the floor. She will provide suggested language to the board.

Corbin Bennet, Kaiser, commented that he would like clarification on CCR 1751.4(d) regarding which surfaces need to be decontaminated.

Ester Kemp, Stanford Heath Care, commented on CCR 1751.4(k). Ms. Kemp stated that in some small people, “comfortable” may not be achievable at 68 degrees or cooler.

Danny Martinez, CPhA, stated on CCR 1751.6(e)(2) they would like to see a regulation amendment versus a FAQ. On CCR 1751.7(e)(1) he stated they are grateful for the opportunity to use the RMM method as an alternative, but they assert other methods need to be used as well. He also asked about exemptions from pyrogen testing for irrigation solutions. Mr. Sodergren stated that staff can consider

that issue.

Ranelle Larson, PCCA, commented on dosage unit and batch. 1735.1(v) provides the definition of a nonsterile to sterile batch. 1735.1(n) provides the definition of dosage unit. With these definitions a one multi-dose 5ml vial is considered a batch if it is for one patient. She stated his creates a problem. Testing can take up to 3 to 5 days. USP 797 definition of a batch is greater than 25 units. Cost will be passed onto the patient. Ms. Larson suggested that maybe we should look at the regulation to carve out an allowance that if the product is just for one patient that compounders need not do this end product testing. In addition under CCR 1751.7(e)(2)(C) she commented that the FDA already has an exemption that one can omit sterility and pyrogen testing if it is on the FDA shortage list. Staff agreed to look at this issue.

Jenny Partridge is concerned about the definitions of batches and dosage units. She stated no other state requires sterility testing on every one vial for every one patient. She asked that the board consider how it can be allowed for a pharmacy to fill one prescription meant for one patient. In addition Ms. Partridge commented on CCR 1751.6(e)(2) with respect to training.
In addition, if a pharmacy has a SOP, that states the PIC does a written test and didactic training but doesn't compound, Ms. Partridge asked if the PIC is required to the glove finger-tip test, the media fill and the three observational audits. This has not been applied inconsistently across inspectors across the state. Pharmacists do not know what is the right thing to do is and would like clarification.

Karla Kutz, Dynalabs, commented on rapid micro. ScanRDI is a fantastic but limited tool. Clear, aqueous solutions, nothing colored, and no solids can be tested with the ScanRDI. She encouraged pharmacists to talk with their labs and make sure the individual who is doing the testing is qualified.

c. Discussion and Consideration of Waiver Requests for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6. and 1751.4. et. seq

Background
Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states that where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver for a period of time to permit the required physical changes. There is a related provision in CCR section 1751.4 which provides the same allowances for sterile compounding facilities.

Initial review of the waiver is performed by staff led by the executive officer, who approves or denies the waiver request. If a waiver is denied by the executive officer, there is an appeal process which will be reviewed by two board members, currently Board Members Schaad and Law. The goal of the construction waiver process is to secure full compliance at the earliest possible time and no latter that implementation date of USP <800> on July 1, 2018.

Discussion and Comment
The waiver review process is ongoing, as board staff continues to work with facilities that have applied for a waiver. There have been instances where the Executive Officer has approved extensions to waivers due to construction delays. The Executive Officer has provided specific timelines to facilities requesting a waiver with respect to the Office of Statewide Health Planning and Development (OSHPD) approval, status reports of construction and final completion dates. Facilities that have been denied a waiver have been made aware that there is an appeal process to the compliance waiver process. Such waiver appeals go to the subcommittee of Mr. Schaad and Mr. Law. Denied applications for waiver were provided an opportunity to re-apply or appeal.

The following statistics were provided regarding waivers received as of 6/27/17:

- Total Waivers Received: 609
- Total Waivers Processed: 607
  - Denied: 40 - 6.5%
  - Withdrawn: 100 - 16.5%
  - Approved: 380 - 62.6%
  - Non-responsive letters sent: 21 - 3.5%
  - In process: 66 - 10.8%
- Total Waivers Pending Review: 2
- Total Waiver Extensions Granted: 60

Ms. Herold commented that the deadline for waivers was July 1, 2017. Many facilities that have been approved for a construction waiver have a report due to board staff on November 1, 2017 which should document their current status. Many approved waivers have an expiration date of January 1, 2018. The status report will provide the licensee with an opportunity to explain to the board why they may need an extension if they will not be in compliance by January 1, 2018.

V. Enforcement Statistics

a. Medication Error Trends

A handout was provided on medication error trends.

b. Compounding Cite and Fines

A two page handout was provided containing the top 10 compounding case citation and fines and compounding inspection data. Also included is the number of compounding pharmacies licenses and top corrections and violations.

Discussion and Comment

Total compounding citations in fiscal FY year 2016-17 was 479. These citations were issued across 193 total licensees, including pharmacists, pharmacies, sterile compounders, and hospitals. The board licenses approximately 1,000 sterile compounding facilities. In FY 2016-17 compounding citations were issued across 52 locations or approximately 5% of the total licensee population. Given the adoption of the new compounding regulation on January 1, 2017, the board has been spending a good deal of time over the past six months in educating the licensing population.

Public Comment

Jenny Partridge commented that 50% of the pharmacies were given correction orders. Ms. Herold commented a correction is similar to a warning. It doesn't result in a citation or a letter of admonishment.

Giselle Witack, Kaiser, asked if the board could break down compounding citations to show many were in state licensees versus non-resident pharmacies.

c. Other Enforcement Statistics

Discussion and Comment

The committee reviewed the end of FY enforcement statics and a three year comparison. A review of

the three year comparison reveals that the board completed about 600 more investigation in FY 2016/17 versus FY 2014/15. Over the three year period there has been a slight increase in the number of cases referred to the Attorney General's Office (8% increase). Pharmacy technician's represent the greatest number of licenses revoked by the board, while pharmacist represents the greatest number of licensees placed on probation.

VI. Review and Discussion of News or Journal Articles

A report from the California Department of Public Health (CDPH) on the End of Life Option Act (Act) was provided. On June 27, 2017, CDPH released the first annual report on the Act, which became law on June 9, 2016 and allows terminally ill adults to obtain and self-administer aid-in-dying drugs. This first reporting covers the time period of June 9, 2016 thru December 31, 2016. Subsequent reports will be for full calendar years.

An article was provided from the *American Society of Health-System Pharmacists (ASHP)*, titled *"Attention Turns to Nonpharmacy Sterile Compounding Activities."* The ASHP article described the potential dangers of compounding in healthcare facilities without a pharmacy professional. The article can be found on ASHP's website: https://www.ashp.org/news/2017/06/12/20/24/attention-turns-to-nonpharmacy-sterile-compounding-activities.

VII. Future Meeting Dates

The next committee meeting is scheduled for September 15, 2017.
Below are the committee dates for 2018:

- March 28, 2018
- June 7, 2018
- September 5, 2018
- December 13, 2018

The meeting was adjourned at 3:06pm.