



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: June 26, 2014

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

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Greg Lippe, Public Member
Victor Law, RPh
Rosalyn Hackworth, Public Member
Albert Wong, PharmD
Lavanza Butler, PharmD
Allen Schaad, RPh
Gregory Murphy, Public Member
Ramon Castellblanch, PhD, Public Member

BOARD MEMBERS

NOT PRESENT: Ryan Brooks, Public Member
Deborah Veale, RPh, Treasurer

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Michael Santiago, DCA Staff Counsel
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting can be found at: <http://www.pharmacy.ca.gov/about/meetings.shtml>

Thursday, June 26, 2014

Call to Order

9:00 a.m.

I. GENERAL ANNOUNCEMENTS

President Weisser called the meeting to order at 9:00 a.m. President Weisser conducted a roll call. Board members present: Stanley Weisser, Amy Gutierrez, Greg Lippe, Victor Law, Rosalyn Hackworth, Albert Wong, Lavanza Butler, Allen Schaad, and Gregory Murphy. Board members not present: Deborah Veale, Ryan Brooks. Note: Ramon Castellblanch arrived at 9:08 a.m.

President Weisser introduced Awet Kidane, the newly appointed Director of the Department of Consumer Affairs. Mr. Kidane introduced himself to the board. He thanked the board and the staff for their hard work on the BreEZe project. Mr. Kidane concluded that he is looking forward to working closely with the board on future projects.

President Weisser also thanked Anne Sodergren, Assistant Executive Officer, for all of her hard work on the BreEZe project.

III. LICENSING COMMITTEE ISSUES HEARD JUNE 18, 2014, BEING REFERRED TO THE BOARD FOR POSSIBLE ACTION AT THIS MEETING

In Deborah Veale's absence President Weisser provided a report of the June 18, 2014 Licensing Committee Meeting.

a. Discussion and Possible Action on Requests for Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Sections 4128 et seq.

President Weisser reported that in 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single-dose medications that are barcoded. These medications could only be provided to the hospital's inpatients.

President Weisser explained that included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read. He added that the board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals.

1. Waiver Request from Mercy Hospital of Folsom

President Weisser reported that representatives from Mercy Hospital of Folsom attended the Licensing Committee Meeting on June 18, 2014. The committee heard the request for a waiver to the requirement that all unit dose medications packaged by the hospital's centralized

packaging pharmacy be barcoded to read specific information that is currently printed on the label. However, a barcode reading of the NDC number would provide a bedside check that would confirm a medication was the right medication in the right dose for that patient. The committee recommended that the board approve a five-year waiver.

Dr. Gutierrez asked if inspectors had conducted a sterile compounding inspection of Mercy Hospital of Folsom. Ms. Herold responded that the board does not have an application for the centralized packaging location, but the sterile compounding facility has been inspected and had no findings. Dr. Gutierrez asked that for all future 4128.4 waiver requests the board be notified of the results of any sterile compounding inspections and current licensure status.

Committee Recommendation (Motion): Approve a five-year waiver for Mercy Hospital of Folsom so that as long as the required labeling elements appear on the label and the lot number is provided on the label, and the required data elements are otherwise retrievable, waive the requirement that the data elements in section 4128.4 be retrievable at the patient's bedside by way of a barcode.

Support: 10 Oppose: 0 Abstain: 0

2. Waiver Request for Loma Linda University Medical Center

President Weisser stated that due to his involvement with Loma Linda University he would be recusing himself from this agenda item and asked Vice President Amy Gutierrez to run the discussion for him.

Ms. Herold noted that Loma Linda University was at the last minute unable to have a representative present at the June 18 meeting; as such, Loma Linda is providing this request directly to the board at today's board meeting.

Michael Campbell, Director of Pharmacy at Loma Linda University Medical Center, stated that similar to the other facilities that have made requests to the board, Loma Linda's barcode system currently has limitations that keep it from fulfilling all of the requirements specified in 4128.4. Dr. Campbell reported that Loma Linda operates the main medical center and three sister hospitals all within a two-mile radius. He added that they do packaging for non-patient specific doses and the six required elements in 4128.4 on the packaging; however, the barcode only reads the National Drug Code (NDC). Dr. Campbell stated that Loma Linda keeps logs and had departmental policies in place in the event of a recall.

Dr. Gutierrez asked if when they prepare the packaging they assign their own NDC. Dr. Campbell explained that they use the drug manufacturer NDC for some things, but for compounded IV's they assign it an "ERX" code in their software.

Dr. Gutierrez asked if Loma Linda envisions that in the future the software will allow recall information to be provided when the barcode is scanned. Dr. Campbell confirmed that they are working with their software vendor to meet all the requirements in 4128.4.

Dr. Castellblanch asked how long the waiver would last. Dr. Gutierrez responded that the board has been granting five-year waivers to allow time for the law to be changed or for technology to catch up. Ms. Herold added that CSHP has a legislative proposal to modify 4128.4 that they would like to move forward this year. However, Ms. Herold noted that as it is late in the legislative year and the Department of Public Health was opposed to this last year she feels it might be best to wait rather than try to add it to a bill.

Dr. Gutierrez asked if Loma Linda had any idea as to when their software would be updated. Dr. Campbell responded that it would take at least six months to a year.

Dr. Campbell commented that they had been inspected for sterile compounding and they had also submitted a centralized packaging application.

Ms. Herold asked what they would do in the event of a recall. Dr. Campbell responded that they have a log and a departmental policy in place that will allow them to segregate the product and determine if any had reached a patient. He added that in the future all of this information will be imbedded in the barcode.

Dr. Robert Ratcliff, supervising inspector, asked Dr. Campbell where their centralized packaging facility will be. Dr. Campbell responded that there were two locations --Loma Linda University Medical Center and Loma Linda University Heart and Surgical Center. Dr. Ratcliff responded that to date the board had only issued a sterile compounding license to the main hospital. Dr. Campbell confirmed that sterile compounding applications would be forthcoming for the other locations.

Dr. Gutierrez asked if they were seeking a waiver for one location or two. Dr. Campbell responded that there would need to be two waiver requests one for the Medical Center and one for the Heart and Surgical Center. Board staff sought clarification if the board had received two applications for centralized packaging.

Ms. Herold commented that the board needs to be informed of all the locations that Loma Linda will be conducting sterile compounding and centralized repackaging.

While board staff researched the applications, Dr. Campbell asked that the board approve the waiver for the Loma Linda University Medical Center at this meeting, as it is the most important to the hospital's functions. Dr. Gutierrez noted that the original 4128.4 request received from Loma Linda had been for the Medical Center.

Motion: Approve a five-year waiver for the Loma Linda University Medical Center that as long as the required labeling elements appear on the label and the lot number is provided on the label and the required data elements are otherwise retrievable, waive the requirement that the data elements in section 4128.4 be retrievable at the patient's bedside by way of a barcode.

M/S: Lippe/Law

Support: 10 Oppose: 0 Abstain: 0

It was noted that the waiver was only for the Medical Center. Dr. Gutierrez stated that if it was determined that there was an application for the Heart and Surgical Center the board would vote on that waiver later in the meeting. Ms. Herold noted that there was also a board meeting at the end of July where Loma Linda could make the request.

b. Discussion and Possible Action on a Request from California Health Sciences University for Recognition by the Board of Pharmacy Under Section 16 CCR § 1719 for Purposes of Issuing Intern Licenses

President Weisser reported that the California Health Sciences University School of Pharmacy, Fresno, has been granted pre-candidate status by the ACPE. The first class of students will be admitted in the fall of 2014. In order for the school's students to secure the training they need, the students need intern licenses. Lacking ACPE candidate status, the board cannot currently issue these licenses to students.

President Weisser stated that recently, the California Health Sciences University School of Pharmacy requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program.

Dr. Lackey, representing the California Health Sciences University School of Pharmacy, Fresno, provided the board with an overview of their pharmacy program.

Mr. Lippe asked if the school anticipates that they will be granted full accreditation status. Dr. Lackey responded that they do anticipate full accreditation. He also highlighted for the board the in-depth review process that the school must complete before ACPE will grant pre-candidate status.

Mr. Law asked what the anticipated class size would be. Dr. Lackey responded that that the first class would be 84 students.

Ms. Butler commented that she had participated in an ACPE review and confirmed that it is a very detailed process.

It was noted that former Board Member Randy Kajioka was present during their ACPE review.

Dr. Gutierrez asked if the school was going to include any of the items in SB 493 (Advanced Practice Pharmacist) in their curriculum. Dr. Lackey responded that their program would be focused on preparing students for primary care, including medication management, travel medicines and immunizations.

Mr. Law asked if the school had all experiential sites ready for their students to work in. Dr. Lackey confirmed that because the Central Valley is often underserved, they were able to confirm twice the number of sites required by ACPE.

Mr. Law asked what the cost of tuition would be. Dr. Lackey responded that the tuition was about \$45,000 per year, similar to other schools of pharmacy. Dr. Lackey noted that the school has one of the largest scholarship foundations of any of the new pharmacy schools.

Dr. Gutierrez asked if the students will gain experience in hospital settings. Dr. Lackey confirmed that they would.

Committee Recommendation (Motion): Recognize California Health Sciences University School of Pharmacy for purposes of issuing intern licenses to its students. Direct staff to maintain contact with ACPE to ensure the school continues to move towards full ACPE accreditation status in the future.

Support: 10 Oppose: 0 Abstain: 0

IV. DISCUSSION AND POSSIBLE ACTION TO MAKE CHANGES IN RESPONSE TO COMMENTS OR TO ADOPT OR AMEND PROPOSED TEXT AT 16 CALIFORNIA CODE OF REGULATIONS SECTION 1707.5 RELATING TO PATIENT-CENTERED PRESCRIPTION CONTAINER LABELS

President Weisser reported that at the October 2013 Board Meeting, the board voted to modify its patient-centered prescription label requirements at Section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items be printed in 12-point sans serif typeface.

President Weisser reported that at the January 2014 Board Meeting, the board approved a motion to initiate a rulemaking to amend Section 1707.5 to Title 16 of the California Code of Regulations. The rulemaking was noticed on April 11, 2014, and the 45-day public comment period concluded on May 26, 2014. A hearing was requested and conducted on May 27, 2014. President Weisser added that the board received four written comments and had four people provide testimony at the hearing on May 27, 2014. The comments received and the proposed language were provided in the meeting materials.

Ms. Herold commented that at the July board meeting there will be a forum on the topic of patient-centered labels.

Blake Griese, representing a long term care pharmacy, commented that his organization has some concerns about how the patient-centered labels will affect the labeling of the labels used in skilled nursing facilities. However, he concluded that they would work with the board and staff on their concerns at a later date.

Michael Santiago asked that the board motion to approve the responses to the comments received.

Motion: Approve the responses to the comments received during the 45-day comment period.

M/S: Lippe/Law

Support: 10 Oppose: 0 Abstain: 0

Motion: Adopt the proposed text at 16 California Code of Regulations Section 1707.5 relating to patient-centered prescription container labels.

M/S: Lippe/Castellblanch

Support: 10 Oppose: 0 Abstain: 0

The board recessed for a break at 9:50 a.m. to prepare for the presentation by Dr. Perz.

V. PRESENTATION BY JOSEPH F. PERZ, DrPH, ON HIS FINDINGS AND ARTICLE “Outbreaks of Infections Associated with Drug Diversion by US Health Care Personnel,” AND DISCUSSION BY THE BOARD ON DRUG DIVERSION ISSUES

Dr. Joseph F. Perz, from the Division of Healthcare Quality Promotion at the Center for Disease Control and Prevention, provided a presentation via telephone. Below, are highlights from the presentation. The entire presentation has been provided immediately following these minutes.

Presentation: Outbreaks of Infections Associated with Drug Diversion by US Health Care Personnel

- The National Association of Drug Diversion Investigators defines drug diversion as “any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient.”
- Patient safety is compromised whenever diversion by health care personnel occurs
 - Harm can include:
 - Failure to receive prescribed medication resulting in failure to obtain adequate pain management
 - Exposure to substandard care from an impaired provider
 - Exposure to life-threatening infections
- Mechanisms of Diversion by Health Care Personnel
 - False documentation (e.g., a medication dose not actually administered to the patient or “wasted” but instead saved for use by the provider)
 - Scavenging of wasted medication (e.g., removal of residual medication from used syringes)
 - Theft by tampering (e.g., removal of medication from a medication container or syringe and replacement with saline or other similarly appearing solution that may be administered to patients)
- Significant US public health outbreaks associated with diversion by health care personnel, from 2003-2013
 - At least 6 documented outbreaks
 - 2 outbreaks: Gram-negative bacteremia
 - 4 outbreaks: Hepatitis C transmission by HCV-infected health care personnel
 - >100 cases
 - >25,000 patients placed at risk of infection

- Key questions to consider when assessing patient safety threat
 - What medications were diverted?
 - Were they injectable?
 - Mechanism of diversion?
 - Did the theft involve substitution or other tampering?
 - What happened to the containers or injection equipment?
 - Were they shared with others?
 - What is the blood-borne pathogen status of the implicated health care worker?
- Summary / Conclusions
 - These outbreaks revealed gaps in prevention, detection, or response to drug diversion in U.S. healthcare facilities
 - Health care facilities should have strong narcotics security measures and active monitoring systems to prevent and detect diversion activities
 - Appropriate response by healthcare facilities includes
 - Assessment of harm to patients
 - Consultation with public health officials when tampering with injectable medication is suspected
 - Prompt reporting to law and other enforcement agencies (e.g., state boards of pharmacy)

At the conclusion of his presentation, Dr. Perz opened the floor to comments and questions.

Dr. Gutierrez noted that the presentation reminded her of the meningitis outbreak that resulted from the New England Compounding Center. She noted that there have been significant changes as a result of the NECC outbreak and the board needs to start looking at ways to detect diversion in hospitals in light of the patient risks of outbreaks.

Dr. Castellblanch commented that the board is gathering materials on prescription drug diversion and abuse to post on the board's website. He noted that one of the criteria for the materials is that they must be from an independent source. Dr. Castellblanch asked if the CDC website has similar criteria. Dr. Perz responded that the CDC wants to maintain its objectivity and reliability so their materials are peer-reviewed publications, links to other federal entities and links to state health departments. Dr. Perz noted that they do include new articles on the subject from sources such as the Wall Street Journal and USA Today.

Dr. Castellblanch asked if the materials on the CDC website are segregated for health care professionals and the general public. Dr. Perz responded that they have not taken this approach as the materials are informative for both health care professionals and the general public.

Ms. Hackworth asked if any of the hospitals are implementing programs to try to prevent the diversion from occurring. Dr. Perz responded that hospitals have federal requirements to have a system to prevent diversion. However, he noted that the requirements are often broad and he hopes that regulatory bodies and accreditation agencies can work together to strengthen them. Dr. Perz noted that that the Mayo Clinic is implementing a program that includes

education, active monitoring and clear policies in regards to drug testing that appears to be very promising.

The board asked if Dr. Perz could provide details about this program and he confirmed that he would do so.

Dr. Gutierrez commented that she had Dr. Perz's report on the Mayo Clinic program and it is very well laid out and would be a great resource for hospitals.

President Weisser asked if hospital workers should be tested to determine if there is a drug addiction problem. Dr. Perz responded that the CDC does not have a position on random drug testing; however, hospitals should have clear policies on for-cause testing. Dr. Perz also stated that consideration should be given to conducting blood-borne pathogen testing.

Dr. Wong commented that he would support testing on those individuals who handle narcotics.

Dr. Gutierrez commented that there is a lot of data available to hospitals that could help indicate an employee that may be diverting and needs to be tested.

Dr. Wong commented that there should be a reporting system in place to help track licensees who have been disciplined when they move from state-to-state. Dr. Perz agreed that there are underfunded programs that need improvements in order to be more effective.

Dr. Castellblanch commented that Dr. Perz's research focused on the hospital setting and asked if he had any thoughts on diversion in non-hospital settings. Dr. Perz responded that while recent outbreaks have occurred in hospital settings, there is potential for diversion anywhere that opioids are being dispensed.

Ms. Herold commented that the board will be seeing disciplinary cases where had the pharmacy reviewed the reports available to them regarding drug storage machines, then diversion would have been detected early.

Ms. Herold stated that she wants to be sure that this information is disseminated because patient infection resulting from a health care provider diverting injectable drugs is a huge threat to patient health.

A retail pharmacist, commented that she has never heard of this issue and asked what the CDC is doing to disseminate this information. Dr. Perz responded that there has been growing public awareness of prescription drug abuse, however, the issues of health care provider diversion and abuse are still immerging and gaining public awareness.

Lynn Paulson, with the University of California, commented that hospital directors often face human resources challenges when they are investigating employee diversion.

BJ Bartleson, with the California Hospital Association (CHA), commented that this presentation illustrated the risk that patients face when a hospital employee is diverting. She added that while there are numerous checks and balances in place in hospitals to try to prevent diversion, CHA's Medication Safety Committee and the board should take action to consider what else can

be done to protect patients.

Dr. Wong commented that this is a very important subject.

Dr. Gutierrez asked Dr. Perz if any other state boards of pharmacy have taken action that the California board could consider. Dr. Perz responded that he has seen other states create coalitions and workgroups and he directed the board to look at actions taken in Minnesota, New Hampshire and Colorado.

Ms. Butler commented that this issue is especially important to her as one of her family members was infected due to a medical procedure; she added that the board needs to take action to help protect consumers.

Dr. Gutierrez offered to work with Ms. Herold and the hospital associations on looking at the problem and creating some guidelines.

President Weisser commented that at previous Enforcement Committee meetings the idea of creating stricter guidelines for taking inventories of controlled substances has been discussed. Dr. Gutierrez responded that the committee would like to see pharmacies take monthly inventories of their controlled substances so that they can more quickly detect diversion. Dr. Castellblanch commented that perhaps this inventory requirement should be handled by the Prescription Drug Abuse Subcommittee Meeting. President Weisser asked Dr. Gutierrez and Dr. Castellblanch to determine which committee's agenda it would be placed on.

VI. DISCUSSION AND POSSIBLE ACTION TO INITIATE RULEMAKING TO ADOPT PROPOSED TEXT AT 16 CALIFORNIA CODE OF REGULATIONS 1735 ET SEQ. AND 1751 ET SEQ. RELATING TO PHARMACY COMPOUNDING

Dr. Gutierrez reported that at the October 2013 Board Meeting, the board moved to notice the proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45-day comment period ran from November 29, 2013 – January 13, 2014. Dr. Gutierrez added that a regulation hearing was held on January 16, 2014, to provide the public with an opportunity to provide comments in another forum.

Dr. Gutierrez stated that during the notice period, the board received many written and oral comments. Board staff sorted all written and oral comments received by section number to facilitate review all of related comments by section. This compilation document was available at the January 2014 board meeting and online. At the January 2014 board meeting, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text based on comments.

Dr. Gutierrez explained that at the April 2014 Board meeting, the Board voted to withdraw the current compounding rulemaking, revise the language to incorporate many of the comments submitted in response to the initial regulation notice and notice the new language as a new rulemaking.

Dr. Gutierrez thanked board staff for their work compiling and responding to the extensive comments received on the language. The revised language was provided in the meeting materials for review by the board and the public prior to the board meeting.

Mr. Lippe commented that he noted several typos and grammatical errors and stated that he would work with board staff to fix them.

Dr. Gutierrez noted that the new USP 800 is currently open for comment period and when it is implemented the language may need to be updated again.

Dr. Steve Gray, representing CSHP, thanked the board for their work on the compounding regulation. Dr. Gray stated that he does not feel that the language is ready to be released for 45-day comment period. He asked that the board to consider separating the language between the compounding requirements for hospitals and requirements for non-hospital facilities prior to releasing the language for comment.

Dr. Gray also highlighted challenges related to building standards for hospitals that will need to remodel based on the requirements in the regulations.

Dr. Gutierrez commented that the board's language in many places is basically an excerpt of USP 797. She asked Dr. Gray if his comment regarding the need for some hospitals to remodel meant that these hospitals are not currently meeting the requirements in USP 797 as enforced by the CA Department Public Health (CDPH). Dr. Gray responded that CDPH used USP 797 only as a guideline and added that Public Health has been silent during the board's regulation process.

Ms. Herold asked Dr. Gray if he believed hospital out-patient facilities will also have difficulty with building requirements. He confirmed that they would have the same difficulties.

Dr. Gray commented that the board's regulations could have the unintended consequence of making hospitals rely on outsourcing facilities to obtain their compounded medications due to the hospital inability to meet the requirements in the regulation. Dr. Gray noted that hospitals currently have to make very difficult financial decisions and remodeling would be extremely difficult.

Ms. Herold commented that last year the CA Hospital Association seeking to ensure a close relationship between California requirement and USP 797 requested an amendment to SB 294 to guarantee that if USP 797 was ever amended, the board would review the changes and implement any necessary updates to its regulation within 90 days. Dr. Gray responded that he was not part of that discussion; however, he speculated that the Hospital Association wanted to ensure that if in the future they are required to comply with USP 797 on the federal level, California's regulation would coincide.

BJ Bartleson, representing the CHA, stated that they have not had the opportunity to conduct a thorough review of the new language. Ms. Bartleson commented that she shared Dr. Gray's concerns regarding the potential cost to hospitals if they need to remodel their facilities.

President Weisser commented that he is surprised to learn that hospitals are currently not in compliance with USP 797. Ms. Bartleson responded that USP 797 is being used as a guideline.

President Weisser asked if when an accreditation body inspects a hospital do they inspect to USP 797. Ms. Bartleson responded that they are silent on USP 797. Dr. Gutierrez added that USP 797 is very technical and perhaps some of those conducting the inspections for accreditation agencies do not have the technical knowledge to inspect to the level of USP 797.

Dr. Gutierrez commented that she did not anticipate the public hospital system she oversees in Los Angeles to have problems complying with the regulation. She asked for specific examples of problems that hospitals anticipate, because to date all comments have been in general terms. Ms. Bartleson responded that CHA would be happy to provide specific examples after they have reviewed the language.

Dr. Gutierrez added that she is not in favor of giving hospitals any exemptions, as she has seen board inspection reports for hospitals, and is shocked at the violations that have been found.

Ms. Herold commented that she is concerned that it has been a year since this law was passed and added that the board has found some locations with egregious violations. Dr. Castellblanch agreed that continuing to prolong the regulation process could potentially harm patients. President Weisser agreed that beginning the 45-day comment period now would allow for stakeholders to address their concerns while still moving forward in the regulation process.

Ms. Herold stated that doing sterile compounding correctly is an expensive process and not everyone can, or should, do it. She reminded the board and the public that in 2001, three patients died as the result of receiving contaminate sterile compounded products from a community pharmacy in Walnut Creek.

Katie Marconi, representing Doctor's Hospital, Manteca, commented that perhaps board members should visit small hospitals so they can see what kind of compounding is being done and what issues they face.

Doug O'Brien, from Kaiser, commented that he sees some conflicts in the regulations that need to be resolved. He noted that doing a major remodel of a Kaiser pharmacy's cleanroom could cost between \$400,000 and \$1 million. Mr. O'Brien stated that the inspectors with the Joint Commission are not particularly well educated on USP 797; he added that CDPH is gaining knowledge on USP 797.

Mr. O'Brien commented that he feels that the board's regulations are slightly more rigorous than USP 797, particularly the requirement to prepare hazardous drugs in a negative pressure room. He asked the board to consider allowing implementation time for hospitals that will need to remodel based on the new regulations.

Mr. O'Brien commented that while requiring hazardous drugs to be prepared in a negative pressure room protects healthcare workers, it does not necessarily add any additional protection for patients. Dr. Gutierrez responded she used to agree with that statement; however after receiving further education she found that this is untrue. For example a study

found that chemotherapy particles were detected in an executive's office that was floors above where the drugs had been prepared in a non-negative pressure room.

Jeff Nigura, Mercy General Hospital, Sacramento, commented that the venting of negative pressure rooms is actually not required in USP 797 – it is just highly recommended. Mr. Nigura also commented that he worries that the board's regulations may unintentionally encourage the preparation of hazardous drugs to move out of hospitals and into doctor's offices where USP 797 is not enforced.

Rich Krazinski, Pharmedium, commented that there are some terms in the language that are not consistent with, or not commonly used, in the pharmaceutical industry.

William Blair, McGuff Compounding Pharmacy, commented that there are only two states that require compliance with USP 797, all other states use it as a guideline. Mr. Blair highlighted several changes in the language he felt should be addressed prior to releasing it for 45-day comment period.

Dr. Gray, clarified that he does not feel that hospitals should be exempt from the regulation, rather separated from other entities so that they can have a different implementation timeline. Dr. Gray again stated that cost of remodeling could potentially be very costly for hospitals and could even result in a hospital needing to shut down.

William Stewart, pharmacist, commented that USP 797 is a good guideline, however there are areas of it that it are deficient. He highlighted sections in USP 797 related to beyond-use dating and fingertip sampling that he feels need improvement.

Kate Palmer, Cedar Sinai Medical Center, commented that they would review the language and provide specific examples of potentials issues in the language.

Dr. Gutierrez provided that the board could either move forward in the rule making process, or bring revised language to the July board meeting based on comments. Dr. Gutierrez stated that she is particularly interested in receiving specific examples of issues with building standards.

Ms. Herold commented that the board could issue a subscriber alert seeking comments prior to releasing it for the official 45-day comment period. Dr. Gutierrez and Mr. Schaad agreed that it would be beneficial for the board to receive additional, high-level comments on potential structural impacts to hospitals.

Motion: Send out a subscriber alert today (June 26, 2014) requesting comments on the proposed rulemaking language. All comments must be submitted by July 9, 2014.

M/S: Gutierrez/Lippe

Support: 10 Oppose: 0 Abstain: 0

VII. UPDATE BY THE EXECUTIVE OFFICER ON IMPLEMENTATION OF SENATE BILL 294 (EMMERSON, CHAPTER 565, STATUTES OF 2013)

Ms. Herold and Ms. Sodergren provided a report to the board on the implementation of SB 294.

Ms. Herold commented that at the beginning of implementation, the board knew of approximately 250 sterile compounding facilities in California, 100 out-of-state facilities and 400 California hospitals.

Ms. Herold reported that inspector staff completed extensive training so that they could gain the appropriate knowledge to conduct inspections. She added that the board has hired, and will continue to hire, inspector staff specifically for their compounding experience.

Ms. Sodergren reported that beginning in January 2014 the board began inspecting California hospitals in anticipation of hospitals seeking a sterile compounding license.

Ms. Sodergren reported that as of June 1, 2014 the board had inspected 427 hospitals and 124 compounding pharmacies. She added that the board has issued 553 sterile compounding licenses, 98 of which are government owned.

Ms. Sodergren noted that upon inspection the board found that some hospitals do not conduct sterile compounding and thus will not require licensure. Dr. Gutierrez was surprised by this and asked to see a list of the hospitals that do not conduct sterile compounding.

Ms. Sodergren reported that as of June 24, 2014 the board had 126 sterile compounding applications pending, 12 of which are government owned.

Ms. Sodergren stated that board staff has been calling hospitals that have not yet submitted applications or appropriate fees, to ask that they be submit them as soon as possible. Ms. Sodergren reported that of the 126 applications pending, 45 of them were received in June and 13 were received in the last 5 days.

Mr. Wong asked how many of the hospitals inspected where accredited and in compliance with USP 797. Ms. Herold responded that two accredited facilities in community pharmacies had such numerous violations that the board denied them licensure and would be pursuing discipline. Dr. Gutierrez asked if they knew that their licenses will be denied. Ms. Herold responded that they are officially notified of their denial.

Ms. Herold reported that two hospitals decided to cease sterile compounding after the board inspectors educated them on the existing requirements - - requirements they were mandated to follow even though they were not specifically licensed. This is evidence of the poor job done by the accreditation agencies.

Mr. Herold stated that the board conducted 19 out-of-state sterile compounding inspections in June.

Ms. Herold noted that due to the volume of sterile compounding applications, the board is behind in processing other license applications.

Mr. Lippe commented that it seemed that for the most part the inspections had positive results. Ms. Sodergren responded that there was potential for improvements; however, for the

most part the inspections did not uncover violations that would result in immediate patient harm.

Mr. Lippe asked if the board had any idea of the amount of sterile compounded medications that are dispensed in California. Ms. Sodergren noted that entities will be required to provide a list of products that they compound each time they renew their sterile compounding license.

Ms. Sodergren stated that at the July board meeting the board will receive more detailed statistics.

The board recessed for a break at 1:55 p.m. and resumed at 2:00 p.m.

VIII. PETITION FOR EARLY TERMINATION OF PROBATION

Jorge Valdez, TCH 87769

IX. PETITION FOR REINSTATEMENT

Naresh Kumar, TCH 49281

X. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the board recessed to closed session to deliberate on disciplinary matters and the petitions for reinstatement and early termination of probation at 2:53 p.m.

XI. RETURN TO OPEN SESSION

The board returned to open session at 3:15 p.m.

Dr. Wong expressed his frustration at the difficulty the public has reaching board staff to have pharmacy law questions answered. It was noted that board members often receive negative feedback on the responsiveness of the board.

Several members expressed the need to have an inspector available to answer licensees' questions, perhaps a window of time each day that inspectors are available to answer questions.

President Weisser agreed to discuss the issue with Ms. Herold on behalf of the board and report back.

There were no comments from the public.

President Weisser adjourned the meeting at 3:21 p.m.