



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

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: September 22, 2016

LOCATION: Embassy Suites Anaheim Orange
400 N. State College Blvd.
Orange, CA 92868

**BOARD MEMBERS
PRESENT:** Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Lavanza Butler, RPh
Greg Lippe, Public Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member
Allan Schaad, RPh
Stanley Weiser, RPh

**BOARD MEMBERS
NOT PRESENT:** Ryan Brooks, Public Member
Albert Wong, RPh

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Counsel
Desiree Icaza Kellogg, Deputy Attorney General
Christine Acosta, Supervising Inspector
Joan Coyne, Supervising Inspector
Janice Dang, Supervising Inspector
Debbie Damoth, Staff Manager
Lori Martinez, Staff Manager

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

President Gutierrez called the meeting to order at 8:01 a.m. Board members present: Greg Lippe, Lavanza Butler, Stanley Weisser, Victor Law, Amy Gutierrez, Debbie Veale and Allan Schaad.

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

President Gutierrez asked if there were any comments from the public. There were no comments from the public.

III. Petitions for Reinstatement of Licensure or Other Reduction of Penalty

- a. Mumbert, William; RPH 48782
- b. Avalos, Albert; TCH 69538

Administrative Law Judge Debbie Ney-Perkins presided over the petition for reinstatement of licensure for William Mumbert, RPH 48782.

Note: Mr. Sanchez arrived at 8:04 a.m. and Ms. Muñoz arrived at 8:17 a.m.

The board recessed for a break at 9:06 a.m. and reconvened at 9:17 a.m.

Administrative Law Judge Debbie Ney-Perkins presided over the petition for reinstatement of licensure for Albert Avalos, TCH 69538.

IV. Closed Session

The board went into closed session at 9:54 a.m.

The board reconvened in open session at 10:33 a.m. to announce a case title and resumed closed session at 10:35 a.m.

The board went into closed session at 10:36 a.m. and ended closed session and recessed for a break at 11:41 a.m.

V. Reconvene Open Session

The board reconvened in open session at 12:02 p.m.

VI. Planning Discussion for Future Stakeholders' Meeting Regarding the Final Rule Implementing Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities, Specifically Including its Impact on Pharmacy Translations and Interpretations

Communication and Public Education Committee Chairperson Law reported that at the September 2016 Communication and Public Education Committee meeting, members discussed a new rule issued by the U.S. Department of Health and Human Services that requires pharmacies to provide "meaningful access" to customers with limited English proficiency. This rule includes posting taglines written in at least 15 languages advising the public that interpreter and translation services are available free of charge. Further,

Chairperson Law noted that the regulation implements Section 1557 of the Affordable Care Act, which forbids discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule went into effect on July 18, 2016. He said that a copy of the board's draft newsletter article on this requirement, the APHA summary documents and Federal Rule itself are included in the meeting materials.

Chairperson Law said that committee members discussed this new rule and how it impacts California law. He told the board that the committee contemplated if a meeting focused on this topic would be appropriate. Chairperson Law said that the meeting would provide stakeholders with the opportunity to discuss efforts to implement the provisions, an opportunity to discuss changes that may be necessary to California Law, and provide the board an opportunity to help facilitate implementation through information sharing and education.

Chairperson Law told the board that the committee is seeking guidance from the board about this issue, including if a dedicated meeting is appropriate and, if so, preferences for how and when such a meeting should be convened. He noted that the new rule would pre-empt many California laws that the board has implemented for label translations.

Board member Stan Weisser noted that the new federal rule pre-empts California Code of Regulations section 1707.6. Ms. Veale said that Communication and Public Education committee members felt it would be helpful to have stakeholders meet and present their solutions to complying with the federal rule, rather than board members trying to develop solutions without the necessary expertise. She said committee members wanted feedback from the board on whether to host a forum for stakeholders as part of the October board meeting and whether to do it as part of the two-day meeting or to add an extra day to the meeting.

President Gutierrez asked if APHA had offered any recommendations on compliance. Ms. Herold said she did not know. Ms. Herold said she was aware of one pharmacy chain that would be ready by the implementation date of the rule on Oct. 18. She said that because of the current California law has been on the books for some time, the California Pharmacists Association (CPhA) told her going from 10 to 15 languages would be straightforward with interpreter services. She said that identifying the top 15 languages would require a process but would be readily achievable.

Ms. Herold said providing translations for prescription labels raises concerns about pharmacists relying on a Google translation app, which she said could be unreliable. She said the board could use certified DCA translators for assistance once the board has determined what is needed.

Brian Warren of the CPhA said CPhA was beginning to look into compliance issues and would be checking with APHA for guidelines.

Ms. Veale said the committee noted that the board might not be able to provide 15 language translations on its website and the board would need to consider the impact on its current regulations. Ms. Herold said a statutory provision and some regulations would have to be amended to comply with the federal rule. President Gutierrez asked what health plans, PBMs or other large organizations that follow federal rules were doing. Ms. Veale said that the committee was told that the new rule had been imposed very quickly and that organizations were not prepared.

Mr. Weisser noted that the federal rule requires more notice to be posted in pharmacies and suggested asking the Communication and Public Education Committee to consider how pharmacies already are impacted by all of the posting requirements already established by the board. Ms. Veale said that already was a goal of the committee.

President Gutierrez noted that the board would not have to duplicate the federal rule, since pharmacies must comply with federal requirements. Ms. Herold said the board has some regulations that are outdated and must be brought into compliance with federal law or eliminated. In addition, she noted that changes also would be required in statutory provisions, including the bill that established label translations.

Ms. Herold suggested scheduling a stakeholder forum in mid-November in Southern California, to accommodate most of the board members. Ms. Herold stated the board could invite national stakeholders, insurance providers and other experts in addition to the public. She said that other boards of pharmacy have not acted yet and that many said they did not know about the new federal requirements.

DCA Counsel Laura Freedman noted the federal rule technically applies only to pharmacies that receive federal funding, and not to all pharmacies. Ms. Herold said the board does not want to provide different standards of care in California based upon whether consumers use pharmacies that receive federal funding or pharmacies that are reimbursed by other sources. President Gutierrez said most retail pharmacies would be covered by the new rule because most do in some way deal with Medicaid.

Ms. Veale suggested that the board not set a specific meeting date and instead direct that the forum be held within six to eight weeks. Chairperson Law noted that the federal rule was effective in July and it requires pharmacies to post taglines in at least two languages within 90 days. President Gutierrez noted that, because the rule is a federal requirement, pharmacies will have to comply regardless whether the board acts or not. She added that the board should focus only on areas where the federal rule impacts state regulations.

Ms. Herold suggested that the forum be organized as a board meeting but if a quorum is not available, then hold it as a committee meeting or a hearing of the board.

Steve Gray of Kaiser Permanente told the board that the new federal rule caught a lot of people throughout the health-care industry by surprise. He suggested that the board check with the Medical Board, other licensing boards and the Department of Health Plans on what they plan to do regarding compliance. He also informed the board that the American Society of Pharmacy Law will discuss the new federal rule during its national meeting Nov. 8-14 and suggested that the board not schedule its stakeholder forum during that period.

Paige Talley of the California Council for the Advancement of Pharmacy asked if the stakeholder forum would be webcast if it held as a committee meeting instead of a full board meeting. Ms. Herold said webcasting depends generally on availability and what other DCA board meetings are happening. She said the board would explore webcasting after a date is selected.

Motion: Set up a meeting to occur preferably before the end of the year to address the implementation of the final rule regarding section 1557 of the Affordable Care Act regarding nondiscrimination in health programs and activities, specifically including its impact on pharmacy translations and interpretations and other regulations and activities that are applicable.

M/S: Veale/Butler

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			

Gutierrez	X			
Law	X			
Lippe	X			
Muñoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong				X

VII. Discussion and Consideration of Proposed Regulations to Add Title 16 CCR sections 1776 et seq. related to Prescription Drug Take-Back

President Gutierrez noted that this item has been a longstanding issue at board meetings. Dr. Gutierrez noted the history of this rulemaking described in the board meeting materials. At the January 2016 meeting, the board approved proposed text to add Sections 1776 et seq. of Title 16 CCR, related to Prescription Drug Take-Back Programs. The 45-day comment period began on Feb. 12, 2016, and ended March 28, 2016. In addition, two regulation hearings were held on April 13, 2016 (one in Northern California and one in Southern California).

At the April 2016 Meeting, the board approved modified text to address concerns expressed during the 45-day comment period and at the regulation hearing. The 15-day comment period began on May 3, 2016, and ended May 18, 2016.

At the June 2016 Meeting, the board reviewed the comments received during the 15-day comment period. The board made policy decisions based on the comments and instructed staff to make the recommended changes to the language and present the modified language to the board at the July 2016 meeting.

At the July 2016 meeting, the board reviewed and approved the modified language as recommended by staff. A 15-day comment period was initiated on Aug. 4, 2016 and ended Aug. 19, 2016. The board received numerous comments.

President Gutierrez reported during the board meeting that members would have the opportunity to discuss the future of the regulation and determine what course of action to pursue. She noted that the meeting packet included an attachment with two drafts of the language – the modified text approved at the July 2016 meeting, and a clean version of the modified text approved at the July 2016 meeting – a compilation documents of the comments received during the 15-day comment period, and the comments themselves.

Ms. Martinez reviewed the comments with the board. She said the certain comments mainly focused on whether sharps would be allowed in take-back programs, which she noted was a policy decision by the board. President Gutierrez asked that the board review each comment by regulation section.

Regarding section 1776, President Gutierrez noted that Douglas Barcon recommended adding “mail-back” to the second paragraph so that they are not excluded from a take-back program. Ms. Herold noted that the board had removed “mail-back” from a prior version because a business does not have to be registered as a collector to distribute mail-back envelopes. President Gutierrez said the board would accept staff recommendation to reject the comment.

Regarding section 1776.1(c), President Gutierrez said Douglas Barcon noted a spelling correction, which the board accepted.

Regarding section 1776.1(e)(2), Ms. Martinez said the San Francisco Department of Environment noted that Department of Transportation does not require that Sharps be removed and added that it was mainly related to EpiPens. She said that the commenter suggested removing the reference to Sharps or else add an exemption for EpiPens. Ms. Freedman advised the board that a statute, section 4146, says that a pharmacist may accept needles from the public if contained in a Sharps container as defined in section 117750 of the Health and Safety Code, so allowing it in the regulation could create a conflict with the statute. Board members agreed to reject the comment.

Ms. Herold advised the board that she had been informed by CDPH that EpiPens disposed in locations to be incinerated pose an explosion risk.

President Gutierrez noted that the next three comments – from Douglas Barcon, about sections 1776.1(h), 1776.1(i) and 1776.1(i)(1) – were related to the previous mail-back comment that the board had rejected.

Ms. Herold asked Ms. Freedman about recent legislation dealing with sharps that the board had supported. Ms. Freedman advised the board that SB 1229 (Jackson) creates minimum standards for pharmacies that operate collection bins and gives them a degree of immunity from civil and criminal liability if they meet those standards.

Another comment regarding section 1776.1(i), from city of Santa Rosa, identified the wrong section. Ms. Martinez said the commenter appeared to be saying that a pharmacy in a skilled-nursing facility should be able to work with any agency, such as law-enforcement, to distribute mail-back envelopes in the facility. Ms. Herold said there is nothing in the pharmacy regulations that forbids skilled-nursing facilities from providing mail-back envelopes on their own. President Gutierrez said the board would reject the comment.

President Gutierrez said the next comment, regarding 1776.1(i) from Douglas Barcon, was about “mail-back,” which the board had previously decided to reject.

The next two comments, regarding section 1776.1(k) from San Francisco Department of Environment and from city of Santa Rosa, asked that the section be removed because a pharmacy that cannot comply with DEA rules cannot collect controlled substances. President Gutierrez said that the board had previously discussed that section and would leave it as it is.

Ms. Martinez said that the next comment, regarding section 1776.1(k) from Kaiser, asked that the language be changed to “collection receptacles” only. President Gutierrez said that the comment was the same as Santa Rosa’s comment, which the board had rejected.

Ms. Martinez said that a comment regarding section 1776.2(c) from Gordon Miller requested that language regarding postage-paid envelopes be added back into the section that is, in fact, already in the section. The board rejected the comment.

Regarding section 1776.3, Ms. Martinez said city of Santa Rosa expressed concern that the language could be misunderstood to mean that the deposit-opening to the receptacle must be locked at all times, not the receptacle itself. Board members expressed satisfaction with the existing language and rejected the comment.

Regarding section 1776.3(b), President Gutierrez said the comment from Fred Mayer was actually a question. The board rejected the comment. Board members also rejected the comments about this section from city of Santa Rosa and San Francisco Department of the Environment, because pharmacies may have an emergency exit door with the location.

Regarding section 1776.3(c) and comment from city of Santa Rosa, Ms. Freedman said that sentence in the regulation should have been deleted. She said the regulation requires that the collection box be closed if the employees of the registrant are not present – but the registrant in a hospital pharmacy setting is the hospital, not the pharmacy. She suggested that the language be changed to mirror the federal regulation.

Ms. Herold crafted new language: “When there is no pharmacy or DEA registrant employee available, the collection receptacle shall be locked so that drugs may not be deposited.” Board members approved the change.

Regarding section 1776.3(d), board members rejected the comments by city of Santa Rosa, Alameda County Hazardous Waste and San Francisco Department of Environment. Ms. Freedman explained that the comments were rejected because in the case of a retail pharmacy, the pharmacy itself is the licensee, not the entire store – so the employee has to be an employee of the pharmacy.

Regarding section 1776.3(d) and comment from Kaiser recommending against use of the term “slot,” board members agreed to change the wording to “opening.”

Regarding section 1776.3(f), board members rejected comment by Douglas Barcon about ASTM bag requirements. Ms. Herold said the board heard much discussion of bag standards before choosing the standards in the regulation.

Regarding section 1776.3(g), board members rejected the comment by Kaiser. Ms. Herold said the regulation could be amended later if it becomes a problem.

Regarding section 1776.3(h), on the advice of Ms. Freedman, board members agreed to add “sealable” to describe covers in the third sentence, and to delete the final sentence.

Regarding section 1776.3(i), board members rejected the comments by Alameda County Hazardous Waste and Douglas Barcon.

Regarding section 1776.3(j), board members rejected the comment by San Francisco Department of Environment recommending the wording “promptly.”

Regarding section 1776.3(m), board members rejected the comment from San Francisco Department of Environment about Sharps for reasons discussed earlier in the meeting.

Regarding section 1776.4(a), board members agreed to remove the sentence cited in the comments from San Francisco Department of Environment and city of Santa Rosa. President Gutierrez said the sentence implies that the pharmacy has to permit a skilled nursing facility to hand out envelopes.

Regarding section 1776.4(c), board members agreed with staff rejection of the comment.

Regarding section 1776.4(g)(2), board members rejected the comment by Kaiser for reasons discussed earlier in the meeting. The board also rejected the comment from Douglas Barcon, noting that pharmacy staff may wear gloves but do not have to wear gloves. The board also rejected the comment from city of

Santa Rosa for reasons discussed earlier in the meeting. The board also agreed to add “sealable” third sentence, as previously discussed in the meeting.

Regarding section 1776.4(h), the board agreed to remove “established by the pharmacy” from the third sentence. Ms. Herold said the board does not want to prohibit the reverse distributor from handing the liner to the pharmacy. She said there is no reason that a reverse distributor that is providing a bag to a pharmacy could not also serialize it.

Regarding section 1776.5(e), the board agreed with staff recommendation to modify the language as recommended by commenter Sharps.

Regarding section 1776.5(e)-(f), board members agreed with staff rejection of comment by city of Santa Rosa and comment by San Francisco Department of Environment.

Regarding section 1776.6, the board rejected the comment by city of Santa Rosa. Ms. Martinez said staff would go through the final language to make sure all the authority and reference citations are correct.

Regarding section 1776.6(a)(1), the board rejected comment by Alameda County Hazardous Waste. Staff noted that this is a DEA requirement.

The board rejected a general comment from San Luis Obispo stating that creating the regulations exceeds the scope of the board’s authority. Ms. Freedman said that the board has authority to regulate what happens in pharmacies; how pharmacists behave and what is professional conduct and what is not; and to enforce federal law. Based on all that authority, she said, the board also has authority to create take-back regulations. Ms. Herold added that the End of Life Option Act also specifically directed the board to develop a process.

The board rejected a comment by San Luis Obispo stating that the regulations would have a negative impact on the environment by forcing kiosks to close. Ms. Freedman said the comment indicated that the board was required to do an EIR under CEQA. She advised the board that the take-back regulations do not qualify as a “project” under CEQA – and even if it did, there are exemptions that would apply in this case.

Regarding a general comment from San Francisco Department of Environment that the board regulations mirror the DEA regulations, President Gutierrez said that has been the intent of the board.

The board rejected a comment about section 1776 from Gordon Miller, who said localities should be allowed to use DEA regulations to administer drug take-back programs. President Gutierrez said that was the board’s intent when the take-back regulations were created. She also noted that pharmacies do have to follow DEA regulations.

The board agreed to adopt three grammatical changes recommended by County of Los Angeles for sections 1776.6(a)(2), 1776.6(a)(4) and 1776.6(a)(5).

Ms. Freedman called the board’s attention to comments regarding section 1776.5(c), which requires two employees of the reverse distributor to pick up or receive inner liners from DEA registrants. She said the language should be amended to match the DEA requirement that only one employee is required to accept delivery. She recommended breaking the sentence into two sentences, with one stating that two employees are required to pick up inner liners and one employee may accept deliveries of inner liners. The board agreed.

Ms. Freedman and the board also clarified that, in section 1776.4, the board's intent is to remove the sentence: "The pharmacy may allow skilled nursing facility employees to distribute mail back envelopes or packages to consumers."

Patrick Holland from County of Los Angeles Department of Public Works expressed several concerns about the regulations. He said that putting EpiPens in a sharps container to be processed in an autoclave would not destroy the medication. Mr. Schaad and Mr. Weisser replied that an autoclave would destroy the drug. Mr. Holland cited an email from the Chief of the Medical Waste Management program of the California Department of Public Health advising that the medication would not be destroyed in an autoclave.

Mr. Holland also disagreed about language permitting a pharmacist to use professional judgment to decide not to host a collection bin. He said the language could cause conflicts in areas like Santa Cruz, which mandates pharmacy participation in take-back programs. President Gutierrez said legal counsel has advised the board that any such conflict would have to be decided by courts.

President Gutierrez read aloud the CDPH email regarding EpiPens, which advised against putting EpiPens in a Sharps container and suggested adding labels to take-back kiosks advising consumers what items should not be placed in them. Ms. Herold said the board chose to restrict labeling on take-back containers to a minimum. President Gutierrez said the board did not want people to simply dump all their syringes and needles in take-back bins.

Mr. Holland suggested an exception to allow Sharps with a self-injected drug attached to them to be deposited in take-back bins. Ms. Herold pointed out that such an exception would allow syringes that have residual medication in them to be deposited as well, which would pose a risk to anyone who handles the collection bin liner.

President Gutierrez asked if "medical Sharps and needles" is the same as a drug product that has a needle attached. Mr. Weisser said that if the board's intent is to protect anybody handling the liners from needle sticks, then the ban on Sharps and needles should remain in the regulation. Ms. Herold noted that the liner standards adopted by the board are not tough enough to prevent a needle stick.

Ms. Herold acknowledged that EpiPens and bronchial inhalers pose an issue. President Gutierrez said that, after the regulations are adopted, the board should issue some guidance and clear instructions to deal with the issue.

Stan Goldberg asked about drug destruction in lower-level care facilities such as assisted-living facilities and board-and-care facilities. He asked if those types of facilities could use products such as Rx Destroyer to render drugs unusable, or a mail-back bag to be sent to a DEA-approved reverse distributor, to destroy medications, including controlled medications. He said the facility would keep a log signed by two facility employees, and when the bag is full, it would be sent to the reverse distributor and properly destroyed.

Ms. Herold said that DEA regulations are for skilled-nursing facilities only. She said the care facilities described by Mr. Goldenberg would be under the auspices of a Department of Social Services licensed-care provider. Ms. Herold stated the facilities can go to law enforcement, use mail-back envelopes and drug destroyer products, but DEA regulations prohibit returning the drugs to the pharmacy.

Mr. Goldenberg asked about pharmacies taking an Rx Destroyer container from these facilities and placing it into a biohazard-waste receptacle. Ms. Herold said products like Rx Destroyer are outside the scope of the board's regulations.

Steve Gray of Kaiser Permanente advised the board that needles used in EpiPens retract after the medication is injected, but the needles do not retract in the generic version of the drug. He also said that many Sharps containers have syringes that still have drugs in them because not all of the drug is used.

Dr. Gray also said that some pilot take-back programs have collection bins with slots or small openings that require users to take pills out of the bottles and containers and put them directly into the bin without the bottle or container. He said the result is often that pills are left on the floor around the bin. He added that some slot openings are not secure mechanisms like mailboxes that prevent users from reaching inside. In other states, he said, thieves have used a vacuum tube to suck the loose pills out of the bins.

Robert Stein, speaking as an individual, pointed out that all the responsibility and liability for drug take-back falls on the pharmacists and not on consumers.

Paige Talley of the California Council for the Advancement of Pharmacy warned that the board’s regulations could conflict with existing rules by CDPH and Department of Waste Management on destroying medications in care facilities. Board members said any conflict could be raised during the next comment period.

Ms. Freedman told the board that section 1776.4(c) regarding removal, transfer or storage of inner liners from a collection bin in a skilled-nursing facility conflicts with section 1776.4(k), which also addresses the removal, collection or storage of liners. Section 1776.4(c) says only the pharmacy shall remove, seal, transfer, store or supervise those actions, but section 1776.4(k) says those actions shall be performed only by one collector-pharmacy employee and one supervisory level employee of the long-term care facility, or by or under the supervision of two employees of the collector pharmacy.

Ms. Freedman recommended deleting section 1776.4(c) entirely. Ms. Herold agreed that section 1776.4(c) was not necessary because it has little impact. The board agreed.

Motion: Notice the regulations for a 15-day comment period.

M/S: Weisser/Law

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board recessed for a lunch break at 1:44 p.m. and reconvened at 2:04 p.m.

VIII. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR sections 1732.05, 1732.2

and 1732.5 related to Continuing Education

President Gutierrez reported that the board had reviewed this item before and noted that in July, the board discussed and recommended consolidating the six specific subject areas into a board-provided CE course in law and ethics. She said the board approved a modified text and initiated a 15-day comment period that began on Aug. 3, 2016, and ended on Aug. 18, 2016.

President Gutierrez reported that the board received one comment during the 15-day comment period. She noted that the comment was anonymous and read: "There should be no Board provided CE requirement at all. All CE should be ACPE accredited and the pharmacist be allowed flexibility to choose among any general CE's that would meet the requirement for license renewal. This is an outrage to mandate pharmacists to take board provided CE's when pharmacists are licensed in multiple states."

Mr. Lippe asked whether there would be a charge for board-provided CE, and President Gutierrez asked about what happens to pharmacists who reside outside California. Ms. Herold said the CE would be available at least in video form and possibly also in webinar form, as well as perhaps a CE form in the newsletter. She noted that the board already provides CE this way, and the only difference is that this CE will be focused on a single topic. She added that the board currently provides CE at no charge.

President Gutierrez said that she was concerned that pharmacists have sufficient access to the CE course. Ms. Herold said the webinar format would be "on demand" and that staff could explore other methods of access, including a YouTube video. She said this would be a new opportunity for the board to explore and use different types of technology to provide CE training.

Brian Warren of the California Pharmacists Association told the board that pharmacists should not have to take board-provided law and ethics CE. He noted that pharmacists already take law and ethics CE courses in various venues throughout the state. He said that they should be able to apply that course to satisfy this CE requirement, unless the board believes there are certain law and ethics areas that are not being provided and that the board wants to provide. In addition, he asked CE provided by the board in person would be accredited by ACPE.

President Gutierrez replied that, based on previous board discussions, the board believes that there sometimes pharmacists do not understand or have trouble complying with new regulations issued by the board. She said that board-provided CE would provide an opportunity for the board to educate pharmacists on those targeted areas.

President Gutierrez also suggested asking the License Committee to look at how the board-provided CE could be done, how it could be accessed by pharmacist and other details about how it would work. Mr. Weisser said the Licensing Committee would be willing to do that.

Ms. Freedman added that board-provided CE does not need to be accredited by ACPE. She explained that the board has authority to approve its own CE course.

Steve Gray of Kaiser Permanente, speaking on his own behalf, expressed support for the board's decision to require two hours of CE on law and ethics rather than six hours on various subjects. He encouraged the Licensing Committee to consider what standards would be used to measure whether pharmacists are actively learning from the board-provided CE course.

Mr. Weisser noted that many educational institutions, including universities and accrediting bodies, struggle with how to measure learning outcomes. President Gutierrez suggested that pharmacy schools

could be invited to advise the Licensing Committee on this issue.

Motion: Adopt the regulatory language as approved on July 27, 2016, and delegate authority to the executive officer to make technical and non-substantive changes as may be required by the Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

M/S: Veale/Sanchez

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

IX. Pending Compounding Regulations, Title 16 California Code of Regulations, 1735 et seq., and 1751 et seq.; Status Update and Discussion and Consideration of Next Steps, If Necessary

President Gutierrez reported that on Sept. 14, 2016, the Office of Administrative Law approved the board's compounding regulations, which go into effect Jan. 1, 2017.

President Gutierrez noted that the compounding regulations contain provisions that will require construction be undertaken in some pharmacies. She said that such construction may require a temporary time waiver to permit a pharmacy to do the structural modifications required. She noted that a process to do this will be completed shortly.

The board meeting materials included slides by Ms. Herold of draft procedures for requesting a waiver. Ms. Herold said that she and Supervising Inspector Christine Acosta also developed a standard form package for waiver requests that Ms. Herold planned to discuss with Ms. Freedman the next day.

President Gutierrez suggested developing a standardized waiver request form that would be available to pharmacies that want to use it and would everyone know what information is required for a request.

Ms. Acosta told the board that she has been collecting questions, license numbers and other information from pharmacists seeking information about the waiver process. She advised that pharmacies perform a gap analysis to determine what changes need to be made to comply with the compounding regulations. She added that the board currently is not accepting waiver requests.

President Gutierrez and Dr. Acosta clarified that waivers would be available only for physical changes in facilities that need to be done to comply with the new regulations, not for other matters such as training. Ms. Acosta added that the waiver allows only a delay in compliance.

Mr. Lippe asked if there could be anything else besides construction that would be a legitimate reason for seeking a waiver for time. Dr. Acosta said the law is written in a way that does not allow the board to approve a waiver for any reason that is not construction. President Gutierrez noted that the draft regulations had been public for a year, affording plenty of time for pharmacies to know what would be required by the new regulations.

Ms. Herold said that typically there is a period of educational compliance when the board issues major new regulations. She said that for the past year, inspectors have been training pharmacists about the new regulations during annual inspections of sterile compounding pharmacies. President Gutierrez noted an earlier question about what happens if a pharmacy cannot escape a lease in time to comply with the new regulations; Dr. Acosta said the new law would not allow a delay in compliance if there were no construction or alteration to the physical environment.

Mr. Law asked if a hospital currently is doing sterile compounding, and some construction changes are needed, could the hospital continue compounding at the current site while construction is being done at a new facility. Supervising Inspector Acosta said it is not clear if the regulation allows for a waiver for construction being done at a new facility, so the board would have to decide. President Gutierrez said board members would gain a better understanding of issues once it begins receiving waiver requests. She added that OSHPD also would be involved in waiver issues.

Supervising Inspector Acosta said many licensees are ready to begin submitted documentation. Ms. Herold said a form for waivers has been developed and that she would review it the next day with Ms. Freedman. President Gutierrez asked that the form be brought to the October board meeting and suggested that the board reconvene its compounding group – including Mr. Schaad, Ms. Freedman and Ms. Herold – to work on the form and bring it to the October meeting.

Supervising Inspector Acosta said she expects to receive 800 waiver requests. She also asked if the waiver process would apply to NSE, who must meet the same requirements and are also asking about the process. She said that if board review of each waiver request would take a lot of time, so she hopes to move forward as quickly as possible. Ms. Herold noted that the board would be asking licensees what they intend to do about compounding while the waiver process is pending.

Ms. Freedman noted that licensees would not be required to use the waiver form developed by the board because it is not part of the regulations. She asked if the form should go to the full board before it is released to the public and noted that it could change over time. Ms. Herold said the board would not be asking to see construction plans. Mr. Weiser noted that construction necessary for some pharmacies to comply with the new regulations could take years. Ms. Herold said that the board would work on those types of issues with OSHPD in the review process. President Gutierrez said that having OSHPD involved in the review group would help minimize delays.

Brian Warren of California Pharmacists Association asked about a time frame for releasing a recommended form. Ms. Herold said it would depend on how quickly a team to review the process could be assembled. She added that the general parameters of what information pharmacies will be required to submit were outlined in a power point presentation at an Enforcement Committee meeting last month. She said the form would be straightforward and easy to complete and would not require an architect to complete it.

Ms. Freedman added that the form also would not be required. Ms. Herold said the form would be “guidance.”

Mr. Warren asked who would review the waivers. Ms. Herold said waivers would be two board members, until the board decides to give that duty to board staff. President Gutierrez said it would helpful for stakeholders on the inspectors' staff to also be involved.

Ms. Acosta suggested that she and another inspector work with the board to review five to 20 waiver forms, get a sense of what the board wants and then take over the task to keep the process moving quickly. If staff members have any questions, they can be presented to the board. President Gutierrez said she agreed with the suggestion.

Mr. Warren asked if the board would require licensees to specify a projected completion date for construction and what would happen if construction were not completed by that date. Ms. Herold said the draft waiver form includes the following questions: Is there an architect? If so, who? Is this a structural modification? Have building plans been developed – yes or no? Has a building permit been secured? What is the time frame for completion of construction. She added that, for health-care providers that would have to use OSHPD, the board also would ask for a copy of the project completion timeline and the general OSHPD project number so that board staff could track the project online.

President Gutierrez asked about the status of FAQs for sterile compounding. Ms. Freedman said she would be discussing the FAQs with Ms. Herold the next day. President Gutierrez said the FAQs would help address many questions about the new regulations. Ms. Herold added that staff is working on a self-assessment form for sterile compounding.

Mr. Warren asked about compounding of hazardous drugs. He said the definitions in the regulations of hazardous drugs specifically initially referred to antineoplastic drugs identified by NIOSH, which has three tables of hazardous drugs – one of antineoplastics and two of nonantineoplastics. He said pharmacies believed the nonantineoplastics were not going to be considered hazardous, according to the regulations. But subsequent communication that the language regarding “any other drug deemed hazardous by the PIC,” and there would be an expectation that there are many drugs on those other two tables of the NIOSH list that ought to be considered hazardous. He said that this has drawn the recent attention of non-sterile compounding pharmacies, who had not expected that this would apply to them.

Mr. Warren said that USP 800 allows for pharmacies to do a risk assessment in which they look at their compounding of one of those drugs on the NIOSH list but, based on the process they are using, the PPE they are using and the engineering control they are using, there is no risk of contamination. He said USP 800, for non-sterile compounding, allows a pharmacy to deem a drug “nonhazardous” in that specific process. He asked if the board is going to take a similar view for pharmacies in terms of doing a risk assessment consistent with USP 800 so that for certain drugs, although they may appear on the NIOSH list, the full-blown USP 800 or negative-pressure room is not required for something that has controls in there.

President Gutierrez asked for the difference between doing a risk assessment and having the PIC identify what is considered hazardous. She said she saw them as similar. Supervising Inspector Acosta said USP 800 asks for an assessment but requires all drugs on all three NIOSH lists to be handled as hazardous drugs. She said that USP 800 does not allow for exclusion of any of the drugs. She said that the board's regulations allow pharmacists to do a risk assessment and use their professional judgment in determining how they handle and use a hazardous drug in their facility for nonantineoplastics. She said the board wanted to do what it could to not hinder the practice of pharmacy while still protecting patients.

Mr. Schaad said the list includes a lot of commonly dispensed drugs, such as Dilantin, Tegretol and others, that meet NIOSH criteria for hazardous drugs. He indicated the list raises concerns about regulatory compliance. Mr. Warren said that USP says that an entity must maintain a list of hazardous drugs “which

may include items on the current NIOSH list.” In addition, he said, USP says that “any antineoplastic HD must follow the requirements in this chapter” and “dosage forms of other hazardous drugs on the NIOSH list the entity may perform an assessment risk to determine alternative containment strategies.” He said those alternative containment strategies may be for certain drugs that are on the NIOSH list that, when treated with a certain procedure, do not need the full requirements of the chapter 800 – mainly, the negative pressure room – because the risk of exposure has been mitigated by specific procedures that the pharmacy has performed a risk assessment for and determined that the risk of contamination is low enough that they should not be deemed hazardous.

Supervising Inspector Acosta said that she and Mr. Warren agree on the issue while relying on different sections of USP 800. She said that, while NIOSH may designate a drug as a hazardous drugs, if one looks at how it is being handled – such as a commonly dispensed drug cited by Mr. Schaad – it may not need all of the protection and room requirements needed in 800.

Mr. Schaad agreed and said he wants to ensure that the public can obtain the drugs without too much regulatory, bureaucratic burden. He said he wants to make sure that the board, while in the business of public protection, uses common sense in the enforcement of it.

Mr. Warren said that pharmacists also want common-sense enforcement as well as clarity. He noted that USP 800 lays out more detail by requiring that, if there is a drug on the NIOSH list that a pharmacist is not going to deem hazardous for how it is being used, the pharmacist must perform a risk assessment. He noted that the regulations say simply “in the PIC’s judgment,” which is less detailed. He said the USP 800 procedure for performing a risk assessment provides greater clarity to pharmacies that are in this situation. He said that if a pharmacy does not have to construct an entire negative pressure room for certain compounding, that could make the difference between the board receiving several dozen waiver requests versus waiver requests from all 900 compounding pharmacies.

President Gutierrez said that if she were a PIC who performs a self-assessment and determines that a nonantineoplastic drug is not a hazardous agent, she would not have to include the drug on the list and would have some justification for that. Mr. Warren agreed and said he would like clarity from the board that he and the board are in agreement on this question. He said that although the agent is still hazardous, what the pharmacist is doing with it has mitigated that hazard. President Gutierrez said they were in agreement.

Supervising Inspector Acosta said the regulations could have been more clear. Instead of “the professional judgment of the pharmacist,” the board could have said “after a risk assessment is performed by the PIC” or something to that effect. She said the board is allowing the PIC to use professional judgment to determine if the product and form and manipulations being performed are considered hazardous. She said the board gave California pharmacists a bit of leeway in the way the regulations are written, but it also created a gray area that raised concern among pharmacists.

Mr. Warren said his organization is trying to establish guidelines for its members so they can feel more comfortable in complying with the regulations. President Gutierrez said the board shares that goal, and she called for feedback back and forth between the board and pharmacists to ensure that understanding is there.

Ms. Freedman noted that the board had a specific motion on the floor. She recommended that the board focus on comments related to the particular motion to resolve the motion and then move on to other comments related to the agenda item so that the board could take further action if necessary, based on the comments being received. Ms. Freedman read the motion to authorize Mr. Schaad and President

Gutierrez to work with staff to help develop the waiver process and review a sample form that will be made available to the public.

President Gutierrez agreed and asked Mr. Warren if he had any comments related to the pending motion. Mr. Warren said the board has discussed that USP 800, for nonsterile hazardous drugs, allows the use of redundant HEPA filtration instead of external ventilation – but the board’s regulations do not allow for that. He said that is a big difference which the board has acknowledged and has said can be cleared up with follow-up regulations.

Mr. Warren asked if there is any way to deal with this problem through the waiver process, because the regulations take effect on Jan. 1 – and even if the board were to file rulemaking immediately, pharmacists still would have an extensive period of time during which it would not be allowed. He asked if there is a way to deal with this issue so that those pharmacies are not harmed. He said that even pharmacies that have been pro-active in trying to comply with USP 800 have already purchased those redundant HEPA filtration hoods at a cost of about \$20,000 each, and now the regulations might not even allow them to use that equipment.

Ms. Freedman noted that the waiver is specifically for physical alterations. Board members discussed whether the issue is one involving only equipment or physical alteration. President Gutierrez said pharmacies would not have to do physical construction because they have the possibility of redundant HEPA filters. Supervising Inspector Acosta said the board could consider a regulation that would allow pharmacies not to do physical construction. President Gutierrez said that would be appropriate as long as it is for non-sterile compounding.

Supervising Inspector Acosta said pharmacies are going to have to externally vent the rooms anyway, so they want the HEPA filters so that they do not have to vent the box or biological safety cabinet that they are compounding in. But she said pharmacies still have to vent the rooms, so the question is whether the board is going to allow a waiver process for the redundant HEPA filter and then an additional one for not externally venting the room.

Ms. Freedman said those types of questions would be presented best on a case-by-case basis which can be addressed as those requests begin coming to the board. She added that right now, the board is talking about the waiver process and form and the pending motion is about delegating authority to President Gutierrez and Mr. Schaad to work with staff to develop something that the board can use. President Gutierrez agreed and said the board would get a better feel on how to handle issues as cases arrive. Mr. Schaad agreed.

Ken Schell, PIC and director of pharmacy at Sharp Grossmont Hospital, offered his services to the board group working on the waiver form process. Paige Talley of California Council for the Advancement of Pharmacy asked if a pharmacist who is not allowed by the property owner to make alterations and is looking to get out of the lease could receive a waiver. Ms. Herold said that situation would not qualify for a construction waiver.

Motion: Authorize President Gutierrez and Board Member Schaad to work with staff to develop a recommended format that can be distributed to stakeholders so that they understand what is being requested of them in the waiver process.

M/S: Gutierrez/Sanchez

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

President Gutierrez invited Mr. Warren for additional comments. Mr. Warren said that CPhA members want to know if the board will accept published literature for determining a BUD for specific formulations or will it require an in-house study for all BUDs.

Ms. Freedman said the question is related to enforcement. She the board meeting was an awkward forum for resolving the issue and suggested submitting questions that could be addressed with FAQs. Mr. Warren agreed and added that time is of the essence.

Mr. Schaad asked what published literature Mr. Warren was suggesting. Mr. Warren said the question is whether each pharmacy would have to do its own in-house study for establishing BUDs.

Supervising Inspector Acosta said pharmacies want to know if they can use another pharmacy’s stability study in its own operations. She said the issue is specifically addressed in the new regulations, section 1735.2(i)(4), which says, that in addition to the requirements in paragraph (3), which is about the extension of the BUD, “the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews and packaging as the finished drug or compounded drug preparation.” She said the regulation is alluding that if pharmacies meet that criteria, it may be possible to use somebody else’s study. But she added that they have to meet that criteria – so the answer is yes and no.

Mr. Warren said another question deals with the conflict between what is in the statute for sterile compounding and what is in the regulations for hazardous compounding. He said the B&P Code requires all sterile compounding to be done in a positive air pressure differential room, and the regulations require all hazardous compounding – including hazardous sterile compounding – to be done in a negative pressure room. He said the room cannot be both positive and negative at the same time.

Mr. Warren recommended that the board enforce the regulations, which is consistent with USP 800 as far as how to deal with sterile hazardous compounding. He said the question is one where pharmacies, which may need to make a physical change, need to know what the board is going to expect to be doing on Jan. 1 and whether they need to change the air pressure differentials or make any construction changes before then, or perhaps submit a waiver.

President Gutierrez said the board needs to have these types of FAQs come up and then take a look at them. Mr. Schaad agreed. President Gutierrez said the board would be modifying and adding to the first draft of FAQs. She said the board’s goal is not to play “gotcha” with pharmacies but to improve and elevate the practice of pharmacy in California.

Mr. Warren said his organization wants the pharmacies to be clear on what they are expected to do. He said they need clarity as soon as possible, because these are questions that may require physical changes to be made at the pharmacy.

Mr. Warren also said that B&P Code section 4127.7 requires that all compounding be done in an ISO class 5 hood within an ISO class 7 cleanroom – while the regulations define an ante-area which can be ISO class 8 or better, which can include staging components and other high-particulate generating activities. He said CPhA is seeking clarity from the board as to whether this allows for pre-sterilization procedures to be performed in the ante-area, which he said is a good policy and consistent with FDA guidance on insanitary conditions. He said the regulations do not make the board’s intent clear regarding allowing the pre-sterilization procedures to be performed in the ante-area. He said he would submit the question to the board.

Ms. Herold asked if the B&P Code needs to be amended to remove inconsistencies and conflicts with the recently approved regulations. Board members said yes. Ms. Herold said staff could present proposed legislation at the October board meeting that could be an omnibus provision.

Supervising Inspector Acosta agreed and said the board needs to change section 4127.7 and also needs to address building code 1250.4 which conflicts with CGMPs and the board’s pending regulations. Ms. Herold said that would be a three-year process, and Supervising Inspector Acosta suggested that the board and legal counsel could find a way to work around the building code.

Ms. Freedman noted that the statute will trump a regulation. She said that staff will develop ways to resolve inconsistencies.

Paige Talley of California Council for the Advancement of Pharmacy asked if section 1735.2(F), which says “30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations” in reference to BUDs, means when the compounding pharmacist is adding water to that product. She said many of the bases come with water in them that pharmacists are not adding. She asked if any water-based base that is used has to be 30 days or less.

President Gutierrez said it was a good question to submit for the FAQs. Supervising Inspector Acosta said she would refer pharmacists to section USP 795 for a clearer answer. Ms. Talley asked that the question be addressed in an FAQ.

Ms. Kellogg suggested that the regulations are sufficiently clear and said there may be a few areas where FAQs are needed. She said it is important for the board to move forward. Ms. Talley said that she had more questions. President Gutierrez asked her to submit them for consideration for FAQs. Ms. Freedman said she agreed with Ms. Kellogg and that clarification about what the regulations require would best be handled by FAQs. Ms. Talley said she would submit the questions for consideration.

X. Federal Food and Drug Administration’s Draft Guidance Documents – Discussion and Consideration, Including Whether to Submit Board Comments, regarding:

- 1. Insanitary Conditions at Compounding Facilities**
- 2. Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug and Cosmetic Act**
- 3. Compounded Drug Products That are Essentially Copies of Approved Drug Products Under Section**

503A of the Federal Food, Drug and Cosmetic Act

President Gutierrez reported that the FDA had released these documents regarding compounding and said they are still in draft form. She said that the FDA notes in each of these documents that the guidance documents “do not establish legally enforceable responsibilities. Instead, the guidance documents describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.”

President Gutierrez said that at its Aug. 31 meeting, the Enforcement Committee discussed several of the guidance documents which contain proposed elements for FDA regulation. She said the committee determined that comments should be submitted on the guidance documents and asked staff to draft comments for the board to review and approve at its next meeting. Ms. Herold said comments are due within 15 to 20 days, by mid-October.

President Gutierrez noted that Ms. Herold had just attended the FDA’s *50-State Meeting on Compounding* on Sept. 20-21. She asked Ms. Herold to update the board on the meeting.

Ms. Herold said the FDA is mostly emphasizing the document on insanitary conditions at this time. She said it was done in the wake of complaints by California and other states about the FDA inspecting and holding 503A compounding pharmacies to good-manufacturing practices, which is the standard for outsourcing facilities – a very high standard that few pharmacies can meet. She said this action forced the pharmacies to issue a recall, retract a lot of product and, in some cases, stop sterile compounding.

Ms. Herold reported that the insanitary guidelines list conditions under which the FDA will take action against either a compounding pharmacy or an outsourcing facility and, if a product is adulterated, will order a recall. She added that she was not aware of any outsourcer that has been required to do this.

Mr. Weisser asked if the document was pushed by the industry in an effort to limit providers who are compounding products. Ms. Herold said she believed that what is happening is that the FDA wants to get to a point where pharmacies are compounding, with rare exceptions, only patient-specific drugs with a prescription in hand. The FDA does not support pharmacies compounding for prescriber-office use unless the entity is an outsourcer, in which case the company is held to CGMPs.

Ms. Herold said she pointed out at the FDA meeting that no one regulates compounding in physicians’ offices. She said that if the board – which has a statute authorizing the board to oversee compounding for future use for prescribers – stops doing that, more drugs potentially will be made in physicians’ offices, because pharmacies would no longer be providing the drugs for doctors’ offices.

President Gutierrez asked if USP 800 is restricted to only pharmacies. Ms. Herold said physicians can compound too, and Mr. Schaad noted that there would be no enforcement. President Gutierrez said the board should reach out to the Medical Board to take action for its licensees just as the Board of Pharmacy is doing. Ms. Herold said the discussion with the Medical Board has been about whether California law even allows physicians to compound. She said that she and the Medical Board executive officer have discussed establishing regular group meetings between board meetings to share issues of concern.

President Gutierrez noted that federal standards for compounding apply to all – not just to pharmacy preparation – and suggested that the state should be enforcing it as well in all areas where preparation takes place. Ms. Herold said the Medical Board would be responsible for enforcing compounding by physicians. Mr. Weisser noted that is not an area where the Medical Board has expertise. Ms. Herold said that some physicians’ offices hire pharmacy technicians – who are simply employees in that setting, not

pharmacy technicians – to do compounding.

Ms. Herold added that the Veterinary Board is in the process of developing regulations for compounding in veterinary offices for their own patients. She added that they would not be allowing sterile compounding in veterinary offices.

Ms. Herold said it was unclear how many physicians' offices do compounding. She added that some specialties do it more than others.

Ms. Herold said the FDA would continue to use the insanitary conditions guidelines in pharmacies to force recalls and push for a higher standard. She added that one way around that would be for the board to sign an MOU. She said that without it, the FDA would limit cross-state transmission to 5 percent.

Jody Jacobson, a pharmacist, asked how a state agency charged with protecting consumers could allow the Medical Board not to put consumers at risk by not regulating compounding in physicians' office.

Ms. Herold asked the board for approval to work with President Gutierrez on comments for the FDA on the guidance documents. Mr. Weisser recommended that Mr. Schaad also be involved in drafting the comments.

Ms. Herold said that one issue being discussed regarding 503B facilities is whether they involve making a copy of a commercially available drug. She said the guidance document is clear that if duplicating a commercially available product is not permitted, unless there is a drug shortage. She said that is to protect manufacturers who have gone through ANDA and NDA testing for their drug products. She said outsourcers do not do stability studies and other necessary documentation, and that threatens the drug approval process and does not protect consumers.

Mr. Schaad said he disagreed with that argument. He said the issue is something that is being pushed by drug manufacturers and is contrary to the laws and regulations that the board enforces.

Andrew Harrison, chief counsel for Pharmedium Services, a 503B outsourcing facility, provided a statement. He said the FDA was incorrectly applying the clinical difference documentation requirement to drugs made without any bulk substance API, such as drugs that are compounded using a sterile-to-sterile process to develop the compounded drug product. He said the guidance blurs the line between 503A pharmacies and 503B outsourcing facilities. He said the FDA document fails to address the public health objective that is stated in the intent of the statute.

Grace Magedman of Children's Hospital of Orange County (CHOC) urged the board to draft comments to the FDA on the compounding of essentially copied products. She said that many commercially made drugs are intended for adults and do not have a pediatric indication. She said CHOC is required to purchase the drugs, which can be very expensive and detrimental to patient care.

Motion: Direct the executive officer to work with President Gutierrez and Mr. Schaad to draft a response to the FDA on the three guidance documents listed on the board's agenda.

M/S: Law/Weisser

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				X

Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board recessed at 3:42 p.m. for closed session

The board adjourned in closed session at 5:10 p.m.