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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

CALIFORNIA STATE BOARD OF PHARMACY

BOARD MEETING MINUTES

DATE: December 13, 2012

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

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Ramon Castellblanch, Public Member
Amy Gutierrez, PharmD
Victor Law, PharmD
Deborah Veale, RPh
Shirley Wheat, Public Member
Albert Wong, PharmD
Tappan Zee, Public Member

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Rosalyn Hackworth, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Legislation/Regulation Manager
Robert Ratcliff, PharmD, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Jan Jamison, Public Information Officer

Call to Order

President Weisser called the meeting to order at 9:40 a.m.

I. General Announcements

There were no announcements.

President Weisser conducted a roll call. Board members Shirley Wheat, Ryan Brooks and Rosalind Hackworth were absent. Ms. Wheat arrived at the meeting late.

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

Executive Officer Herold announced that the meeting would be webcast and asked that speakers approach the speakers' table and identify themselves.

Scott Guess, owner operator of two independent Pain Management Pharmacies in Southern California, provided that his pharmacies have utilized the CURES database, but that most chain pharmacies don't have access to it. He provided that wholesalers have now restricted his purchase of controlled substances to no more than 30% of his entire stock. As a result, most pain management patients have been diverted out to retail pharmacies, where diversion is more likely to occur. Mr. Guess presented a proposal to address the issue and suggested the board present it to the National Association of Boards of Pharmacy (NABP).

III. Discussion on the Board of Pharmacy and Medical Board of California's Joint Forum on Appropriate Prescribing and Dispensing of Controlled Substances Scheduled for February 21 and 22, 2013

Linda Whitney, Executive Officer of the Medical Board of California, provided that the Medical Board and the Board of Pharmacy will jointly be sponsoring a summit on appropriate prescribing and dispensing of controlled substances. The summit is scheduled for February 21 and 22 in San Francisco. Ms. Whitney explained that the first day of the forum will focus on discussion of the issues surrounding prescription drug abuse and diversion and the second day would be devoted to finding solutions. Pharmacists, physicians, policy makers and other prescribers will be invited to attend.

IV. Regulation Hearing and Possible Action on Proposed Regulations

President Weisser opened the hearing at 10:04 a.m. and explained that a regulation hearing is being conducted in response to a request for hearing related to the board's proposed regulations to Add Title 16 California Code of Regulations Sections 1747 and 1747.1, Related to E-Pedigree.

President Weisser invited interested persons to provide oral testimony.

Nancy Noe, representing Johnson & Johnson, sought the board's clarification on the first sentence of Section 1747 related *to the smallest package or smallest container for sale by the manufacturer* She stated the language could be interpreted to mean the small unit, such as a blister. She recommended that the language should state it applies to the smallest unit of sale by the manufacturer.

Mandy Lee, representing the California Retailers Association referenced the statutory requirements at Business and Professions Code Section 4163.2 regarding written declarations that are required to be submitted to the board under penalty of perjury. She stated the language at 1747.1(c) exposes their members to criminal liability for accidental or unintended inaccuracies that may be submitted in these declarations. She described the inventory efforts that will be conducted by the CRA's members in conforming to the proposed requirements.

Jennifer Snyder, representing the National Association of Chain Drug Stores, echoed the comments of Ms. Lee. She stated that the way the regulations are currently drafted does not allow for human error. She asked how the regulations would be enforced, if there would

be a civil penalty for errors, and what the appeals process would be. She referenced language / modifications in the written comments submitted and asked the board to consider that language. She asked the board to clarify the enforcement of the regulations and describe the appeals process. Ms. Snyder sought clarification on the distribution provisions found at proposed section 1747.1(b)(3) related to statements that would specify the anticipated means of any subsequent distribution or disposition of drug products.

Brian Warren, representing the California Pharmacists Association, expressed agreement with the presentations by Mandy Lee and Jennifer Snyder.

There were no further public comments from the public and President Weisser closed the hearing.

Mr. Weisser requested that Deputy Attorney General Joshua Room explain the technical language in the regulations.

Mr. Room provided stated that statute refers to a unique identification number. He said the board's proposed language at Section 1747 would require that this unique identification number that will be attached to each package or unit. He explained that the board's proposal would require this identification number to conform to the FDA's guidance document (which is incorporated by reference).

Mr. Room stated that the proposed language at Section 1747.1 has two main parts. He said the first (subdivision (a)) deals with the manufacturer's designation of 50 percent of their drug stock distributed in California, that statute requires be serialized by January 1, 2015, and the remainder that shall be serialized by January 1, 2016. He explained that subdivision (a) specifies the information that shall be included in the declarations that shall be submitted to the board.

Mr. Room explained that the second part (subdivisions (b), (c) and (d)) has to do with "grandfathering" – the designation by all members of the supply chain of stock that was in their possession prior to the effective date of pedigree, as it relates to that member of the supply chain, of drugs that will not be subject to pedigree because they were already in their possession.

The board indicated they would review the written comments received during the 45-day public comment period.

Ms. Herold commented on the oral testimony of Ms. Noe and noted that many of the comments contained in the written comments were not specific to the board's proposal. She referenced Ms. Noe's comment to clarify the *smallest package or smallest container for sale by the manufacturer* and asked Mr. Room if the board should include the information that already exists in statute within the proposed regulation. Specifically, Ms. Herold asked if the board wished to duplicate the language in B&PC 4034(d) in the regulatory proposal.
Mr. Room indicated that proposed Section 1747 could be modified to include a reference to B&PC 4034(d) – and suggested this be included in the first sentence after the words "…that is to be established and applied to the smallest package or immediate container…"

Board Member Veale made a motion to modify proposed section 1747 (the first sentence) to read as follows:

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container as defined in subdivision (d) of Section 4034 by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), herein incorporated by reference.

Public Comment
Steve Gray, President of the California Society of Hospital Pharmacists, suggested that more discussion should take place between the Board of Pharmacy and pharmacy staff and that additional guidance be provided for industry on how the provisions of the proposal will be enforced. He explained that when hospitals share medications, the package size is sometimes changed. He provided an example of hospitals sharing unit-dose medications and how those types of transfers may need to be documented. Ms. Herold encouraged Mr. Gray to submit written comments to the board, so that the board could respond for the benefit of all.

There were no additional public comments.

M /S: Veale / Lippe
Support: 10 Oppose: 0 Abstain: 0

Staff Counsel Kristy Shellans requested that she direct the discussion to review each of the written comments to the board's proposed / specific text for the rulemaking file, and ask for the board's action on each one. She directed the board's attention to the written comments, adding that many of the comments contained in the documents are not directed at the board's specific proposal.

Comment #1 – Mike Durschlag, Allermed Laboratories, Inc. Ms. Shellans noted that the comments contained in Mr. Durschlag's letter were not regarding the board's specific proposal. She added that the only comment that was somewhat related was in the form of a question, where he asked if the board had a recommendation for including or omitting the lot number and expiration date in the SNI. Ms. Shellans noted that the board's proposal was pretty clear with respect to the lot number and expiration date, and she reflected on the regulatory proposal at 1747 where the proposed language states what the serialized numeric identifier shall be comprised of (a unique numeric or alphanumeric number attached to the NDC number). She recommended that the board reject the comment.

Ms. Herold provided that this language is reflected in the FDA's model.

Motion: Reject the comments of Mr. Durschlag.
There was no public comment.
M /S: Lippe / Gutierrez
Support: 10 Oppose: 0 Abstain: 0

Comment #2 – Jean-Pierre Allard, Optel Vision, Inc. recommended that the SNI (as defined in the FDA guidance document), adding that California requirements already require the GTIN and serial number. Ms. Shellans noted that staff has not been able to locate any such requirement in California (to use the GTIN + serial number) and, as such, the comment is a little unclear. Mr. Room and Ms. Herold added they saw no reason to depart from the FDA's guidance document in this area.

Motion: Reject comments of Mr. Allard.

M / S: Lippe / Gutierrez

There was no public comment.

Support: 10 Oppose: 0 Abstain: 0

Comment 3# – Consuelo Hernandez, California Healthcare Institute (CHI), requested that all changes to the drug distribution system be made at the national or international level, rather than the state level. Ms. Shellans noted that CHI opposes California's regulatory efforts until a national standard is established. There was a comment in support of the board's proposal at 1747.1(a)(1)(b) that allows manufacturers flexibility in how to measure percentages of drugs for serialization. Further, CHI asked that the board address the economic impact where staff did not identify any costs associated with creating a serialized number. Ms. Herold stated she believed CHI's comments regarding the economic impact (and also that of another commenter) are related to the entire implementation of e-Pedigree which is required by statute. She stated the board's proposal is to implement a law that is already on the books.

Motion: Reject comments of Ms. Hernandez requesting changes.

M / S: Lippe / Gutierrez

There was no public comment.

Support: 10 Oppose: 0 Abstain: 0

Comment #4 – Joint comments from the California Retailers Association, the National Association of Chain Drug Stores and the California Pharmacists Association. Ms. Shellans noted that the written comments are in line with the oral testimony received at the regulation hearing related to the declarations required by proposed section 1747.1. Ms. Shellans reflected on the commenters' concern with the language that requires certification "under penalty of perjury" and directed the board's attention to modified language (additional affirmation) offered by the group. Ms. Shellans noted that adding such a statement would add a requirement that every pharmacy or pharmacy warehouse include in their declaration an affirmative statement as described.

Mr. Lippe made a motion to accept the comment and modify the board's proposal to include the language offered by the group.

Board Discussion

Dr. Kajioka asked Mr. Room to provide input on the legal aspects of the recommendation. Mr. Room indicated that this comment is much ado about nothing. He stated that any declaration under penalty of perjury is always based on personal knowledge and due diligence. Also, these are declarations that are voluntarily submitted. Mr. Room noted that

the regulation does not preclude the inclusion of such a 'due diligence' statement; rather, the regulation specifies the minimum requirements for information to be included. Mr. Room felt the recommended language created a greater burden on those who would be submitting declarations pursuant to the proposal. Ms. Shellans noted that including a statement "to the best of your knowledge" would add an additional proof element in the declaration.

Ms. Herold noted that a pharmacy annually conducts an inventory of the 'eaches' in the pharmacy. She stated this could provide the basis for moving forward with what will be included in the declaration. She indicated that the board can also use enforcement discretion when it goes out on inspections and makes findings. She noted that if a pharmacy distributes a product after the implementation dates that are not serialized, they could be open to a lawsuit from the patient. She said that for violations of Pharmacy Law, there are citations and fines, along with an established appeal process in which a pharmacy would have an opportunity to explain their side of the issue. She also noted that much of the industry is down to "just in time inventory" – that many pharmacies don't have stocks of drug products that sit on the shelves for one or two years (or greater). With this, she asserted that complying with the board's regulation may not be the burden that it is made to sound like. Mr. Room commented on the way that the board may use the declarations. He noted that in the future, if a Board of Pharmacy Inspector found a stock of drugs in a facility that is not serialized, the Inspector would compare the stocks discovered with the declarations that may have been submitted with the board.

Ms. Veale seconded and spoke in support of the motion. Mr. Zee spoke in opposition to the motion. Mr. Kajioka spoke to the enforcement challenges, should the language be modified.

Public Comment
Mandy Lee, Jennifer Snyder and Brian Warren stated they shared the goal and mission of the board. They indicated that the intention of the proposed language was as a 'starting point' for the board. Ms. Lee stated it was not the intention to water down the requirements, rather to account for human error. She stated that some of the group's members use third party companies to inventory drugs. Ms. Snyder said they were looking for clarity. She said she felt the board would be sensitive to some types of human error and they would like some written assurance that there will be some type of due process. Ms. Snyder said this is a one-time situation where industry is counting drugs and she encouraged the board to include the language, or something similar.

Ms. Herold noted that the law provides for staggered implementation dates. She said that over a 2 ½ year period, they believe the majority of drugs in a pharmacy will be serialized. She asked what the average shelf life of the drugs is in a pharmacy, referencing that many wholesalers are delivering drugs to pharmacies twice a day, and that pharmacies are not keeping large stocks on the shelves. Mr. Room made it clear that under common law and California law that "perjury" is a specific intent crime – not for unwitting mistakes. He said it is not possible to be prosecuted for perjury for an unwitting mistake. He said he did not understand the question about 'due process.' He said there is no enforcement mechanism for using declarations. He said a declaration could possibly be used as evidence in some subsequent case, and that he did not see the declarations being used for an enforcement mechanism nor for prosecution for making an unwitting mistake.

Mr. Law reflected on the comments made. Dr. Gutierrez called for the question.

Motion: Accept the comment and modify the board's proposed language to include the language offered in the written comment related to an affirmation of due diligence.

M / S: Lippe / Veale

There was no public comment

Support: 2 Oppose: ***8*** Abstain: 0

Motion: Reject comments submitted by the California Retailers Association, the National Association of Chain Drug Stores and the California Pharmacists Association.

M / S: Zee / Gutierrez

There was no public comment.

Support: 9 Oppose: 1 Abstain: 0

Comment #5 – Dirk Rodgers commented that language at 1747.1(a)(1) and also 1747.1(a)(2) requires declarations to be submitted to the board by December 1, but no later than December 31, and that the dates seem contradictory. He questioned if the deadline was December 1, or December 31. Ms. Shellans recommended that the board accept the comment and that the board modify the language to strike the reference to December 1 these provisions.

Motion: Accept the comment and strike the reference to December 1 throughout the board's proposed regulation.

There was no public comment.

M / S: Lippe / Wheat

Support: 10 Oppose: 0 Abstain: 0

Comment # 6 – Ronald McGuff, McGuff Pharmaceuticals, Inc., commented on the regulation as a whole (not specific text) noting that the regulation does not recognize that implementing a system to apply and track a 'unique identification number' is not a viable option in all instances; that the technology for creation, application and control of a unique identification number is not easily obtained; and will be costly to implement and manage. He added that his company has determined that they are not able to implement such a system to ensure it is capable, reliable and well managed; and that MPI is not prepared to meet the board's expectations. Ms. Shellans noted that the comment does not appear to be directed to the board's specific text, that it is a general objection to implementing Pedigree.

Motion: Reject comments submitted by Ronald McGuff.

M / S: Lippe / Law

There was no public comment.

Support: 10 Oppose: 0 Abstain: 0

Oral Testimony #1 - Ms. Shellans provided that she received public comment that day. Commenter requested clarification of the language in 1747.1(c) (3) as to what subsequent disposition means. Ms. Shellans did not have a recommendation as to how to better clarify

the language. Mr. Room agreed that the language is fairly clear and inclusive, and that the commenter did not offer any suggested language.

Motion: Reject the oral comment to clarify the language in the board's proposal at 1747.1(c)(3).

M / S: Lippe / Zee

There was no public comment.

Support: 10 Oppose: 0 Abstain: 0

Ms. Shellans also provided a suggestion to modify the text at the board's proposal at 1747.1(b) and (c). She stated that section of the proposal requires the submission of declarations no later than August 1, 2016, or August 1, 2017. She noted that Business and Professions Code Section 4163.2(a)(2) requires the written declaration to be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. She noted that the effective dates are July 1, and that 30 days later would be July 31 – not August 1. Therefore, she recommended that the board modify its proposal at Section 1747.1(b) and (c) to strike the references to August 1, and instead include July 31.

Motion: Accept staff counsel's recommendation to modify Section 1747.1(b) and (c) to strike references to August 1 and, instead, state July 31.

M / S: Lippe / Gutierrez

There was no public comment.

Support: 10 Oppose: 0 Abstain: 0

Motion: Motion to direct staff to modify the text of proposed Section 1747 and 1747.1 as discussed at this meeting and issue the modified text for a15-day comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulations at Sections 1747 and 1747.1 as described in the modified text notice.

M / S: Lippe / Gutierrez

There was no public comment.

Support: 10 Oppose: 0 Abstain: 0

President Weisser recessed the meeting for a break at 11:18 a.m.

The meeting was resumed at 11:31 a.m.

Presentation by Jon Rosenberg, MD, California Department of Public Health

President Weisser called on Jon Rosenberg, MD, Chief, Healthcare-Associated Infections Program, Center for Health Care Quality, California Department of Public Health, who provided a presentation on "Outbreaks Associated with Contaminated Medication from Compounding Pharmacies Affecting California."

Public Comment

Bruce Vinson, representing Cedars Sinai, commented that some patients can't tolerate preservatives so a non-sterile powder must be used. Single-use, non-preservative vials have been encouraged, but multi-use vials do require preservatives.

V. Update on Implementation of Recently Enacted Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Licensing Committee Chair Deborah Veale reported on the following legislation updates:

a. AB 377 (Solorio, Chapter 687, Statutes of 2012) – Centralized Hospital Packaging Pharmacy

Ms. Veale referenced the materials provided in the board packet related to new provisions that authorize the board to issue a specialty license for the purpose of conducting centralized pharmacy packaging. This specialty license would allow the centralized hospital packaging pharmacy to prepare medications, by performing specified functions, for administration only to inpatients within its own general acute care hospital, and one or more general acute care hospitals if the hospitals are under common ownership, as defined, and that are within a 75-mile radius of each other.

Ms. Veale provided that board the new Centralized Hospital Packaging application and instructions are current available.

There was discussion regarding the 75-mile radius as defined in the bill. Mr. Room explained that the 75-mile radius refers to a 75-mile hub that surrounds the centralized hospital packaging pharmacy.

Steve Gray spoke in support of Mr. Room's characterization of the 75-mile hub for distribution of centralized packaging. He also sought clarification regarding a hospitals need for a sterile compounding license if the hospital holds a centralized hospital packaging permit. Ms. Herold provided that, at the current time, the facility would have to be accredited or possess a sterile compounding pharmacy license.

b. AB 1904 (Block, Chapter 399, Statutes of 2012) – Military Spouses; Expedited Licensure

Ms. Veale summarized AB 1904 which provides an expedited licensure process for an applicant who holds a license in the same profession in another jurisdiction, and who is married to, or in a legal union with, an active duty member of the Armed Forces of the

United States who is assigned to a duty station in California under official active duty military orders. She noted the new law goes into effect on January 1, 2013.

c. SB 1095 (Rubio, Chapter 454, Statutes of 2012) – Licensing: Clinics

Ms. Veale provided a summary of SB 1095 which authorizes the board to expand its authority to issue a clinic license to: 1) A surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code; 2) An outpatient setting accredited by an accreditation agency as defined in Section 1248 of the Health and Safety Code; or 3) An ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) available on the board's website no later than January 1, 2013.

She noted that clinic applications and instructions are now available on the board's website. Ms. Gutierrez asked if this measure will impact the board's oversight of the clinics. Ms. Herold responded that the board will incur an additional workload to inspect these clinics.

Lunch Recess

President Weisser adjourned the meeting for a lunch recess at 1:08 p.m.

Board Member Deborah Veale left the meeting at 1:08 p.m.

Resumption of Meeting

The meeting was resumed at 1:49 p.m.

VI. Discussion on Compounding and Manufacturing by Pharmacies

Ms. Herold referenced the congressional inquiry related to compounding, and the board's responses. She noted that the inquiries and responses were provided in the meeting materials. She explained that the California State Board of Pharmacy has provided a much higher level of enforcement than many other states, but that the recent meningitis outbreak has required the board to review current regulatory and statutory requirements that address non-resident sterile compounding. She also provided that she would be attending an FDA-sponsored conference the following week that would focus on compounding regulations.

Ms. Herold noted the current emergency involving the New England Compounding Center and the pharmacy in Florida that distributed contaminated sterile injectable product to California physician offices requires that the board reevaluate its regulation program in this area to ensure it provides optimal public protection. She encouraged the board to reexamine everything the board does, review the regulatory and statutory requirements, see what others are doing, and determine if we are doing what is best for the public. She stated that the public health emergency is critical. She noted that she was invited to participate in a FDA forum with Boards of Pharmacy and she will be attending.

In California, existing law requires an additional specialty license issued by the board or specific accreditation for any pharmacy that compounds sterile injectable products within, or ships such products into, California. The statutory requirements were developed in 2001

following the deaths of three patients in the Bay Area who had received injections of contaminated compounded medication.

Ms. Herold noted that NABP is inspecting nonresident pharmacies that are shipping into Iowa. She said the NABP is looking critically at what is being done at the federal level, and referenced some of the concerns noted. She said that in California we continue to do random unannounced inspections and that for nonresident pharmacies, the accreditation agency does the inspection. She noted that she is not aware of any other states that delegate inspection of these pharmacies to an accreditation agency. Ms. Anne Sodergren noted that for those nonresident pharmacies that are accredited, they are not required to have a separate sterile compounding permit with the board, so this is a group for which we have little information. Mr. Lippe asked about out-of-state inspections resources and costs. Ms. Herold responded that she believes allocating two inspectors to this group would be sufficient and that the cost of inspection could be covered by the pharmacy applicant seeking licensure, as well as licensing fees.

Ms. Gutierrez asked about trying to trend data that we receive from board inspections; she and Ms. Herold will work together on this. Dr. Kajioka spoke in support of board inspectors conducting the inspections of nonresident pharmacies licensed in or seeking licensure in California. Mr. Room asked if California has data that denotes what each state is authorized to do in terms of anticipatory compounding versus only producing patient-specific sterile compounding. Ms. Herold stated that the NABP may be collecting this type of data, and that the top three states in the nation do not allow anticipatory sterile compounding for in-state or out-of-state distribution.

Currently, the board specifies compounding regulations at Title 16 California Code of Regulations Article 4.5 Compounding, and Article 7 Sterile Injectable Compounding Area, which went into effect in July 2010. She noted that in 2011, the board discussed several modifications to portions of the regulations which are still awaiting notice. The board has crafted specific proposed regulation requirements for accreditation agencies that can accredit pharmacies that compound sterile injectable compounded medications in conjunction with the approval of five agencies that have board approval to accredit sterile injectable compounding pharmacies. The text for these regulations has been moved to release for public comment (which had been initially planned for late 2012 release). Meanwhile, the accreditation agencies that have received board approval to accredit pharmacies will again undergo review by the board as their three- or two-year term of approval ends in 2013.

Public Comment

Public comment was provided by Carmen Catizone, National Association of Boards of Pharmacy; Rita Shane, Cedars Sinai Medical Center; Jarra Banworth, compounding pharmacist; Natalia Mazina, Carman & Mazina, Frey Mayer, Pharmacy Planning Services, Maria Serpa, Sutter Health, Luci Power, Power Enterprises, Charles Lighter, private sterile compounder, Bob Calia, Medline Industries, Lynn Paulsen, University of California, Doug O'Brien, Kaiser Permanente, Tom Kupiec, HRL, Pierre DelPrado, Paul Lofholm and Bob Brenzle, Pharmacy Compounding Accreditation Board.

VI. Discussion on Proposed Legislation Relating to Sterile Injectable Compounding Pharmacies

At the October board meeting, the board discussed various elements of proposed legislation developed by staff to amend existing law regarding statutory requirements to enhance public protection regarding sterile injectable compounding. The board agreed to sponsor legislation in this area, but sought more discussion on the proposal. However, legislative deadlines for the 2013 Legislative Session make waiting for the February board meeting too late to refine the language. As such, the board authorized the Licensing Committee to review and adjust the proposed text at the next Licensing Committee Meeting (which had been set for December 13) unless there was a board meeting in December. Since there was no Licensing Committee meeting, the board discussed proposed statutory amendment options for sponsorship of legislation, which were provided and made available to meeting participants.

Ms. Herold provided that Senator Emmerson has indicated a willingness and interest in possible authorship of the legislation once it is finalized. Other legislators at the state level are also interested in this topic, so there are likely to be multiple legislative proposals on this topic introduced this session

Motion: Amend the language in Business and Professions Code Sections 4127.1 and 4127.2 Sterile Injectable Compounding Pharmacy Requirements to include enhancements to licensing and reporting requirements and that the final language be reviewed by the board president and the chair of the Legislation and Regulation Committee before submitted to the author.

M / S: Lippe / Law

Support: 8 Oppose: 0 Abstain: 0

Public Comment

Public comment was provided by Jennifer Snyder, John Roth, Rita Shane, and Bill Jones.