



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE: February 17, 2010

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

BOARD MEMBERS

PRESENT: Kenneth Schell, PharmD, President
Randy Kajioka, PharmD, Vice President
Stanley C. Weisser, RPh, Treasurer
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Greg Lippe, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

BOARD MEMBERS

NOT PRESENT: Rosalyn Hackworth, Public Member
Shirley Wheat, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Fraga, Staff Analyst

Call to Order

President Kenneth Schell called the meeting to order at 9:30 a.m.

General Announcements

President Schell recognized former Board President William Powers, who was present in the audience.

I. Possible Action on Proposed Regulations

Kristy Schieldge, DCA Senior Staff Council, stated that the board is required to consider all presented relevant matter before taking action to adopt a regulation. She explained that several of the comments submitted during the 45-day comment period were not provided to the board prior to the board's action after the regulatory hearing at the January 2010 Board Meeting. Ms. Schieldge advised that the board has now reviewed these three additional comments and today's meeting is an opportunity for the board to reconsider the action taken during the January Board Meeting leading to development of modified text for section 1707.5, patient-centered prescription labels.

President Schell apologized for the audio difficulties that occurred during the January regulation hearing, that were beyond the board's control. He explained that all testimony provided during the hearing has been considered by the board's members, and that there will be no additional opportunity for testimony at today's meeting.

Ms. Schieldge provided an overview of the board's options. She stated that the board can either choose to notice the language approved at the January 2010 Board Meeting or choose to rescind its previous order. Ms. Schieldge indicated that if the order is rescinded, the board will need to evaluate and vote on each subdivision of the language that was originally noticed in October. She advised that an opportunity for an additional comment period will be provided in the event the board votes to make changes to the initially noticed language.

Deborah Veale sought clarification regarding what information should be considered when the board is making its determination.

Joshua Room, Deputy Attorney General, provided that the board members should be exercising their discretion based on the complete record of comments. He stated that today's meeting provides the board with the opportunity to act based on the complete record.

A member of the public requested that each member of the board identify the organization that they represent as they are voting.

President Schell provided that all board members represent the people of the state of California. He clarified that members of the public will be provided an

opportunity to speak during public comment periods as noticed on the meeting agenda.

Other Announcements

President Schell recognized new board member Tappan Zee.

A. Discussion on the Proposal to Adopt New Section at Title 16 California Code of Regulations Section 1707.5 – Requirements For Patient-Centered Prescription Container Labels

Executive Officer Virginia Herold provided an overview of the regulation process that led to the development of the proposed regulation for patient-centered prescription labels. She advised that material related to the regulation has been posted on the board's Web site since 2008.

Board Discussion

The board discussed the confirmation of their original order to modify the initially noticed text that was taken at the January Board Meeting.

Dr. Ramón Castellblanch provided that Senator Corbett has expressed concern that the regulation language does not adequately reflect the intent of SB 472. He provided comment regarding the requirement for use of a 10-point font minimum and stated that a recent study has indicated that at least 300,000 people in California will have significant difficulty in reading their prescription label if this requirement is implemented. Instead a larger font size is necessary.

Dr. Randy Kajioka provided that this requirement is not reducing the font size that is currently being used in practice. He stated that in many cases, this requirement will increase the font size on the label.

Mr. Brooks provided that there has been ample consideration and opportunity for public comment on this issue. He stated that the new comments have been considered and do not differ from what has been previously submitted. Mr. Brooks offered support for the confirmation of the original order.

Dr. Castellblanch provided comment regarding a demonstration of translation software made during the January 2010 Board Meeting and the board's role in providing translations on the prescription label. He discussed the importance of the board's vote and stated that its decision regarding the minimum font size will not only become a standard for California, but also for the country.

Ms. Veale provided that the software that was demonstrated can only provide translations in seven languages. She indicated that the board will have the

opportunity to revisit this area and any advancement in technology in 2013. Ms. Veale stated that the requirement for a 10-point font minimum is a step forward. She reviewed other requirements that will be implemented in the regulation that will also promote readability and emphasis including bolding and the use of blank space. Ms. Veale discussed that the regulation language and its requirements will offer a solution without creating other consequences or problems.

MOTION: Reaffirm the board's order made at the January 2010 Board Meeting to modify section 1707.5.

M/S: Brooks/Weisser

Approve: 6 Oppose: 2 Abstain: 0

Ms. Herold asked the board for technical clarification regarding subdivision (a)(1)(B).

The board discussed striking the manufacturer name from the language in subdivision (a)(1)(B). No action was taken at this time.

Proposed Language

To Add Section 1707.5. of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707.5. Patient Centered-Labels on Medication Containers

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~12-point~~, 10-point, sans serif typeface, and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.
 - (C) Directions for use.
 - (D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is ~~desired~~ requested by the patient.
- (2) For added emphasis, the label ~~may~~ shall also highlight in bold typeface or color, or use "~~white space~~" blank space to set off the items listed in subdivision (a)(1).

- ~~(3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.~~
- (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
- (4) When applicable, directions for use shall use one of the following phrases:
- (A) Take 1 ~~tablet~~ [insert appropriate dosage form] at bedtime
 - (B) Take 2 ~~tablets~~ [insert appropriate dosage form] at bedtime
 - (C) Take 3 ~~tablets~~ [insert appropriate dosage form] at bedtime
 - (D) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning
 - (E) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning
 - (F) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning
 - (G) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, and Take 1 ~~tablet~~ [insert appropriate dosage form] at bedtime
 - (H) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, and Take 2 ~~tablets~~ [insert appropriate dosage form] at bedtime
 - (I) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, and Take 3 ~~tablets~~ [insert appropriate dosage form] at bedtime
 - (J) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, 1 ~~tablet~~ [insert appropriate dosage form] at noon, and 1 ~~tablet~~ [insert appropriate dosage form] in the evening
 - (K) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, 2 ~~tablets~~ [insert appropriate dosage form] at noon, and 2 ~~tablets~~ [insert appropriate dosage form] in the evening
 - (L) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, 3 ~~tablets~~ [insert appropriate dosage form] at noon, and 3 ~~tablets~~ [insert appropriate dosage form] in the evening
 - (M) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, 1 ~~tablet~~ [insert appropriate dosage form] at noon, 1 ~~tablet~~ [insert appropriate dosage form] in the evening, and 1 ~~tablet~~ [insert appropriate dosage form] at bedtime
 - (N) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, 2 ~~tablets~~ [insert appropriate dosage form] at noon,

- ~~_____ [insert appropriate dosage form] in the evening, and
2 tablets [insert appropriate dosage form] at bedtime~~
- (O) ~~Take 3 tablets [insert appropriate dosage form] in the
morning, 3 tablets [insert appropriate dosage form] at noon,
3 tablets [insert appropriate dosage form] in the evening, and
3 tablets [insert appropriate dosage form] at bedtime~~
- (P) ~~Take 1 tablet as needed for pain. You should not take more
than _____ tablets in one day~~
- (P) ~~If you have pain, take _____ [insert appropriate dosage form] at
a time. Wait at least _____ hours before taking again. Do not
take more than _____ [appropriate dosage form] in one day~~
- (Q) ~~Take 2 tablets as needed for pain. You should not take
more than _____ tablets in one day~~

(b) _____ By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) _____ Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

~~(d) _____ For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.~~

(d) _____ The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) _____ The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) _____ As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

1. Review of All Comments Submitted During the 45-Day Comment Period and Testimony Provided During the Regulation Hearing Held January 20, 2010

Ms. Schiedge requested that the board identify any modifications to be made to the proposed response to the submitted comments.

Dr. Castellblanch requested that the response include the study results indicating that at least 300,000 Californians would be adversely impacted by a 10-point font.

Ms. Schiedge clarified that the proposed responses must be in line with the board's action.

Mr. Room provided that board staff is in the process of preparing a packet to be submitted to the Office of Administrative Law (OAL) to provide justification for the regulation. He stated that the rulemaking file will reflect the will of the majority of the board.

Mr. Room provided that the study results can be submitted during an additional written comment period.

Board Discussion

The board again discussed striking the manufacturer name from the language in subdivision (a)(1)(B).

Dr. Castellblanch and Mr. Brooks sought clarification regarding the possible impact of this change.

Ms. Herold provided that the manufacturer name has not been identified as patient-centered information and does not need to be emphasized, although it needs to appear on the label.

Dr. Kajioka provided that this information does not need to be emphasized and can lead to confusion for the patient.

Mr. Room provided that the manufacturer name is only required on the label when a generic drug is being dispensed.

Public Comment

Fred Mayer provided comment on the recall capabilities of both small and large pharmacies as well as the role of a patient during a recall. He explained that deemphasizing the manufacturer name can adversely impact the consumer during a recall.

Jay Vandertorren encouraged the board to move forward with the regulation. He expressed concern regarding the board's authority to make an amendment after its reaffirmation of their order.

Diana Madoshi provided comment in support of providing the manufacturer name on the label.

Margie Metzler, representing OWL, the California Alliance for Retired Americans (CARA), Gray Panthers and Health Care for All, provided comment in support of maintaining the manufacturer information on the label.

Dr. Michael Negrete, representing the Pharmacy Foundation of California, discussed the difficulty of including a large amount of information on the label while maintaining reading comprehension. He stated that the patient-centered information must be the focus. Dr. Negrete provided that the manufacturer name needs to be on the label but not in the patient-centered area.

Alan Pope, representing Safeway, provided comment regarding the various levels of recalls. He stated that pharmacists are obligated to contact patients in the event of a patient-level recall. Mr. Pope indicated that the manufacturer name should be on the label but does not need to be included in the patient-centered area.

There was no additional board discussion or public comment.

MOTION: Strike "and the name of the manufacturer" in subdivision (a)(1)(B).

M/S: Kajioka/Zee

Approve: 4 Oppose: 4 Abstain: 0

2. Final Review and Possible Modification to 15-Day Modified Text and Notice for Section 1707.5

The board did not discuss this agenda item as the board voted to reaffirm its order made at the January 2010 Board Meeting.

B. Discussion and Possible Action to Adopt New Section at Title 16 California Code of Regulations Section 1702 -- Fingerprint Submissions for Pharmacists

Background

At the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions

during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file. The proposed rulemaking further specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The Initial Notice for the rulemaking was published on December 25, 2009, and the 45-day comment period concluded February 15, 2010.

Board Discussion

Assistant Executive Officer Anne Sodergren provided that the board received four comments.

President Schell reviewed the proposed language.

The board considered the adoption of the proposed language.

Ms. Herold provided that this regulation is part of an enforcement upgrade to require electronic submission of fingerprints via Live Scan and will require, as a condition of renewal, the disclosure on the renewal form of any arrest or conviction information since the licensee's last renewal. She explained that the fingerprinting of applicants allows the board a mechanism to enhance public protection by conducting a thorough screening of applicants for the purpose of issuing a pharmacist licensure. Ms. Herold indicated that a pharmacist licensed prior to 2000, did not submit fingerprints via Live Scan, but instead on fingerprint cards. As such, these licensees' fingerprints are not electronically tracked as are those who submitted fingerprints via Live Scan. Also, these licensees were not routinely required to submit fingerprints to the board for purpose of securing a background check by the United States Federal Bureau of Investigation (FBI). She stated that this requirement will ensure that the board receives timely notification of any arrest or conviction. Ms. Herold advised that technicians will be added to this process in the future.

There was no additional board discussion. No public comment was provided.

MOTION: Adopt section 1702 as noticed. 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. However, the board authorizes the Executive Officer to make any non-substantive changes to the proposed regulations prior to the filing, and adopt the proposed regulation as filed.

M/S: Brooks/Kajioka

Approve: 8 Oppose: 0 Abstain: 0

Proposed Language

To Add Section 1702 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Section 1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after (IOAL insert effective date).

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and

license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

C. Discussion and Possible Action to Initiate Rulemaking Regarding Awarding Continuing Education Credits

Ms. Herold provided an overview of the board's policy on awarding continuing education (CE) credits to pharmacists and pharmacy technicians.

Ms. Herold provided that the Competency Committee serves as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists and completes a detailed final review of all test questions prior to administration. She explained that this regulation will allow for up to six hours of continuing education (CE) credit to be awarded annually to complete review of examination questions if the committee member is not seeking reimbursement for their time.

The board reviewed and evaluated the proposed language for the regulation.

No public comment was provided.

MOTION: Approve the proposed language for Section 1732.2 and to add the requirement of a sign-in sheet to subdivision (d).

M/S: Veale/Weisser

Approve: 8 Oppose: 0 Abstain: 0

Ms. Sodergren provided that there is a drafting error in subdivision (c) of the proposed language. She stated that the sign in sheet requirement provided at the end of subdivision (c) should be stricken and added to subdivision (d) instead.

MOTION: Reconsider the prior motion.

M/S: Brooks/Lippe

Approve: 8 Oppose: 0 Abstain: 0

MOTION: Direct staff to initiate the rulemaking for the proposed text for Section 1732.2 with the requested technical changes.

M/S: Veale/Weisser

Approve: 8 Oppose: 0 Abstain: 0

Proposed Language

To Amend Section 1732.2. of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education ~~credit~~ hours for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence

Professions Code may annually be awarded six hours of continuing education hours for conducting a review of exam test questions as directed by the subcommittee. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions as directed by the subcommittee

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded up to six hours of continuing education on an annual basis. The board shall designate on its public agenda which day shall be eligible for continuing education credit. Pharmacists or pharmacy technicians requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet provided by the board.

(e) A pharmacist or pharmacy technician who attends a committee meeting of the board may be awarded up to two hours of continuing education on an annual basis. A maximum of four continuing education hours may be earned each year by attending the full meetings of two different board committees. Pharmacists or pharmacy technicians requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet provided by the board.

(f) A pharmacist who completes the Pharmacist Self-Assessment Mechanism (PSAM), administered through the National Association of Boards of Pharmacy, may be awarded up to six hours of continuing education.

D. Public Comment

Mary Magill, representing the California Alliance for Retired Americans (CARA), expressed concern regarding the 10-point font requirement on the labeling regulation. She encouraged the board to reconsider this action.

Diana Madoshi expressed concern that the input provided by the senior population was not adequately considered. She stated that the board's actions are not patient-centered.

An unidentified member of the public expressed concern regarding the board's actions.

Fred Mayer expressed concern that the board is not adequately addressing the needs of the senior citizen population. He encouraged the public members of the board to appeal the 10-point font requirement.

Jay Vandertorren provided that he is encouraged that the board has designated a font minimum that is larger than the current font being used in practice. He stated that there is opportunity for other increases in the future.

Anthony Valdez, representing the Office of Senator Corbett, shared a statement from Senator Corbett. Concern was expressed regarding the board's action and its adherence to its directive. Mr. Valdez asked if the 2010 report to the legislature has been submitted.

Carolyn Klein, Legislation and Regulation Manager, indicated that the 2010 report was transmitted to Senator Corbett's office on December 20, 2009.

Syed Sayeed, representing Consumers Union, expressed concern regarding whether the proposed regulation meets its directive with regards to an adequate font size and the availability of translations. He urged the board to reconsider its action in these areas.

Michael Lyon, representing CARA and Gray Panthers, expressed concern regarding the board's action and adherence to its patient-centered focus.

Doreena Wong, representing the National Health Law Program, expressed concern regarding the board's adoption of the regulation. She shared her disappointment with the manner by which the board released the regulation prior to the hearing and stated that the regulation fails to comply with state and federal requirements as well as the needs of the senior population. Ms. Wong encouraged the board to reconsider its action and offered recommendations to improve the regulation.

Carry Sanders, representing the California Pan-Ethnic Health Network, expressed concern regarding the board's action and urged the board to reconsider. She stated that consumers have a right to be able to read and understand the label on their medications.

Lynn Rolston, representing the California Pharmacists Association, commended the board for their efforts. She provided that the 10-point font requirement is a minimum and that pharmacies can and will increase the font size on the label if possible.

William Powers urged the board to reconsider its action. He provided comment on other prescription container technology including the implementation of talking pill bottles.

Missy Johnson, representing the California Retailers Association, provided that the board has taken initiative in improving the label and commended the board for its efforts. She stated that the approved regulation is more prescriptive than what it is required.

There was no additional public comment

II. Discussion Regarding the Board's Ability to Issue Clinic Permits Pursuant to California Business and Professions Code Section 4190 et seq. Without a Permit from the Department of Public Health

Ms. Schieldge provided an overview of Section 4190. She stated that California Pharmacy Law allows the board to issue a "clinic permit" to "surgical clinics" as defined in Health and Safety Code section 1204(b)(1). She stated that the permit issued by the board allows the clinic to have a single drug stock for use by the facility. Ms. Schieldge indicated that without such a clinic permit, each practitioner must own his or her own drug stock and must dispense dangerous drugs only to the prescriber's own patients as mandated by Section 4170 of the Business and Professions Code.

Ms. Schieldge provided that Health and Safety Code section 1204(b)(1) also determines what surgical clinics are subject to licensing by the Department of Public Health (CDPH). She stated that CDPH's regulatory authority over "surgical clinics" extends to the regulation of the facilities themselves, including establishment of minimum standards for safety including minimum staffing requirements, qualifications and equipment. (Health & Safety Code, §§ 1226, 1248.15.) Ms. Schieldge indicated that to qualify for either a Pharmacy Board permit or a license issued by CDPH, an ambulatory surgical clinic must meet the definition of "surgical clinic" provided in Health and Safety Code section 1204(b)(1). She advised that any clinic that does not meet the definition contained in Section 1204(b)(1) of the Health and Safety Code does not qualify for a clinic permit issued by the board.

Ms. Schieldge provided that Health and Safety Code section 1204(b)(1) provides the following definition of what is considered a "surgical clinic":

(b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter: (1) A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure.

Ms. Schieldge provided that about three years ago, the California Department of Public Health was involved in a lawsuit regarding the regulation of a physician-owned ambulatory surgical clinic. She stated that in deciding that lawsuit, the California Court of Appeal interpreted the Health and Safety Code exclusion

highlighted above to "...exclude physician owned and operated surgical clinics from licensing by the Department, leaving them, when using general anesthesia, to accreditation and regulation by the Medical Board." (*Capen v. Shewry* (2007) 155 Cal.App.4th 378, 384-385.) Ms. Schieldge explained that this ruling means that ambulatory surgical clinics owned and operated by physicians do not qualify as "surgical clinics" within the meaning of Health and Safety Code section 1204(b)(1).

Ms. Schieldge stated that consequently, pursuant to the "*Capen* decision," the California Department of Public Health (CDPH) no longer issues their licenses to physician-owned (either in whole or in part) ambulatory surgical clinics. She stated that although the Court opined that the Medical Board was the appropriate regulator of these physician-owned clinics, the Medical Board does not have statutory authority to regulate these facilities, only the physicians practicing in them. Ms. Schieldge advised that the Medical Board only has authority to approve the agencies that accredit outpatient surgery centers where general anesthesia will be used. (Business and Professions Code section 2216; Health and Safety Code section 1248.1.)

Ms. Schieldge provided that as a result of the foregoing, the California State Board of Pharmacy cannot issue permits to ambulatory surgical clinics (ASCs) with physician ownership. She stated that these unlicensed ambulatory surgical clinics are outside the board's jurisdiction. Ms. Schieldge advised that the board has not issued a clinic license to physician owned clinics since 2007, since they lack the underlying Department of Public Health license. She indicated that several legislative remedies introduced since 2007 have not been enacted and were either vetoed or stalled in the Legislature.

Ms. Schieldge provided that where a currently licensed ambulatory surgical clinic undergoes a change of ownership (i.e., a change of 50% or more), it is required to submit a change of ownership application to the Board of Pharmacy for its clinic permit (16 CCR § 1709). She stated that under those circumstances, if the ambulatory surgical clinic has physician ownership (and thus no CDPH license), the Board cannot issue the facility a clinic permit. Ms. Schieldge explained that as a result, Business and Professions Code section 4170 requires a prescriber at these ASCs to be responsible for his/her own drug stock at the location from which he/she dispenses. She indicated that in order to continue to dispense drugs at the ASC site, each prescriber at the ASC must maintain his or her own separate drug supply in the absence of a board clinic permit. Ms. Schieldge advised that if the prescriber fails to maintain his/her own supply while the ASC continues to dispense drugs, such failure could subject the prescriber or the owners of the facility to sanctions by CDPH or the Medical Board for violation of Business and Professions Code section 4170.

Ms. Schieldge provided that the board is being asked to review and evaluate its policy in this area. She stated that board staff does not believe the board has the authority to issue these permits.

Board Discussion

Tappan Zee asked if pharmacy law can be changed in this area.

Ms. Schieldge provided that a legislative change can be made. She advised that the board would need to determine if it would like to be responsible in this area.

Ms. Herold provided that regulation of this area would increase workload for the board, which would be offset by the licensing fees.

Dr. Castellblanch sought clarification regarding what the license would permit.

Ms. Schieldge stated that the permit would allow surgical clinics to maintain a central drug supply for administration or distribution to patients at the clinic.

Mr. Room provided that the license would allow surgical clinics to comingle their drug stock.

Anita Scuri, DCA Supervising Senior Staff Counsel and Legal Counsel for the Medical Board of California, provided comment regarding this issue and the authority of the Medical Board. She stated that the Medical Board does not have the authority to issue surgical clinic licenses. Ms. Scuri advised that this issue is beyond the scope of the Board of Pharmacy as the board does not have jurisdiction to regulate aspects of a clinic other than those related to pharmacies. Issuance of a pharmacy permit would not be an adequate substitute for clinic licensure.

Discussion continued regarding pharmacy law and its applicability to this issue.

Public Comment

Bryce Docherty, representing the California Ambulatory Surgery Association, thanked the board for its efforts with this issue and provided comment in support of a Pharmacy Board issued permit. He asked the board for its forbearance with regards to a pharmacy issued permit.

Steven Manis, Fort Sutter Surgery Center, provided comment regarding how this license can benefit the operations of his facility.

Discussion continued regarding the board's authority to issue permits to these facilities. It was reiterated that the board has been advised that it does not have the authority to issue these permits.

Bill Conae, representing Fort Sutter Surgery Center, provided comment on licensure exemption. He reviewed the difference between “dispensing” and “administering” and stated that the requirements for these issues are within pharmacy law. Mr. Conae stated that he believes the board does have the authority for the issuance of these permits to surgical clinics.

Steve Gray, representing the California Pharmacists Association, provided comment regarding the distinction between the “dispensing” and “administering” of medications. He expressed concern regarding whether surgical clinics should be permitted to dispense. Mr. Gray explained that allowance in this area will help to promote public protection and safety.

Discussion continued. It was the consensus of the board to direct staff to obtain information and conduct further research to present to the board at the next board meeting.

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

Misdee Guess provided comment regarding the auditing of pharmacies. She encouraged the board to consider the licensing of pharmacy auditors as a means to ensure safe, legal dispensing without endangering the pharmacy profession and to support the board.

There was no additional public comment.

IV. Petitions for Reinstatement

The board heard petitions for reinstatement from the following licensees:

- Michael Morales
- Lori DiBenedetto

V. Closed Session

Pursuant to Government Code section 11126(c)(3), the board convened in closed session to deliberate on the petitions for reinstatement.

The meeting was adjourned at 3:34 p.m.