

**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: October 25 & 26, 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
Amy Gutierrez, RPh
Victor Law, PharmD
Greg Lippe, Public Member, Treasurer
Deborah Veale, RPh
Shirley Wheat, Public Member
Albert Wong, PharmD**BOARD MEMBERS
NOT PRESENT:** Ryan Brooks, Public Member
Ramon Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Tappan Zee, Public Member**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Legislation/Regulation Manger
Robert Ratcliff, 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 9:11 a.m.

President Weisser recognized Darlene Fujimoto, past president of the board and representing UCSD; Jerry Moore, former president of the National Association of Boards of Pharmacy; and John Roth, president of the California Pharmacists Association, all in attendance.

President Weisser conducted a roll call. Eight board members were present.

I. General Announcements

There were no announcements.

II. Approval of Full Board Meeting Minutes of July 17 and 18, 2012

Carolyn Klein noted formatting changes to the minutes from the July 17 & 18 board meeting and an expansion of the segment regarding *Section 800 Reports*.

MOTION: Approve the minutes of the July 2012 board meeting.

M/S: Lippe / Gutierrez

Support: 8 Oppose: 0 Abstain: 0

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

There were no comments on items not on the meeting agenda or items for future meetings.

IV. Recognition and Celebration of Pharmacists Licensed for 50 Years in California

President Weisser recognized John Fuller, who graduated from pharmacy school in 1958. Mr. Fuller worked for Thrifty Drug Store in Los Angeles for nine years and then went on to own his own pharmacy for 35 years. For the past 12 years, Mr. Fuller has been a pharmacist consultant for the state.

Charles Alstrom was also recognized by President Weisser as being a licensed pharmacist in California for 50 years. Mr. Alstrom received his pharmacist license in 1962 and joined his father in business at College Pharmacy in Fresno, where his father had been in business since 1937. Mr. Alstrom continued in business until 2005, when he became semi-retired.

V. Communication and Public Education Committee Report

Committee member Deborah Veale reported on the activities of the Communication and Public Education Committee in the absence of Committee Chair Ryan Brooks.

a. Update on the New Notice to Consumers Poster

Ms. Veale reported that since the beginning of 2012, the Communication and Public Education Committee has been working on production of a new *Notice to Consumers* poster.

After multiple design modifications, the final poster was presented at the August committee meeting. The poster prominently displays the text "California law requires a pharmacist to speak with you every time you get a new prescription."

The new poster incorporates suggestions made at the July 18 board meeting to add numbering to attract the reader's attention, as well as a larger logo and state seal. The

poster will also be translated into additional languages and made available to any pharmacies that request a translated poster.

The poster is a standard poster size of 18" x 24" and board staff is working with the Office of State Printing to print and mail the posters. The cost for printing and mailing the posters is currently being estimated.

The text which must be printed on the poster is pursuant to 16 California Code of Regulations section 1707.6 is:

The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

Discussion

Board President Virginia Herold explained that the new poster replaces the two existing posters that are currently posted in pharmacies. The new posters will be mailed in mailing tubes with a Board of Pharmacy label, so they will be easily identified when received by pharmacies.

Ms. Herold further provided that once the poster has been released and mailed, the board will be inspecting for compliance.

There were no comments from the board or the public.

b. Video Display Format for the Notice for Consumers

The *Notice to Consumers* video display format has been finalized and will be available on CD for pharmacies that request it. The final version incorporates design elements from the *Notice to Consumers* poster and reflects a greater diversity in the actors, as recommended at the July board meeting.

The requirements for this format are:

§ 1707.6. Notice to Consumers.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-Sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as:

- (1) The video screen is at least 24 inches, measured diagonally;
- (2) The pharmacy utilizes the video image notice provided by the board;
- (3) The text of the notice remains on the screen for a minimum of 60 seconds; and
- (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

There were no comments from the public.

c. Notice of Interpreter Availability

Ms. Veale reported that the notice of interpreter availability poster has been finalized and is ready for distribution. The poster will be mailed along with the *Notice to Consumers* poster and will also be available for download from the Board of Pharmacy website. It will print on 8.5 x 11 inch paper.

The relevant section of this new notice is:

1707.6 (c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Discussion

Ms. Herold explained that pharmacies that want to use their own versions of the poster will be required to get approval from the board.

There was discussion about the need to include Cantonese and Mandarin symbols on the notice so consumers who speak those dialects can easily identify their language.

There were no comments from the public.

d. FOR INFORMATION: Update on Patient-Centered Prescription Drug Container Labels and Review of Labels in Use

Since January 1, 2012, board inspectors have been directed to pick up sample prescription container labels from every pharmacy they enter. The goal is to secure copies of actual labels in use and compare these with the board's regulation requirements to see if additional changes in the requirements may be needed.

The consumer survey soliciting feedback regarding the readability of prescription drug container labels has been widely distributed. An electronic version of the survey was recently sent to several consumer groups, who in turn distributed the survey to their ListServe contacts. The survey was also translated into Chinese and Spanish and distributed by The California Pan Ethnic Health Network (CPEHN) to the appropriate audiences. We have received only 49 electronic surveys, and 20 hard copy surveys. We hope to receive more.

Discussion

Ms. Herold provided that to date, there have been 767 inspections of pharmacies to ensure compliance with the new labeling requirements and the availability of interpreter services. Of those, approximately 700 chain stores and community pharmacies were fully compliant. Of the remaining 67 pharmacies, many had corrective issues and

subsequently became compliant. About 13 pharmacies were not compliant, and seven out of eight clinics inspected were not in compliance.

Ms. Herold explained that inspectors were also checking for compliance with the new interpreter services requirement. Out of 349 chain stores inspected, 23 were not compliant and were issued correction notices. Among 253 community pharmacies, more than 150 were not in compliance. Since that time, the American Pharmacists Association has provided information about an interpreter telephone service that is available through their organization.

Public Comment

Carol and Jerry Bailey from the California Alliance for Retired Americans thanked the board for their efforts to improve prescription container labeling. They provided that they have received many positive comments about the larger font size and readability of labels.

Michelle Thomas, an independent professional, sought clarification regarding the requirement to include the reason for taking a medication on the container label.

Ms. Herold provided that the board is currently soliciting feedback from the public regarding the issue. Currently, the reason is included on the label only if the prescriber has included it on the prescription, or if the consumer requests it.

Steve Gray, representing Kaiser Permanente, shared that there seems to be confusion in the industry regarding their obligation to include a reason on the label. He suggested that the board establish clear standards.

Jonathan Tran, representing the Southeast Asia Resource Action Center, thanked the board for its efforts and requested continued inclusion and collaboration with such organizations that have expertise in language access areas. He added that patient discussion and education regarding the issue should begin in doctor's offices.

e. The Script

The next issue of *The Script* is currently in production. The issue will focus on application of laws and the forthcoming e-Pedigree requirements. The newsletter also lists the multiple disciplinary decisions made by the Board since the beginning of 2012.

Ms. Veale recognized the efforts of Hope Tamraz, who has been *The Script* newsletter editor since the early 1990s. Ms. Tamraz ended her tenure with the board at the end of August and Jan Jamison, the board's public information officer, will be assuming the editor role.

There were no comments from the board or the public.

f. Public Outreach Activities Conducted by the Board

State government continues to be subject to a travel freeze that restricts all but the most essential travel. The Department of Consumer Affairs must still preapprove all travel

where a travel claim will be submitted. This has restricted board operations in all areas, including public and licensee outreach.

Public and licensee outreach activities performed during the second quarter of fiscal year 2012 include:

- May 11 – Executive Officer Herold provided the commencement address to USC's 2012 graduating class of the School of Pharmacy
- May 17 – Executive Officer Herold provided a webinar on California's e-Pedigree requirements hosted by RfXcel
- June 19 -- Executive Officer Herold provided a webinar on California's e-Pedigree requirements hosted by Axway
- June 20 – Inspector White provided a CE presentation on the board's enforcement program to pharmacists in Pasadena
- July 10 – Executive Officer Herold provided a webinar on California's e-Pedigree requirements hosted by Mettler
- July 15 – Executive Officer Herold provided a webinar on California's e-Pedigree requirements and problems identified by the board in the supply chain, hosted by the University of Florida
- July 18 – Supervising Inspector Hunt provided a presentation to the Diablo Society of Health System Pharmacists and the Contra Costa Pharmacists Association on "New Pharmacy Laws for 2012"
- July 18 – Inspector Kazebee provided a presentation on "Surviving as the Pharmacist-in-Charge" at a CE session for 39 pharmacists in Orange County
- July 25 – Executive Officer Herold testified before a federal Congressional Committee on board enforcement activities regarding pharmacies and wholesalers manipulating drug shortages for profit
- July 27 - Supervising Inspector Hunt delivered a presentation on consumer awareness at Assemblymember Mary Hayashi's 3rd Annual Senior Health Fair in Hayward. Dr. Hunt also collected consumer surveys soliciting feedback regarding the new Patient-Centered Labels.
- August 13 and 22 – Public Information Officer Jamison staffed a booth at two Senior Scam Stopper seminars hosted by the State Contractors' Licensing Board. Both seminars were very well attended and Ms. Jamison collected a number of consumer surveys on the new patient-centered labels.

There were no comments from the board or the public.

VI. Licensing Committee Report

Committee Chair Deborah Veale reported that the Licensing Committee did not meet this past quarter.

a. Competency Committee Report

Ms. Veale referenced the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE), which were included in an attachment.

Background

The referenced attachment included examination statistics for the CPJE and the NAPLEX exams from October 2011 through March 2012. The overall pass rate for the CPJE was 70.4%; however, the pass rate was higher for graduates from the California Schools of Pharmacy at 80%. Applicants with a PharmD degree also continue to perform better on the exam with an overall pass rate of 73.2% versus those with a BS degree which has a pass rate of 59.6%.

The overall pass rate for the NAPLEX was 95.6% and graduates from the California Schools of Pharmacy perform slightly higher than graduates from outside of CA, 98.6% versus 97.2% and applicants with a PharmD degree also perform better on the NAPLEX than those with a BS degree, 98% versus 86.1%

Examination Development

Competency Committee workgroups held its annual joint meeting in August 2012 and each workgroup also convened a meeting in the fall of 2012. The committee will resume meetings next year, focusing its activities again on examination development.

There was no comment from the public.

Discussion

Board Member Gutierrez asked if any missing skill sets had been identified that might be missing from the exam so the pharmacy schools could be alerted.

Ms. Herold provided that the committee is very structured and includes school representatives, so each of the schools is aware of any potential deficiencies.

b. Licensing Statistics

Chairwoman Veale referenced the first quarter licensing statistics. During the first three months of the fiscal year, the board has received over 4,800 applications and issued over 4,100 licenses. The number of applications received is down compared to the same period last year by about 12%; however, there is a 2.6% increase in the number of licenses issued.

There were no comments from the board or the public.

c. First Quarterly Report on the Committee's Goals for 2012/13

Ms. Veale referenced the first quarterly report on the Licensing Committee's goals. This is the first quarterly update in the board's new strategic plan formatting. Because of programming challenges with the board's existing computer system, some of the success indicators remain under development. She stated that the issue should be resolved before the next board meeting.

As indicated in the quarterly update, the board is not meeting its success indicator measurements. This is due to staff vacancies as well as two staff members who are on leaves of absence. Significant improvement is expected in several areas over this next quarter as several key positions will be filled.

Discussion

Ms. Herold provided that the new format for reporting on the committee's goals is still under development, but that the board strives to achieve the level of performance that the public deserves.

Ms. Sodergren explained that one of the biggest challenges in meeting the success indicators has been staff vacancies due to salary reduction.

VII. Discussion on Compounding and Manufacturing by Pharmacies

Ms. Herold announced that this portion of the meeting would be dedicated to a discussion about the New England Compounding Center (NECC), the pharmacy identified as being responsible for the nationwide meningitis outbreak.

Ms. Herold provided that NECC has voluntarily surrendered its license, so they cannot ship into California. The board also issued a Cease & Desist Order on October 5, 2012.

Ms. Herold further explained that out-of-state sterile injectable compounding pharmacies that ship product into California must be licensed by the board as non-resident sterile injectable compounding pharmacies or accredited by an accrediting agency. Because the board isn't able to conduct physical inspections for out-of-state facilities, we request a copy of the inspection report from the home state on an annual basis. Unfortunately, many of the out-of-state boards are short-staffed and don't have the resources to conduct adequate inspections. Accrediting agencies sometimes conduct periodic inspections, but not on a regular basis.

Currently, California licenses 6,890 pharmacies, 468 non-resident pharmacies and 93 non-resident sterile injectable compounding pharmacies. The board has also recently resumed out-of-state inspections for new facilities. This practice had been discontinued but has been started again.

There was continued discussion about the role of the FDA vs. state boards of pharmacy. Deputy Attorney General Joshua Room provided background on case law related to this topic. Typically, the FDA oversees pharmaceutical manufacturers, but there has been some difficulty in determining the point at which a compounding pharmacy should be classified as a manufacturer. In the case of NECC, the pharmacy had produced 17,000 vials of the suspect sterile injectable.

Public Comment

John Grasela, representing the University Compounding Pharmacy in San Diego, commended the board inspectors for their great work. He suggested that inspections be increased from once every three years to every year. He also suggested forming sub-committees made up of compounding pharmacies to establish tighter regulations.

Steve Gray, representing Kaiser Permanente, suggested that pharmacy schools increase their curriculum requirements for compounding pharmacists and that they be required to hold a specialty license. He supported the practice of conducting annual inspections of compounding pharmacies.

Doug Hellman stated that the presence of an NDC does not guarantee that the drug is an approved drug.

John Roth, representing the California Pharmacists Association (CPhA) spoke in support of the previous comments. He suggested that physician compounding and veterinary compounding should also be evaluated and that the board should collaborate with the Medical Board and the Veterinary Board to address the issue.

Lynn Paulsen, representing the University of California Office of the President, spoke about the increase in the need for compounded drugs.

The board recessed for a break at 11:17 a.m.

The meeting was resumed at 11:37 a.m.

VIII. Legislation and Regulation Committee Report

PART I – LEGISLATION

a. Enacted Legislation

Legislation and Regulation Manager Carolyn Klein provided a recap of the chaptered bills that would be effective on January 1, 2013.

1. SB 1575 (Senate Committee on Business, Professions and Economic Development) Omnibus Provisions – Chapter 799, Statutes of 2012

The Governor signed SB 1575 on September 29, which contained two board-sponsored proposals. These provisions go into effect on January 1, 2013.

- Amends Section 4209 to provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned for pharmacist applicants.
- Adds Section 4300.1 to ensure the board can put discipline on record even if the license is cancelled.

2. AB 377 (Solorio) Hospital Central Packing Pharmacy – Chapter 687, Statutes of 2012

The Governor signed AB 377 on September 28. The board supported this measure which adds Section 4128 and authorizes the board to issue a specialty license to a hospital pharmacy. Such a license will authorize a hospital chain under common ownership to prepare consolidated packaging operations to prepare single (unit-) dose medications that are bar coded. The unit-dose medications would be delivered to any of multiple campuses of the general acute care hospitals under the same

ownership for patient administration. These bar coded medications will also aid hospitals in improving patient safety and in reducing medication errors. Reading a medication's bar code at the patient's bedside prior to administration will help ensure that the right drug is being administered to the right patient at the right time.

The board is developing the license application and processes for this specialty license and intends to have the application available for the next Licensing Committee scheduled for December 11, 2012.

3. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products – Chapter 75, Statutes of 2012

AB 389 was signed by the Governor in July 2012 and establishes in the Health and Safety Code (commencing with Section 125286.10) the "Standards of Service for Providers of Blood Clotting Products for Home Use Act" ("Act") and requires the Board of Pharmacy to administer and enforce the provisions of the Act. The board had a position of "Oppose" on this legislation, which specifies that "providers of blood clotting products" include hospital pharmacies, health system pharmacies, pharmacies affiliated with hemophilia treatment centers, specialty home care pharmacies and retail pharmacies.

4. AB 1442 (Wieckowski) Common Carriers Transporting Pharmaceutical Waste – Chapter 689, Statutes of 2012

The Governor signed AB 1442 on September 28, 2012. This bill amends the Medical Waste Management Act ("Act" - commencing with Health and Safety Code section 117637) to define, for purposes of the Act, "pharmaceutical waste" and "common carrier"; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste. The Act is under the jurisdiction of the California Department of Public Health. The board was neutral on this measure.

5. AB 1588 (Atkins) Reservist Licensees: Fees and Continuing Education – Chapter 742, Statutes of 2012

The Governor approved this measure on September 29, 2012. The board supported AB 1588 which adds section 114.3 to specify conditions under which the board may waive renewal fees, continuing education requirements and other renewal requirements for a licensee that is called to active duty. It also specifies a license may be placed on "Active Military" – this status is not currently specified in the board's licensing system. Because this measure applies to all boards and bureaus at the Department of Consumer Affairs, the board is working with the department to determine how it will implement the necessary system changes to reflect the requirements of the bill.

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

The Governor approved AB 1904 on September 20, 2012. This bill requires a board within the Department of Consumer Affairs to expedite the license process for an applicant who holds a license in another state, as specified, and who supplies evidence satisfactory to the board that he or she is married to, or in a domestic partnership or other legal union with an active duty member of the Armed Forces. The bill does not waive any licensing requirements. AB 1904 also authorizes the board to adopt regulations to administer the section. The board supported this legislation.

7. AB 1896 (Chesbro) Tribal Health Programs: Health Care Practitioners – Chapter 119, Statutes of 2012

AB 1896 adds Business and Professions Code section 719 which applies to all health care boards in the Department of Consumer Affairs. The bill provides that a health care practitioner licensed in any other state and who is employed by a tribal health program, as specified, is exempt from California licensing requirements where that health care practitioner performs services for the tribal health program.

8. AB 2570 (Hill) Licensees: Settlement Agreements – Chapter 561, Statutes of 2012

Ms. Klein summarized the provisions of the bill. First, the bill prohibits a licensee who is regulated by the Department of Consumer Affairs or various boards, as specified, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board. The board did not have a problem with these provisions.

The bill also prohibits a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action, to pay additional monies to the benefit of any plaintiff in the civil action. Ms. Shellans noted that this provision limits the board's ability to order restitution in a disciplinary case, where the licensee had been ordered to pay restitution in a civil settlement. Thus, the board opposed this provision in the bill.

9. SB 71 (Leno) Board of Pharmacy Reports – Chapter 728, Statutes of 2012

SB 71 eliminates the requirement that certain state agencies submit certain reports to the Legislature and other agencies on a variety of subjects. This bill deleted the board's requirement to submit to the Legislature by January 1, 2013, the status of the implementation of the prescription drug label requirements required by section 4076.5(f). The board did not have a position on this legislation.

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

SB 1095 amends Pharmacy Law to expand the definition of a clinic (§ 4190) to include clinics that are (1) licensed by the CDPH pursuant to section 1204 of the Health and Safety Code, (2) an outpatient setting accredited by an accreditation agency per Section 1248 of the Health and Safety Code, or (3) a Medicare certified ambulatory surgical center. Board licensure is optional. The legislation provides that a clinic licensed by the board may purchase drugs at wholesale, as specified.

The board is modifying the existing clinic application and is updating instructions for applicants. Staff intends to have the clinic application available at the Licensing Committee meeting schedule for December 11, 2012.

11. SB 1099 (Wright) Regulations: Quarterly Effective Dates – Chapter 295, Statutes of 2012

The Administrative Procedure Act specifies requirements for the promulgation of regulations. Currently, and in general, when a regulatory action is adopted or repealed by the board and is subsequently approved by the Office of Administrative Law (OAL), the OAL files the action with the Secretary of State and, with certain exceptions, the regulation is effective 30 days after the date it is filed with the Secretary of State. This bill requires, instead, that the effective date of a regulation shall be effective on a quarterly basis, as follows:

- *January 1, if the regulation is filed with the SOS on September 1 – November 30*
- *April 1, if the regulation is filed with the SOS on December 1 – February 29*
- *July 1, if the regulation is filed with SOS on March 1 – May 31, and*
- *October 1, if the regulation is filed with SOS on June 1 to August 31*

An agency may specify a later effective date, and an agency can request an earlier effective date if the agency makes a written request demonstrating cause for the earlier date.

12. SB 1236 (Price) Board of Pharmacy: Sunset – Chapter 332, Statutes of 2012

SB 1236 extends the “sunset” of the Board of Pharmacy to January 2017. The board provided its “Sunset Review Report 2011” to the Senate Committee on Business, Professions and Economic Development in November 2011 and in March 2012, Board President Stan Weisser and Executive Officer Giny Herold appeared before the committee to respond to the committee’s questions.

13. SB 1301 (Hernandez) Prescription Drugs: 90-Day Supply – Chapter 455, Statutes of 2012

SB 1301 added section 4064.5 to permit a pharmacist to dispense a 90-day supply of a dangerous drug, so long as specified requirements are met, and provided the prescriber did not indicate “no change to quantity.” The section does not apply to controlled substances or to psychotropic drugs. The board supported this measure.

14. SB 1329 (Simitian) Prescription Drug Collection and Redistribution Program – Chapter 709, Statutes of 2012

SB 1329 amends the Health and Safety Code (starting at section 150200) to significantly broaden the Surplus Medication Collection and Distribution program. Currently, the law narrowly prescribes those that can donate unused medications, and those to whom the medication can be dispensed. Board staff is concerned that the overly broad amendments could very well compromise the pharmaceutical supply available to all Californians. The board requested that the Governor veto the measure; however, the Governor signed the legislation on September 28.

15. SB 1481 (Negrete-McLeod) Clinical Laboratories: Community Pharmacies – Chapter 874, Statutes of 2012

SB 1481 adds section 1206.6 to the Health and Safety Code and amends other related sections to allow a community pharmacy to perform only specified tests that are classified as waived under CLIA and that are approved by the FDA for over-the-counter sale to the public, provided the pharmacy obtains a valid CLIA certificate of waiver, obtains a registration from the CDPH, and provided that only a pharmacist performs the tests authorized, as specified. The board supported this measure.

b. Legislation Not Enacted

The following measures were not enacted in the 2011-2012 Legislative Session

- 1. SB 419 (Simitian) Solid Waste: Home Generated Sharps --** The Governor vetoed Senator Simitian's bill that would have required a pharmaceutical manufacturer to submit an already required report electronically to the Department of Resources, Recycling and Recovery and also to post the report on its web site.
- 2. SB 616 (DeSaulnier) CURES Program --** This measure died in committee. Staff believes the CURES fund will be solvent this fiscal year, but a permanent solution needs to be identified to sustain this valuable system.

Discussion

Ms. Herold provided that the board supported SB 616 and initially funded CURES, because it is an important tool for drug diversion. In the past, the program has been funded by a combination of monies from the state's General Fund, the Department of Justice and a small fee from regulatory boards. The program was dropped at the end of the legislative session because it wasn't viewed as providing a long-term solution. Currently, other options for funding the program are being researched.

c. 2013 Legislative Proposals for Consideration

Ms. Klein referenced the staff's draft text of each legislative proposal for consideration.

1. Addition of Business and Professions Code Section 4008.5 – Requirement to Provide Arrest and Court Documents as Requested by the Board

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; these agencies cite the board's lack of authority to receive these documents. Staff is proposing an amendment to section 4008.5 to provide for the board's explicit authority to receive certified records for this purpose.

2. Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. Staff is proposing an amendment to section 4053 to clearly specify that the one year of paid work experience shall be earned in a licensed facility, as specified.

Motion: Authorize staff to pursue board-sponsored legislation to seek statutory changes to Business and Professions Code Sections 4008.5 and 4053.

M / S Deborah Veale / Gregg Lippe

S: 8 Oppose: 0 Abstain: 0

There were no comments from the board or the public.

3. Amendment to Business and Professions Code Sections 4127.1 and 4127.2 – Sterile Injectable Compounding Pharmacy Requirements

The board discussed a proposal to amend sections 4127.1 and 4127.2 that would require address licensing requirements for non-resident pharmacies compound sterile injectable drug products in this state, to notify the board when it issues a recall for a sterile injectable drug product, as specified. The proposal to amend section 4127.2 would enhance the licensing and reporting requirements of nonresident pharmacies that are licensed to ship these products into or dispense these products to Californians.

Also, to provide for protection of the public, the board believes it is necessary to enhance the licensing and reporting requirements of nonresident pharmacies that are licensed by the board to compound sterile injectable drug products and who ship these products into or dispense these products to Californians. Requiring accreditation, as specified, will ensure the pharmacy has necessary standards and practices in place. Requiring the nonresident pharmacy to complete the board's Compounding Self-Assessment prior to licensure and prior to renewal will assist the pharmacy to ensure it is compliant with California's laws and regulations related to the compounding of drug products. Requiring the pharmacy to provide the board, within specified timeframes, recalls issued for sterile

injectable drug products and disciplinary actions or suspension of accreditation will assist the board in the effective enforcement and application of Pharmacy Law.

Discussion

Ms. Herold explained that the goal will continue to be to require licensed, non-resident sterile injectable compounding pharmacies (NRLSC) to have a secondary license with the board. Those pharmacies would be inspected by one of our accrediting agencies. We would like to add the requirement that the accrediting agencies monitor the out-of-state facilities against the standard the board establishes for in-state pharmacies. Ms. Herold continued that if the NRLSC pharmacy is accredited, their license cannot be reissued or renewed until a number of contingencies have been met, including:

1. We have the most recent inspection report by the pharmacy board in the state where they are located;
2. A report from a private accrediting agency approved by the board within the prior 12 months documenting the pharmacy's compliance with the board's regulatory requirements regarding the compounding of sterile injectable compounding products;
3. A copy of the non-resident pharmacy's proposed policies for sterile compounding;
4. A copy of the self-assessment form required by California law for compounding;
5. The pharmacy must advise the board within 30 days of disciplinary action taken by the resident state or any act to suspend their accreditation status with an accrediting agency;
6. The pharmacy must provide to the board, within five days, any recall notice issued by the pharmacy for sterile injectables.

In addition, Ms. Herold provided that the board would request documentation of all products shipped into California so we could get a sense of what is being shipped and the quantities involved.

Mr. Room provided that any new regulations would be required to apply equally to out-of-state pharmacies and in-state pharmacies.

Ms. Shellans shared Mr. Room's concerns and recommended that the issue be moved to a committee for further exploration.

President Weisser moved the matter to the Licensing Committee for further discussion.

Ms. Herold recommended that the board introduce a spot bill to secure a place in the upcoming legislative session, and secure an author for the bill.

Motion: Authorize staff to seek board-sponsored legislation addressing licensing requirements for non-resident sterile injectable compounding pharmacies.

M / S: Veale / Lippe

Support: 8 Oppose: 0 Abstain: 0

There was no public comment.

4. Proposal to Clarify Authorized Acquisition Sources of Dangerous Drugs by Pharmacies

There is no proposal/language to bring forward at this time. Ms. Klein provided that Section 4107 of the Business and Professions Code specifies that the board may not issue more than one site license to a single premises, except as specified in that section. With the passage of AB 377, Ms. Klein noted that Section 4107 should be amended to provide the board with the statutory authority to issue a centralized hospital packaging license where the premises already has a board-issued hospital license. Ms. Klein indicated this could be a possible omnibus provision.

Motion: Seek legislation to amend section 4107 to include an exemption for a centralized hospital packaging license.

M / S: Gutierrez / Lippe

Support: 8 Oppose: 0 Abstain: 0

Public Comment

Steve Gray explained that the word "premises" is used in several different places in the statute and refers to different meanings, so should be clarified to avoid confusion.

5. Other Legislative Proposals

Ms. Klein provided that the board was contacted to determine its interest in a possible amendment that could allow the board to take administrative action for a violation specified in that section, where a district attorney did not prosecute criminally. The suggestion was initially considered by the Contractors State License Board and other boards were contacted to determine if there was additional interest. While no legislative proposal was drafted or offered, Ms. Klein sought the board's interest in this type of legislation, should the Department sponsor such a provision on behalf of the DCA boards.

Motion: Express the board's interest in amending Section 119 as described.

M / S: Gutierrez / Lippe

Support: 8 Oppose: 0 Abstain: 0

Gutierrez/ Lippe to clarify 4107 as outlined in the attachment.

PART II REGULATIONS

a. Approved -- Undergoing Review by the Administration

Proposal to Amend Title 16, California Code of Regulations Section 1735.1, 1735.2, 1735.3, and 1751.2 Related to Compounding Drug Products

Regulation Committee Chair Gregg Lippe referenced the information provided in the board packet related to this item. He noted that the Executive Officer, in accordance with the board's motion at the July Board Meeting, has adopted the proposed regulations and that the rulemaking file is undergoing administrative review. Mr. Lippe noted that staff will continue to keep the committee and the board apprised of the status of this rulemaking.

b. Discussion and Possible Action – Board Approved Regulations Previously Noticed

Proposal to Amend Title 16, Section 1746 – Emergency Contraception Protocol

Mr. Lippe referenced the board materials related to the board's rulemaking, adding that this is an item for the board's discussion and possible action. Mr. Lippe provided a background of the notice periods associated with this rulemaking and noted that the protocol must be adopted by both the Board of Pharmacy, and the Medical Board of California (MBC).

Mr. Lippe summarized that when the MBC met on July 20, 2012, it considered and approved the modified text (which was approved by the Board of Pharmacy on July 17th) that included the newly approved generic one-dose regimen and that clarified dosing instructions. At its meeting, the MBC made additional modifications to the language at § 1746(b)(3), striking the language related to the insertion of an IUD and further modified the subdivision to encourage patients to follow up with their physician or healthcare provider after the use of emergency contraception. It is this modified language that is before the board for consideration today.

The board reviewed the modified language that was approved by the MBC on July 20, 2012. Ms. Herold noted that following the adoption of a new emergency contraception protocol, the board will then need to update its patient information fact sheet. This fact sheet is required by Section 4052.3(e) of the Business and Professions Code and is provided to the patient by the pharmacist using the protocol to dispense emergency contraception. The update of a fact sheet would be vetted through the board's Communication and Public Education Committee.

Motion: Direct staff to take all steps necessary to complete the rulemaking process, including issuing the modified text for a 15-day comment period. If, after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt section 1746 as approved by the Medical Board and as noticed in the modified text notice.

M / S: Lippe / Veale

Support: 8 Oppose: 0 Abstain: 0

There were no comments from the public.

c. Board Approved Regulations – Currently Noticed

1. Combined Rulemaking related to e-Pedigree: Proposal to Add Section 1747 – Requirement to Specify a Unique Identification Number for Prescription Medication, and to Add Section 1747.1 – Grandfathering

Mr. Lippe noted that on September 21, 2012, the board issued a Notice of a proposed rulemaking related to e-Pedigree. Specifically, the board proposed to add section 1747 to specify the requirements of a unique identification number for prescription medication, and to add section 1747.1 related to declarations that are to be filed with the board regarding existing drug stock (grandfathering) and suppliers' readiness to comply with statutory e-Pedigree provisions. Mr. Lippe noted that the board is accepting written comments to the proposal until 5:00 p.m. on November 5, 2012, and that the board has received a request for a regulation hearing on this rulemaking. Ms. Herold noted that we will have to have a board meeting, ideally, before January 1, 2013, to conduct the regulation hearing.

2. Combined Rulemaking: Proposal to Amend Section 1745 – Partial Fill of Schedule II Controlled Substance Prescription; Add Section 1762 – Unprofessional Conduct; and Add Section 1769 – Criteria for Rehabilitation

Mr. Lippe referenced the materials provided in the board packet, noting that the board's notice of proposed rulemaking will be published in the *California Regulatory Notice Register* on October 19, 2012. The 45-day public comment period will conclude on December 10, and the comments will be brought back to the board for consideration at the January 2013 Board Meeting. He noted the proposed language is in the packet as Attachment 4. There was discussion as to who should preside over the regulation hearing and if the board members were required to attend.

d. Board Approved Regulations – Awaiting Formal Public Notice

Mr. Lippe referenced the board materials (Attachment 5), adding that staff is preparing a combined rulemaking to Notice the following board-approved proposals. Mr. Lippe noted that staff hopes to notice the rulemaking by the end of the year.

*Amend Section 1732.2 – Board Accredited Continuing Education
Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas
Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education
Add Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies*

e. Under Development

Mr. Lippe noted that proposals to amend Sections 1780 and 1785 (previously considered by the Legislation and Regulation Committee) have been referred to other committees or subcommittees of the board. Mr. Lippe noted that the Regulation Chair Report contains additional background on these items. There was no further discussion or comments from the public.

f. Discussion and Possible Action to Delegate to the Executive Officer the Authority to Adopt “Changes Without Regulatory Effect” (1 CCR § Section 100 Changes)

Mr. Lippe directed the board members to the information contained in the chair report, noting this is a possible action item. Mr. Lippe described the proposed language relative to “Section 100” changes, stating that these include changes to regulations that would include grammatical corrections; updating, reordering, renumbering or re-locating laws or regulations listed on the self-assessment forms; and updating “authority and reference” citations in a regulation. He added that Section 100 changes could also include other types of changes that do not materially alter any requirement, right, responsibility, condition or other regulatory element of a regulation.

Mr. Lippe also noted that the packet does not include a copy of the board’s current regulation at Title 16 CCR Section 1703, which specifies the board’s delegation to the Executive Officer certain functions (such as filing accusations, setting cases for hearing, issuing notices of suspension, etc.) He stated that it is intended that any action taken by the board on this agenda item would be effective for a specified time frame, during which time the board could pursue a regulation change to add the “Section 100” delegation to the board’s existing regulation at 16 CCR §1703.

Motion: *For the period November 1, 2012 through December 31, 2013, the board delegate to the Executive Officer the authority to adopt regulation changes that are deemed to be “without regulatory effect” in accordance with Section 100 of Title 1 of the California Code of Regulations, and that upon the adoption of any “Section 100” regulation change, the Executive Officer shall report to the board at its next regularly scheduled Board Meeting any regulations authorized by this motion. Further, direct staff to prepare draft amendments to add the “Section 100” delegation to the board’s existing regulation at 16 CCR 1703 and bring the draft to the next meeting of the Legislation and Regulation Committee for consideration.*

There was no public comment.

M / S: Lippe / Gutierrez

Support: 8 Oppose: 0 Abstain: 0

President Weisser adjourned the meeting for lunch at 12:34 p.m.

The meeting was resumed at 1:37 p.m.

g. Discussion and Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1760 – Disciplinary Guidelines, and to Add a New Section Regarding Implementation of Uniform Standards for Substance Abusing Licensees

Assistant Executive Officer Anne Sodergren provided that the board had discussed a section of the disciplinary guidelines at the last board meeting and that this was an extension of that discussion.

Mr. Room further explained that the discussion was in response to a specific request that the board develop language that defines what a “substance abusing licensee” is for the purpose of diagnosis. The definition would be beneficial in identifying persons who have real and lasting issues with substance abuse.

Ms. Sodergren presented a draft of a definition for “substance abusing licensees” and explained that it wasn’t an action item, but was an opportunity to present additional information. She explained that the issue will be fully vetted by the subcommittee that was established by the board. Ms. Sodergren sought the board’s input as to whether the board was comfortable with the direction of establishing such a definition. Mr. Room commented that this definition was not included in SB 1441, and that the origin of the definition presented is a paraphrasing of the definition found in the Diagnostic and Statistical Manual of Disorders (DSM4). Ms. Sodergren read the draft definition that was presented. Mr. Weisser noted that this is not an action item. Mr. Room reflected on the board’s discussion at its July 2012 board meeting which would be to create such a definition for purposes of implementing. Anne noted that staff will be pursuing an AG opinion and will work on different definition strategies that would go through the subcommittee and eventually to the full board.

There was no additional board or public comment.

PART III – LEGISLATION AND REGULATION COMMITTEE

First Quarterly Report on the Committee’s Goals for 2012/13

The strategic goals update for the Legislation and Regulation Committee is under development by staff and will be reviewed by the committee in advance of the January 2013 Board Meeting.

IX - ENFORCEMENT COMMITTEE REPORT

Committee Chair Randy Kajioka presented a report of the meeting held September 11, 2012.

a. Process by Which the Board May Accept the Surrender of a License from a Licensee on Probation with the Board.

Background

Enforcement Committee Chair Randy Kajioka, PharmD, referenced the board packet, and presented the Enforcement Committee's recommendation to utilize the (4) forms provided in Attachment 1 for cases when a license is already on probation, and wishes to surrender the license. Ms. Shellans noted that the language on the forms is derived from the board's Disciplinary Guidelines and is a standard term and condition of probation. She added that the language is not new to the licensee.

License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

Current Process

Currently, a licensee who wishes to surrender would send a letter to the board requesting to surrender his or her license pursuant to the license surrender term. The board, in turn, acknowledges the acceptance by way of letter. This current process does not really provide a means for the board to make the surrender a matter of public record for purposes of public disclosure.

As a result, when a probationer surrenders his or her license, the board has no formal document to reflect that the surrender has occurred.

Currently, there are four specialized applications for the surrender of a license: pharmacist/intern, pharmacy technician, designated representative, and premises permits, would provide the licensee with details related to the surrender. This document would

become a public document that would be appended to the related decision and order on the board's website.

The committee discussed the proposal and proposed a motion to implement the use of the forms to accept the surrender of a license from a licensee on probation.

Committee Recommendation / Motion: **Approve the forms presented, and delegate acceptance of the surrender to the board's Executive Officer.**

Favor: 8 Oppose: 0 Abstain: 0

There was no discussion from the board or the public.

b. The DEA's Electronic Prescribing Requirements and Verification of Compliant E-Prescribing Systems for Controlled Substances

Dr. Kajioka summarized the information contained in the Enforcement Committee Report for this item, adding that in June 2010, the DEA's Interim Final Rule for the electronic prescribing of controlled substances took effect. There has been no adoption of a final rule yet.

The interim requirements are detailed and place requirements on prescribers and dispensers (and technology application vendors) that use electronic prescribing for controlled substances. A detailed explanation of the requirements was developed by the Board of Pharmacy (specifically Joshua Room) and the Medical Board of California and is available on our board's web site:

<http://www.pharmacy.ca.gov/publications/eprescribing.pdf>.

The law requires in part:

Audit and Selection of Software Application(s)

Before being used to create, sign, transmit, or process controlled substance prescriptions, electronic prescribing applications or pharmacy applications (stand-alone or integrated Electronic Medical Record (EMR) types) must have a third-party audit of the application certifying that it meets the requirements of the DEA regulations.

The application provider must secure an audit from (1) a person/entity qualified to conduct a SysTrust, WebTrust, or SAS 70 audit; (2) a Certified Information System Auditor that performs compliance audits; or (3) a certifying organization whose certification process has been approved by the DEA.

The auditor issues a report and/or certification to the application provider. The application provider must keep that report and/or certification for two years, and make it available to any prescriber or pharmacy that uses the application or is considering using the application. May be on provider's website.

Prescribers and pharmacies must review audit/certification report prior to using application to confirm that it performs the appropriate functions successfully. A prescription created using an application that does not meet requirements is invalid.

1. **Identity Proofing of Prescribers (Practitioners)** Identity proofing is the process by which a prescriber is uniquely identified, so that only that prescriber has the access necessary to authorize and sign electronic prescriptions using a software application. Identity proofing of prescriber must be done by an approved credential service provider (CSP) or certification authority (CA) [for digital certificates].

Prescribers and pharmacies must review audit/certification report prior to using application to confirm that it performs the appropriate functions successfully.

A prescription created using an application that does not meet requirements is invalid.

Furthermore, both prescribers and pharmacies have an **ongoing responsibility** to immediately cease using an application (and ensure that any designated agents also cease using the application) if:

- any required function of the application is disabled or appears to be functioning improperly;
- the application provider notifies them that a third-party audit or certification report indicates that the application no longer meets DEA requirements; or
- the application provider reports that the application is non-compliant.

2. **Receipt and Processing of Prescription(s) by Pharmacies**

The pharmacy application must be certified by the third-party auditor to, among other things:

- import, store, and display the information required for prescriptions;
- import, store, and display an indication of signing transmitted by the prescriber;
- import, store, and display the number of refills; and
- import, store, and verify the prescriber's digital signature, where applicable.
-

The second and the fourth of these listed requirements are particularly important to a pharmacy's proper verification of transmitted prescriptions.

At the Enforcement Committee Meeting/At this Board Meeting:

The board had hoped that with respect to certification and audit requirements that the DEA would post approved providers on its website. The board's staff recently learned that the DEA does not currently intend to do such posting. As such, it will be the prescribers and pharmacies themselves that must ensure when e-prescribing prescriptions, the systems and processes comply with the DEA's requirements.

Discussion

Discussion followed regarding the fact that the documentation provided by the DEA certifies that the software meets regulations. Ms. Herold explained that our inspectors will ask for confirmation and certification for e-prescription software during inspections. A hard copy must be provided if requested.

Ms. Herold provided that this is a federal law but that it has been difficult to get clarity about how the industry is complying.

Mr. Room explained that the DEA regulation states software must be certified by a vendor. The certification will state that the platform can perform the functions to accomplish the security features that are necessary.

Public Comment

Doug Hillblom explained that there are currently four vendors that offer certification of the software, and that both the physician systems and the pharmacy systems must be certified appropriately to successfully transmit. If one or the other isn't certified, the system won't transmit.

Steve Gray provided that there has been confusion because some of the major prescriber organizations have internal systems and provide software to the prescriber, which then certifies for the prescriber and their pharmacies. But not all organizations provide for this.

Darlene Fujimoto suggested talking to someone who has the certification software to get more information about how it works. She explained that it would be very difficult to comply when there aren't specific guidelines about what industry should be doing.

Also on E-Prescribing:

Mr. Kajioka explained that the committee briefly discussed a request for proposals from the California HealthCare Foundation. For a number of years, the California HealthCare Foundation has been vigorously promoting the use of e-prescribing for all prescription drugs in California. Despite the efforts of this group and others, e-prescribing in California is at a very low adoption rate compared with e-prescribing in other states.

To aid in implementation of e-prescribing systems for controlled drugs, the California HealthCare Foundation recently announced a request for proposals to support up to three pilot implementations of electronic prescribing systems in ambulatory provider organizations.

c. Clarification Regarding 16 California Code of Regulations 1707.5(d) Availability of Interpreters for Patients with Limited Speaking Skills by Nuclear Pharmacies

Regulations adopted to implement California Business and Professions Code section 4076.5 regarding use of patient-centered labels for all prescription medication dispensed to patients in California, require the availability of interpreters. Specifically:

- (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. 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.

The board was recently asked if this paragraph applies to nuclear pharmacies. A nuclear pharmacy will compound product that is patient-specific, but it does not dispense the drug to the patient. Instead the drug is provided to the practitioner who will administer the drug.

In such case, does a nuclear pharmacy need to comply -- and have available – interpreter services for patients they never see?

During the committee meeting, Staff Counsel Kristy Shellans clarified that because the medication is not provided to the patient, the interpreter requirement does not apply.

There was no comment from the board or the public.

d. Implementation of California's Electronic Pedigree Requirements for Prescription Medication

1. Presentations and Questions from the Pharmaceutical Supply Chain Provided During the Enforcement Committee on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule

Until late 2008, when California's e-pedigree requirements were amended to delay implementation until at least 2015, the Enforcement Committee held public discussions with the supply chain to discuss readiness issues. The committee resumed these discussions in early 2012, after a three-year hiatus.

Mr. Kajioka referenced an article describing Brazil's efforts to establish a Track and Trace System.

There were no formal presentations made on general e-pedigree issues during the Enforcement Committee Meeting, although there was discussion and presentations under the inference topic.

2. Update on the Status of Proposed Regulations to Specify a Unique Identification Number for Prescription Medication, and "Grandfathering" Provisions for Non-Pedigreed Dangerous Drugs

Chairperson Kajioka advised attendees that the board planned to release these regulations for the required 45 days of public comment from September 21 through November 5, 2012. The board will consider the comments at the February 2013 Board Meeting.

There were no comments from the board or the public.

3. Elements for Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3.

On July 23 the board released a request for comments from interested parties on the need for inference. The solicitation request was developed by Deputy Attorney General Room and released via a subscriber alert, seeking comments from industry to gather the

information the board needs to review to assess the conditions upon which inference may, or may not, be used. Provisions in Business and Professions Code section 4163.3 direct the board to balance the need for inference with the risks of permitting inference.

Comments were due from interested parties by September 1. Comments were received representatives of 9 manufacturers, 5 wholesalers, 2 pharmacies and 2 other organizations. These comments encourage the use of inference but do not provide the specific detail needed to develop regulatory provisions. The specific comments themselves were provided for the board members.

During the meeting on September 11th, the committee discussed the comments received and Mr. Room emphasized that while grateful for the comments, they do not have the specificity needed to develop regulations.

As such, the board released a second request for information on inference after the Enforcement Committee Meeting. To date, no additional comments have been received.

Also:

At the September 2012 Enforcement Committee Meeting, presentations were made by:

- (1) Bill Fletcher of Pharmacy Logistic Solutions: on how other industries already have implemented serialization and aggregation to track products. He described why the pharmaceutical supply chain needs aggregation and inference to implement California's e-pedigree requirements, and highlighted some of the issues.
- (2) Bob Celeste of GS1 provided an update on the development of standards by GS1. Mr. Celeste described GS1's work to develop information on inference. He also described a statistical sampling process for inference that was developed by Stanford University.
- (3) Lynn Paulsen of the California Society of Health-System Pharmacists provided the concerns of hospitals to ensure that they would be able to use inference in accepting medication shipments into hospitals.
- (4) Liz Gallenagh of Healthcare Distribution Management Association, emphasized the necessity for wholesalers to be able to use inference in moving product through the supply chain. She showed examples of wholesalers' facilities, and the quantity of packages/pallets being received and shipped daily. Julie Kuhn of Cardinal Health provided specific information about the operations of wholesalers to respond to board member questions.
- (5) Steve Gray, representing Kaiser Permanente, also emphasized the need for inference.
- (6) Ruby Raley representing Axway, advised that independent pharmacies rely on wholesalers to manage much of their inventory needs, and these needs should be part of the authorization for inference.
- (7) Steve Drucker representing Merck indicated that lot level tracking would allow the supply chain to learn to accept tracking without the complexity required for serialization and inference.

Mr. Kajioka provided that future meeting dates for the Enforcement Committee would be as follows:

December 4, 2012 – LAX Hilton
March 5, 2013 – Bay Area

June 4, 2013 – Southern California
September 10, 2013
December 3, 2013

There were no comments from the board or the public.

Enforcement Statistics

Assistant Executive Officer Anne Sodergren referenced the enforcement statistics and explained that as we continue to train new inspector staff we will be moving closer to the success indicators we have established. We will be reevaluating the success indicators in six to nine months after we are fully staffed.

Ms. Herold provided that we currently have all our inspector positions filled. We have 37 inspectors, as well as in-house research investigators.

She further explained that the travel freeze has greatly impacted our ability to train new staff, as we are no longer allowed to fly them into Sacramento for centralized training. Instead, we have been required to deploy our field inspectors to do the training. During the last year, we have brought on about 15 new inspector staff, which created a substantial training need.

Mr. Room also provided that the nature of the investigations has changed in the last five to seven years and are now more complex in nature and take longer to investigate.

Discussion continued about the need for increased investigations to address the growing drug diversion problem. In addition, there has been an increased demand on internal staff and resources to keep pace with the growing inspector staff and the results of their investigations.

There were no comments from the public.

f. First Quarterly Report on the Committee's Goals for 2012/2013

Ms. Herold provided that the report was referenced during the Enforcement Statistics portion of the meeting.

IX. Closed Session

Pursuant to Government Code Section 11126(C)(3), the Board adjourned the meeting and convened in Closed Session at 2:54 p.m.

ADJOURNMENT FOR THE DAY

Friday, October 26, 2012

XI. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board convened in Closed Session to deliberate on disciplinary matters.

Call to Order -- RESUMPTION OF THE OPEN SESSION

President Weisser called the meeting to order at 9:50 a.m.

President Weisser conducted a roll call. Board members present were: Randy Kajioka, PharmD, Vice President; Amy Gutierrez, PharmD; Victor Law, RPh; Greg Lippe, Public Member, Treasurer; Deborah Veale, RPh; Shirley Wheat, Public Member; Stan Weisser, RPh; and Albert Wong, PharmD.

XII. EXECUTIVE OFFICER'S REPORT

a. Update on the Co-Sponsored Conference with the Medical Board of California Scheduled For February 2013; Work on Securing the Continuation of Controlled Substance Utilization Review and Evaluation System

Ms. Herold reported that the Board of Pharmacy is planning to co-sponsor a conference with the Medical Board of California on February 21 and 22 in San Francisco. The conference, titled Safe & Appropriate Controlled Substance Prescribing and Dispensing, will seek to find ways for pharmacists and physicians to work together to make wise prescribing and dispensing decisions.

b. Summary of the Technology Summit held on October 24, 2012

Ms. Herold provided that board inspectors had discovered unauthorized drug dispensing machines and technology in use during the course of their inspections. Since the role of the board is to protect the health and safety of Californian's, the technology in use is an important component of that.

She continued that the Technology Summit was very educational, and included presentations by both board inspectors and industry representatives. Our intent is not to sponsor legislation, but to combine our role as a regulator with the role of patient safety.

Ms. Herold added that the topic will be added as an agenda item for the Licensing Committee and the presentations will be made available on the board's website.

Ms. Herold also briefly discussed the board's strategic plan and indicated that the intent is to continue to work toward meeting the goals. Board members endorsed the new reporting structure.

Prescription drug abuse continues to be a major problem and Ms. Herold explained that funding for the CURES Program remains an issue. The program is a major initiative in the fight against prescription drug abuse and Ms. Herold reinforced the board's commitment to supporting it.

XIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

President Weisser announced that there was no meeting of the Organizational Development Committee in the past quarter.

a. Budget Update/Report

1. Budget Report for 2012/13

President Weisser reported that the budget year began on July 1, 2012, with a budget of \$15,289,000. Personnel expenses totaled approximately \$3 million for the first three months of 2012 and there is currently \$10.5 million in the fund balance. Mr. Weisser continued that the board has discussed avenues for increasing the fund balance, and that the goal is to have a year's worth of revenue in the fund.

2. Update on BreEZe, DCA's New Computer System

President Weisser reported that work continues on the Department of Consumer Affairs' new computer system, BreEZe. Full rollout is expected within two years and the Board of Pharmacy continues to commit resources to the project.

3. Reimbursement to Board Members

President Weisser referenced the attachment in the meeting materials.

b. Update on the Recognition Program of Pharmacists Who Have Been Licensed 50 Years

President Weisser explained that this has been a wonderful program and a great opportunity to recognize pharmacists who have dedicated their careers to serving patients and their local communities.

c. Personnel Update

President Weisser welcomed Victor Law to the board as a new professional member.

d. First Quarterly Report on the Committee's Goals for 2012/13

Ms. Herold provided that all 37 inspector positions have been filled. She continued that the board is now set up for video conferencing and the goal is to use that method for inspector meetings and as a training tool. The board is also looking at adding additional inspector staff and possibly a fee increase in the future.

Mr. Room provided that new legislation targeting a track and trace system had a deadline of November 7th for submission of comments. It was suggested that Mr. Weisser and Ms. Herold work together to draft comments.

Public Comment

Darlene Fujimoto suggested that the board provide more direction to pharmacists regarding compounding regulations and that the issue be followed up at a future board meeting.

Ms. Gutierrez suggested that the issue of compounding be placed on the next agenda and was advised that this will be done through the Licensing Committee.

Dr. Kajioka indicated that compounding will also be discussed at the next Enforcement Committee meeting.

President Weisser adjourned the meeting for a five minute break.

The meeting was resumed at 12:17 p.m.

XIV. PETITION FOR REINSTATEMENT

The following petitions were presented for reinstatement:

- a. **Reza Abolahrar, RPH 47355**
- b. **Clifford Victor, RPH 41656**

XV. PETITION FOR REDUCTION OF PENALTY

The following petition was presented for a reduction of penalty:

Gary Sabistina, RPH 36143

XVI. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the board convened in closed session to deliberate on the petitions for reinstatement and to deliberate on disciplinary matters

ADJOURNMENT