California State Board of Pharmacy
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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: July 30-31, 2013

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

BOARD MEMBERS PRESENT:
Stanley C. Weisser, RPh, President
Amy Gutierrez, PharmD, Vice President
Ramón Castellblanch, PhD, Public Member
Deborah Veale, RPh
Greg Lippe, Public Member, Treasurer
Victor Law, RPh
Ryan Brooks, Public Member
Albert Wong, PharmD
Lavanza Butler, PharmD
Randy Kajioka, PharmD (July 30th only)
Tappan Zee, Public Member

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

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, Supervising Inspector
Kristy Shellans, DCA Staff Counsel
Joshua Room, Supervising Deputy Attorney General
Desiree Kellogg , Deputy Attorney General
Carolyn Klein, Manager II
Debbie Damoth, Manager
Laura Hendricks, Staff Analyst

Note: The webcast for the second day of this meeting (July 31, 2013) is available at: http://www.pharmacy.ca.gov/about/meetings.shtml

Note: The Legislation and Regulation Committee Meeting was held immediately prior to the Board Meeting.

Call to Order

President Weisser called the meeting to order at 12:35 p.m.

I. GENERAL ANNOUNCEMENTS

President Weisser announced 6 hours of continuing education credit would be offered for attending the entire meeting on July 31, 2013.

President Weisser provided that discussion and action may be taken on any item on the agenda. The board may discuss agenda items in any order on each day, unless noticed as "time certain." An opportunity for public comment is provided for each open agenda item and at the end of each committee's report.

President Weisser conducted a roll call. Board members present: Stanley C. Weisser, Randy Kajioka, Ramón Castellblanch, Tappan Zee, Greg Lippe, Amy Gutierrez, Victor Law, Ryan Brooks, Albert Wong, Lavanza Butler and Deborah Veale. Board members not present: Shirley Wheat and Rosalyn Hackworth.

II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF APRIL 24-25, 2013

Discussion:
No comments provided by the board or by the public.

Motion: Approve the minutes of the April 24-25, 2013 meeting.

M/S: Lippe/Veale

Support: 9 Oppose: 0 Abstain: 2 (Brooks and Zee)

III. BOARD MEETING DATES FOR 2013 AND 2014

President Weisser directed the board's attention to the meeting dates provided in the meeting materials for the remainder of 2013 and 2014. The executive officer was directed to work with staff to finalize dates for the January Board Meeting to accommodate legal counsel's scheduling conflict.

IV. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

Dennis McAllister, from Express Scripts, commented that the board's citation and fine process is creating an issue for large, national companies because when one location is cited it has an unintended adverse action on the *entire* company.

Phil Wickizer, from Express Scripts, commented that Express Scripts wants to work with the board to educate them on the challenges of shipping temperature sensitive medications

Heidi Sanborn, from the Product Stewardship Council, invited the board to visit collection locations for unused drug they have established. Mr. Brooks asked who pays for the hauling of the unused medications. Ms. Sanborn answered that the pharmacy pays. Dr. Castellblanch expressed his desire to add drug take-back to a future meeting agenda.

Nancy Tilcock, from California Alliance for Retired Americans (CARA), commented that she agrees with the need for take-back programs.

LuGina Mendez Harper, from Prime Therapeutics, agreed with Mr. McAllister's comment that the board's citation and fine program does have unintended consequences.

V. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

President Weisser directed the board members and public to review the budget charts provided in the meeting materials and noted that the final 2012/13 number would be provided at the October Board Meeting.

President Weisser noted the fund imbalance being caused by the board's expenditures exceeding its revenue. He added that the board has discussed the need for a fee increase at prior meetings – and it will be discussed again during the regulation hearing later in the meeting.

Anne Sodergren reported the first phase of the BreEZe system is scheduled to be released mid-September (subject to change). Despite the board being in phase 2, there will be a one week system shut down affecting all DCA entities. During that time no applications can be processed, no renewals can be cashiered and no license verifications can be conducted. Dr. Kajioka asked if a subscriber alert will be sent out notifying the public of the system shut down. Ms. Sodergren answered that a subscriber alert will go out and the homepage of our website will be updated with any information the board receives. It was noted that board members and staff highly recommended applicants and licenses submit any documents/payments to the board as soon as possible to avoid a delay in processing due to the system shut down.

Ms. Herold reported that Carolyn Klein has been promoted to an SSMII and will oversee the Board's managers. Debbie Damoth has filled behind Ms. Klein as the Administration Unit Manager. Ms. Herold also announced that Ms. Deborah Veale and Ms. Lavanza Butler have been reappointed to the board.

Ms. Herold noted that the Executive Officer evaluation scheduled for this Board Meeting will be conducted at a later date.

VI. REGULATION HEARING

Regulation Hearing Regarding a Proposal to Amend Title 16 California Code of Regulations Section 1749 Regarding the Board's Fee Schedule

President Weisser conducted the regulation hearing as follows.

This hearing is to consider the board's proposal to Amend Title 16, California Code of Regulations, Section 1749 related to the board's Fee Schedule.

For the record, the date is July 30, 2013, and the time is 1:00 p.m.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record, which is now being electronically recorded. All oral testimony and documentary evidence will be considered by the board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed regulation or recommends changes which may evolve as a result of this hearing.

A record of this hearing, as well as testimony received, will become a part of the rulemaking file. A complete copy of the rulemaking file will be available for review at the board's main office in Sacramento.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and gives his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations. Responses by the board to all recommendations or objections will be included in the Final Statement of Reasons that is filed with the Office of Administrative Law.

B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.

C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin?

Discussion

No questions from the board or from the public were made.

President Weisser called on those persons wishing to testify regarding the board's proposed action.

Discussion

No comments from the board or from the public.

As no comments were made by the board or by the public. President Weisser closed the hearing.

The regulation hearing closed at 1:07 p.m.

VII. DISCUSSION AND POSSIBLE ACTION TO MAKE CHANGES IN RESPONSE TO COMMENTS OR TO ADOPT OR AMEND PROPOSED TEXT AT TITLE 16 CALIFORNIA CODE OF REGULATIONS SECTION 1749 REGARDING THE BOARD'S FEE SCHEDULE

Responding to Comments:
Ms. Sodergren reported that only one written comment was received by the board from Joe Kern and it was not responsive to the proposed text. The comment reads as follows. "Look at increases!!!"

Motion: To direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the executive officer the authority to make any non-substantive changes to the

proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1749 as noticed on June 14, 2013.

M/S: Veale/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

VIII. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

President Weisser recognized Donald Brooks, Charles Duncan, Robert Bitter, Norman Tanaka, William Rogers, William Murray and Vernon Nichols for 50 years of service as pharmacists. In addition President Weisser was recognized by Dr. Gutierrez for his 50 years of service as a pharmacist.

IX. EXECUTIVE OFFICER REPORT

a. Update on Activities of the Medical Board of California

Ms. Kim Kirchmeyer provided an update on Activities of the Medical Board of California as follows.

- Linda Whitney, the Medical Board's executive director, retired on May 31st after 37 years of state service.

- The Medical Board has appointed Ms. Kirchmeyer as the interim executive director.

- The Medical Board's most significant project and activity right now its Sunset Review. The Medical Board raised several problems or concerns in its report and about 20 of those issues were placed into the report by the Senate Business and Professions Committee. The board is working on resolution of the items raised in the committee report and the sunset bill – SB 304 will be heard on August 13th.

- One of the biggest issues raised by the committee in regards to sunset review was the issue of overprescribing. There are bills that have come out of this issue, including SB 62, which requires coroners to report to the board when the cause of death is due to a Schedule II-IV controlled substance, and SB 670, which will allow the board to impose limitations on a physician's ability to prescribe, furnish, administer or dispense controlled substances if probable cause has been found that a physician prescribed or dispensed controlled substances in violation of the Medical Practice Act.

- In looking at the Medical Board's role in the overprescribing issue, the board has redirected staff to a special strike force investigative unit called Operation Rx. The tam is working

with local police and the DEA to resolve these cases. The team will also begin to utilize CURES data to identify top prescribers and add those cases to the strike force queue.

- The Medical Board has also developed a Prescribing Task Force. This task force, requested by the board, came from both information obtained at the Joint Forum and the need to really look into this issue and find resolution to some of the problems before the Medical Board and the Board of Pharmacy.
- The Prescription Task Force, made up of a public board member and a physician board member have identified the following mission statement:

  "The Task Force will identify ways to proactively approach and find solutions to the epidemic of prescription drug overdoses through education, prevention, best practices, communication, and outreach by engaging all stakeholders in this endeavor."

- The Prescription Task Force will hold its first meeting on Monday, September 23, 2013 in Sacramento. The first issue the Task Force will be looking into is identifying the appropriate patient information that can be shared and discussed between the prescriber and the pharmacist. The Task Force hopes to have a document that identifies appropriate information that can be shared between the prescriber and the dispenser based upon input from all stakeholders. This document could be shared and posted on all the licensing boards' Web sites who prescribe and dispense. Ms. Herold and Ms. Sodergren will not only attend the meeting, but also will provide pharmacists' contacts so we can ensure we can have a full discussion on this issue.

  President Weisser noted that Mr. Castellblanch and Dr. Darlene Fujimoto will be working with the Medical Board on this Task Force. Dr. Castellblanch commented that he is looking forward to working with the Medical Board.

- The Prescription Task Force also wants to identify best practices for prescribing. Once best practices have been identified, then the Task Force will move to revisiting the pain management guidelines; educating prescribers, dispensers, and the public on prescribing issues; and developing an outreach plan to provide information to all interested parties.

- These Prescription Task Force meetings will have representatives from numerous interested parties, including all prescribers – physicians, nurse practitioners, dentists, etc.; pharmacists; prescribing and dispensing associations; law enforcement agencies, such as DEA, DA's office, sheriff's office, etc.; consumer and advocate groups; other healing arts boards; insurance companies; DHCS, CDPH, and Senate and Assembly committees. The meetings will be closely facilitated.

- In follow-up to our Joint Forum, the Medical Board Members have requested Board staff to work with Pharmacy Board staff on brochures that could provide educational ideas for prescribers, dispensers, and the public.

- Additionally, the medical members requested a list of the top 10-20 issues related to prescribing and dispensing that could be discussed in a Newsletter article and used for educational purposes.

- The Medical Board has approved moving forward with another Joint Forum in the spring of 2014.

Discussion

Dr. Kajioka commented that the Board of Pharmacy wants to see the prescription purpose on labels to make it easier for patients to understand their prescriptions. Ms. Herold noted that two Medical Board members commented that they feel purpose should be on the label at the last meeting she attended.

Mr. Brooks commented that a challenge that needs to be addressed is how to dispose of unused drugs and suggested the use of radio and billboard ads to educate the public of proper disposal methods.

Mr. Law asked if the Medical Board will be working on changing its history of being lenient on its licensees. Ms. Kirchmeyer responded that the Medical Board is right in line with the national average on disciplining its licensees. She added that a new bill that will allow them get medical reports if a patient dies from a prescription drug overdose without needing to go to the next of kin, will further help them discipline doctors who are over-prescribing.

b. Items from the Executive Officer

Ms. Herold announced that the next DEA Drug Take-Back Day would be on October 26th. She added that it is only aimed at take back from patients *not* facilities.

Ms. Herold stated that The University of San Diego School of Pharmacy was placed on probation by A.C.P.E. The school is currently working with A.C.P.E. to make corrections to their program in order to be removed from probation. She also reported that California Nortstate is now fully accredited by A.C.P.E.

Ms. Herold provided a brief update on the Controlled Substance Utilization Review and Evaluation System ("CURES").

Ms. Herold reported that for the first time the board is seeing wholesalers limit, and in some cases cut-off, the supply of controlled substances to pharmacies if they feel that the pharmacy is over dispensing. This is creating a shortage of drugs and the board anticipates seeing an increase in diversion and counterfeiting as a result.

Ms. Herold announced that the Governor has re-configuration several agencies and as a result the name for the "State and Consumer Services Agency" has been changed to "Business, Consumer Services and Housing Agency."

X. LICENSING COMMITTEE REPORT

Chairperson Veale provided a report of the Licensing Committee Meeting held May 28, 2013

a. Licensing Committee Dates

- September 24, 2013
- December 11, 2013

b. Discussion and Possible Action on a Proposed Regulation Change to Require or Standardize the Reporting of Convictions and Discipline at the Time of Renewal for Pharmacists, Pharmacy Technicians and Designated Representatives, Proposed Amendment to 16 California Code of Regulations Section 1702 and Proposed Addition of 16 California Code of Regulations Sections 1702.1 and 1702.2

Relevant Statutes and Regulations
Business and Professions Code Section 4036 provides the definition for "pharmacist" and specifies that the holder of an unexpired and active pharmacist license is entitled to practice pharmacy as defined in pharmacy law.

Business and Professions Code Section 4022.5 provides the definition of "designated representative" and Business and Professions Code Section 4038 provides the definition of a pharmacy technician.

California Code of Regulations Section 1702 details the fingerprint and criminal conviction requirements that are currently required as a condition of renewal for a pharmacist.

Background
As part of the Consumer Protection Enforcement Initiate in 2008/2009, the board undertook review and evaluation of several areas of its enforcement and licensing functions to identify areas where the board could improve its ability to ensure it received or had access to information necessary to make appropriate licensing decisions as well as ensure it received relevant information to initiate investigations and take appropriate action to better protect consumers.

As part of this effort the board sought new regulatory authority to require fingerprinting of pharmacists that had not previously submitted fingerprints to the Department of Justice in an electronic format. To augment this effort, the board also sought to require as a condition of

renewal, that a pharmacist also self-report any convictions. These changes took effect in December 2010. At the time the board adopted the changes, they requested that similar provisions be implemented for pharmacy technicians and designated representatives in the future.

During the April 2013 Licensing Committee meeting, the committee discussed a staff recommendation that would make changes to the existing pharmacist renewal as well as place similar renewal requirements for the pharmacy technician and designative representative licenses. The proposed changes specific to the pharmacist renewal include:

- Disclosure of disciplinary action
- Removing reference to the implementation date
- Clarifying that disclosure of criminal conviction information and disciplinary action is for action taken since the last renewal of the license.

At the April 2013 Licensing Committee meeting, Chair Veale directed staff to determine the number of pharmacy technicians and designated representatives that require retro fingerprinting and to provide information relating to the costs associated.

Board staff estimates approximately 13,588 licensees will require Live Scan to be completed consisting of 13,305 pharmacy technicians and 283 designated representatives. The cost of the Live Scan to the licensee is approximately $51 plus rolling fees that vary based on the Live Scan location.

Based on the comments received during the committee and counsel, the language was revised and presented to the committee for consideration.

Committee Discussion & Action

At the May 2013 Licensing Committee meeting, the committee discussed the definition of disciplinary action. The committee agreed to revise the proposed language to add "reprimand" and expand the definition of disciplinary action.

Committee Motion: Direct staff to take all steps necessary to initiate the formal rulemaking process with the proposed changes and to add "reprimand" and expand the definition of disciplinary action. Authorize the Executive Officer to make any non-substantive changes in the rulemaking package and provide for a public comment period.

Support: 11 Oppose: 0 Abstain: 0

c. Discussion and Possible Action to Initiate a Rulemaking to Require Site Licenses to Report Disciplinary Actions by Other Entities at Time of Renewal, Proposed Addition of 16 California Code of Regulations Section 1702.5

Relevant Statutes and Regulations

Business and Professions Code Section 4112 provides for the regulation of a pharmacy located outside of California that ships, mails, or delivers, in any matter, controlled substances, dangerous drugs, or dangerous devices into this state.

Business and Professions Code Section 4161 provides for the regulation of a wholesaler located outside of California that ships, sells, mails, or delivers dangerous drugs or devices into this state or that sells, brokers or distributes such products.

Background

As part of the requirements for initial licensure as either a nonresident pharmacy or nonresident wholesaler an applicant must hold a current license in the resident state. Prior to issuance of a CA license, such applicants provide the board with license verification from the resident state that provides our board with confirmation of the current standing with the other state board as well as notification if the license has been disciplined. This information is very valuable when making a licensing decision; however, it only provides information at the time of licensure.

During the April 2013 Licensing Committee meeting, board staff recommended that the committee discuss, and if it so chooses, recommend to the full board, initiation of a rulemaking that would require, as a condition of renewal, disclosure of any disciplinary action taken against the entity in its home state.

The committee discussed the proposal and the policy behind the recommendation and expressed support for the concept. Chair Veale directed staff to refine the language and to clarify exactly what staff is requesting the licensee provide.

Based on the comments received during the committee and counsel, the language was revised and presented to the committee for consideration.

Committee Discussion & Action

At the May 2013 Licensing Committee meeting, the committee discussed the definition of disciplinary action. The committee agreed to revise the proposed language to add “reprimand” and expand the definition of disciplinary action.

Committee Motion: Direct staff to take all steps necessary to initiate the formal rulemaking process with the proposed changes and to add “reprimand” and expand the definition of disciplinary action. Authorize the Executive Officer to make any non-substantive changes in the rulemaking package and provide for a public comment period.

Support: 11 Oppose: 0 Abstain: 0

d. Discussion and Possible Action on Request from Det Norske Veritas to Renew Board of Pharmacy Approval as an Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies

Relevant Statutes
Business and Professions Code Sections 4127 – 4127.8 provides for the regulation of pharmacies that compound sterile injectable drug products in a pharmacy. Pharmacy law creates an exemption from the licensure requirements for a pharmacy that is accredited by a private accreditation agency approved by the board (B&PC 4127.1 (d) and 4127.2 (c).

Background
For the past several years the board has been discussing several elements of pharmacies that compound sterile injectable products, including the requirements for private accreditation agencies. As part of the current approval process, such agencies apply to the board for consideration and approval by the board.

Det Norske Veritas (DNV) was previously approved by the board for a three year period. This approval will expire later this year. As such DNV has submitted a new request to the board. Regrettably because the April Licensing Committee meeting was rescheduled, a representative from DNV was unable to attend the committee meeting. The committee recommended to the board to extend DNV's approval for three months so that DNV would be able to attend the May Licensing Committee meeting. The board approved this recommendation.

Supervising Inspector Janice Dang conducted an inspection of four hospitals accredited by DNV. This summary was provided as part of the meeting materials.

The committee discussed the summary of inspections for the four hospitals accredited by DNV inspected by Supervising Inspector Janice Dang. DNV was not present at the Licensing Committee meeting. Chair Veale advised the committee of pending legislation SB 294 (Emerson) that if approved, will supersede accrediting approval by the board. Chair Veale indicated if the bill fails, accreditation in lieu of licensure will be allowed.

A summary of hospital pharmacy initial and follow up inspections of hospital accredited by Det Norske Veritas Healthcare Inc. was provided in the meeting materials.

Discussion
Supervising Inspector Janice Dang gave the board an overview of the report that was provided in the meeting materials.

Dr. Castellblanch commented that the report reflected several violations and noted that he was concerned about patient safety. Chairperson Veale provided that many of the violations in the

report were relatively minor and have since been corrected. Chairperson Veale asked Dr. Dang if the locations would have been cited and fined for the violations she reported. Dr. Dang responded that they would not.

Ms. Veale noted that the committee was disappointed that a pharmacist was not included in the accreditation process by DNV.

Dr. Gutierrez added that while the violations noted were minor they should not be ignored.

Dr. Gutierrez asked the representative from DNV if they require full compliance with USP 797. Troy McCan, from DNV, responded that DNV does not.

Ms. Herold added that the board has the capability to issue a cease and desist to a sterile compounding pharmacy if the board finds significant violations that put the public's health at risk.

Dr. Gutierrez asked to clarify if the motion was to extend DNV's accreditation for one year. Mr. Brooks responded that the motion was to extend it, however extending it does not impede the board's ability to go into the sites and inspect them.

Chairperson Veale reported that DNV's original request was to extend their accreditation for three years. However the committee feels pending legislation (SB 294) will pass that will require the sites to become licensed with the board making the three year extension unnecessary.

Dr. Castellblanch expressed his opinion that until a bill is signed they should not count on it passing. Chairperson Veale responded that if SB 294 does not pass then in one year DNV will have to come back to the board for approval. Additionally if it does not pass the board will make changes to the requirements for the accreditation process to address the current problems. Ms. Herold added that the board has a regulation they are holding back until they know the outcome of SB 294, that will clearly define the requirements for becoming board approved accreditation agency.

Committee Motion: One-year approval of DNV accreditation. Along with this approval the board will send a letter requesting inclusion of the elements the board requires: adding a pharmacist to the survey team, providing information to the board, and updating the board when the deficiencies have been corrected.

Support: 8 Oppose: 2 (Gutierrez and Castellblanch) Abstain: 1 (Lippe)

e. <u>Update on the Evaluation of the Pharmacy Technician Certification Board (PTCB) Exam and the Examination for the Certification of Pharmacy Technician (ExCPT) Exam</u>.

Relevant Statutes
Business and Professions Code section 4202 establishes the requirements for licensure as a pharmacy technician. There are several routes to licensure:

- Obtain an associate's degree in pharmacy technology,
- Completion of a technician training course specified by the board,
- Graduation from a school of pharmacy recognized by the board, or
- Certification by the Pharmacy Technician Certification board.

Business and Professions Code 139 requires a psychometric assessment description of the occupational analysis serving as the basis for the examination and an assessment of the appropriateness of prerequisites for admittance to the examination.

Background
During the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT).

The results of the review would ensure that these applicants who qualify for licensure as a pharmacy technician have passed a validated exam, consistent with the requirements in B&PC 139. The board was advised in 2010 that the Department of Consumer Affairs' Office of Professional Examination Services (OPES) will conduct these evaluations for the board. The board signed an interagency agreement with the OPES.

Board staff has been working with OPES to coordinate two workshop dates required for this as part of this review. The workshop dates were identified as June 5-6, 2013, and July 16-17, 2013, in Sacramento, CA. However, the July workshop was rescheduled to August 15-16, 2013. Additionally, a third workshop has been tentatively set at September 5-6, 2013. Board staff continues to recruit licensed pharmacy technicians and pharmacist to participate in the workshops.

Upon completion of the workshops, OPES will provide the board with the findings of the psychometric assessment for the PTCB and ExCPT certification examinations.

Discussion
No comments from the board or from the public.

f. Review of the Board of Pharmacy's Emergency Response Plan

Relevant Statutes
Business and Professions Code Section 4062 sets forth the general parameters for furnishing dangerous drugs during an emergency.

Business and Professions Code Section 900 sets for the general provisions that allow for health care practitioners licensed in another state to provide services in CA upon request of the Director of the California Emergency Medical Services Authority.

Background
Over the years, the board has dedicated resources to the subject of emergency response. The board's current policy statement was developed and subsequently published in the January 2007 newsletter. Following that, the board licensing committee and the full board have discussed several aspects of emergency response and disaster planning. Chair Veale provided a brief synopsis of actions taken by the board in this area.

Assistant Executive Officer Anne Sodergren provided the committee with an overview of the Rx Response's discussion-based disaster response exercise that she and a board inspector participated in the previous week. Executive Officer Virginia Herold discussed the board's current plan and indicated the board would republish it soon.

Discussion
No comments from the board or from the public.

g. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)
The board instituted a quality assurance review of the CPJE effective April 1, 2013. This process is done periodically to ensure the reliability of the examination. The quality assurance review was completed and ended June 17, 2013. Since the completion of the quality assurance review, CPJE results are mailed to applicants on a bi-weekly basis.

Examination Development
Competency Committee workgroups continued to conduct examination development meetings during the spring of 2013. Both Competency Committee workgroups will meet August 2013 at the annual meeting to discuss examination development.

Discussion
No comments from the board or from the public.

h. Fourth Quarterly Report on the Committee's Goals for 2012/13

The fourth quarterly report on the Licensing Committee's goals were provided in the meeting materials.

As demonstrated in the quarterly update, the board is meeting the acceptance parameters for Success Indicators 2C – Review Received Deficiency Items to Determine Application Completeness within Five Working Days of Receipt and 2E – Update Information Changes to Licensing Records within Five Working Days.

The board is not meeting the acceptance parameters for Success Indicators 2A – Cashier All Revenue Received within Three Working Days; 2B – Review Initial Applications within 30 Working Days or 2D – Issue Licenses within Three Working Days of Completed Application. In these success indicators, a majority of the work is completed within a time frame close to the specified indicators. For example, in Success Indicator 2A where the indicator is three days, 80% of the revenue is cashiered within four days. In Success Indicator 2C where the indicator is 30 days, 99% are processed within 45 days. In Success Indicator 2D where the indicator is three days, 67% of the licenses are issued within this time frame; however, a total 86% of licenses are issued within four days or less and 94% of licenses are issued within 5 days or less. The board is not meeting these success indicators primarily due to staff vacancies, antiquated databases and a realized increase by 42% in the number of applications received in the 4th quarter when compared to the 3rd quarter primarily due to pharmacist license examination candidates.

Discussion
No comments from the board of from the public.

i. Licensing Statistics for July 2012 – June 2013 and Three Year Comparison Data

A three year comparison with data trend lines for each license type and the licensing statistics for Fiscal Year 2012/13 was provided in the meeting materials and is summarized below.

Licensing Statistics for July 2012 – June 2013

In Fiscal Year 2012/13, the board received 16,891 applications which reflects a decrease of 2% from Fiscal Year 2011/12. The board issued 13,038 licenses which reflects approximately a 12% decrease when compared to Fiscal Year 2011/12.

Three Year Comparison

Applications Received

The three year comparison reflects a 21% decrease in the number of pharmacy technician applications and a 33% decrease in hospital pharmacy applications received in Fiscal Year 2012/13 when compared to Fiscal Year 2010/11.

In Fiscal Year 2012/13, the board experienced a 72% increase of pharmacy applications and a 94% increase of clinic applications when compared to Fiscal Year 2010/11. The pharmacy applications increased due in part to a small buyout of a retail store. If the applications as a result of the buyout are not factored in, the pharmacy applications increased 30%. The clinic applications increased as a result of a statutory application requirement change effective 1/1/2013. This change increased the methods by which a clinic may apply for licensure.

Licenses Issued

The board experienced a decrease of the following licenses issued in Fiscal Year 2012/13 when compared to Fiscal Year 2010/11: intern pharmacist-11%; pharmacy technician-1%; designated representative-5%; and hospital pharmacy-51%.

Business licenses issued experienced an increase in percentage change growth ranging from 33% to 79%. The increase of pharmacy licenses issued was 68% including the buyout. When this buyout is removed, the increase is 20%. Nonresident pharmacies issued realized an increase of 79%.

Licenses Renewed

When comparing renewals received for Fiscal Year 2012/13 to those received in Fiscal Year 2010/11, the board realized an increase of renewal of licensees for all license types except Veterinary Food-Animal Drug Retailer licenses.

Discussion

Mr. Law asked noted that there is an increase in new pharmacies licensed. He asked if there was any breakdown of what type of pharmacies they were (hospital, retail, or community). Ms. Herold answered that she could not provide the exact numbers at the time.

Mr. Brooks asked if there was any data on the job outlook for newly licensed pharmacies. Ms. Herold answered that it is difficult to discern as it is a transitional time with the aging of the baby boomers. Ms Sodergren provided that the Office of Statewide Health Planning collects data on the projected needs for pharmacists and offered to provide the information at the next Licensing Committee Meeting. Dr. Castellblanch noted that UC San Francisco also collects such data. Mr. Brooks concluded that this is an issue that the board should consider in the future.

Note: Mr. Zee left the room at 2:40 p.m. and returned at 2:46 p.m.

XI. DISCUSSION AND POSSIBLE ACTION TO ADOPT AS A BOARD PRECEDENTIAL DECISION UNDER GOVERNMENT CODE SECTION 11425.60 - PACIFICA PHARMACY; TRAN, THANG - BOARD OF PHARMACY CASE 3802

Desiree Kellogg, Deputy Attorney General, presented the final decision adopted by the boad Pacifica Pharmacy and Tran Thang as appropriate for designation as a presidential decision because it contains significant legal or policy determination of general application that is likely to reoccur. The precedential decision would be cited and relied upon in future proceedings. The Pacifica decision contains significant legal and policy determinations as to the scope of a pharmacist's, pharmacy, and pharmacist-in-charge's corresponding responsibility under California Safety Code Section 1153 which requires pharmacists to verify if a controlled substance prescription was issued for a legitimate medical purpose. If the case is made precedential it will provide guidance to the board, judges, prosecutors, and the pharmaceutical industry. If the board decides to designate the decision as precedential it would become

effective 5 to 10 days from the meeting date (July 30, 2013) to allow for administrative processing time.

Mr. Brooks asked what would happen if the board did not choose to designate it as precedential. Ms. Kellogg responded that the AG's office is recommending it be made precedential as it provides enough factual background and explanation of corresponding responsibility to be applied to other cases. She also added that until a decision is made precedential it cannot be cited in other cases.

Ms. Shellans asked for clarification on the effective date and recommended that it become effective one week from the meeting date (July 30, 2013).

Ms. Herold added that corresponding responsibility cases are some of the hardest to prosecute and the board recently tried a similar case and the judge refused to look at the Pacifica Decision because it was not precedential.

Tony Parks, representing California Pharmacists Association, commented that he would like the board to reconsider the full implications of making this a presidential decision.

Motion: Designate Pacifica Pharmacy (CI 3802) as a precedential decision as authorized under Government Code Section 11425.60 effective one week from July 30, 2013.

M/S: Lippe/Castellblanch

Support: 11 Oppose: 0 Abstain: 0

The board recessed for a break at 3:05 p.m. and resumed at 3:21 p.m.

President Weisser conducted a role call. Board members present: Stanley Weisser, Randy Kajioka, Ramón Castellblanch, Tappan Zee, Greg Lippe, Amy Gutierrez, Victor Law, Ryan Brooks, Albert Wong, Lavanza Butler and Deborah Veale. Board members not present: Shirley Wheat and Rosalyn Hackworth.

XII. PETITIONS FOR REINSTATEMENT

a. Johnny Lang, RPH 50571
b. Erin Maloney, RPH 46916

XIII. PETITION FOR MODIFICATION OF PENALTY

Warren Kingdon, RPH 28125

XIV. CLOSED SESSION

The board recessed to closed session at 5:55 p.m.

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters and the Petitions for Reinstatement and Modification of Penalty

ADJOURNMENT FOR THE DAY **6:27 p.m.**

Thursday July 31, 2013

Resumption of Open Session **9:20 a.m.**

President Weisser conducted a roll call. Board members present: Stanley C. Weisser, Tappan Zee, Greg Lippe, Amy Gutierrez, Victor Law, Ryan Brooks, Albert Wong, Lavanza Butler and Deborah Veale. Board members not present: Shirley Wheat, Randy Kajioka and Rosalyn Hackworth. Note: Ramón Castellblanch arrived late at 12:33 p.m.

XV. PRESENTATION BY TECHN'ARTS

On January 1, 2010 Turkey implemented a unit serialization e-tracking system for prescription drugs, somewhat similar to California's requirements. Mr. Taha Yaycı provided a presentation via Skype on an overview of the requirements of Turkey's system, and how the system has operated since implementation. The presentation has been provided on the board's website: www.pharmacy.ca.gov/meetings/agendas/2013/13_jun_e_ped_presentation.ppt

Discussion

Ms. Veale asked if in Turkey they authenticate everything before an item is paid for by the PBM. Mr. Room answered yes.

Dr. Gutierrez asked if having a centralized government has helped their system be implemented faster/smoother. Mr. Room answered having a one centralized entity making the decisions did smooth the implementation process.

George Penebaker, Rph, commented that he agrees with the way Turkey uses authentication at the end of every transaction.

XVI. E-PEDIGREE COMMITTEE REPORT

In Dr. Kajioka's absence, Ms. Herold provided the report of the E-Pedigree Committee Meeting held June 24, 2013 as follows.

a. Next Meetings Scheduled of the E-Pedigree Committee

- September 26: Southern California
- December 10: San Francisco

b. Discussion on Comments Submitted by the Board of Pharmacy in Response to Federal Legislation in April 2013

In April different versions of federal legislation to provide supply chain security were introduced in both the House of Representatives and the Senate. In May, the House passed its version. The Senate bill was developed by the Senate HELP Committee, but a Senate vote has not yet occurred. If the Senate passes the bill pending there, the matter will go to a conference committee, likely in the fall committee to resolve the differences.

At the request of President Weisser, the board submitted comments to both houses on their legislation. Copies of these letters are provided in the meeting materials.

The Senate version of the bill that is still pending a final vote also contains provisions dealing with pharmacy compounding, and provisions dealing with when a pharmacy's compounding would be subject to FDA regulation. There is nothing in the House bill that was passed that deals with compounding. This is another area that will need to be worked out federally.

Discussion

Ms. Veale asked if the compounding section contained in the bill raises any concerns for the board. Ms. Herold answered that in reading the bill she feels that it finds a middle ground between doing non-patient specific compounding and becoming a full fledged manufacturer. She added that our legislation, if enacted, it would be compatible.

Ms. Veale asked if the main concern the board has with the federal legislation is that it pushes back the implementation date for e-Pedigree. Ms. Herold answered, yes, the board feels that the industry will lose its momentum in preparing for implementation. President Weisser commented that there are other significant differences that the board has concerns with and noted that they were outlined in the letters provided.

Mr. Law commented that the letters were very well written and commended President Weisser for his work on them.

c. Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)

At the February Board Meeting, the board held a regulation hearing and approved regulation requirements for the following items (the specific language is provided in the meeting materials):

1. The serialized numeric identifier (section 1747)
2. The process for advising the board how a manufacturer will reach the 50 percent of its products that will be sold in California after January 1, 2015, and the remaining 50 percent by January 1, 2016 (section 1747.1)
3. How to designate unserialized product that may exist in the supply chain after the staggered implementation dates (section 1747.1).

The rulemaking file was prepared and submitted to the Department of Consumer Affairs in early April. It was approved by the State and Consumer Services Agency mid-July. The board is now waiting for the Department of Finance to complete its review. After this review is completed, the rulemaking file will be submitted to the Office of Administrative Law, which has 30 working days to review the file. We hope to have the review process fully completed by September. The board's staff has been nudging agencies to help speed the review of these important requirements.

In recent months, the board's Executive Officer has been providing webinars on California's e-pedigree requirements and timelines. A number of questions asked during these presentations focus on provisions in these regulations especially those dealing with the 50 percent of product that must be compliant by January 1, 2015.

Discussion

Mr. Room stated that he would like to clarify a comment that he made during the June E-Pedigree Meeting. During the June meeting the point was made that on January 1, 2015

manufacturers would be sending out pedigrees, but wholesalers would not be required to receive them until 2016. Mr. Room clarified that in his response to this comment in June, he did not intend to imply that manufacturers are not subject to the 50% compliance requirement starting January 1, 2015, but rather that pedigrees sent out during this time would serve more as a test mechanism until the wholesaler compliance date comes into effect in 2016.

Ms. Veale asked if the webinars that Ms. Herold has been giving on e-Pedigree implementation were mostly with manufacturers to clarify the requirements. Ms. Herold answered that most of the meetings have been run by vendors for manufacturers. She also added that with manufacturers right at the gate for implementation, she is making every effort to participate in as many webinars she can fit in her schedule on the subject.

Ms. Veale asked what the feedback has been from the webinars. Ms. Herold answered that everyone is concerned about the 50% requirement and how to report it, and added that the board is working on a Q&A document to put on the website in response to the feedback.

d. Discussion on GS1 Healthcare US's Implementation Guideline *Applying GS1 Standards to US Pharmaceutical Supply Chain Business Processes, Release 1.0*

Discussion

Ms. Herold reported that the 100 page report by GS1 was provided in the meeting materials to ensure interested parties have easy access to it. She added that while it is long and seems very technical, if the report is read from the beginning it contains valuable information and considerable background about tracking and tracing in the pharmaceutical supply chain.

e. Discussion and Possible Action to Initiate a Rulemaking on the Use of Drop Shipments in an E-Pedigree System Pursuant to California Business and Professions Code Section 4163.1

The committee is working on the process by which drop shipments will be addressed in the e-pedigree system. The reference in California's Business and Professions Code with respect to drop shipments is provided below.

> 4163.1. Drop Shipment by Manufacturer
> (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:
> (1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.
> (2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

In February, the board released a request for comments on drop shipments. One comment was received before the March Enforcement Committee Meeting (provided in meeting materials).

During the March committee meeting, the committee saw a PowerPoint presentation about drop shipments prepared by HDMA. An excerpt of the minutes of this meeting and the HDMA PowerPoint were provided in the meeting materials.

During the June meeting, the committee continued its discussion about this topic and determine its policy on drop shipments.

Board staff had not drafted a regulation proposal. The proposal submitted as part of the February request for comment from John Valencia is:

> *"For the purposes of Business and Professions Code Section 4163.1, when a manufacturer utilizes the "drop shipment" means of sale for a dangerous drug product as defined by that section, only those entities involved in the physical handling, distribution, or storage of a dangerous drug product, are required to provide or receive the "pedigree" required by Section 4034. Any entity, including but not limited to a wholesale distributor, that is not involved in the physical handling, distribution, or storage of the dangerous drug product sold by means of "drop shipment," is not required to provide or receive a pedigree for that dangerous drug product, [even if such entity holds legal title to the dangerous drug product]. For purposes of this section, facilitating the distribution of a product by providing various administrative services, including processing of orders and payments,[even if holding title,] shall not, by itself, be construed as being involved in the physical handling, distribution, or storage of a product."*

During the meeting the committee discussed various items related to this draft. Supervising Attorney Joshua Room agreed to modify the language and bring the new version to this board meeting. The modified language provided by Mr. Room was also edited by Staff Counsel, Kristy Shellans, who made edits based on OAL guidelines. Two options were created and provided to the board. The options (including edits) are listed below.

Proposed Regulation Language for Drop Shipments (Option 1 with Ms. Shellans' edits)

For the purposes of Business and Professions Code section 4163.1, when a manufacturer utilizes the "drop shipment" method of sale as defined by that section, ~~whereby the pharmacy or other person authorized by law to dispense or administer a dangerous drug receives delivery of the dangerous drug directly from the manufacturer~~, a wholesale distributor takes ownership but not physical possession of the dangerous drug in transit,

and the wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer, the transfers of ownership to and from the wholesale distributor may be excluded from the pedigree ~~data record,~~ and the manufacturer may convey the pedigree ~~data~~ directly to the pharmacy or other person authorized by law to dispense or administer the dangerous drug prior to or contemporaneous with delivery of the corresponding dangerous drug. This ~~exclusion~~ alternative process shall not affect the wholesale distributor's existing obligation pursuant to Business and Professions Code sections 4081 and 4105 to maintain records of manufacture, sale, acquisition, or disposition of dangerous drugs ~~that are at all times during business hours open to inspection by authorized officers of the law, that are preserved for at least three years from the date of making, and that are at all times retained on the licensed premises in a readily retrievable form.~~

"Other persons authorized by law" includes persons authorized to dispense or administer under Sections 4180 and 4190 of the Business and Professions Code.

Note: Authority cited: Sections 4005, 4034, and 4163.1, Business and Professions Code. Reference: Sections 4034, 4037, 4163, 4163.1, 4180, 4190, Business and Professions Code.

Proposed Regulation Language for Drop Shipments (Option 2 with Ms. Shellans' edits)

For the purposes of Business and Professions Code section 4163.1, when a manufacturer utilizes the "drop shipment" method of sale as defined by that section, ~~whereby the pharmacy or other person authorized by law to dispense or administer a dangerous drug receives delivery of the dangerous drug directly from the manufacturer,~~ a wholesale distributor takes ownership but not physical possession of the dangerous drug in transit, and the wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer, the data elements pertaining to transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery thereby, may be omitted from the pedigree ~~data record~~, in which case the manufacturer shall convey the pedigree ~~data~~ directly to the pharmacy or other person authorized by law to dispense or administer the dangerous drug prior to or contemporaneous with delivery of the corresponding dangerous drug.

"Other persons authorized by law" includes persons authorized to dispense or administer under Sections 4180 and 4190 of the Business and Professions Code.

Note: Authority cited: Sections 4005, 4034, and 4163.1, Business and Professions Code. Reference: Sections 4034, 4037, 4163, 4163.1, 4180, 4190, Business and Professions Code.

Discussion

Mr. Room gave a brief background on drop shipments and reviewed Mr. Valancia's proposed language. He noted that both options accomplish the same thing: when you are within a drop shipment scenario, the pedigree need only reflect the physical movement of the product from the manufacturer to the pharmacy.

Ms. Shellans noted that her edits to Mr. Room's version were mainly to strike duplicative language. She added that in her opinion the board should include the definition of "other persons authorized by law." Ms. Shellans then proceeded to read the two options to the board.

Mr. Room expressed his opinion that while some of the language may be duplicative, it makes it easier for the regulated public if all the relevant information is in the same place.

Mr. Room noted that option 2 was written more recently and in his option is slightly better.

Mr. Zee asked if the committee should review the two options at their next meeting and then bring their recommendation to the full board. Ms. Herold answered that taking it back to the committee will delay the regulation process until the end of the year.

Dr. Steve Gray, from Kaiser, expressed his opinion that the language should be broadened to "authorized to receive" as not all drop shipment occur between a manufacturer and a wholesaler. Mr. Room responded that in statute the board was given a very narrow definition of drop shipment as solely those transactions where a manufacturer ships directly to a pharmacy and the wholesaler managers the financial transaction.

Mr. Valencia, representing various oncology manufacturers, expressed his support of the board accepting Option 2.

George Penebaker, Rph, commented that authentication would provide a simple solution for e-Pedigree and this option should be brought to the Legislature. Mr. Room reported that in 2008 one of the options that was considered was authentication.

Motion: Accept Option 2 as edited. Delete the sentence, "Other persons authorized by law includes persons authorized to dispense or administer under Sections 4180 and 4190 of the Business and Professions Code." Add 4170 in the Reference Section between 4163.1 and 4180.

M/S: Lippe/Zee

Support: 9 Oppose: 0 Abstain: 0

Motion: Direct staff to take all steps necessary to initiate the formal rulemaking process with the text as modified at option #2, authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and set the proposed regulations for a hearing.

> For the purposes of Business and Professions Code section 4163.1, when a manufacturer utilizes the "drop shipment" method of sale as defined by that section, ~~whereby the pharmacy or other person authorized by law to dispense or administer a dangerous drug receives delivery of the dangerous drug directly from the manufacturer,~~ a wholesale distributor takes ownership but not physical possession of the dangerous drug in transit, and the wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer, the data elements pertaining to transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery thereby, may be omitted from the pedigree ~~data record~~, in which case the manufacturer shall convey the pedigree ~~data~~ directly to the pharmacy or other person authorized by law to dispense or administer the dangerous drug prior to or contemporaneous with delivery of the corresponding dangerous drug.
>
> "Other persons authorized by law" includes persons authorized to dispense or administer under Sections 4180 and 4190 of the Business and Professions Code.
>
> Note: Authority cited: Sections 4005, 4034, and 4163.1, Business and Professions Code. Reference: Sections 4034, 4037, 4163, 4163.1, 4180, 4190, Business and Professions Code.

M/S: Lippe/Law

Support: 9 oppose: 0 Abstain: 0

The board recessed for a break at 10:55 a.m. and resumed at 11:14 a.m.

f. Update on Proposed Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163

At the June meeting, the committee discussed work on the proposed regulation language for inference.

Background
Since July 2012, the board has several times released written requests for specific comments needed to develop possible regulations to authorize inference. Until the March e-pedigree meeting, the board received only a few comments directly responsive to these requests. The initial comments provided by the supply chain are available in the meeting materials for the December 4, 2012 Meeting Materials of the Enforcement Committee: http://www.pharmacy.ca.gov/about/meetings.shtml#enforce

At the March Enforcement and E-Pedigree Meeting, draft language was released for discussion purposes to develop the regulation language for inference. A copy of this proposal is provided in the meeting materials.

Following the March meeting, the board received additional comments specific to the draft language released. These comments are also provided in the meeting materials.

During the June meeting, the committee considered inference requirements. There was general discussion about the written comments received on the draft requirements that were prepared by staff. These proposed provisions were intended for discussion. Staff recommended that the committee and board determine the direction for the regulation so that it can be finalized by the October board meeting.

The committee asked that comments be integrated into the text of the regulation for easier committee review. This integration document has been provided in the meeting materials.

The committee encourages a discussion by the board at the July Board Meeting on the elements for this first regulation on inference. Especially critical for the imminent January 2015 and 2016 serialization deadlines is the inference that may be used between the manufacturer and the wholesaler.

Once a wholesaler opens the case, each item in the case must be scanned and pedigree of the item appended. If a sealed case is shipped through the wholesaler without being opened and the seals on the box remain intact, the case can continue to be inferred until it is finally opened by a downstream partner (each item within the case does not need to be independently scanned).

Discussion

Mr. Room provided a brief definition of inference for the public and new board members. He added that inference became an issue in 2008 when it was determined that RFID was not going to be used, and line-of-sight barcodes would have to be scanned on each individual unit package. Opening a large shipment to scan each unit would add additional risk to the supply chain integrity, so the idea of inference was introduced.

Mr. Room reported that current draft language proposes that inference may be used on a homogeneous case of product, shipped in a sealed container from the manufacturer to a wholesaler. Many wholesalers have commented that when they receive a pallet they would also like apply inference to the cases on the pallet. Mr. Room is bringing the issue before the board so they can decide to what aggregate containers an inference should be permitted.

Ms. Veale commented that the board needs to consider if inference can be used at another location besides a wholesaler. Ms. Herold answered in the interest of getting the regulation completed, the board should first address inference at the first handoff between the

manufacturer and the wholesaler and address inference further down the supply chain at a later date.

Mr. Room stated that in the proposed language a manufacturer and wholesaler must have a trusted trading partner relationship that ensures a positive track record of the ability of the manufacturer to accurately aggregate the specific serialized items in the case. Many of the comments received expressed the need to define a trusted trading partner. Mr. Room added that when the proposed language was drafted it was assumed that a trusted trading partner was established through a contact, the comments received indicated that this is not the industry norm.

President Weisser asked the board to return to the issue of defining a "case." Mr. Room agreed that the board needs to decide if they want to define what a case is or if they want to just leave the language as "sealed case." He added that if they board chooses to define case they also need to decide if there is some rational outer limit they want to place on what can be constituted as a case (i.e. , less than "x" units constitutes a case).

Mr. Brooks asked why the board needed to define a ceiling for the number of units that make up a case. Mr. Room responded that the reason the board would define a case is to place a limit to the size of the container that someone can call a case. In essence the board is creating an exception to the law by saying that the contents of cases do not need to be scanned at each stop in the supply chain. Therefore a limit needs to be placed on the size of cases so that someone cannot say that every single container they receive is a case and the contents do not need to be scanned individually.

Ms. Veale expressed her concern that defining a case as a specific number of individual units may not be wise. President Weisser agreed.

Mr. Law noted that manufacturer cases vary based on the product. Mr. Room agreed, and added that if two years from now the board finds that manufacturers have begun creating huge cases in order to take advantage of the exception, the board can choose to address the issue then.

Ms. Shellans asked if the e-Pedigree committee has seen these comments. Ms. Herold answered that they have seen the comments, but they were not integrated into the language.

Mr. Room provided that we would make changes to simplify and clarify the language based on the comments received and bring it back to the board. He asked the board to decide if they want to expand inference beyond a sealed homogeneous case.

Dr. Gutierrez asked if sealed meant the original seal placed on it by the manufacturer. This was confirmed by President Weisser and Mr. Room.

Ms. Veale again expressed her concern that they board is placing too many restrictions on the size of cases. Mr. Room replied that a possibility could be to allow inference on a shrink-wrapped pallet between a manufacture and a wholesaler - with the restriction that the wholesaler cannot pass the inference down the supply chain.

Motion: From a manufacturer to a wholesaler, inference can be applied to a sealed homogeneous case which contains only one dangerous drug product.

M/S: Lippe/Law

Support: 9 Oppose: 0 Abstain: 0

Discussion

Mr. Room requested the board address the issue of trusted trading partners. He asked the board to consider if they want to make a trusted trading partner relationship a requirement for the use of inference. If so, they would then need to consider if they wanted to define the relationship and make a written contract a requirement. He noted that comments received indicated that the industry does not currently use contracts in trusted trading partner relationships.

President Weisser asked if it was critical to require supply chain integrity to ensure that the supply chain is not compromises. Mr. Room responded that he would leave that to the board's consideration.

Mr. Brooks asked if the board could reach out to the industry to see how they currently handle the relationship. He also asked how a new vendor could become a trusted trading partner. Mr. Room responded that both he and Ms. Herold have reached out to the industry for input. In response to the second question Mr. Room answered that the current language requires that 5 shipments be received and verified as correct before someone can become a trusted trading partner.

Mr. Law commented that there must be some contracting currently in use to address things like billing and recalls. President Weisser agreed he thought currently contracts were being used in the industry.

Mr. Lippe commented that the board should leave it to the industry to determine if a vendor is reliable or not.

Mr. Room commented that the language could be kept very minimal.

Dr. Gutierrez noted that she agreed with Mr. Law and President Weisser's comments that it seems logical that contracts would already be in use by the industry. Mr. Room responded that the comments received did not reflect this.

Dr. Gutierrez asked if the removal of the trusted trading partner requirement would allow anyone to receive a sealed homogenous case from any vendor and infer its contents. Mr. Room confirmed this. Ms. Herold added that this might be such a risky business move that even without the requirement the industry may choose not to do it.

Motion: Remove trusted trading partner as a requirement to take advantage of the sealed homogeneous case inference.

M/S: Veale/Lippe

Support: 9 Oppose: 0 Abstain: 0

Discussion

Mr. Room asked the board to provide feedback on points (listed below) in the additional concepts section of the draft language.

1. When a sealed case is opened the contents must be immediately scanned to validate the inference.
2. When any discrepancies are discovered in the data or the product it must be remedied within 48 hours.

Ms. Veale asked for clarification as to why the contents must be scanned immediately, when inference had been applied up until that point. Ms. Herold answered that unless you scan it when the case is unsealed, you will never know if a discrepancy occurred when it was packaged or after the contents were beginning to be shipped. Mr. Room added that if it is not scanned immediately when it is unsealed there is no way of knowing when counterfeiting or diversion occurred.

The board expressed the desire to change the language for reporting discrepancies to three business days to allow for weekends/holidays.

Dr. Steve Gray, Kaiser Permanente, expressed his concern over the logistics of scanning all items immediately when a case is unsealed. He also asked the board to clarify what the board

means by “remedy.” Mr. Room asked if Mr. Gray would be willing to submit his comments in written form. Dr. Gray confirmed that he would submit his comments in writing.

Mandy Lee from California Retailers Association shared Dr. Gray’s opinion that the contents of a case should not be required to be scanned immediately when it is opened.

Mr. Room noted that in the comments people further down the supply chain placed great importance on manufacture tape indicating a case is sealed and un-tampered with, however manufactures commented that they just use regular packaging tape that could easily be replicated.

Dr. Wong commented that if a case is opened to scan the contents you will not be able to return it to the manufacture. Mr. Room responded that he was not aware that this would be an issue.

Ms. Veale expressed her concern that opening a case to scan the contents immediately when it is received, then re-packaging it for storage, could actually lead to more diversion.

Mandy Lee, from California Retailers Association, commented that instead of three business days it should be “a reasonable period of time.”

Ms. Veale and Dr. Gutierrez provided that the language should be changed from “remedied” to “reported.”

Steve Tadovich, from McKesson, provided insight into McKesson’s warehouse operations and explained how their operations do not mesh with the requirement to immediately scan the contents of a case when it is unsealed.

Motion: Remove the requirement to immediately scan the contents of a case when it is unsealed.

M/S: Veale/No Second

Motion tabled

Note: Dr. Castellblanch arrived at 12:33 p.m.

Motion: When a sealed case is opened its entire contents must be scanned immediately.

M/S: Lippe/Gutierrez

Support: 7 Oppose: 2 Abstain: 1

Motion: Change the language to from “48 hours” to “three business days” and change “remedied” to “reported.”

M/S: Lippe/Gutierrez

Support: 9 Oppose: 0 Abstain: 1

Discussion

Mr. Room commented that the rest of the concepts may be too large for the board to discuss at this meeting and recommended that they be discussed at the next E-Pedigree Committee Meeting. Ms. Herold added that they had a feel for the board’s views on the language and that together she and Mr. Room could massage the language and then bring it back to the committee. Ms. Veale asked that the board finish the discussion with the certification piece.

g. Discussion Concerning Possible Regulation Requirements on the Certification Process Needed to Comply with California’s E-Pedigree Law

A copy of the certification proposal was provided in the meeting materials**.** Also included in this section is proposed language for a regulation to specify board access to e-pedigree information during inspections.

Written comments submitted following the March meeting that pertain to these proposals are contained as part of the comments provided in the meeting materials.

Discussion

Mr. Room provided that the largest issue that the board needs to resolve with the certification proposal is what the party is actually certifying to. In other words, to what level of information are they verifying or confirming as true or correct for the next recipient of that product.
Mr. Room asked the board if they were comfortable with the concept that certification will refer to the party attesting, under penalty of perjury, that what they are transmitting is true and accurate to the best of their knowledge. Likewise when a party is receiving product what they are certifying is that to the best of their knowledge they have received the products that the data reflects has been shipped.

Ms. Shellans asked if the board had any reaction to the comments that the Healthcare Distribution Management Association submitted. Mr. Room responded that in his opinion there is a need for additional input from the industry to determine if there is a reasonable substitute for a digital signature in terms of conveying information data in a secure format that cannot be altered.

Mr. Room volunteered to rework the language in response to the comments received on certification and bring it to the committee.

Mr. Room expressed that the inspection language did not currently require board input, and volunteered to rework the language in response to the comments received and bring it to the committee.

No public comments on certification and/or inspection.

Ms. Herold provided clarification on the drop shipment proposal. She reported that the regulation hearing on drop shipment could be held at a separate hearing not associated with a board meeting. This practice is more in line with how other board's in the department conduct regulation hearings. The board members and public will be advised of the hearing date when it is scheduled.

Note: Mr. Brooks left the meeting at 12:46 p.m.

XVII. ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT

Chairperson Gutierrez provided a report of the Enforcement Committee Meeting held June 4, 2013 as follows.

ENFORCEMENT MATTERS:

a. Enforcement and Compounding Committee Meeting Dates for the Remainder of 2013

Future Enforcement and Compounding Committee meetings are scheduled for September 10, 2013 and December 3, 2013. These dates are subject to change. The locations have yet to be determined.

b. Request from Sharp Healthcare on a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines

Relevant Regulation

California Code of Regulations Section 1713 establishes the requirements for use of an automated prescription delivery device and provides the condition under which it can be used. Under the current regulation the device can be used to furnish refill medications in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate.

California Code of Regulations Section 1706.5 allows the board to waive particular regulation requirements to allow for experimental plans or programs for drug handling, teaching, and research or to develop better moths involving the ethical practice of pharmacy.

Background and Previous Committee Discussion

In 2009-10, Pharmacist Consultant Philip Burgess, on behalf of a manufacturer of one of these machines (Asteres), sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change). There was no further interest pursued by Asteres after the January 2010 meeting.

Further, at the Committee's March 14, 2013 meeting, Al Carter, representing Walgreens, discussed a request that would allow for Walgreens to place kiosks in workplace clinics. Mr. Carter provided an overview of the types of services that are provided at the clinic and how Walgreens would provide medication. Mr. Carter highlighted that the kiosk would not be stored in the clinic, but would be housed across the street in a separate building. The board did not approve the request, indicating there was insufficient evidence to act.

During the committee meeting, the committee heard a presentation from representatives from Asteres and Sharp HealthCare discussing the need to revise CCR section 1713 to expand the use of automated delivery devices. The presentation included a request to allow three separate pilot studies on the campuses of Sharp, UCSD Health System and USC Hospital to review the use of automated delivery devices. The committee was reminded that section 1713(b) already allows the delivery of prescriptions to employees at their worksite.

Specifically the proposal would revise section 1713(d)(6) to allow for the placement of automated devices in a secure building controlled by a board licensee at an alternate location readily accessible for board inspection, but not adjacent to a secure pharmacy area.

In response to questions by the committee members about the location of the devices, members were advised that the devices would not have to be on the premises of a licensee but could be at corporate offices, for example, a non-licensed facility.

In addition, the proposal seeks to revise section 1713(d) to also allow the dispensing of new prescriptions delivered from automated devices as the delivery system allows the ability to load filled prescriptions in the device. This would only occur after a pharmacist provided consultation, and proper documentation has been reviewed and saved. The prescriptions would not be released to the patients until the patients had been counseled by a pharmacist via telephone (adjacent to the device).

The committee heard information on the uses of these devices and was provided pictures. It was noted that in one location employee utilization of the device had grown from 13 percent to 44 percent.

The committee was provided information about the security measures for the device including a camera which takes a photo of every patient as well as the requirement to collect signatures of the patient. The device also weighs over 1,350 pounds and is bolted to the ground. The committee was advised that more than 700,000 prescriptions have been delivered without incident in other states.

The committee was provided with information about Sharp's current structure including seven hospitals, seven retail pharmacies and 22 clinics in San Diego serving 200,000 patients. Representatives stated that use of the automated devices align with their vision of providing patient/employee-centered care to the 3000 employees who work in their corporate offices and noted that although their pharmacy is only two miles away, getting to the pharmacy can be difficult due to work schedules and heavy traffic. The committee was provided photos of the proposed location of the device and advised that that the building in which the device would be placed has 24-hour security and requires a badge for entry.

The committee discussed the logistics from the patient's perspective including that a patient could drop off a paper prescription through a slot in the device which would subsequently be picked up and delivered to the pharmacy the following day when the device is serviced.

Counsel discussed whether the board could act on the request because current law does not allow for the storage of dangerous drugs at a location not licensed by the Board. In response proponents of the proposal argued that current law allows for the delivery of prescription medications to a patient at his or her office and that the Board should focus on delivery of medications as opposed to the storage of medications.

In response to committee questions, the committee was advised that Sharp planned to have only one pharmacy responsible for filling and delivering prescriptions to an automated device.

The committee heard a second proposal in which Sharp would use the same pharmacy to deliver prescriptions to an automated device located at Sharp Memorial Hospital Campus to dispense discharge medications. Sharp envisions a patient being counseled by a pharmacist at the bedside or over the phone, receiving an access code, then being discharged and obtaining their prescriptions from the automated device. The device allows for the use of a credit or debit card for payment. The committee was advised that Sharp does provide next-day home delivery via mails, but prefers delivery via an automated device because the device is secure in that it allows for the tracking of who picks up their medications and who does not.

The committee was advised that delivery transaction date is kept forever and there is no purge criteria. Further, the committee was advised that the data includes a full audit trail which includes a photo of the person picking up the prescription and the signature log.

The presenters were advised to create a formal proposal for the board to review including specifying some parameters from the school explaining parts such as what measurements they would take and how long the pilot study would last. It was also suggested that two separate proposal may be appropriate based on the proposed locations being licensed.

The committee was reminded that the board has limited authority to waive a regulation based on an experimental program pursuant to the requirements listed in section CCR 1706.5. The results of the experimental program would have to demonstrate to the board that the automated device is safe and that a regulation revision would be advantageous.

Included in the meeting materials were the relevant regulations as well as the written proposal and supporting materials submitted by Asteres, Sharp HealthCare and UCSD as well as information on prior board discussion on the use of these machines.

Discussion at Board Meeting

Phil Burgess, consultant for Asteres, Kim Allen, Sharp Health Care, and Sara Lake, Asteres, provided a formal presentation on the waiver request to allow for new prescriptions to be delivered from an automated kiosk location in a non-pharmacy location. The presentation and related documents were provided in the meeting materials.

Dr. Gutierrez asked if the proposal would include new prescriptions for employees being dispensed at the machine. Mr. Burgess confirmed that it would.

Ms. Veale asked where the phone that would be used if a patient needed to talk to a pharmacist. Ms. Lake answered that no phone would be attached to the machine, an alert would appear on the machine providing the phone number for someone to call and the prescription would be placed on hold until the call was made.

Dr. Castellblanch asked if controlled substances would be dispensed. Mr. Burgess answered that they would. Ms. Allen provided that at this time controlled substances would not be dispensed.

Mr. Law asked if refrigerated medications would be dispensed. Mr. Burgess responded that no refrigerated items would be dispensed at the machine.

Mr. Burgess clarified that this system is “opt-in” and the patient is told what will and will not be dispensed from the machine.

Ms. Allen reported that Sharps feels the machine will offer easier access to their medications.

President Weisser and Dr. Castellblanch expressed concern that anyone with a Sharps employee badge could get to the machine and get medication for someone other than themselves. Mr. Burgess clarified that there is 24/7 security on site and you need a pin number and thumb print to be dispensed your medication from the machine.

Dr. Wong asked if there was a cost saving for the patients to use the machine. Ms. Allen responded that there is no incentive, except convenience, to use the machine.

Chairperson Gutierrez asked what the physical pharmacy hours are and what would happen if a patient needed a consultation after hours. Ms. Allen reported that they are 8:30am-5:30pm Monday through Friday and a pharmacist would be on call for after hour needs.

Mr. Burgess commented that increased access to medications improves patient health, and that is the goal of the machine.

Dr. Castellblanch asked if patient health would be measured in the study. Ms. Lake responded that a survey would be on the machine, but it would focus on satisfaction with the machine, not improvement in health.

Mr. Zee asked council to clarify if the board had the authority to grant the waiver. Ms. Shellans expressed her opinion that the board does not have the authority to allow drugs to be stored or dispensed from a location not associated with a licensed pharmacy because it is a statutory requirement in 1410 and 1437. She also commented that she is concerned about how the study is being conducted, in that a private corporate entity is running the experiment while the school is simply monitoring and reporting.

Mr. Burgess disagreed with counsel's opinion that the location of the machine would need to be licensed as a pharmacy as the drugs are being kept there solely for patient pick-up. He explained that in his opinion using the same logic, drug delivery companies like UPS would have to be licensed with the board.

Mr. Room asked if Sharps would be willing to become licensed as it may address some of the board's concerns. Ms. Allen responded that they would be willing to consider it.

Dr. Wong asked if the board approved the waiver then any pharmacy would be able to use a machine. Mr. Burgess responded that the request was only for a 6 month pilot of one machine and at the end of the 6 months the board could review the results and deny the request for the program to continue.

Dr. Castellblanch expressed his concern that the study proposal does not meet academic standards. Ms. Lake commented that in order for UCSD and Sharp to fully get behind the study they need indication from the board that the project could move forward.

Ms. Herold commented that she feels the board needs to recognize that council has advised that the board does not have the authority because they are asking to waive a statute not a regulation. She agreed that the study needs to be more robust.

Mr. Burgess provided that they are willing to work on the issues raised by the board and come before the board again prior to beginning the study to ensure that the issues have been resolved to the board's satisfaction.

Ms. Veale asked if Sharps chooses to get licensed as a pharmacy if they would have to meet all the requirements required for a pharmacy (sinks, bathrooms, etc.). Ms. Herold commented that the board could waive some of these requirements.

Dr. Castellblanch asked counsel what the board's liability would be if they vote to violate a statute. Mr. Room responded that he did not think the board would have any liability; however, Ms. Shellans expressed her opinion that they could be held criminally liable.

Mr. Law commented that new technology is a good way to give patients more access; however, he is concerned about the possibility of language barriers being a problem with the use of the machines.

Ms. Herold asked who would be at fault if there was an error in the dispensing at the machine. Mr. Burgess commented that the pharmacist-in-charge would be responsible.

Elizabeth Shitaki, registered nurse, commented that she feels there are too many uncertainties for the board to approve the waiver and added that taking away direct contact with a pharmacist will harm the patient.

Dr. Steve Grey, Kaiser Permanente, commented that current law allows for the delivery of medications to a patient's place of employment and the use of technology will make this already existing practice safer.

Allison Fuller, pharmacist-in-charge, expressed her concern with the use of these machines in retail pharmacies.

Dennis McAllister, Arizona Board of Pharmacy, commented that this is not new technology and he does not feel that a study is needed.

Motion: Waive California Code of Regulations Section 1713(b) and allow Asteres to install one automated dispensing machine in Sharp Headquarters for a period of 6 months. As a provision of the waiver Asteres must provide a more substantive research report and draft an agreement giving the board unlimited access to the location and study data.

M/S: Zee/Veale

Support: 4 Oppose: 5 Abstain: 0

Ms. Veale and Chairperson Gutierrez asked if adding the requirement for the location to become licensed as a pharmacy would change the board's decision.

Motion: Waive California Code of Regulations Section 1706.5 and allow Asteres to install one automated dispensing machine in Sharp Headquarters for a period of 6 month. As a provision

of the waiver Asteres must provide a more substantive research report (meeting academic standards and approved by the board) and draft an agreement giving the board unlimited access to the location and study data. In addition the location at Sharps Headquarters must become licensed as a pharmacy subject to waivers of certain conditions (i.e. bathrooms, skinks ect.)

M/s: Zee/Veale

Support: 8 Oppose: 1 Abstain: 0

The board recessed for lunch at 2:16 p.m. and returned at 2:51 p.m.

Note: Dr. Castellblanch returned at 3:00 p.m.

Chairperson Gutierrez continued the Enforcement Chair Report as follows:

c. <u>Request from California Society of Health-System Pharmacists to Discuss Drug Shortages</u>

At the March 13, 2013, committee meeting, Jonathon Nelson, representing the California Society of Health-System Pharmacists (CSHP), addressed the committee to discuss prescription drug shortages and requested the topic be discussed at a future meeting.

<u>Previous Committee Discussion</u>
The committee heard information on the issue of drug shortages and was provided with an article from the Washingtonian Magazine which detailed rationing, hoarding and bartering of medications in Washington area hospitals.

The committee heard a presentation from a pharmacist sharing her experiences with drug shortages and how they are impacting patients' every day. The committee heard the practices currently employed to manage drug shortage issues which include monitoring and anticipating drug shortages, constantly look for alternative drug sources and medications, creating back orders with wholesalers, and when necessary, rationing of drugs. The committee was advised that shortages have created an informal bartering system where healthcare centers share drugs with each other. The committee learned that results are being reviewed of alternative equivalent therapies being used in the treatment of cancer patients revealed that patients have a significant increase in cancer recurrence.

The committee asked about why shortages are occurring and was advised there are multiple reasons including financial decisions which result in a dropped product line; drugs dropped

from the market due to regulatory issues; and short supplies of raw product used in drug production.

The committee chair stated that President Obama issued an Executive Order in 2011 to have the FDA begin tackling the issue of drug shortages.

The committee discussed whether a database could be created so healthcare centers would more easily locate other healthcare centers with a surplus of the specific drug and discussed the legal requirements for licensure if an entity is brokering drugs. The committee discussed the current provisions that allow a pharmacy to sell drugs back to the wholesaler in response to drug shortages.

The committee also heard public comment regarding the possibility of relying more on compounding pharmacies to fill the need during times of drug shortages as well as the need for state and federal government to oversee the safety of compounding manufacturing while also allowing flexibility in allowing compounding manufacturers to fill an important need.

The committee took no action on this item.

Discussion

No comments from the board or from the public.

d. Update on the Implementation of Penal Code Section 11105 – Requirements to Provide Criminal Offender Record Information to an Applicant or Licensee When the Information Is Used as the Basis for a Licensing Decision

Background

As part of its licensing process, the board is required to conduct a criminal background check to determine whether an applicant has committed acts that would constitute grounds for denial of a license. Applicants must submit their fingerprints to the California Department of Justice (DOJ) that then matches the fingerprints against state and federal criminal history databases. The DOJ provides the results of the background check to the board that uses the information to help determine the suitability of the applicant for licensure. The Board also receives a notice from the DOJ when a licensee is arrested or convicted in California after initial licensure.

Penal Code section 11105 authorizes the DOJ to release criminal offender record information (CORI) to law enforcement and other authorized agencies such as the board. The board cannot share criminal offender record information (CORI), including responses that indicate no criminal history exists, with anyone unless expressly authorized. Individuals have the right to request a copy of their own criminal history record from the DOJ to review for it accuracy and completeness, but CORI is not subject to disclosure under the Public Records Act. Release of information to unauthorized individuals can result in civil or criminal penalties pursuant to Penal Code sections 11142 and 11143.

Effective January 1, 2013, however, Penal Code section 11105 (Amended by Stats. 2012, c. 256, A.B. 2343) requires authorized agencies to expeditiously furnish a copy of CORI to the person to whom the information relates if the information is the basis for an adverse employment, licensing or certification decision.

The board implemented procedures on January 1, 2013, to comply with this new requirement and since that time has provided a copy of the CORI to every applicant who has been denied and every licensee who has received a letter of admonishment, citation or has been referred to the Attorney General's office for disciplinary action based, to some degree, on information contained in the CORI.

Discussion

There was no comment from the board or from the public.

e. Discussion and Possible Action on the National Association of Boards of Pharmacy Report on Sales of Fake and Substandard Medications

The National Association of Boards of Pharmacy (NABP) issued a report on April 26, 2013 which focused on the global distribution of counterfeit and substandard medications. The report found that the proliferation of these medications was primarily due to illegal distribution by internet pharmacies operating out of compliance with US pharmacy laws.

A copy of the report is provided in the meeting materials, and can also be found on the NAB website at https://awarerx.s3.amazonaws.com/system/redactor_assets/documents/179/NABP_Internet_Drug_Outlet_Report_Apr2013.pdf

Previous Committee Discussion

Ms. Herold stated the board has a very limited role in regulating internet pharmacies short of disciplining people or businesses for unlicensed activity. Ms. Herold described the video on the board's website that educates and warns the public about the appropriate way to deal with internet pharmacies. She stated the board rarely gets complaints regarding internet pharmacies because the people using them are happy to get their drugs without a prescription or without having to see a prescriber. The board generally receives complaints only when there's a problem regarding continued shipping or billing. When the board receives complaints, they are generally referred to the National Association of Boards of Pharmacy and the FDA.

Dr. Gutierrez mentioned consumers can look for ***VIPPS*** (Verified Internet Pharmacy Practice Sites) symbol on the website which indicates that the internet pharmacy is accredited by the NABP and licensed in the state in which they're located.

Discussion

No comments were made by the board or by the public.

f. Discussion on NABP's Announcement of the Development of Standards for the *.pharmacy* Generic Top Level Domain for Internet Pharmacy Web Sites

Background
According to the NABP, 97 percent of the 10,300 Internet drug outlets it has reviewed are out of compliance with pharmacy laws and practice standards established to protect patients. Correspondingly, NABP has labeled 10,082 Web sites as "Not Recommended"; nearly half of these are offering foreign or non-FDA approved drugs, and many include counterfeits.

Generic top level domains are the suffix part of a Web site address (e.g., .com, .org, .edu). Late last year, the NABP sought the formal approval to be able to approve anyone using the general top level domain (gTLD) of .pharmacy. Earlier this year, an international group of experts were convened by the NABP to develop parameters for anyone that would be able to use the .pharmacy gTLD. The board's executive officer was one of the individuals who participated in this process, and the intent is to have the parameters for the .pharmacy gTLD in place by the end of 2013.

A copy of the press release was provided in the meeting materials.

Discussion
There were no comments from the board or from the public.

g. Fourth Quarterly Report on the Committee's Goals for 2012/13

The Quarterly Report was provided in the meeting materials.

Discussion
There were no comments from the board or from the public.

h. Enforcement Statistics for July 2012- June 2013 and Three Year Comparison

The Enforcement Statistics for July 2012- June 2013 and Three Year Comparison were provided in the meeting materials.

Discussion
No comments from the board or from the public.

COMPOUNDING MATTERS

a. Discussion on Pending California Legislation on Sterile Compounding: Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva)

Background

Following two large-scale public health emergencies last year in which dangerous products compounded by two out-of-state pharmacies were shipped nationwide, staff suggested modifying existing sterile compounding requirements in California. As a result, Senator Emmerson has authored Senate Bill 294 (SB 294) to carry this board-sponsored legislation.

Senate Bill 294 strengthens the board's ability to regulate and monitor pharmacies that compound sterile drug products. This legislation will prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board.

Additionally, on April 22, 2013, Assembly Member Quirk-Silva amended Assembly Bill 1045 to carry provisions that would amend existing law to allow the board to suspend or revoke a nonresident pharmacy's license if its license is suspended or revoked in the pharmacy's home state. It would also require resident and nonresident pharmacies that issue a recall notice regarding a sterile compounded drug to contact the recipient prescriber or patient of the recalled drug as well as the board within 24 hours of the recall notice if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in Californa.

The committee heard public comment asking about current licensing requirements. With regard to AB 1045, Ms. Herold clarified that the qualifying method for someone to become licensed as a non-resident pharmacy in California is for the pharmacy to be licensed in the home state. If the license in the home state is revoked, suspended or cancelled for any reason, the California license will correspondingly be revoked, suspended or cancelled by operation of law. Ms. Herold also clarified that the California license could still be disciplined whether or not the license is disciplined in the home state.

Copies of SB 294 and AB 1045 were provided in the meeting materials.

Discussion

Ms. Herold commented that both bills are moving.

b. Discussion of Recent Federal Reports and Articles Relating to Compounding Pharmacies

The below listed article were provided in the meeting materials.

1. *FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?*

2. Office of Inspector General Memorandum Report: *High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them,* OEI-01-013-00150
3. ASHP Guidelines on Outsourcing Sterile Compounding Services
4. FDA's Guidance for FDA Staff and Industry – Marketed Unapproved Drugs, Compliance Policy Guide
5. U.S. Senate Health, Education, Labor and Pensions Committee Report: The Case for Clarifying FDA Authority: Large-Scale Drug Compounding and the Ongoing Risk to Public Health
6. Miscellaneous Articles

Discussion

No comments were made by the board or by the public.

c. Proposed Federal Legislation on Compounding Introduced by the U.S. Senate (S. 959)

Background

On May 22, 2013, the United States Senate Committee on Health Education Labor & Pensions passed S. 959, the *Pharmaceutical Compounding Quality and Accountability Act*. A copy of a statement from Senator Harkin made Wednesday, May 22, 2013, and was provided in the meeting materials**.**

Ms. Herold stated the pending Senate legislation is currently linked with the supply chain security provisions which would preempt California's e-pedigree law if enacted. There is competing legislation for the e-pedigree law which just passed the House.

Regarding compounding, the proposal would require non-patient specific drugs moving across state lines to be regulated by the FDA and drugs within a state would be regulated by the respective state board.

Discussion

No comments from the board or from the public were made.

d. Discussion Regarding USP's 797 Standards and the Regulation Requirements of the Board of Pharmacy

Background

For a number of years, California has had its own statutory and regulation requirements for those pharmacies that compound medication or perform parenteral compounding. Since 2001, again through legislation as well as through regulations, the board has several times developed additional requirements to respond to emergent public health or regulatory concerns.

Many states rely upon USP 797 components to regulate compounding activities. California, instead, relies on its own standards for compounders and sterile compounding.

Discussion and Comments of the Committee

Dr. Ratcliff and Dr. Smith presented a crosswalk document that compared CA law to USP 797. The committee reviewed and compared the two sets of requirements. Ms. Herold advised the committee that specific requirements in USP 797 may eventually be included in the Board's regulation and that the regulations be written as clearly and concisely as possible for the benefit of everyone.

The committee and public made several comments regarding the best process for making sure the board's regulations are inclusive of the requirements in USP 797.

The committee heard several comments from the public on the best path to move for with its analysis of the two requirements and recommended changes that may result from this analysis including creation of a list of suggested regulations then invite comments as opposed to having other associations submit suggestions.

A workgroup was formed to work with staff to create a third column on the crosswalk document with proposed regulation changes for public comment.

e. Discussion Regarding "Batches"

Background

Board regulations related to compounding are found in Title 16 of the California Code of Regulations, Article 4.5 (all compounding) and Article 7 (related to sterile injectable compounding). On April 1, 2013, regulation changes went into effect that apply to compounding definitions, expiration dating, recordkeeping requirements, and labeling of cytotoxic agents. During this rulemaking, the board was asked what the board's definition of "batch" is, and what requirements apply to batching – but these topics were not included within the scope of the regulation change.

The committee considered the following references as part of its discussion.

Existing Board Regulation

§ 1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

United States Pharmacopeial Convention (USP)
"Batch" – More than 25 units

[1]**American Society of Health System Pharmacists** (ASHP)
Excerpt:
Risk Level 2.
Risk level 2 sterile products exhibit characteristic 1, 2, *or* 3, stated below. All risk level 2 products should be prepared with sterile equipment, sterile ingredients and solutions, and sterile contact surfaces for the final product and with closed-system transfer methods.
[1] American Society of Health-System Pharmacists. ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products. *Am J Health-Syst Pharm.* 2000; 57:1150-69. Available at http://www.ashp.org

Risk level 2 includes the following:

1. Products stored beyond 7 days under refrigeration, stored beyond 30 days frozen, or administered beyond 28 hours after preparation and storage at room temperature.
2. Batch-prepared products *without preservatives* (e.g., epidural products) that are intended for use by more than one patient. (Note: Batch-prepared products without preservatives that will be administered to multiple patients carry a greater risk to the patients than products prepared for a single patient because of the potential effect of inaccurate ingredients or product contamination on the health and well-being of a larger patient group.)
3. Products compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer; for example, TPN solutions prepared with an automated compounder. (Note: So many risks have been associated with automated compounding of TPN solutions that its complexity requires risk level 2 procedures.)

Discussion
There were no comments from the board or from the public.

f. Discussion of the Board of Pharmacy's Questions and Answers Document on Compounding

Background
To provide guidance to pharmacies and others, the board has various "Questions and Answers" on its website in response to questions from practitioners. To reflect recent changes in the board's compounding regulations which took effect April 1, 2013, the Board is in the process of amending some of its "Questions and Answers."

Discussion
Dr. Steve Gray, Kaiser Permanente, asked if there would be opportunity for public review and comments of the Q+A document. Chairperson Gutierrez confirmed that there would be.

g. Outcomes of Recent Sterile Compounding Inspections

Dr. Ratcliff provided the committee with a summary of outcomes from recent board inspections of sterile compounding pharmacies. Between January 1, 2013 and mid-May 2013, staff completed 87 inspections. The meeting materials included more specific information.

Discussion
There was no comments from the board or from the public.

h. Recalls of Compounded Drugs Throughout the United States

Background
Between April 11, 2013 and May 20, 2013, the board posted seven subscriber alerts related to compounding drug recalls and two subscriber alerts related to cease and desist orders issued. A summary of the alerts are listed below.

- Green Valley Drugs in Henderson, Nevada, voluntarily recalled all lots of sterile products compounded, repackaged, and distributed by the pharmacy due to lack of sterility assurance and concerns associated with the quality control processes.
- ApotheCure, Inc. recalled all lots of sterile products compounded by the pharmacy that are not expired to the user. The recall was initiated due to lack of sterility assurance and concerns associated with the quality control processes.
- NuVision Pharmacy recalled all unexpired lots of lyophilized compounds of HcG 5000IU-5ml and Sermorelin/GHRH6-5ml to the user. The recall was initiated due to the lack of sterility assurance and concerns associated with the quality control processes identified during a FDA inspection.
- Balances Solutions Compounding Pharmacy, LLC recalled all lots of sterile products compounded by the pharmacy that were not expired. The recall was initiated due to concerns associated with quality control processes, which present a lack of sterility assurance.
- Nora Apothecary & Alternative Therapies recalled a multi-state recall of all sterile drug products compounded by the pharmacy that have not reached the expiration date listed

on the product. The compounded products that are subject to the recall were products within their expiration date that were compounded and dispensed by the pharmacy on or before Friday, April 19, 2013. The recall was initiated due to concerns associated with quality control processes that present a lack of sterility assurance and were observed during a recent FDA inspection.

- The U.S. Food and Drug Administration alerted health care providers, hospital supply managers, and pharmacists that the FDA's preliminary findings of practices at The Compounding Shop of St. Petersburg, Florida, raised concerns about a lack of sterility assurance for sterile drugs produced at and distributed from this site.
- Pentec Health, Inc. initiated a limited recall of in-date nutritional prescriptions for renal patients due to lack of sterility assurance associated with one of its laminar flow hoods used in compounding.
- Southern California Compounding Pharmacy, LLC was issued a cease and desist order on April 19, 2013, for any and all non-sterile compounding.
- Advance Outcome Management Pharmacy Services was issued a cease and desist order on April 29, 2013, from furnishing sterile injectable compounded products.

Discussion
No comments from the board or from the public.

XVIII. LEGISLATION AND REGULATION COMMITTEE REPORT

Chairperson Lippe provided a report of the Legislation and Regulation Committee Meeting Held July 30, 2013 as follows.

LEGISLATION REPORT:

a. SB 204 (Corbett) Prescription Drugs: Labeling (Translations)

SB 204 would require that non-English translations of the "directions for use" as published on the board's web site be printed on prescription container labels. SB 204 would permit a pharmacy to use its own translations of the "directions for use" if a trained and qualified translator or translation service is utilized. In addition, SB 204 provides that a pharmacist has not breached his or her legal duty if the pharmacist uses a translation on the board's web site, where the directions contained an error, and where the pharmacist did not know, or have reason to know of the error. SB 204 provides that where a non-English translation is used on a prescription container label, the English directions for use also be provided.

In April, the board determined it would not take a position on this bill, as we are in the process of re-evaluating the requirements of patient-centered labels. However at the committee meeting held July 30, 2013, and after much discussion voted to recommend an *Oppose* position on the bill. Following that meeting and recommendation, Senator Corbett sent a letter to the board asking that it not take a position on the bill and work with her office on making changes.

Discussion

Dr. Gutierrez asked what the committee's thought process was on taking oppose positions to the bills. Mr. Zee responded that the issue of translations and font size has been thoroughly discussed by the board when it created patient centers labels. The committee felt that these bills are attempting bypass the work the board did because the author disagreed with the board's end product.

Chairperson Lippe provided that those in the committee that choose to oppose the bills felt that the board spent a significant amount of time working on patient centered labels and the legislation is undoing that work.

Dr. Castellblanch commented there is a large population in California that is not proficient in English and need to have translations, which is what SB 204 would accomplish. He also added that the legislature has the right to introduce bills to address changes they feel need to be made to the work the board has done. Dr. Castellblanch also expressed his disagreement with the opinion that free market would dictate if a pharmacy should provide translations.

Dr. Wong commented that he has seen large chain pharmacies provide labels in different languages. He expressed his opinion that if there is a demand for translations in a community, than pharmacies will provide them.

Mr. Zee commented that as an immigrant, he agrees with Dr. Castellblanch's point that everyone should have access to medical information in their language. However, the board worked for 6 years on patient centered labels and heard numerous testimonies from stakeholders and the public on the issue.

Ms. Herold commented that the Senator has asked the board to remove their position of oppose.

Chairperson Lippe commented that during the committee meeting it was asked if SB 204 could be made a two year bill. Sara de Guia, from California Pan-Ethnic Health Network (sponsor of the bill) responded that they have not received a clear answer from the Senator's office.

Ms. Herold provided that as there was no clear answer on it being made into a two year bill, the board should work under the assumption that the bill will continue to move this year. She added that if the board does not take a position on the bill at this meeting, the bill could continue to move and they will not be able to take a position.

Mr. Room noted that the committee had expressed concern over the fact that SB 204 would require *both* the translated and English directions for use to be on the label, leaving little room for anything else. He commented that the letter from the Senator stated that this issue had already been resolved by allowing the English version to be placed somewhere other than the label. However he had not seen an updated version of the bill that reflected this change.

Dr. Castellblanch commented that if the board wanted to work with the Senator on changes to the bills they should not take a position of oppose.

Sara de Guia, from California Pan-Ethnic Health Network (sponsor of the bill), commented that while drafting the bill they found that there are still pharmacies that do not provide translations. She also added that the Affordable Care Act will add a whole new population of people who will be getting prescriptions and may need translations. Ms. De Guia also provided that New York has recently passed legislation that requires pharmacies to provide translations.

Mr. Lippe asked to clarify if the board's current regulations require pharmacies to provide translations using the material on the board's website. Mr. Room responded that the current regulation does not require that a translation be given.

Hene Kelly, from the California Alliance for Retired Americans, asked that board to not take a position on SB 204 and expressed her opinion that it is essential for the directions for use to be provided in the translated language as well as English.

Elizabeth Shitaki, a member of the public, expressed her support for SB 204.

Brian Warren, from the California Pharmacists Association, commented that CPHA has an oppose position on both bills. The reason they oppose is not that they disagree with the intent of the bills, but that the bills put specific requirements in statute that the board could not override with regulations if it determined changes needed to be made to the label requirements at a future time.

Mandy Lee, from the California Retailers Association, commented that CRA also opposes the bills.

Mr. Law asked counsel if the board could modify its regulation to require pharmacies to provide language translations in the 5 languages that the board has translated on its website. Ms. Herold answered that the board does have the authority to do that, they would just have to promulgate another regulation.

Dr. Castellblanch commented that the board could not guarantee that the modified regulation would go through and as currently there is no requirement to provide translated language the board should provide its support to SB 204.

Mr. Zee asked Ms. Shellans if SB 204 and 205 passed, if they would prevent the board from making any changes to labels in the future as it would be in stature. Ms. Shellans confirmed that would be the case.

Dr. Castellblanch expressed his opinion that an oppose vote would in essence kill the bill.

Committee Motion: Oppose SB 204

Support: 4 Oppose: 5 Abstain: 0

b. SB 205 (Corbett) Prescription Drugs: Labeling (Font Size)

SB 205 would amend Section 4076 to require that any prescription dispensed meets the requirements of state and federal law, and that certain items on the label be printed in at least a 12-point font. Existing regulation at 16 CCR 1707.5 requires that specified "patient-centered" information on a prescription drug label be printed in a minimum 10-point sans serif typeface, but that the pharmacy shall print the drug label in 12-point sans serif typeface if requested by the patient. SB 205 also amends a reference to a facility *licensed* pursuant to Health & Safety Code 1250 to require that the facility be *defined by* that section.

At the April 2013 Board Meeting, the board did not take a position on the bill, as it is in the process of re-evaluating the requirements of patient-centered labels, a review that is to be completed by the end of the year. The bill is scheduled to be heard in the Assembly on August 13th, and the board does not have a position on the bill. However, at the committee meeting held July 30, 2013 the committee recommended a position of oppose.

Discussion

Chairperson Lippe explained that SB 205 will require that specific patient centered information be provided on a prescription label in 12 point font. Currently the information is required in 10 point font and the patients have the right to ask for 12 point font if they would like it. The committee recommended an oppose position.

President Wiesser reported that most pharmacies are already providing the information in 12 point font even though it is not currently required.

Mr. Room commented that this legislation is the result of Senator Corbett not being happy with the board's decision to require 10 point font as the minimum.

Dr. Castellblanch expressed his concern that the Notice to Consumer Poster does not adequately inform the public that they have the right to ask for 12 point font if they would like it.

Dr. Gutierrez asked if the bill would prohibit the font being provided in a larger font if the patient wanted it. Ms. Shellans responded that the language states *at least* 12 point font.

Henne Kelly, from the California Alliance for Retired Americans, expressed her organizations support for SB 205 and added that not many consumers know they have the right to ask for 12 point font.

Sara de Guia, from California Pan-Ethnic Health Network, expressed her organizations support of SB 205 and asked the board to remain neutral on the bill.

Brian Warren, from the California Pharmacists Association, commented that this bill would tie the board's hands to make any further changes to labeling requirements if they find a need to do so in the future.

Elizabeth Shitaki, a member of the public, asked the board to remember the aging population who need larger font size.

Jodi Reed, Executive Director for the California Alliance for Retired Americans, stated that the national standard for font size is 12. She added that the fact that studies show that most pharmacies already provide the information in 12 point font illustrates that the public supports 12 point font.

Chairperson Lippe commented that perhaps the board has failed to properly educate the public about their right to request 12 point font.

Committee motion: Oppose 205

Support: 6 Oppose: 3 Abstain: 0

Dr. Castellblanch asked when the board can look at changing its regulation to require 12 point font. Ms. Herold responded that the board could move it to a regulation hearing in October 2013. However she noted that the board is in the middle of evaluating the patient-centered labels.

Mr. Law stated that the board understands that the public is concerned about font size; however, he did not feel that SB 205 was the appropriate way to address the issue.

c. <u>SB 306 (Torres) Automated Dispensing Machines</u>

SB 306 would provide for board licensure of physician group practices, allow these groups to purchase drugs at wholesale; allow for the use of automated drug delivery systems in these settings for the purpose of providing prescription medications. To accomplish this, SB 306 proposes to amend Pharmacy Law to allow physician group practices the ability to acquire a board license, own comingled inventories of drugs, and allow all physicians in the group practice, or in a contract with the group practice, to be able to dispense patient medications from that inventory, including controlled substances. In addition, SB 306 will amend current provisions related to automated drug delivery systems to allow non-pharmacists to stock, re-stock and maintain these systems, and 'designees' of physicians to have access to the drug stock. Further, this bill would amend existing law to remove the requirement that an

automated drug dispensing system have 2-way video (a current requirement), if a prescriber provides a drug to a patient.

Discussion

Chairperson Lippe reported that there was committee consensus that SB 306 was a considerable departure from the current requirements for drug distribution for patients and would remove pharmacists from patient care. Additionally the dispensing machines could be stored in unsecured locations and drugs could be handled by non-pharmacists, thus increasing the risk for diversion or patient harm. Therefore the committee recommended that the board oppose SB 306.

Maureen O'Haren from Molina Healthcare, sponsor of SB 306, commented that the bill would require oral consultation by the physician following the same requirements that pharmacists have. She also added that the bill would require the physician to dispense only to their own existing patients and the machines would have to be located in a secure location that would be licensed by the Board of Pharmacy. Molina feels that the dispensing machines provide more safety and immediate access to medications for patients.

Dr. Rafael Amaro, medical director for Molina, reported that Molina has seen many patients who have been prescribed acute medications not picking up their medications from the pharmacy and were ending up in the emergency room. Molina believes that placing dispensing machines in its clinics will encourage patients to take their medications.

Julie Gisman, director of pharmacy for InstaMed, highlighted the safety and security features of the dispensing machines. Dr. Gutierrez asked how the medications were re-stocked. Ms. Gisman answered that the drugs are shipped to the site in prepackaged containers ready to put in the machines.

Brain Warren, from the California Pharmacist Association, asked the board to take an oppose position on the bill and noted that they are concerned that this bill completely takes pharmacists out of patient care, and could put patients' health at risk.

Jonathan Nelson, from California Society of Health System Pharmacists, provided that CSHP is concerned that this bill is making a lot of changes to current law very late in the legislative process.

Dr. Steve Gray, from Kaiser, expressed that the bill does not limit the use of dispensing machines to Molina Clinics and would allow any two prescribers who want to own a machine to do so. He added that the bill would allow any "licensed healthcare practitioner" to handle the medications, not just doctors. He asked the board to oppose the bill to allow more time to review the significant changes to current law this bill is proposing.

Committee motion: Oppose SB 306 unless amended

Support: 9 Oppose: 0 Abstain: 0

Ms. Sodergren asked the board to clarify if they would like staff to draft proposed amendments and seek approval from the president and chair before submitting them. Chairperson Lippe and President Weisser responded yes.

d. SB 598 (Hill) Biosimilars

SB 598 would add Section 4073.5 to specify conditions under which a pharmacist can exercise professional discretion to substitute a biosimiar where a biologic has been prescribed. For prescriptions filled prior to January 1, 2017, SB 598 requires the pharmacy to notify the prescriber of any substitution made within five business days of the selection. The board opposed SB 598 at the April 2013 Board Meeting because the bill is premature, the burden placed on the pharmacy to provide follow-up notification to a prescriber is unnecessary, as well as the role a pharmacist plays in substitutions. The board noted that once deemed "biosimilar," the board would support an approach similar to the authority that allows the substitution of generics. The board also has conveyed to the author that where there is an adverse event attributed to the use of a biosimilar that such an event be required to be reported to the FDA's "Medwatch."

Discussion
Chairperson Lippe reported that the committee expressed concern that the bill is premature and would take away a pharmacist's professional discretion as he or she would be required to notify the prescriber each time a biosimilar was dispensed.

No board action was required, the report on SB 598 was provided to the board for information purposes.

e. SB 305 (Price) Healing Arts: Boards

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; some of these agencies cite the board's lack of authority to receive these documents. At the October 2012 Board Meeting, draft language was approved to add Section 4008.5 to the B&PC to provide the board with the express authority to receive certified records for this purpose. To address the board's request, and that of other healing arts boards, Senator Price introduced a provision to add Section 144.5 to the Business and Professions Code, applicable to all DCA boards that would authorize boards to request and receive such documents for the purpose of completing applicant and licensee investigations. The board's original proposal included a requirement that upon request, the courts and law enforcement jurisdictions would be required to provide the records being requested. This provision equated to a state mandate, which drew concerns from local jurisdictions. Thus, it was not included in the bill.

Section 144.5 was amended into SB 305 on April 15, 2013, and since that time has passed the Senate. The Assembly Committee on Business, Professions and Consumer Protection passed the measure on June 25th, and the bill was referred to Assembly Appropriations where it awaits hearing.

Discussion
Note: Mr. Zee left the room at 4:33 p.m.

No comments from the board or from the public.

Committee Motion: Support SB 305.

Support: 8 Oppose: 0 Abstain: 0

Due to time constraints Chairperson Lippe did not review any two year bills or any legislation that did not require board action. The complete list of items and additional information was provided in the meeting materials.

REGULATION REPORT

No items in the Regulation Report required board action. Rather than give a full report Chairperson Lippe requested board and public comments on any item in the Regulation Report.

XIV COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

In Chairperson Books absence, Ms. Herold provided a report of the Communication and Public Education Committee Meeting Held July 16, 2013 as follows.

a. Discussion Regarding Recent Public Outreach Activities to Address Prescription Drug Abuse

Discussion
Ms. Herold reported the following major outreach events for the board.

- Public Continuing Education Training Sessions Provided by the California State Board of Pharmacy and the Los Angeles Field Division of the Drug Enforcement Administration: June 27 and July 25, 2013
- Four Public Continuing Education Training Sessions by the California State Board of Pharmacy and Federal Drug Enforcement Administration scheduled for August 2013

b. Discussion Regarding the Implementation of 16 California Code of Regulations Section 1707.6 Notice to Consumers Poster, Video Display Format of Notice to Consumers Poster and Notice of Interpreter Availability

Discussion
Ms. Herold reported that the new "Notice to Consumer" posters and the "Point to Your Language" posters have been distributed to all pharmacies. The board has also alerted pharmacies that the board has a video version that they can use.

c. Discussion Regarding Requests from California Pharmacies to Use Their Own Notice of Interpreter Availability Posters in Place of the Board's Notice Pursuant to the Waiver in 16 California Code of Regulations Section 1707.6(e)

Discussion
Ms. Herold provided that the board has received 3 requests from pharmacies for waivers so that they do not have to use the board's specific interpreter notice. Ms. Herold asked if the board wished to review the requests or refer them back to the committee. She noted that the waivers received were originally submitted missing elements and neither she nor the committee had been able to review the amended requests.

Dr. Castellblanch and Ms. Veale commented that they did not feel comfortable taking action until the requests were reviewed.

Ms. Shellans clarified that the waivers did not allow pharmacies to change the content of the interpreter notice, only the format.

d. Review and Possible Approval of Updated Emergency Contraception Fact Sheet as Required by 16 California Code Regulations Section 1746

Discussion
Ms. Herold announced that the emergency contraception Fact Sheet was being re-formatted and updated to incorporate the comments from the board as well as the medical board. It will also be translated into different languages.

Mr. Law commented that the current notice of interpreter poster listed Mandarin and Cantonese as languages, however they are simply a dialect of Chinese. Ms. Herold responded that Mr. Law should review the notice and provide feedback on any corrections.
Dr. Castellblanch added that the regulations would need to be changed to make the correction.

Ms. Herold reported that at the next Communication and Public Education Committee Meeting they would review the waiver requests.

e. Assessment of California's Patient-Centered Labels Regulation Requirements, Due by December 2013 as required by California Code of Regulations Section 1707.5(e)

Background

Title 16 CCR Section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, it included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5.

Business and Professions Code Section 4076.5 required the Board to consider the following factors when developing requirements for the patient-centered prescription label requirements:

- Medical literacy research that points to increased understandability of labels.
- Improved directions for use
- Improved font types and sizes
- Placement of information that is patient-centered
- The needs of patients with limited English proficiency
- The needs of senior citizens
- Technology requirements necessary to implement the standards.

The patient-centered label requirements went into effect on January 1, 2011, and since that time the Board has worked to secure compliance by educating licensees, conducting surveys, distributing notices, and reviewing pharmacies' compliance with requirements. Accomplishments include:

1. Finalized regulations to update the "Notice to Consumers" poster.
2. Finalize a new "Notice to Consumers" poster and video format of the poster to explain to the public essential information about pharmacy services and taking medications and distribute these to California pharmacies.
3. Finalize regulations to require "Point to Your Language" consumer notices in pharmacies; finalize the notice itself, and distribute to California pharmacies.
4. Conduct surveys of pharmacies for compliance with label requirements.

In April 2013, this committee initiated the review of the patient-centered prescription label requirements and continued the discussion at this meeting.

Discussion

Ms. Herold reported that the work the board has done on patient centered labels have been used to develop a national standard. She noted that the United States Pharmacopeia Guidelines for Prescription Drug Labels closely mirror the board's regulations. She added that New York does require 12 point font however USP actually allows for smaller font depending on the font style.

Ms. Herold provided that The National Council for Prescription Drug Programs developed the "Universal Medication Schedule White Paper" (draft April 2013 provided in meeting materials). This document supports the standardized directions in the board's regulation at 16 CCR Section 1707.5. The goal of the universal medication schedule is to increase patient understanding and

adherence to medication instructions by standardizing the phrasing of directions, thereby improving health outcomes. The hope is to secure the use of directions for use in a Universal Medication Schedule into e-prescribing systems.

Ms. Herold noted that a survey was conducted in 2012 and was used to measure pharmacies' compliance with the patient-centered label requirements. It included components related to the 10- and 12- point fonts used on labels and how pharmacies have been complying with the interpreter requirements. Ms. Herold reported that over the course of approximately seven months, board inspectors collected prescription labels used in California 767 pharmacies to determine compliance with the patient- centered label requirements. In general, nearly 70 percent of the labels in use as found by the board's inspectors are printed in 12-point font; 15 percent use both 10 and 12 point font on the labels; and about 15 percent are printed in 10 point.

Additionally, Ms. Herold reported that during the inspections described in the above survey, the board's inspectors also inquired how pharmacies are complying with the requirements for the availability of interpreters to provide services to limited English speaking patients.

Ms. Herold stated that board is currently surveying pharmacies to determine if they are providing consumers with translated labels, and if they are using the translation 'directions for use' that are on the board's website.
Ms. Herold reported that the board conducted a survey in 2012 to determine if consumers were satisfied with their prescription labels and how they could be improved. Several consumer groups including AARP, Consumers Union, and California Pan Ethnic Health Network (CPEHN) distributed the survey electronically. The survey was also translated into Chinese and Spanish by the board and distributed by CPEHN to the appropriate audiences. Further, surveys were distributed and collected in person at local Senior Scam Stopper seminars (public protection fairs) sponsored by the Contractors State License Board. The board received a total of 1,204 completed surveys.

Dr. Castellblanch asked what the process would be to reconsider the font size for prescription labels. Ms. Herold added that this item would be on the next Communication and Public Education Committee Meeting.

Ms. Shellans commented that during the last Communication and Public Education Committee adding "purpose" to the label was discussed. She noted that this idea was originally discussed during the development of the patient centered label regulation; however it has always been a point of contention between the board and the medical community. Ms. Shellans added that as the Medical Board has recently expressed interest in adding "purpose" to the labels the board should consider a legislative change. Ms. Herold responded that two members of the medical board have expressed their support.

Dr. Wong commented that many members of his community ask for the purpose to be added. Ms. Herold responded that the complication is when a drug is being used for something other than its intended use.

f. Discussion and Possible Action on Committee's Goals for 2012/2017 to Fulfill the Board's Strategic Plan

Ms. Herold commented that this item would be further discussed by the committee.

g. Update on *The Script*

Ms. Herold reported that The Script had been provided to legal and it was returned to board staff for correction.

h. Review of the Board's New Consumer Education Materials

Background

The following new consumer brochures have been produced in response to current pharmaceutical industry events:

1. *Prescription Drug Abuse*
2. *Prescription Drug Abuse Among Teens*
3. *Purchasing Pet Meds Safely from Online Pharmacies*

Discussion
Ms. Herold provided that the materials are still being reviewed.

i. Report on Media Activity During the Fourth Quarter of FY 2012/13

Ms. Herold directed the board and the public to the meeting materials to view board's media activity for the fourth quarter.

k. Public Outreach Activities Conducted by the Board During the Fourth Quarter of FY 2012/13

Ms. Herold directed the board and the public to the meeting materials to view the board's outreach activity for the fourth quarter.

Discussion
Dr. Steve Gray, from Kaiser Permanente, commented that "purpose" is the item is most requested by consumers to be added to the label. He asked that this be further discussed at the next committee meeting as this information is critical to patient safety. President Weisser responded that he supports adding purpose to the label.

Mr. Lippe asked what happens if the medication is being used off label purposes. Dr. Gray responded that this has been discussed and it was determined that in order to do a consultation the pharmacist must know what the medication is being used for, therefore they would still be able to provide the "purpose" even if it was for off label use. Mr. Weisser noted that if a pharmacist couldn't tell a patient why they were taking a medication, the pharmacist is probably are not doing consultations.

Mr. Law commented that certain patients may not want to the purpose for their medication on the label. Dr. Gray responded that patient confidentiality should always be considered, he just wants it made clear to pharmacists that they can use their professional judgment to add the purpose to the label if it will benefit the patient.

Mandy Lee from California Retailers Association commented that while the association supports purpose on labels conceptually, there are some areas that need to be looked at further.

Dr. Gutierrez commented that the use of automated dispensing machines would also further complicate adding purpose to the label.

No further comment from the board or from the public.

ADJOURNMENT **5:08 p.m.**