



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: October 29-30, 2013

LOCATION: Sheraton Garden Grove
12221 Harbor Blvd.
Garden Grove, CA 92840

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Victor Law, RPh
Ramón Castellblanch, PhD, Public Member
Rosalyn Hackworth, Public Member
Albert Wong, PharmD
Deborah Veale, RPh
Lavanza Butler, PharmD
Shirley Wheat, Public Member
Tappan Zee, Public Member

**BOARD MEMBERS
NOT PRESENT:** Randy Kajioka, PharmD
Ryan Brooks, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Supervising Deputy Attorney General
Desiree Kellogg, Deputy Attourney General
Michael Santiago, DCA Staff Counsel
Kristy Shellans, DCA Staff Counsel
Debbie Damoth, SSM1
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting can be found at:
<http://www.pharmacy.ca.gov/about/meetings.shtml>

CALL TO ORDER

President Weisser called the meeting to order at 9:34 a.m.

I. GENERAL ANNOUNCEMENTS

President Weisser conducted a roll call. Board members present: Gregg Lippe, Rosalyn Hackworth, Debbie Veale, Albert Wong, Amy Gutierrez, Lavanza Butler and Victor Law. Note: Tappan Zee arrived at 9:43 a.m., Shirley Wheat arrived at 9:48 a.m. and Ramon Castellblanch arrived at 10:09 a.m. Board members absent: Ryan Brooks and Randy Kajioka.

President Weisser welcomed Kim Kirchmeyer, interim executive director of the Medical Board and Michael Santiago, the board's new DCA staff counsel.

President Weisser advised the public that there would be a 5 minute time limit for public comment and announced 6 hours of continuing education credit for those attending the meeting.

II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JULY 30-31, 2013

Ms. Shellans noted that on page 37 in the 5TH paragraph, "1410B" should be changed to "1410 and 1437."

Motion: Approve the July 30-31, 2013 meeting minutes with Ms. Shellans corrections.

M/S: Lippe/Law

Support: 8 Oppose: 0 Abstain: 0

III. BOARD MEETING DATES FOR 2014

President Weisser announced the future board meeting dates (below) and noted that due to budgetary restraints all board meetings will be held in Sacramento until further notice.

- November 14, 2013
- January 29-30, 2014
- April 23-24, 2014
- July 30-31, 2014
- October 22-23, 2014

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

No comments from the board or from the public.

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

President Weisser recognized Tim Chrisney and James L. Caras and presented them each with a 50-year pin.

VI. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

President Weisser provided a report of the Organizational Development Committee held September 10, 2013.

President Weisser provided a brief overview of the board's revenue and expenditures for FY 2012/2013, noting that the board over-expended on its attorney general line item. President Weisser directed the board's attention to the FY 2013/2014 fund condition (provided in the meeting materials) to illustrate the growing decline in the board's funds in reserve. He added that the fee increase would help, however, that alone would not get the board to where it needs to be.

Ms. Sodergren gave the board and the public an update on the progress of the implementation of DCA's New Computer System, BreEZe. Dr. Gutierrez asked how the board's licensees were impacted when the systems were shut down for release 1 of BreEZe. Ms Sodergren responded that she is not aware of any issues and noted that the board sent out many subscriber alerts, worked with various associations and contacted facilities via phone to ensure that services to consumers were not interrupted.

Ms. Sodergren provided the board with a personnel update and highlighted the board's recruitment efforts to fill vacancies. She added that the board is currently administering the inspector exam and offered to provide information to anyone who was interested in taking the exam.

There were no comments from the public.

c. Discussion and Possible Action on Recommendation for Board Policy to Delegate Decisions Regarding Requests for Extensions of Time to Submit Arguments to the Board in Cases Under the Administrative Procedure Act to the Board President

Background

The Administrative Procedure Act sets forth the provisions of the disciplinary process, including the process to for the non-adoption of a proposed decision or stipulated settlement. Because the board does not have a policy in this area, there are times when board staff have a very short time to respond to a request from a respondent making it difficult to secure the necessary votes to make a timely decision. Although this does not happen very frequently, having a policy that can be implemented when the opportunity arises will streamline the decision process without compromising the requestor's rights.

Discussion

President Weisser asked if the delegation could be for the president *or* the vice president if the president was not available. Ms. Shellans responded that it is best to designate one person (president) and designate one other person (vice president) only in their absence.

Ms. Veale asked if the board had ever missed a deadline. Ms. Herold responded that a deadline was never missed, but it is very difficult for staff to get the 7 votes needed in time.

No comments from the public.

Motion: Update the board's policy to allow the board president to decide to grant or deny a request for an extension of time to submit arguments to the board under the Administrative Procedure Act. In the absence or unavailability of the president, the vice-president of the board may act upon the request.

M/S: Lippe/ Law

Support: 10 Oppose: 0 Abstain: 0

d. Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 California Code of Regulations to Delegate to the Executive Officer the Authority to Initiate a Rulemaking to Adopt "Changes Without Regulatory Effect" (Title 1 California Code of Regulations Section 100 Changes)

Background

California Code of Regulations Section 1703 sets forth activities delegated to and conferred upon the executive officer by the board.

Title 1 California Code of Regulations Section 100 specifies the requirements for regulatory changes that are "without regulatory effect."

"Section 100" changes generally include:

1. Grammatical corrections
2. Updating, reordering, renumbering or re-locating the laws or regulations listed in a form (e.g., self-assessment forms, application forms, etc.)
3. Updating the authority and reference citations for regulations when the number of the cited statutes or regulations changes,
4. Any other type of change that does not materially alter any requirement, right, responsibility, condition, or other regulatory element or a regulation.

A “Section 100” rulemaking is significantly shorter than a traditional rulemaking in that the board does not make a formal notice or the proposed action nor is an opportunity for public comments required.

During the October 2012 Board Meeting, the board voted to delegate to the Executive Officer the authority to adopt regulation changes that are deemed to be “without regulatory effect” in accordance with Section 100 of Title 1 of the California Code of Regulations. Further, the board specified that upon the adoption of any Section 100 regulatory changes, the Executive Officer shall report to the board at its next regularly scheduled Board Meeting any regulations authorized by this motion. This delegation will expire December 31, 2013.

Further, as part of its motion, the board directed staff to prepare draft amendments to add the “Section 100” delegation to Title 16 CCR 1703 and to bring the draft to the next meeting of the Legislation and Regulation Committee for consideration. This did not occur.

Discussion

Ms. Herold noted that this will only apply to straight-forward changes that have no regulatory affect.

Mr. Law asked what the new expiration date would be if the board decided to approve the motion today. Ms. Shellans explained that this rulemaking, if approved, would not require the board to renew the delegation each year.

Motion: Direct staff to initiate the formal rulemaking process, issue the amended text as discussed at this meeting for a 45-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process and adopt the proposed regulation at Section 1703 as described in the text notice.

M/S: Lippe/Hackworth

Support: 10 Oppose: 0 Abstain: 0

VII. EXECUTIVE OFFICER REPORT

a. Updated on Activities of the Medical Board of California

Ms. Kirchmeyer, interim director of the Medical Board, thanked the board for the opportunity to speak with them. She reported that both boards are continuing to work on improving collaboration on issues that pertain to multiple DCA boards. Ms. Kirchmeyer added the Federation of State Medical

Boards, the National Association of Board's of Pharmacy and National Council of State Boards of Nursing have begun meeting to discuss collaboration on a federal level.

Ms. Kirchmeyer reported that the Medical Board has created a prescribing task force whose first meeting was held on September 23, 2013. The task force will be working to create a document for prescribers that will provide them with guidance on information that can be shared and other educational tips. Ms. Kirchmeyer noted that the task force will meet with other regulatory agencies to discuss the document before it is released. The next task force meeting will be focused on reviewing the current pain management guidelines.

Ms. Kirchmeyer reported that the board created a prescribing strike force to address overprescribing in California and so far they have made four arrests, issued numerous search warrants and have 25 cases in the pipeline.

Ms. Kirchmeyer reported that a bill was recently vetoed by the governor that would have required coroners to provide the Medical Board with the coroner's report of anyone who had died of prescription overdose. The bill was vetoed due to financing issues raised by the Coroner's Association. The board will be working with the Coroner's Association to bridge the financial gap.

Ms. Kirchmeyer provided that another Medical Board and Board of Pharmacy Joint Forum would be held in the spring of 2014 in Southern California.

Ms. Kirchmeyer reported that the U.S. Attorney in San Francisco would be holding a meeting on prescription drug abuse in January 2014, both the Medical Board and Board of Pharmacy would be participating.

Ms. Kirchmeyer reported that a piece of federal legislation called the Tele-Med Act of 2013 (HR 3077) sponsored by Representative Nunes, would amend title XVIII of the Social Security Act to permit certain Medicare providers licensed in one state to provide telemedicine services to certain Medicare beneficiaries in a different State.

Ms. Hackworth asked if the Medical Board knew what specific expenses caused the coroner bill to be vetoed. Ms. Kirchmeyer answered that the expenses noted came from the Coroner's Association and the Medical Board would be working with them to find ways to reduce expenses.

Ms. Herold advised Ms. Kirchmeyer that on December 4, 2013 the Board of Pharmacy's Prescription Drug Abuse Subcommittee would be meeting and invited representatives from the Medical Board to attend.

b. Update on Federal Legislation Relating to Track-and-Trace

Mr. Room reported that the Federal Track-and-Trace Bill (HR 3204) has passed the House and the Senate is expected to vote on it in the coming week. Ms. Room provided the board with a high-level overview of the bill.

Ms. Herold and Mr. Room noted that the compounding piece of the bill is not as robust as the board would like.

Dr. Gutierrez asked what the inspection requirements were in the bill. Mr. Room answered that the bill has an ongoing inspection requirement, but the frequency is not specified. He added that the FDA is going to create a risk-based inspection frequency paradigm to determine an inspection schedule based on a facility's risk-level.

c. Discussion on Implementation of SB 493 (Chapter 469, Statutes of 2013, Hernandez)

Ms. Herold reported that at the licensing committee meeting on December 10, 2013 the committee will begin the discussion on advanced care pharmacists and the development of the required protocols.

Jonathan Nelson, from CSHP, thanked the board for their support on SB 493.

d. Discussion on Implementation of SB 294 (Chapter 565, Statutes of 2013, Emerson)

Ms. Herold reported that SB 294 was signed and requires facilities that do sterile compounding to become licensed with the board. Prior to licensure or renewal, the facility must go through a random inspection by a board inspector. To prepare for the inspection of these facilities all of the board's inspectors are going through 53 hours of training on sterile compounding. Ms. Herold encouraged hospitals to begin the licensure process so that they can be fully licensed by July 1, 2014 to avoid interruption of patient care. Dr. Gutierrez asked Ms. Herold to also reach out to home healthcare groups to work on the new licensure requirements.

Stan Goldenberg, pharmacist and former board member, asked if the new license would be a one year license. Ms. Herold responded that both the pharmacy/hospital license and the sterile compounding license would expire at the same time.

Mr. Subash Mediratta, from People's Pharmacy, asked for clarification on the 5 percent threshold in HR 3204. Ms. Herold responded that at this time she was not prepared to discuss this requirement and the board would need more time to review HR 3204 in detail. Mr. Room commented that in his review of HR 3204 he did not see a 5 percent threshold requirement.

VIII. LICENSING COMMITTEE REPORT

Note: The Licensing Committee did not meet in the first quarter of FY 2013/14

Ms. Veale provided the Licensing Committee Report as follows.

a. Competency Committee Report

Effective August 1, 2013, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that there was a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board released scores on September 16, 2013.

The Competency Committee workgroups continues to meet throughout 2013 for examination development. Both Competency Committee workgroups met once during the fall to discuss examination development.

Discussion

No comments from the board or from the public.

b. First Quarterly Report on the Committee's Goals for 2013/14

The first quarterly report on the Licensing Committee's goals was provided in the meeting materials. The board is meeting the acceptance parameters for the Success Indicators listed below

- Review Received Deficiency Items to Determine Application Completeness within five working days of receipt
- Update Information Changes to Licensing Records within five working days.

The board is not meeting the acceptance parameters for the Success Indicators listed below.

- 2A – Cashier All Revenue Received within three working days
- 2B – Review Initial Applications within 30 working days
- 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 working days, 91% is cashiered within four working days and 97% is cashiered within five working days. In Success Indicator 2C where the indicator is 30 working days, 99% are processed within 45 working days. In Success Indicator 2D where the indicator is three working days, 57% of the licenses are issued within this time frame; however, a total 80% of licenses are issued within four working days or less and 88% of licenses are issued within five working days or less. The board is not meeting these success indicators primarily due to staff vacancies and antiquated databases.

Discussion

No comments from the board or from the public.

c. Licensing Statistics for July 2013 – September 2013

The first quarters licensing statistics were provided in the meeting materials. During the first three months of fiscal year, the board has received over 5,000 applications and issued over 4,000 licenses. The number of applications received is up compared to the same period last year by about 9%; however, there is a 2.3% decrease in the number of licenses issued.

Discussion

No comments from the board or from the public.

d. Examination Statistics for the California Practice Standards and Jurisprudence Examination for Pharmacists and the North American Pharmacy Licensure Examination

The examination statistics for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacy Licensure Examination (NAPLEX) exams from April 2013 through September 2013 were provided in the meeting materials.

The overall pass rate for the CPJE was 82.6%. The pass rate was higher for graduates from the California Schools of Pharmacy at 89.6%. Applicants with a PharmD degree also continue to perform better on the exam with an overall pass rate of 84.1% versus those with a BS degree which has a pass rate of 55.7%. The overall pass rate for the NAPLEX was 96%. Applicants with a PharmD degree also perform better on the NAPLEX than those with a BS degree with pass rates of 96.7% and 84.3% respectively.

Discussion

Mr. Law and a member of the public asked the committee to consider changing the reporting of the exam statistics so that it is not broken out by PharmD vs. BS.

A member of the public, from People's Pharmacy, commented that in her experience PharmD degree holders have little to no compounding experience.

Dennis McAllister, from the Accreditation Council for Pharmacy Education, reported that they are currently in the middle of doing a review of the standards of accreditation for 2014. Two items that they often hear need to be improved are the teaching of compounding and veterinary medicine. He added that there would be many opportunities for comments from members of the profession at their meetings.

Mr. Law commented that in his opinion, the number of intern hours required for licensure is a burden to students. Mr. Weisser responded that this topic would be placed on the next Licensing Committee agenda.

The board recessed for a break at 11:05 a.m. The board reconvened at 11:21 a.m.

IX. ENFORCEMENT COMMITTEE REPORT

Dr. Gutierrez provided a report on the Enforcement and Compounding Committee meeting that was held on September 10, 2013

1. Enforcement Matters

a. Review of Walgreens' New Business Model for Pharmacies

Background

Walgreens has developed a new model for its community pharmacies where a pharmacist is located outside the normal pharmacy licensed area, so as to be more accessible to patients. This model is being rolled out nationally.

During the January 31 and February 1, 2012 Board Meeting, Al Carter, Pharm.D, Manager of Pharmacy Affairs for Walgreens, made a presentation to the board on Walgreens new pharmacy design called "Well Experience." Dr. Carter indicated the new format, which has been implemented in several states, is designed to enhance the patient's interaction with the pharmacist.

During his 2012 presentation, Dr. Carter reviewed the following features of the new model:

- An open, redesigned layout with no view into the dispensing area. Pharmacists will monitor the dispensing area and activity with video surveillance.
- A pharmacist desk area in front of the pharmacy counter to provide greater accessibility for consultation about medications and to provide additional clinical services. Pharmacists will verify each prescription digitally before it is dispensed to the patient.
- Confidential consultation areas for patient consultation and other services such as immunizations, blood pressure, blood glucose testing, etc.

Dr. Carter discussed that the new environment is more comfortable, less stressful and improves patient access to the pharmacist. Dr. Carter indicated patient counseling had been increased by 40 percent since the new model had been implemented in 100 Walgreens pharmacies throughout the country.

Following this presentation, the board asked for the board's inspectors' assessment of the model.

Supervising Inspector Ratcliff provided an overview of the inspection results from various Walgreens' locations where the new model is currently in use or in the process of transitioning to the new model. Dr. Ratcliff noted that the proposed model appears to comply with pharmacy law. .

In response to questions, the committee learned that the dispensing area is monitored by video surveillance and is viewable at the front desk area where the pharmacist is located. The committee was advised that this model currently is operational in four states and was most recently implemented in Florida and Arizona.

When asked, the committee was also advised that there have been no incidents of diversion from pharmacies using this model and that prior to transitioning to this model pharmacy personnel received six months of additional training.

The committee was advised that the video surveillance footage would be available for at least 120 days and that Walgreens has seen a slight decrease in medication errors and that Walgreens would provide the board with the outcomes of consumer satisfaction surveys conducted.

Counsel noted that there is nothing in the law that prohibits implementation of this model. DCA counsel also cautioned that each situation should be looked at on a case by case basis and would recommend that Walgreens not determine everything is compliant with the law without looking at case specific situations.

The committee noted that this model would appear to give greater opportunity for patient consultation as well as promote the pharmacist-patient relationship.

Discussion

Ms. Veale asked to clarify if this model meets current requirements, as she thought that there was an issue regarding the direct pharmacist supervision of ancillary personnel. Ms. Shellans answered that at the last committee meeting counsel noted that on its face, the model does not violate the board's current legal requirements, but that the question of whether adequate supervision was provided would have to be analyzed on a case-by-case basis. She added that after discussion with Mr. Room, counsel believes that the technology used in the model could allow for adequate pharmacist supervision of ancillary personnel.

Ms. Hackworth provided that since the last committee meeting some potential problems with the model had been brought to her attention via emails, letters and a report from Change-to-Win.

Dr. Castellblanch noted that he had not received the Change-to-Win report, even though he knew reports for each board member had been mailed to the office. He asked what the board's mailing procedures were. Ms. Herold responded that office staff mails items received for board

members regularly, however, they do wait for a few items to come in rather than mailing things individually. Ms. Hackworth and other board members added that she had received the report in the mail on Monday.

Mr. Lippe commented that in his opinion, supervision was not an issue in the model as currently when a pharmacist is conducting a consultation with a customer they are not watching the technicians. He added that the model might even be better as the technology would allow the pharmacist to electronically watch the pharmacy even while consulting. Mr. Room responded that all the law currently requires is that all ancillary staff be under the direct supervision of a pharmacist, meaning the pharmacist is fully aware of the activities in the pharmacy. Mr. Room added that until a case came before the board for a pharmacist failing to supervise in this model, they would not know if the technology would serve as a better or worse way to supervise ancillary staff.

Dr. Butler expressed that as a practicing pharmacist she would not feel comfortable supervising the pharmacy while not physically being in the pharmacy.

Mr. Room reported that when this model was initially brought before the board one concern that was discussed was the pharmacist's supervision of the actual medication because in the model there is less opportunity for the pharmacist to physically inspect the medication. Dr. Butler added that a pharmacist having to identify medications via a video camera was a concern for her. Dr. Gutierrez commented that there is a lot of automation currently in use in pharmacies where pharmacists do not actually touch the medications.

Ms. Veale asked Supervising Inspector Bob Ratcliff to give a brief report of what he saw when he inspected the Walgreens in Hollywood with this model in use.

Ms. Hackworth asked if the board had looked at other states where the model is already in use. Ms. Herold responded that she has been to a location in Chicago.

Supervising Inspector Ratcliff provided an overview of the inspection results from various Walgreens' locations where the new model is currently in use or are in the process of transitioning to the new model. Dr. Ratcliff noted that he personally visited the location in Hollywood and its model appeared to comply with pharmacy law. Mr. Ratcliff reported that when he visited the Hollywood location there was only one pharmacist on duty and the pharmacist had reverted back to the "traditional" practice of being behind the pharmacy counter. Mr. Ratcliff asked the pharmacist at the location what the policy was when there was only one pharmacist on duty. The pharmacist responded that was it is up to the pharmacist's professional judgment if they wanted to revert back to the traditional model when there is only one pharmacist on duty.

Mr. Lippe asked if it was possible for customers to see patient information on the computer screen since the model has the pharmacist in a kiosk beyond the pharmacy counter. Mr. Ratcliff responded that there is a privacy screen on the computer that prevents anyone from seeing the screen unless they are directly in front of it.

Dr. Castellblanch asked if the pharmacy Mr. Ratcliff visited had only one pharmacist on duty. Mr. Ratcliff confirmed this and added that the pharmacist on duty said he felt more comfortable being behind the pharmacy counter while he was alone and Walgreens allowed this practice.

Dr. Gutierrez asked if in the California models data entry was done onsite (other states use offsite data entry). Mr. Ratcliff confirmed that in California all data entry was done onsite.

President Weisser asked Ms. Shellans if Dr. Gutierrez was permitted to finish the rest of the Enforcement Committee report before opening it up to public comments. Ms. Shellans confirmed that this was allowed.

b. Summary of Presentation From the California Product Stewardship Council on Take Back Programs for Prescription Medications in California

Background

Heidi Sanborn, of the California Product Stewardship Council, requested the opportunity to share information about their bin collection program “Don’t Rush to Flush, Meds in the Bin, We All Win.” Additional information can be found on the Council’s website at <http://dontrushtoflush.org>. Ms. Sanborn provided information about this program and drug take-back programs in general.

On a related note, a recent decision in U.S. District Court upheld an Alameda County ordinance which requires pharmaceutical manufacturers that sell drugs in Alameda County to fund and operate a county-wide medicine take-back program. The Pharmaceutical Research and Manufacturers Association of America, the Generic Pharmaceutical Association, and the Biotechnology Industry Organization filed suit against Alameda County claiming the ordinance violated the Commerce Clause of the U.S. Constitution. In his ruling, the U.S. District Judge said the relatively modest compliance costs did not unduly burden interstate commerce and that “the ordinance serves a legitimate public health and safety interest . . .” The Alameda County ordinance, regarded as the first of its kind in the nation, will go into effect in November 2013.

In 2009, California developed model guidelines for drug take-back programs. These guidelines, developed over a period of months by the then California Integrated Waste Management Board working with several other state agencies including this board, were disseminated in a February 2010 The Script article to board licensees.

Earlier in 2013, this board provided comments to the federal Drug Enforcement Administration (DEA) in its efforts to develop parameters for drug take-back programs that can include controlled substances.

In general, the board has supported drug take-back collection bins that:

- Are voluntary for the pharmacy to establish
- Require patients to personally deposit the drugs into the receptacles – no pharmacy staff assistance in sorting or depositing the drugs
- Require two-key locks – one key with the pharmacy and the other with the waste hauler, to serve as a double check

In the board's comments to the DEA is one additional component – attach a shredding device to the bin to pulverize contents (like coffee grinders in grocery stores).

Previous Committee Discussion

The committee heard a presentation from representatives from several different programs that have drug take back programs including representatives from the San Francisco Department of the Environment and the County of Los Angeles Department of Public Health. The committee was provided with various methods by which drug take back programs have been implemented in California as well as the pros and cons to the various methods.

The program in San Francisco currently includes participation by 13 pharmacies that accept non-controlled and over the counter medications, as well as sharps. Currently, dual key collection bins are used and returned medication is taken away by a waste hauler. In addition, the San Francisco Police Department accepts controlled and non-controlled drugs as well. The committee was advised that the costs for the San Francisco program are approximately \$250,000 a year, which includes the bins, medical waste hauler and disposal fees.

The program in Los Angeles also uses drop-off bins and was initiated as a way to reduce crime and illicit drug use as well as to prevent these medications from getting into the environment.

Discussion

Dr. Castellblanch commented that it is unfortunate that the DEA Drug Take Back Day it is not a more regular event.

Ms. Veale asked if the San Francisco or Los Angeles program was better. Dr. Gutierrez commented that the San Francisco program was organized well.

Ms. Herold commented that the board is waiting for the DEA to take action on drug take back.

c. Summary of Request from Da Vita Rx for Discussion Regarding Prescription Drugs Dispensed to Renal Clinics for Administration to Patients

Discussion

This item was moved to the January board meeting.

d. Review and Discussion of Federal Government Accountability Office Report on the Difficulties of Regulating Internet Pharmacies

Relevant Statutes

Business and Professions Code section 4067 sets forth the requirements for dispensing internet prescriptions and establishes sanctions of up to \$25,000 per prescription for pharmacies that fill prescriptions where there is no underlying prescriber-patient relationship.

Background

The Federal Government Accountability Office (GAO) issued a report on July 8, 2013 which focused on the difficulties of regulating rogue internet pharmacies that are often complex, global operations composed of thousands of related websites. The report found that, despite challenges, state and federal agencies have taken actions to combat and disrupt internet pharmacy operations through convictions, asset seizure and public education.

This practice was the subject of multiple investigations in the early 2010s by board investigators, and more than 20 pharmacies and their pharmacists-in-charge were fined large amounts for filling such prescriptions (the board is empowered by the California Business and Professions Code to issue citations of \$25,000 per prescription where there is no valid prescription). In the last few months, the board has again identified several pharmacies filling such prescriptions for internet website operators.

In an attempt to combat these sites, the National Association of Boards of Pharmacy (NABP) sought formal approval last year to be able to approve anyone using the general top level domain (gTLD) of .pharmacy. Generic top level domains are the suffix part of a Web site address (e.g., .com, .org, .edu). According to NABP, which monitors Web sites selling prescription drugs among its various programs, 97 percent of the 10,300 Internet drug outlets it has reviewed are out of compliance with U.S. pharmacy laws and practice standards established to protect patients. 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 intent is to have the parameters for the .pharmacy gTLD in place by the end of 2013.

Previous Committee Discussion

Mr. Room clarified that there were two issues; 1) international internet pharmacies; and 2) internet providers (domain) that are being used and have relationships with brick and mortar pharmacies. The board doesn't have any jurisdiction over either of these entities.

Discussion

Ms. Veale asked if the board has jurisdiction over the internet sites that sell the drugs. Mr. Room responded that the board has jurisdiction over the pharmacies that are supplying the drugs for the internet sites.

e. Role of a Pharmacist's Corresponding Responsibility in the Dispensing of Controlled Substances

Relevant Statutes

Business and Professions Code Section 4306.5 specifies that failure to exercise corresponding responsibility with regard to dispensing or furnishing controlled substances, etc. is unprofessional conduct.

Health and Safety Code Section 11153 provides that corresponding responsibility rests with a pharmacist who fills a prescription.

Background

During the July 2013 Board Meeting, the board adopted a precedential decision involving a pharmacist's corresponding responsibility. Mr. Room provided an overview of the precedential decision and the violations that occurred as it related to corresponding responsibility of a pharmacy and pharmacist.

Discussion

Mr. Room commented that at the September 23, 2013 Medical Board Meeting the board made it clear that doctors would be getting questions from pharmacists if they had concerns about a prescription and if the doctor would not answer the questions then the pharmacist would not fill the prescription.

Dr. Castellblanch asked staff to put the summary of the precedential decision on the board's website.

f. First Quarterly Report on the Committee's Goals 2013/14

The first quarter report of the Committee's Goals were provided in the meeting materials. Regrettably the board is not meeting its success indicators for its enforcement related activities. This is in part because of a number of vacancies within the office as well as the training of new

inspector staff that has occurred over the past two years, when the board received a significant number of new staff. As we continue to focus our efforts on completing the oldest cases as well as fill vacant positions, we anticipate gradual improvement in all areas.

Discussion

No comments from the board or from the public.

g. Enforcement Statistics for July 2013 – September 2013

The enforcement workload statistics for the first quarter as well as SB 1441 Program Statistics were provided in the meeting materials. This quarter the board opened 695 new investigations and completed 1037. The board currently has 1827 investigations pending. The board has issued 92 Letters of Admonishment, 702 Citations and Fines and referred 119 cases to the Office of the Attorney General. The board has secured discipline on 36 licenses including 13 revocations and 6 voluntary surrenders. The board also secured two Interim Suspension Orders, five Penal Code 23 restrictions and issued one cease and desist order.

Discussion

There were no comments from the board or from the public on agenda item “g.” President Weisser opened public comment on previous enforcement agenda items.

Mariah Montgomery, from Change To Win, summarized their report and highlighted the organization’s concerns for patient confidentiality and increased pharmacist interruption with the new Walgreens model. Ms. Montgomery also reported that Senator Ed Markey, of Massachusetts, has concerns with the Walgreens model and has sent a letter to Walgreens seeking clarification on the model.

Dr. Castellblanch noted that it is important for the board to consider that Senator Markey has expressed concerns with the model and asked that the Enforcement Committee review the model at a future meeting.

Mandy Lee, from California Retailers Association, expressed the CRA’s support for the Walgreens model.

Victor Law commented that the new model may create a liability for Walgreens.

Dr. Gutierrez stated that she supports the use of technology in pharmacy.

Al Carter, from Walgreens, provided an invitation to the board members to come visit any of their locations. Mr. Carter commented that the problems with the model outlined in the Change To Win report were the result of deviations from Walgreens’ procedures and noted that Walgreens is working with the locations to ensure they fix any issues with the system. Mr. Carter added that there are already small independent pharmacies who are using a similar model.

Dr. Gutierrez asked if a Walgreens pharmacist has a problem with the new model do they have a choice to participate. Mr. Carter responded that the pharmacist could transfer to another store or they would modify their schedule so that they would be one of two pharmacists on duty so they could work behind the counter.

Dr. Gutierrez asked how the pharmacists have been responding to the new model so far. Mr. Carter responded that it is a change so it takes getting used to, but once they do change they prefer the model.

Ms. Hackworth asked if the independent pharmacies Mr. Carter referred to are operating in California. Mr. Carter answered that there are two in California.

Dr. Wong commented the he feels that the new model puts undue hardship and additional distractions on a single pharmacist and asked at what prescription count a second pharmacist would be brought in. Mr. Carter answered that stores with larger volumes would have a second pharmacist on duty and Walgreens feels that the new model actually eliminates many distractions.

Mr. Law asked if Walgreens has done any studies on the number of prescription errors with the new model. Mr. Carter answered that the biggest prescription error for Walgreens is giving the wrong prescription to the wrong patient. The new model has technological enhancements designed to actually prevent this from occurring. Since implementing the new model, giving the wrong prescription to the wrong patient has decreased by 80%.

The board recessed for a break at 12:28 p.m. and resumed at 1:24 p.m

2. Compounding Matters

a. Update on California Legislation on Sterile Compounding: Senate Bill 294 (Chapter 565, Statutes of 2013, Emmerson) and Assembly Bill 1045 (Chapter 302, Statutes of 2013, Quirk-Silva)

Background

This year the board sponsored legislation following two large-scale public health emergencies in which contaminated products compounded by two out-of-state pharmacies were shipped nationwide. Senator Emmerson authored SB 294 for the board.

Senate Bill 294 (Chapter 565, Statutes of 2013) 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 and dispensing into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy

license – following a board-performed inspection – from this board. It will also eliminate accreditation by designated agencies as an alternative to licensure.

Assembly Member Quirk-Silva authored AB 1045 (Chapter 302, Statutes of 2013) that amends existing California law to revoke a nonresident pharmacy's license by operation of law if its pharmacy license is suspended or revoked in the pharmacy's home state. It will also require resident and nonresident pharmacies that issue a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber or patient of the recalled drug and 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 this state.

Discussion

Dr. Gutierrez reported that the governor signed both measures.

No comments from the board or from the public.

b. Update on Proposed Federal Legislation on Compounding

Background

Currently there is pending federal legislation that would establish new federal requirements for pharmacies that compound sterile medications, particularly for those pharmacies that compound medications in large quantities and without a patient-specific prescription. However, the status of enactment of such a proposal at this time is still pending – the bill is awaiting a vote in the Senate, which may take place in the next few weeks.

Also, in early August the GAO issued a report on compounding by pharmacies. The report can also be accessed on the GAO's website at: <http://www.gao.gov/assets/660/656388.pdf>

Discussion

Dr. Gutierrez reported that in the last week of September 2013 draft legislation was passed by the House to establish additional federal compounding requirements and to establish requirements to establish a track and trace system (and preempting California's requirements) to secure the nation's pharmaceutical supply.

No comments from the board or from the public.

c. Subcommittee Recommendations to Amend California's Compounding Regulations in Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.

Relevant Regulations

Article 4.5 of Title 16 California Code of Regulations Sections 1735 et seq. establishes the regulations for compounding in a pharmacy.

Article 7 of Title 16 California Code of Regulations Sections 1751 et seq. establishes the regulations for sterile injectable compounding in a pharmacy.

Background

As part of the board's efforts to strengthen the regulation and enforcement of pharmacies that compound sterile drug products, the board in 2012 established a Compounding Subcommittee for the purpose of conducting an in-depth review of the board's regulations of sterile compounding pharmacies. At the December 2012 Board Meeting, President Weisser appointed Dr. Gutierrez and Dr. Kajioka to serve on the committee.

The subcommittee first met in January 2013, which resulted in the subcommittee's request that staff prepare a comparison of the board's current regulations versus the compounding requirements of USP 797. This 'crosswalk' comparison was provided and discussed at the April 2013 Board Meeting and June 2013 Enforcement and Compounding Meeting, a committee that was created by merging the Enforcement Committee and Compounding Subcommittee.

Previous Committee Discussion

The committee discussed the draft regulation proposal and made several changes. The committee evaluated each proposal and either accepted or requested that the workgroup re-evaluate the suggested amendments.

Previous Committee Action/Recommendation

Review and take action on the proposed changes to amend California's Compounding Regulations in Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.

Recent Update

A workgroup of board staff and two board members met on October 4 and October 21, 2013, to incorporate the changes made during the committee meeting, and to reevaluate portions identified by the full committee.

Discussion

Ms. Shellans asked Dr. Gutierrez to outline the changes that the work group made to the proposed regulation language.

Dr. Gutierrez said that the workgroup modified some of the compounding definitions to be more in line with USP 797 and added the definitions for cold freezer and room temperature. They also added the definition for gloved fingertip sampling, added a section on record keeping of compounded drug products, added requirements for sterile compounding attire and

modified the section on validation. The “beyond use dating” section was also modified to be more in line with USP 797.

Jonathan Nelson, from CSHP, commented that after CSHP sent out the language to their members they received numerous comments. Mr. Nelson asked that before the board takes action on this item the subcommittee reconvene to allow for more comments from the public.

Kate Palmer, from Cedar Sinai Medical Center, also requested that the board not take action on this item at this meeting.

The pharmacy director from Providence Little Company of Mary Medical Center -Torrance, voiced his concerns with the proposed language and asked the board to allow for more time to receive comments.

Motion: Return to subcommittee for further discussion and vetting.

M/S: Lippe/Castellblanch

Mr. Room said that the board could initiate the rulemaking so that comments could be received as part of the rulemaking process.

Ms. Shellans said that the board should keep in mind that their goal is to get this regulation in place in a timely manner and initiating the rulemaking would accomplish this.

Ms. Wheat said that she would prefer to initiate the rulemaking rather than sending it back to the subcommittee.

Motion withdrawn

Dr. Gray, from CSHP, reminded the board of the importance of this rulemaking to Californians and encouraged open discussion on any modifications.

Motion: Initiate the rulemaking to Amend California’s Compounding Regulations in Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq. and authorize the executive officer to take all steps necessary to initiate that process.

M/S: Law/Veale

Approve: 8 Oppose: 2 Abstain: 0

d. Recalls of Compounded Drugs Throughout the United States

The board continues to use its subscriber alert system to alert licensees and other subscribers of cease and desist orders that have been issued, and advise licensees of drug recalls, including recalls of compounded drug products.

The meeting materials included a list of recalls issued between May 21, 2013 and October 21, 2013.

Discussion

No comments from the board or from the public.

3. Future Meeting Dates

Dr. Gutierrez said the next committee meeting would be on December 3, 2013 in Los Angeles.

Discussion

No comments from the board or from the public.

XI. E-PEDIGREE COMMITTEE REPORT

In Chairperson Kajioka's absence Shirley Wheat gave the report of the E-Pedigree Committee Meeting Held September 26, 2013

a. Discussion and Possible Action Regarding 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)

Note: Tappan returned at 2:25 p.m.

Background

At the February 2013 Board Meeting, the board held a regulation hearing and approved regulation requirements for the following items (the specific language is provided in Attachment B):

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 was initiated on September 21, 2012. Following the adoption of the rulemaking, the file was reviewed and approved by the Department of Consumer Affairs; the Business, Consumer Services, and Housing Agency; and the Department of Finance. On September 13, 2013, the file was transmitted to the Office of Administrative Law (OAL) for final review. OAL's deadline to review the file is October 25, 2013.

Board staff was advised by the Office of Administrative Law on October 18, 2013, that OAL will be disapproving the file because the file does not sufficiently address the fiscal and economic impact assessment of the regulation. Specifically, the Board's Form 399 and its assessment of the impact the regulation has regarding the creation or elimination of jobs within the state; the creation of new businesses or the elimination of existing businesses within the state; and the expansion of businesses currently doing business within the state (see Government Code Section 11346.3(b)(1)). Staff understands that, outside of this issue, there are no other substantive issues that need to be addressed with the file. The regulation language itself should not need to be adopted.

Following disapproval by OAL, the board will have 120 days to address any deficiency identified in OAL's disapproval decision. Based on feedback, staff is preparing an Addendum to the Initial Statement of Reasons, as well as an Addendum to the Economic Impact Analysis. Both addendums will be noticed for a 15-day public comment period. If comments are received, the board would need to review and accept or reject comments related to the information that is noticed prior to resubmitting the file to OAL (within the 120-day period).

Discussion

Dr. Castellblanch asked if the economic impact assessment problem will be a problem for future rulemaking. Ms. Shellans said that OAL had no problem with the proposed text, they just wanted the board to provide more data on the economic impact. Ms. Shellans added that this is an issue that many boards are dealing with.

Motion: Direct staff to prepare an Addendum to the Initial Statement of Reasons and an Addendum to the Economic Impact Analysis to address the necessity issues and to expand on the impact of the regulation with respect to the creation or elimination of jobs within the state; the creation of new businesses or the elimination of existing businesses within the state; and the expansion of businesses currently doing business within the state, and issue these addendums for a 15-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law and delegate to the Executive

Officer the authority to make any non-substantive changes to the rulemaking before filing the rulemaking with the Office of Administrative Law prior to the expiration of the 120-day period.

M/S: Wheat/Veale

Support: 10 Oppose: 0 Abstain: 1

b. Update on Proposed Regulation on Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3

Background

Since July 2012, the board has several times released written requests for specific information helpful to developing 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 on inference was released for discussion purposes to develop the regulation text. 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.

During the June meeting, the committee again considered inference requirements. There was general discussion about the written comments received on the draft requirements (intended for discussion) that were prepared by staff. As recommended by staff, the matter was taken to the July Board Meeting so that the board could determine the direction for the regulation in advance of the September E-Pedigree Meeting.

At the July 2013 Board Meeting, the board made the following policy decisions related to Inference:

- From a manufacturer to a wholesaler, inference could be applied to a sealed, homogeneous case which contains only one dangerous drug product, where the case remains unopened by the wholesaler and the package shows no signs of tampering (there is no requirement for trusted trading partners).
- When a sealed case is opened, its entire contents must be scanned immediately to validate inference.
- When discrepancies are discovered in the data or the product, they must be reported within three (3) business days.

Previous Committee Discussion

The committee had considerable discussion regarding the proposed language, including discussions involving the conditions under which inference would be allowed and to what extent. This discussion is detailed in the September meeting minutes. The committee also discussed under what, if any, additional circumstances should inference be applied. Although the committee did not take action on this item, discussion from committee members resulted in the recommendation to the board that additional discussion on the elements of inference is needed and should be scheduled unless the pending federal legislation passes.

Chairperson Kajioka asked the public to submit any comments they have in writing. To date, no comments have been submitted since the September e-Pedigree Meeting.

A copy of the draft regulation language discussed during the committee meeting was provided in the meeting materials.

Discussion

Ms. Herold said that being 14 months from implementation, the board needs to encourage public comments so that they can initiate the rulemaking. Ms. Wheat said that the committee's goal was to have a final recommendation for the board after its December 10, 2013 meeting.

Angela Blanchard, from HDMA, said HDMA would like to see flexibility as to when a case can be scanned and asked the board to allow for more time for public comment prior to initiating the rulemaking. President Weisser and Ms. Wheat asked HDMA to submit their comments in writing.

Ron Bone, from McKesson, invited the board members to come to a McKesson facility to view the distribution process.

Mr. Room and Ms. Wheat discussed the scanning requirements in the proposed language.

Ms. Mary Staples, with the National Association of Chain Drug Stores, stated that at the last committee meeting she had provided oral comments and she plans on submitting additional comments in writing prior to the December committee meeting.

c. Discussion Concerning Possible Regulation Requirements on the Certification Process to Comply with California's E-Pedigree Law

Background

At the March Enforcement and E-Pedigree Meeting, the board distributed possible regulation language for the certification of each sale and purchase into the e-pedigree record. Included

in the draft was proposed language related to the board's access to e-pedigree information during inspections.

Written comments submitted following the March meeting were considered along with a discussion draft at the committee's June 2013 meeting. Thereafter, the board discussed the policy related to the certification of e pedigree information at the July Board Meeting.

Previous Committee Discussion

The committee was provided with a brief explanation of the certification language and well as the basic concept of the regulation, to require each party in the supply chain to certify delivery and receipt of drugs. The committee did not discuss this proposal in great detail but received public comment that included that the new version of the regulation was much improved. Public comment also suggested that the board may want to define "responsible party" for purposes of the regulation. Chairperson Kajioka asked the public to submit any comments they have in writing to allow for a more detailed discussion at the future December committee meeting. The committee did not take action on this item.

A copy of the draft regulation language discussed by the committee was provided in the meeting materials.

Discussion

No comments from the board or from the public.

d. Update on the Status of Proposed Regulations for the Use of Drop Shipments in an E-Pedigree System Pursuant to California Business and Professions Code Section 4163.1

Background

At the July 2013 Board Meeting, the board approved proposed language to add Section 1747.2 to Title 16 California Code of Regulations to specify the process by which drop shipments will be utilized in e-pedigree. The board noticed this rulemaking for public comment on September 23, 2013, and the 45-day public comment period will conclude on October 28, 2013.

At this board meeting, the board will conduct a regulation hearing on the matter on October 29, 2013. As of October 24, 2013, the board has received one written comment during the comment period. If additional comments are received, the comments will be brought to the board meeting. A copy of the comment received was provided in the meeting materials.

The language noticed for public comment is:

Proposal to Add a New Section 1747.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1747.2 Drop Shipments.

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, 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, in which case the manufacturer shall convey the pedigree 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.

Reference: Sections 4034, 4037, 4163, 4163.1, 4170, 4180, and 4190, Business and Professions Code.

Previous Committee Discussion

There was not committee discussion or action on this item.

Discussion

This will be discussed during the regulation hearing at 4 p.m.

e. Future Meeting Dates

Ms. Wheat reported that the next committee meeting will be on December 10, 2013.

Discussion

Ms. Shellans asked if the meeting would be held in the bay area. Ms. Herold answered that that was the goal, however budget constraints may require it to be in Sacramento.

The board recessed into closed session at 3:30 p.m. and resumed at 4:03 p.m.

XII. REGULATION HEARING

4:03 p.m.

Regulation Hearing Regarding a Proposal to Add Title 16 California Code of Regulations Section 1747.2 Regarding Electronic Pedigree Requirements for Drop Shipments.

Mr. Greg Lippe conducted the regulation hearing as follows.

This hearing is to consider the board's proposal to Amend Title 16, California Code of Regulations, Section 1747.2 related to the e-pedigree requirements for drop shipment.

For the record, the date is October 29, 2013, and the time is 4:03 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? Note: There were no questions from the board or from the public on the proceedings?

I will now call on those persons wishing to testify regarding the board's proposed action.

Discussion

Mr. John Valencia, representing Millennium Pharmaceuticals Inc., commented that his organization supported the proposed regulation as drafted.

Mary Staples, from the National Association of Chain Drug Stores, commented that the association supports the concept of drop shipment. The association asked that the board clarify the requirements for instances when the product doesn't go directly from the manufacturer to the pharmacy, but rather is sent by the manufacturer to the manufacturer's third party entity and then is sent to the pharmacy. The association also asked the board to clarify if transactions between wholesalers and pharmacies would be considered inter-company transfers.

Mandi Lee, from the California Retailers Association, commented that CRA supports the concept of drop shipments. CRA asks that the board clarify what happens when there is an intercept between the drugs being shipped from the manufacturer to pharmacies, as

pharmacies do not take ownership of the drugs until they are received at the pharmacy location.

Mr. Lippe closed the hearing at 4:13 p.m.

XIII. 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 1747.2 REGARDING Electronic Pedigree Requirements for Drop Shipments

Discussion

Ms. Shellans asked the board to consider the comments received on the proposed regulation text to determine if changes needed to be made to the language. Ms. Shellans added that she did not have any concerns with the language as proposed and asked Mr. Room to provide feedback. Mr. Room stated that while the National Association of Chain Drug Stores' concerns may be valid, he believes they are outside what the statute would permit the board to do in terms of regulating drop shipments.

Motion: 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 1747.2 as noticed on September 13, 2013.

M/S: Lippe/ Hackworth

Support: 11 Oppose: 0 Abstain: 0

ADJOURNMENT FOR THE DAY

4:22 p.m.

WEDNESDAY, OCTOBER 30, 2013

President Weisser conducted a roll call. Board members present: Gregg Lippe, Rosalyn Hackworth, Debbie Veale, Albert Wong, Shirley Wheat, Ramon Castellblanch, Amy Gutierrez, Lavanza Butler, Tappan Zee and Victor Law. Board members absent: Ryan Brooks and Randy Kajioka.

XVI. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

In Chairperson Brooks' absence President Weisser provided a report on the Communication and Public Education Committee meeting that was held on October 7, 2013

1. Report of the Communication and Public Education Committee Meeting Held October 7, 2013**a. Review and Discussion of the 42nd Annual Report of the Research Advisory Panel of California**

President Weisser reported that Patrick R. Finley, Pharm.D., is the board's appointment to the seven member advisory panel. Mr. Weisser referenced the copy of the 42nd Annual Report of the Research Advisory Panel of California (July, 2012) provided with the meeting materials. The committee recommended that Dr. Finley come to a future meeting of the committee or board to tell them more about the Advisory Panel's activities and to share additional information on studies that may be of interest to the board or related to the pharmacy profession.

Discussion

No comments from the board or from the public

b. Discussion on Requests from California Pharmacies for Exemption from Title 16 California Code of Regulations Section 1707.6(e) to Use Alternate Notice of Interpreter Availability Posters

President Weisser provided that existing Board regulation requires pharmacies to prominently post the "Notice to Consumers" required by 16 CCR Section 1707.6. In addition, Section 1707.6(c) requires every pharmacy to post or provide a "point to your language" notice so that consumers are aware that interpreter services will be provided to them at no cost. That subdivision specifies that the pharmacy shall use the standardized notice provided by the Board unless the pharmacy has received prior approval of another format or display methodology. The board has delegated to the Communication and Public Education Committee the authority to act on all requests to use another format or display methodology of these posters.

At the October 7, 2013 meeting the committee considered and denied two requests to use an alternate format Notice of Interpreter Availability. One request was from Costco, and the other from Walmart Stores (for both Walmart and Sams Club pharmacies). While each request specified additional languages (in addition to the twelve mandated by board regulation),

neither contained the specific language/phrasing that is required by 16 California Code of Regulations Section 1707.6(c): "Point to your language. Interpreter services will be provided to you upon request at no cost." Copies of the alternate format notices considered by the committee are provided in Attachment 2. In addition, the committee would like to see any alternate format notice submitted for the committee's approval to include the statement "This notice is required to be posted by the California Board of Pharmacy."

Board staff drafted a form that can be used for future requests for the committee's consideration. Staff will add to that request form a reminder that any alternative format notice must contain the language required by 1707.6(c).

Discussion

No comments from the board or from the public.

c. Update on the Status of the Updated Emergency Contraception Fact Sheet, as Required by Title 16, California Code of Regulations Section 1707.5(e)

President Weisser reported that the board is in the process of securing bids to have the Emergency Contraception Fact Sheet (required by 16 CCR Section 1746(b)) translated into six languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. These are the same six languages in which the board makes available its "Notice to Consumers" posters (upon request, or download). When available, the Fact Sheets will be available upon request, and will also be available for download from the board's web site. A copy of the updated Emergency Contraception Fact Sheet (English version) was provided in the meeting materials.

Discussion

No comments from the board or from the public.

d. Results of Assessment of California's Patient-Centered Labeling Requirements as Required by Title 16 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. The committee reviewed the factors considered when developing the current regulatory requirements, as well as the board's efforts to date to review the patient-centered requirements, which was initiated by the committee in April 2013. The committee discussed the USP guidelines published in November 2012, noting the close resemblance to the board's requirements, and Ms. Herold indicated that staff continues to search for medical literacy research regarding standardized directions for use, noting the goal of such a schedule is to increase patient understanding, adherence to medication instructions and improving health

outcomes. Board staff has been trying to build support among groups by highlighting the benefits of utilizing standardized directions for use, and that there may be educational opportunities to work with the prescribing boards to this end.

One of the recommendations in the NCPDP White Paper is to implement the use of universal medication instructions in an effort to help get the e-prescribing directions for use standardized. In its surveys, the board has looked at the use of font sizes, how interpretive services requirements are being implemented, patient satisfaction (a general framework of what patients are thinking) – noting they want larger font, and the purpose on the label.

At the October 7, 2013 meeting the committee discussed the distribution of the surveys, noting that CPEHN had the survey translated and distributed among limited English and other groups. Results of a recent survey conducted by the board are provided in the meeting materials.

Discussion

President Weisser reported that at the October 7, 2013 Committee Meeting, as part of the review requirement, the committee discussed what should be considered “patient-centered.” Regulation currently requires that “patient-centered” items (listed below) shall be clustered into one area of the label that comprises at least 50 percent of the label:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

The committee recommended that these four items, and only these four items, shall be clustered into the one area of the label that comprises at least 50 percent of the label in at least 10 point font (or 12 point if requested).

President Weisser provided that the committee also discussed whether changes should be made to 1707.5(a)(1)(B) regarding the “name of the drug and strength of the drug.” The committee recommended that Section 1707.5(a)(1)(B) be modified to remove the requirement that the manufacturer be in the “patient-centered” clustered items. They also recommended amending the language where a generic is dispensed to say “generic for” (the trade name). Staff worked with counsel to develop this language.

At the October 7, 2013 committee meeting, the committee also discussed if purpose or condition should be on the patient centered portion of the label. President Weisser reported that there was wide consensus among the committee and the public that the purpose or condition should be on the prescription label within the clustered patient-centered items. Currently the purpose is only required to be on the label if it is specified on the prescription. The committee directed staff to work with legal counsel to draft language to amend Section

1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items.

The committee acknowledged the Governor's recent veto of legislation (SB 205) that sought to mandate a 12-point font on prescription labels. The committee discussed the current requirements at the October 7, 2013 meeting. President Weisser reported that staff summarized surveys, which indicated that pharmacies, by a wide preponderance are using 12 point font as the primary font on prescription labels. The committee noted there are many reports, research and legislative efforts to increase the font size on a prescription label. It was the consensus of the committee that the regulation should be modified to require a minimum 12 point font. The committee recommended modifying Section 1707.5(a)(1) to read as follows:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in ~~at least a 10-point sans serif typeface or, if requested by the consumer, at least a~~ 12-point sans serif typeface, and listed in the following order:

President Weisser and staff counsel asked that each of the committee recommendations be discussed and voted on separately.

Mr. Zee asked if this should be handled by the Legislation and Regulation Committee. It was confirmed that this review was the duty of the Communication and Public Education Committee.

Ms. Herold noted that in the Governor's veto message for SB 205 he stated that rather than mandate a change to prescription labels he would like to wait for the Board of Pharmacy to finish its review of its patient centered label regulation.

Ms. Veale commented that she has no issue with the 12 point font, however she expressed concern that requiring the patient centered portion to be 50 percent of the label would not leave enough room for other information, such as number of refills. President Weisser commented that in the surveys he did not see that there was a concern with refills being in too small of font. Ms. Herold added that she does recall anyone saying the four items that are considered "patient centered" are not the most important information for patients and caregivers. The goal has been to keep the portion of the label containing those four items as uncluttered as possible. Ms. Herold added that overall the feedback received by the board mainly focused on making the font for the patient centered items as large as possible.

Mr. Lippe commented that an issue that had been previously discussed is what to do if the directions for use are very long. He asked if that had been resolved. Ms. Herold responded that Dr. Wong brought in samples of labels he uses in his pharmacy which have long directions for use that he was able to make fit.

Ms. Wheat commented that she is opposed to the committee recommendations because the sample size that of the surveys received was so small that the board should not take action based on the results. Ms. Wheat added that she does not feel the board needs to change the law to require 12 point font as patients are able to get 12 point font if they request it.

Ms. Shellans asked the board to vote on each committee recommendation and save discussion on font size until that recommendation is up for vote.

Mr. Law commented that he is uncertain if the board really needs to assign a specific percentage requirement for the patient centered label.

Dr. Castellblanch asked that the board discuss and vote on each recommendation separately to avoid confusion.

Dr. Wong commented that the market will regulate itself so the board does not have to create regulations that may perhaps be unnecessary.

Ms. Herold stated that this regulation was very controversial from the beginning and that is why the board agreed to review the regulation in two years. She added that the U.S. Pharmacopeia has created guidelines that almost exactly mirror the board's regulations. The board needs to recognize that the public *strongly* requested 12 point font. Ms. Herold added that the board does not have to decide on everything at this meeting, if additional items need to be considered, such as the 50 percent requirement, it can be placed on a future agenda.

Ms. Wheat commented that the law is working as it is, people are asking 12 point font and they are getting it. She added that the board is not required to change it just because people ask.

President Weisser and Ms. Herold reminded the board and the public that they are taking each committee recommendation in order and, currently, the board would be voting on the following recommendation:

Amend Section 1707.5(a)(1) to read as follows, to specify that only the four items listed in that paragraph are to be within the patient-centered clustered area.

(1) Each of the following items, **and only those four items**, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

Manly Lee, from the California Retailer's Association, commented that the board seemed to be discussing multiple recommendations at once and asked for clarification on what the board was voting to change. President Weisser responded that currently the board is voting on adding the phrase "and only those four items" to the regulation. Ms. Shellans noted that there would not be any adoption at this meeting, the board would just be deciding if they want to move in that direction and possibly initiate the rulemaking.

Ms. Herold noted that the board has seen other items (such as address) be placed in the patient centered section of the label. This committee recommendation clarifies that *only* those four items can be in that section of the label.

Mr. Castellblanch stated that he thought that if the board voted on the committee recommendations it would move to rulemaking today. He added that many people have shown up to this meeting specifically to give comments on patient centered labels.

Mandy Lee, from the California Retailers Association, commented that prescription bottle labels are one of the most over-regulated pieces in pharmacy and she cautioned the board from adding additional requirements.

Committee Recommendation: Amend Section 1707.5(a)(1) to read as follows, to specify that only the four items listed in that paragraph are to be within the patient-centered clustered area.

(1) Each of the following items, **and only those four items**, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

Support: 10 Oppose: 1 Abstain: 0

President Weisser moved the discussion along to the next committee recommendation, which was the removal of the requirement that the manufacturer be in the "patient-centered" clustered items (knowing the manufacturer name will be elsewhere on the label); and amending the language where a generic is dispensed to say "generic for" (the trade name).

Ms. Herold commented that at a previous meeting someone gave a very clear example of a patient who had been given a brand name drug and they already had a generic at home. The patient did not realize it was the same medication and took both. The amendment would address that issue.

Mr. Room pointed out that the language that was given to the board did not include the “generic for” section, so it would need to be added before a vote could be taken.

Mr. Zee commented that due to some of the language being missing he would like to table the motion until the board could receive complete language clearly showing what was being added and removed.

Dr. Castellblanch asked if Mr. Zee wanted to table just this particular committee recommendation or the entire patient centered label discussion. Mr. Zee responded that he would like to table the entire patient centered discussion for a future meeting.

Mr. Castellblanch commented that the board noticed to the public that the patient centered labels would be discussed at this meeting. He expressed his opinion that it is the board’s responsibility to take action on items that have been properly noticed.

Mandy Lee commented that she would support Mr. Zee’s motion to table the entire discussion.

Carrie Sanders, from the Pan Ethnic Health Network, commented she had traveled to the meeting from the Bay Area specifically for the patient centered label discussion.

Donna Hernandez, from the California Alliance of Retired Americans, commented that many of their members traveled a long way to be at the meeting and she asked the board to continue their discussion.

Jonathan Nelson, from the California Society of Health System Pharmacists, supported Mr. Zee’s motion.

Dr. Castellblanch again expressed his desire for the board to continue with the discussion rather than tabling it for future meetings.

Ms. Wheat added that she supported Mr. Zee’s motion to table the entire patient centered label discussion until proper language could be provided at a future meeting.

Motion: Table the discussion regarding the entire patient centered label regulation because of the problems and inconsistencies in the language provided to the board.

M/S: Zee/Wheat

Support: 4 Oppose: 7 Abstain: 0

As the motion to table the discussion failed, Mr. Room reported that he had been able to create language for the board and public to view on the projector screen. While the language was being put on the projector he recommended that the board move to the next committee recommendation – 12 point font.

President Weisser moved the discussion to the next committee recommendation: Each item shall be printed in 12-point sans serif typeface.

Dr. Castellblanch commented that the U.S. Pharmacopeia has created a national standard of 12 point font and the public has been very vocal in their support of 12 point font.

Ms. Wheat commented that she feels the law currently allows for flexibility in choosing whether to use 10 or 12 point font and she would not support the motion to require 12 point font only.

Ms. Don Braun Seema, from the California Alliance for Retired Americans, expressed her support for requiring 12 point font.

Ms. Pat Stanyo, from the California Alliance for Retired Americans, commented that she supports the committee recommendation to require 12 point font as many people do not realize that currently they have to request it if they need it.

Donna Hernandez, from the California Alliance for Retired Americans, expressed her support for 12 point font as well as having the purpose on the label.

Lorenzo Reals, from California Alliance for Retired Americans, commented that some of his friends have gone to pharmacies that refuse to provide larger font, so the 12 point requirement is necessary. President Weisser responded that any time someone goes into a pharmacy and finds that they are violating pharmacy law the patient should file a complaint so the board can investigate.

A representative from Peoples Pharmacy commented that fitting all the ingredients for a compounded medication in 12 point font would be nearly impossible.

Sharron Nacamoto, from California Alliance for Retired Americans, commented that she supports the 12 point font.

Al Carter, from Walgreens, asked if the “generic for” would need to be in 12 point font. Ms. Herold responded that it would not be.

Carrie Sanders, from the Pan Ethnic Health Network, stated that the network strongly supports the use of 12 point font.

Mandy Lee, from the California Retailers Association, asked the board to consider allowing a year or two time period for all of their members to get in compliance with the 12 point font requirement if it passed today. Mr. Zee asked how long the members would need. Ms. Lee commented that they would need a year or two. Ms. Herold responded that even if the board finalized the regulation today the earliest they could get the regulation in place would be at least a year, if not longer.

Committee Recommendation: Modify Section 1707.5(a)(1) to read as follows:

(1) Each of the following items, and only those four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in ~~at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point~~ sans serif typeface, and listed in the following order:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

Support: 10

Oppose: 1

Abstain: 0

Dr. Gutierrez thanked the public for attending the meeting and providing feedback.

President Weisser indicated that the board would now move back to the previous committee recommendation to modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say “generic for” (the trade name).

Mr. Room had been able to finalize the language on the “generic for” section of the language. The language Mr. Room created was displayed on the projector screen so the board and the public could view it. The language was displayed as follows:

Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means ~~either~~ the manufacturer’s trade name of the drug or, if a generic is dispensed, or the generic name of the ~~manufacturer drug and a parenthetical containing~~ “generic for” and the trade name of the drug.

Mr. Lippe commented that the pharmacy he goes to already does this.

Ms. Veale expressed her opinion that manufacturer is a very important piece of information asked that the public provide feedback if the removal of the manufacturer from the patient centered label would be a problem.

Dr. Gutierrez clarified that the manufacturer would still be on the label, it would just not be in the patient centered portion. This was confirmed.

Dr. Wong commented that he feels the manufacture should be on the patient centered section of the label, right next to the drug name.

Donna Hernandez, from the California Alliance for Retired Americans, asked to clarify if “manufacturer” means the company who is making the drug, not the generic name of the drug. Mr. Room confirmed. Ms. Hernandez replied that she does not think manufacturer is important enough to be in the patient centered portion of the label as long as the generic name was there.

Lorenzo Reals, from California Alliance for Retired Americans, commented that he does not feel the language needs to be changed at all.

Dennis McAllister, from Express Scripts, agreed with Mr. Reals that the current language is good enough.

Carrie Sanders, from the Pan Ethnic Health Network, expressed her support of listing both the brand name and generic name.

Al Carter, from Walgreens, stated that manufacturer should remain in the same location on the label.

Megan Harwood, from San Gabriel Medical Pharmacy, commented that listing the manufacturer right next to the drug name may actually confuse the public.

Mr. Room clarified that this committee recommendation would actually accomplish two things. First, it would require that you provide the trade name of the drug if you are substituting a generic. Second, it eliminates the requirement for the manufacturer name to be included in the cluster on the patient centered portion of the label. The manufacturer’s name would still be provided in another location of the label. President Weisser added that the “generic for” information *would* be in the patient centered portion of the label.

Ms. Wheat asked to clarify if the law currently requires the use of both the manufacturer name and the generic name. Mr. Room responded that currently, if you use a generic, you have to list the manufacturer; if you do not use a generic you do not have to list the manufacturer. Ms. Wheat asked if currently you have to list the brand name if you use a generic. Mr. Room responded that currently you are *not* required to list both the brand name and generic name.

Dr. Wong asked if a doctor writes the prescription for the generic does the label need to list both the brand name and generic name. Mr. Room responded that the proposed language would require both to be listed.

Mr. Wong asked if a pharmacist could list the manufacturer name as well as the generic and brand name. Mr. Room replied that the manufacturer name could not be in the patient centered portion of the label, it would have to be provided in another section of the label.

Mr. Wong asked why the board feels it is a problem to list the manufacturer in the patient centered portion of the label. Mr. Room responded that as the board moved toward requiring

12 point font, the idea was to eliminate any information that was not needed to avoid cluttering the patient centered portion. Ms. Herold added that the board also considered the value of the information to the patient, often time the manufacturer name is abbreviated and the patient has trouble understanding what the abbreviation means.

Jonathan Nelson, from the California Society for Health System Pharmacists, commented that the board should return this item to the committee to allow for further comments from the public.

Mandy Lee, from the California Retailers Association, agreed with Mr. Nelson's comments and again asked the board to allow for a one year buffer period once the rulemaking is finalized.

Ms. Veale asked to table this specific motion and to allow time for more comments from stakeholders. Ms. Herold provided that the regulation cannot move forward until the board votes on this item.

Dr. Gutierrez commented that it makes sense for the entire regulation to be modified and implemented at one time.

Motion: Table the motion to modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the "patient-centered" clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say "generic for" (the trade name).

M/S: Veale/Hackworth

Support: 8 **Oppose:** 3 **Abstain:** 0

Mr. Zee asked if the all of the changes to 1707.5 would be in one regulation package. Ms. Herold confirmed that all of the changes would be handled in one regulation.

Upon Mr. Lippe's request, Ms. Herold provided the board with an overview of the regulation process. Mr. Lippe commented that Mandy Lee's request for a one year buffer period after the regulation is finalized to allow time for implementation seemed reasonable and asked for a motion to be made to allow for it.

President Weisser clarified that in light of the motion being tabled, the recommendation to remove the requirement that the manufacturer be in the "patient-centered" clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say "generic for" (the trade name) would be sent back to the committee.

Mr. Room recommended that the committee recommendation to amend Section 1707.5(a)(1)(D) to allow the purpose or condition to be included in the patient-centered clustered items

also be sent back to the committee. President Weisser agreed that this item would be sent back to the committee.

e. Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5

As a result of the board's discussion, the board will not be initiating a rulemaking to amend Title 16 California Code of Regulations Section 1707.5 at this meeting.

f. Update on *The Script*

President Weisser reported that the next issue of *The Script* is being finalized and prepared for being posted online. Staff leaves of absences and other issues have delayed the publication, but it should be available by the end of the October.

g. Public Outreach Activities Conducted by the Board

President Weisser encouraged the board and the public to review the public outreach activities provided in the meeting materials.

h. Update on the Development of Committee Goals for 2012-2017 to Fulfill the Board's Strategic Plan

President Weisser noted that staff has suggested that at a future meeting, the committee augment its goals for the Strategic Plan.

The board recessed for break at 11:42 p.m. and resumed at 12:00 p.m.

2. Report of Prescription Medication Abuse Subcommittee Held October 7, 2013

Dr. Castellblanch provided the subcommittee Report as follows.

a. Discussion on Proposed Mission Statement for the Subcommittee

This subcommittee was formed to continue to explore ways to address the misuse and abuse of prescription medication, particularly of controlled substances. At the end of the forum, a list of possible "next steps" was mentioned in the closing ceremony. This list was provided in the meeting materials.

The subcommittee has various issue areas:

- Educate the public and licensees about the dangers of prescription drug abuse
- Collaborate with prescribing boards to promote and strengthen the sharing of information among practitioners (prescribers and dispensers)
- Promote the use of CURES by practitioners
- Continue to work with the Medical Board and other prescribing boards on topics in this area

Chair Castellblanch has suggested that a mission statement be developed for this committee. For reference, the mission and general goals of the board are provided below. The board has only one mission:

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacists care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.

Each of the five committees has general goals:

- Enforcement: Exercise oversight on all pharmacy and drug distribution activities
- Licensing: Ensure the qualifications of applicants and licensees advance the vision and mission of the Board of Pharmacy
- Communication and Public Education: Provide relevant information to consumers and licensees
- Organizational Development: Achieve regulatory efficiency, customer service and consumer protection

Previous Subcommittee Discussion

The committee discussed several elements to be incorporated into the mission statement including that the focus should be to promote the prevention and treatment of prescription drug abuse, particularly the abuse and misuse of controlled substances. The mission should focus its efforts on education directed to practitioners as well as the general public. The subcommittee will also focus efforts on education of various tools available to practitioners including use of the CURES system.

No action was taken on this item however staff was asked to refine language for a mission statement that will be discussed during the next subcommittee meeting.

Discussion

No comments from the board or from the public.

b. Review and Discussion of Statistics Documenting the Issue of Prescription Medication Abuse

Background

A number of references are pointing to the increasing incidents of controlled substances being misused by individuals.

Previous Subcommittee Discussion

The subcommittee was provided with an overview of drug abuse statistics including that California is one of the leading states for prescription drug abuse, particular the abuse of hydrocodone. The subcommittee was advised that board staff is seeing an increase in pharmacies filling prescriptions for what the DEA calls the “holy trinity” which is a combination of drugs including painkillers, muscle relaxants and anti-anxiety medications. The committee was also advised that the overuse and abuse of Adderall is another item that should be discussed by the subcommittee.

The committee discussed several publications that are highlighting the problem and referred to the National Institute on Drug Abuse article that highlights that there are patients who are not receiving adequate pain treatment however the number of people who are abusing prescription drugs is on the rise and that the Center for Disease Control is now calling it the “opioid epidemic.” The subcommittee also referenced an article in The American Journal of Public Health that indicates that opioids are a serious cause of addiction and the death rates have increased dramatically over the last few years, making it the second leading cause of accidental death in the United States. Dr. Castellblanch noted that so many prescription pain killers are being prescribed, that every man and woman in the United States would have a month supply every year.

The subcommittee also discussed that the Board and the Medical Board need to help lead the way in dealing with this issue and that it is up to medical professional to protect the public. Members also commented that people don’t think of pharmaceuticals as dangerous like they do street drugs.

The subcommittee did not take action on this item however; they will be receiving information on the initiatives members of the Health Distribution Management Association (HDMA) are developing. This information will be discussed at the next subcommittee meeting.

Discussion

No comments from the board or from the public.

c. Discussion of Joint Efforts with the Medical Board of California to Address and Educate Licensees and the Public about Prescription Medication Abuse

Background

Two years ago the board started working with the Medical Board as a result of a legislative proposal sponsored by the American Cancer Society who felt patients were not getting proper

pain treatment. One of the outcomes of this effort was the February 2013 Joint California Medical Board and Board of Pharmacy Appropriate Prescribing and Dispensing Forum.

The Medical Board has also formed a subcommittee to work on the issue of prescription medication abuse and perhaps to coordinate another forum in the future in Southern California. The first meeting of their task force was September 23, 2013.

Previous Subcommittee Discussion

The subcommittee was provided with some events that occurred prior to the Medical Board's Subcommittee meeting on September 23, 2013 that contributed to the scope of that subcommittee's meeting including:

- The American Medical Association released a policy statement saying that pharmacists have no business questioning a prescription written by a prescriber
- A large chain drug store wrote an \$80 million check for the DEA for excessing furnishing.
- The board's precedential decision on corresponding responsibility confirming a pharmacist's duty to verify that prescriptions are issued for a legitimate medical purpose.

The subcommittee also discussed the best way forward working with the Medical Board as well as the possible need for the board to develop prescribing guidelines for pharmacists, especially in light of SB 493 that provides new opportunities for pharmacist to have a larger role in patient care.

d. Discussion of the New CURES Program and Elements Needed in a Prescription Medication Monitoring Program for California

Background

In California, the Controlled Substance Utilization Review and Evaluation System (CURES) is an electronic tracking program that reports all pharmacy (and specified types of prescriber) dispensing of controlled drugs in Schedules II, III, and IV by drug name, quantity, prescriber, patient, and pharmacy.

Data from CURES aids this board in efforts to identify, prosecute and reduce prescription drug diversion. CURES provides invaluable information that offers the ability to identify if a person is "doctor shopping" (when a prescription drug addict visits multiple doctors to obtain multiple prescriptions for drugs, or uses multiple pharmacies to obtain prescription drugs). Information tracked in the system contains the patient name, prescriber name, pharmacy name, drug name, amount and dosage, and is available to law enforcement agencies, regulatory bodies and qualified researchers. The system can also report on the top drugs prescribed for a specific time period, drugs prescribed in a particular county, doctor prescribing data, pharmacy dispensing data and is a critical tool for assessing whether multiple prescriptions for the same patient may exist.

CURES now has more than 100 million controlled substance prescriptions electronically filed. The system has been key in investigations of doctor shoppers, pharmacies and prescribers. For the board, this data is critical in allowing for the identification of pharmacies involved in massive dispensing of controlled substances, which can be a potential sign of drug diversion, and serves as a trigger for important investigations.

In addition to CURES' value to regulatory and law enforcement agencies, CURES also has a prescription drug monitoring component whereby DOJ-preapproved providers may access reports on specific patients to see what controlled substances have been dispensed to the patient by various pharmacies. Use of this system can prevent prescribers from prescribing and pharmacies from dispensing medications to doctor and pharmacy shoppers. However, the computer system supporting CURES in the DOJ needs upgrading.

Previous Subcommittee Discussion

The Subcommittee was advised that the governor signed SB 809 (Chapter 400, Statutes of 2013) which provides for upgrades to the CURES system as well as sustained funding for the system. In addition, practitioners will be required to sign up for the CURES system by 2016 as a condition of licensure.

The subcommittee has requested a timeline for the project to upgrade the CURES system and discussed that the upgraded system needs to provide for better and more immediate access.

The subcommittee did not take action on this item, but requested that implementation of the CURES system be included on the agenda for the next subcommittee meeting.

Discussion

No comments from the public.

e. Corresponding Responsibility of Pharmacists and the Board's Recent Precedential Decision in this Area

Relevant Statutes

Health and Safety Code Section 11153 establishes the duty for a pharmacist to exercise corresponding responsibility prior to filling a prescription.

Business and Professions Code section 4306.5 provides that failure to exercise or implement corresponding responsibility is unprofessional conduct.

Background

At the July Board Meeting, the board voted to make its decision in Pacifica Pharmacy a precedential decision regarding a pharmacist's corresponding responsibility. This decision is now posted on the board's website as a precedential decision, and has been the subject of a

subscriber alert. Recently, Supervising Deputy Attorney Joshua Room did a summary of the decision which was provided in the meeting materials.

Previous Subcommittee Discussion

The subcommittee discussed the precedential decision and was advised that the decision clarifies that it is the duty of a pharmacist to exercise corresponding responsibility and that the decision provided some of the “red flags” a pharmacist should be aware of when filling a prescription. Some of the “red flags” mentioned include nervous patient demeanor, irregularities in the prescriptions, cash payments, requests for early refills, prescriptions written for duplicative drugs, the same combinations of drugs being prescribed to patients regardless of patient ages as well as long distances traveled by the patient to fill prescriptions.

The subcommittee did not take action on this item but noted that pharmacists as a whole need to consider the larger picture, not just a single prescription.

Discussion

No comments from the board or from the public.

f. Discussion on the Board of Pharmacy’s Previously Published Health Notes on Pain, A Monograph for Pharmacy Practitioners

Background

In the mid-1990s and ending in the early 2000s, this board published a series of eight monographs for pharmacists whereby the board could ensure the consistency of education being available on specific topics, and for which a pharmacist could earn continuing education credit by completing and passing an exam on the materials’ content. The board generally subcontracted with pharmacist experts in the field, and relied on academic editors to develop the articles. Each issue was attractive, but development of each issue was relatively expensive and time consuming.

The first issue was on treating pain, including appropriate pain management, and other topics. This was developed following the then Administration’s work in addressing under-treatment of pain.

This monograph is still available on the board’s website:

http://www.pharmacy.ca.gov/publications/health_notes_pain_mgmt.pdf

However, a recent review of the monograph indicates that the messages in this issue may be at odds with federal and state thinking about pain management.

Previous Subcommittee Discussion

The subcommittee discussed the publication and that much of the information contained within it is very outdated and that the board should remove outdated documents from its

website. The subcommittee also suggested that the board may want to consider providing links to materials that other reputable entities have created on the topic.

Discussion

Dr. Gutierrez commented that in addition to sending the Health Notes to the Communication and Public Education Committee for review, the subcommittee discussed reviewing the all of the information on the board's website. Dr. Castellblanch agreed that the website should be reviewed to be sure the information provided is current.

No comments from the public.

Note: Tappan Zee left the meeting room at 12:10 p.m. and returned at 12:17 p.m.

Subcommittee Motion: Send the *Health Notes* and other educational items on the board's website to the Communication and Public Education Committee for review.

Note: Mr. Zee was not present for the vote.

Support: 10 **Oppose:** 0 **Abstain:** 0

g. Discussion about Public Education Efforts for Prescription Drug Abuse and Community Outreach

During the April Board Meeting discussion on the success of the February Joint Forum with the Medical and the need for greater public activity with respect to prescription drug abuse led the board to form this subcommittee. Some of the items suggested include a brochure for pharmacists on corresponding responsibility, sharing information on improving opioid use in hospitals, and possible curriculum development for use in schools to advise students and parents of the dangers of prescription drug abuse and the attraction such drugs hold for youth. The DEA has developed such a curriculum.

Previous Subcommittee Discussion

The subcommittee discussed the need to look at ways to get information out to the community and parents, and perhaps using the curriculum already developed by the DEA. The subcommittee also discussed the significant amount of interest in the DEA/Board sponsored events.

The subcommittee did not take action on this item; however the chair requested that during its next meeting, the subcommittee look at ways to most effectively educate pharmacists, as well as evaluate the San Diego Task Force, its materials and how it is working with school districts. During its next meeting, the subcommittee will also evaluate what continuing education is currently required for renewal.

h. Discussion about Public Outreach to Address Prescription Drug Abuse

Background

Over the last two years, the board has hosted several one-day seminars for pharmacists and other interested parties on drug diversion, prescription drug abuse and corresponding responsibility for pharmacists. The board's partner in this has been the Los Angeles Office of the Drug Enforcement Administration. Attendees are awarded six hours of CE. These events are well attended and feedback from attendees show high evaluation scores. Two sessions were provided, one in June and one in July 2013.

Also, in mid-August 2013, this board joined with the Washington, DC headquarters office of the DEA to co-host four, one-day seminars for pharmacists in California on controlled substances issues, prescription drug abuse, corresponding responsibility and other matters related to curtail drug diversion. Two were held in San Diego and two in San Jose. At least 300 pharmacists have attended each of these presentations.

Discussion

Dr. Castellblanch reported that board hopes to host another educational event in Orange County later in the year.

No comments from the public.

i. Future Meeting Dates

Dr. Castellblanch announced that the subcommittee did not have a specific date set for the next meeting, however, the intention is to meet in early December 2013.

Discussion

Ms. Herold and Mr. Room discussed the need to meet with Mike Small from the Department of Justice on CURES funding.

Ms. Veale and President Weisser thanked the subcommittee for their work in the important area of prescription drug abuse.

Megan Harwood, from the Orange County Prescription Drug Abuse Prevention Coalition, expressed the organization's support for the work the subcommittee is doing and outlined the educational and drug take back work the coalition is currently working on.

Subash Mediratta, from People's Pharmacy, expressed the difficulty he encounters when trying to dispose of expired Schedule 2 drugs. Ms. Herold responded federal law requires these drugs to be turned in to local law enforcement. Inspector Ratcliff added that when drugs are turned over to law enforcement a record of disposition needs to be obtained so that if an audit is conducted it will be clear where the drugs were disposed.

XVII. LEGISLATION AND REGULATION COMMITTEE REPORT

Note: The Legislation and Regulation Committee did not meet this quarter.

Due to time constraints Mr. Lippe provided an abbreviated Legislation and Regulation report as follows.

AB 467 (Stone) Prescription Drug Collection and Distribution Program

Last Amend: September 6, 2013

Board Position: Oppose Unless Amended (prior version, est. 8/23/13)

Status: 9/6/13 – Re-referred to SEN BP&ED

Assembly Bill 467 would provide for the licensure of a “Surplus Medication Collection and Distribution Intermediary” to allow such an entity to perform duties related to the movement of drugs donated through a Surplus Medication Collection and Distribution program.

The previous version of AB 467 (as amended 8/19/13) was a “gut & amend” where the bill would have exempted an entity (now referred to as an ‘intermediary’) from oversight by the board with regard to the movement of drugs through a Surplus Medication Collection and Distribution program and would have declared that such an entity’s activities would not be deemed wholesaling activities. The board thereafter (on 8/23/13) established a position of *Oppose Unless Amended* and provided the author with suggested amendments.

The current version of the bill amends Pharmacy Law to define these intermediaries and provide for the board’s licensing of these entities. However, the bill does not specify the term of the license (annual, biannual) or address any renewal requirements for the license. AB 467 also amends the Health & Safety Code (Division 16. Surplus Medication Collection & Distribution) to exempt these intermediaries from civil or criminal liability with regard to the distribution of donated drugs for these programs.

Staff has engaged in discussions with the author, sponsor and other interested parties; the next stakeholders meeting may be scheduled for some time in November. A bill analysis, current version of the bill, and the board’s (8/23/13) position letter are provided in the meeting materials.

Discussion

Ms. Sodergren provided that while the author did not accept all the changes the board recommended, the author is working with the board to address our concerns. Board staff recommends that the board change their current position of “oppose unless amended” to “support if amended.”

Motion: Change the board’s position to Support if Amended, and amend AB 467 to specify the term and renewal requirements of the license.

M/S: Lippe/Law

Support: 11 Oppose: 0 Abstain: 0

The board recessed for lunch at 12:38 p.m. and returned at 1:03 p.m.

XIX. PETITIONS FOR EARLY TERMINATION OF PROBATION

- a. Daryl Wolf, RPH 46273
- b. William Allen, RPH 54535

The board recessed for a break at 2:50 p.m. and resumed at 2:58 p.m.

XX. PETITION FOR REINSTATEMENT

- a. Carol Zalez-Simon

XXI. CLOSED SESSION

The board recessed to closed session at 4:00 p.m.

- a. 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 Early Termination of Probation
- b. Pursuant to Government Code Section 11126(a)(1) the Board Will Convene in Closed Session Evaluate the Performance of the Board's Executive Officer

ADJOURNMENT

4:23 p.m.