



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

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: January 29-30, 2014

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

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Gregory Murphy, Public Member
Victor Law, RPh
Allen Schaad, RPh
Ramón Castellblanch, PhD, Public Member (January 30th)
Albert Wong, PharmD
Deborah Veale, RPh
Ryan Brooks, Public Member (January 29th)
Lavanza Butler, RPh

BOARD MEMBERS

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

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Supervising Deputy Attorney General
Michael Santiago, DCA Staff Counsel
Robert Ratcliff, Supervising Inspector
Carolyn Klein, SSM2
Laura Hendricks, Staff Analyst

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

Note: The Legislation and Regulation Committee Meeting was held immediately before the board meeting from 8:00 a.m. – 9:30 a.m. in the First Floor Hearing Room.

CALL TO ORDER

9:30 a.m.

I. GENERAL ANNOUNCEMENTS

President Weisser conducted a roll call. Board members present were Greg Lippe, Albert Wong, Allen Schaad, Victor Law, Gregory Murphy, Ryan Brooks, and Stan Weisser. A quorum of the board was established.

Note: Lavanza Butler and Deborah Veale arrived at 9:33 a.m. Amy Gutierrez arrived at 9:50 a.m.

President Weisser welcomed two new board members, Allen Schaad and Gregory Murphy. President Weisser also noted that former board member, Holly Strom, was in the audience.

President Weisser and the board thanked Kristy Schellans for her six years of service as the board's legal counsel and wished her well as she begins her work with other departmental boards.

II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF OCTOBER 29-30, 2013 AND NOVEMBER 14, 2013

Motion: Approve the October 29-30, 2013 and the November 14, 2013 meeting minutes.

M/S: Lippe/Veale

Support: 7

Oppose: 0

Abstain: 2

III. BOARD MEETING DATES FOR 2014

President Weisser announced the board's meeting dates (below) for 2014 and noted that all meeting dates are posed on the board's website.

October 22-23, 2014

July 30-31, 2014

April 23-24, 2014

March 17-18, 2014

IV. INTRODUCTION AND REMARKS FROM HIEU T. TRAN – DEAN OF SCHOOL OF PHARMACY AMERICAN UNIVERSITY OF HEALTH SCIENCES

Dr. Hieu T. Tran provided a brief overview of the American University of Health Sciences' new California School of Pharmacy program.

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

President Weisser recognized John McCormick and David Ash for 50 years of service as pharmacists.

VI. PRESCRIPTION DRUG ABUSE PRESENTATION BY JOSEPH RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, US DRUG ENFORCEMENT ADMINISTRATION

Joseph Rannazzisi, DEA Deputy Assistant Administrator, provided an in-depth and insightful presentation on the prescription drug abuse epidemic in the United States. The presentation highlighted a pharmacist's role in preventing patient abuse of prescription medications.

Mr. Rannazzisi's presentation can be viewed using the link below.

<http://www.youtube.com/watch?v=INmBqZbQOwg&feature=youtu.be>

The board recessed for a break at 10:55 a.m. and resumed at 11:12 a.m.

Discussion

Ms. Veale asked what the Board of Pharmacy can do to help the DEA in its efforts to stem the epidemic. Mr. Rannazzisi responded that in his experience the pharmacy boards aren't really the problem. It is the prescribing boards who seem to have a "second chance" policy for their errant licensees. The best thing the pharmacy boards can do is create relationships with the prescribing boards.

Mr. Lippe noted that the board is getting more aggressive with corresponding responsibility cases and offered to provide Mr. Rannazzisi with information on the board's recent precedential decision. Mr. Rannazzisi commented that schools of pharmacy need to more intensely teach corresponding responsibility to their students.

Ms. Veale commented that she had seen a report that drug abuse in high school students is going down and asked how is this could be true in light of the epidemic? Mr. Rannazzisi responded that he thinks the numbers are going down falsely because they are generated self-reporting surveys.

Mr. Books noted that marijuana is referred to as a gateway drug and asked Mr. Rannazzisi if he had any data that supported this? Mr. Rannazzisi reported that the American Society of Addiction Medicine has done several studies that show marijuana is a gateway drug. He added that there are no valid, legitimate academic studies that show that marijuana is a legitimate medication.

Dr. Wong asked what the DEA is doing to change the attitude of doctors towards over prescribing pain medications. Mr. Rannazzisi responded that the DEA has met with the AMA on two occasions to discuss the problem. He added that 99.5 percent of doctors are good and care about their patients.

Mr. Schaad commented that the CDC considers addiction a disease, and there is no easy access to treatment. Mr. Rannazzisi agreed that there needs to be better treatment options.

The board recessed for a lunch break at 12:32 p.m. and resumed at 1:25 p.m.

VII. LICENSING COMMITTEE

Deborah Veale provided a report on the Licensing Committee meeting held on December 11, 2013.

a. Evaluation of the Text for Criminal Conviction Questions on Board Applications

Background

Currently applicants are advised that failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application.

The Legal Office has asked boards to review the criminal conviction questions on its applications and consider changes to ensure consistency with legal requirements.

Committee Discussion and Action

The committee discussed briefly the need for review of the application questions used by the board to ascertain arrest and conviction history as part of its process in evaluation of an application for licensure. Counsel suggested that this review should include conformance with legal requirements that may have changed since the questions were originally developed.

The committee took no formal action on this item, but directed staff to work with counsel to complete the necessary review and bring the matter back to the committee for further discussion and possible action.

Board Discussion

Dr. Wong noted that the majority of the disciplinary cases that come before the board are for pharmacy technicians. Dr. Wong added that improving the questions and creating minimum requirements for technicians may help reduce the number of cases that come before the board.

Mr. Brooks commented that in his opinion a lot of times people check “no” because they think that having a conviction expunged or closed means they don’t have to disclose it to the board. He would like to see the conviction question specifically ask if the applicant has any convictions that have been expunged.

Mr. Lippe inquired if the board could simply ask if applicants had ever been arrested. Mr. Room responded that the board cannot ask about arrests that do not lead to convictions.

Mr. Room reported that with every dismissal under 1203.4, there is an order issued that specifically says even though this conviction has been dismissed you are still required to disclose this conviction in response to a direct question on a licensing application.

Dr. Wong expressed his opinion that the board should have a list of “ground rules” for automatic disqualification of licensure so people don’t waste their time and money going to school.

Mr. Room briefly explained the application process and clarified that when an applicant does not disclose a conviction, and the board is made aware of it via the fingerprinting process, the board sends out a letter asking the applicant for an explanation of the conviction and why it was not disclosed. The board does not deny applications solely on the honest mistake of not disclosing information; rather it considers the facts of the underlying conviction.

Ms. Veale commented that the board should consider if the language used in the questions is confusing.

Ms. Herold added that while there is no specific list of disqualifying convictions pharmacy technician schools know that the board considers how long ago the conviction was, if there are multiple convictions and if the convictions are substantially related to the practice of pharmacy or work in a pharmacy.

Steve Gray, individual, commented that applicants are often confused about what they need to disclose in regards to past convictions, especially where they are not from California or if the conviction occurred while they were juveniles. Mr. Room responded that juvenile “convictions” are actually adjudications and the board does not have access to juvenile adjudications via the fingerprinting process as these records are sealed. Dr. Gray stated that clarification of disclosing juvenile adjudications would be helpful on the application.

Dr. Gutierrez asked if the board could look at the language other departmental board’s use on their applications. Mr. Room stated that in his opinion the board’s language is as good, or better than other department applications. Anne Sodergren provided that the request to review the application conviction question language was made to all of the Department of Consumer Affairs not just the board. Mr. Room added that the department began the review process as the result of a statute that no longer requires certain types of marijuana related convictions to be disclosed.

Ms. Veale asked if the board has questions and answers for filling out applications on its website. Ms. Herold responded that there are instructions provided to applicants.

Ms. Herold stated that if the board wants to make certain types of convictions automatic disqualifiers they would need to promulgate a regulation. Mr. Room noted that the Registered Nursing Board has a regulation that defines what specifically what type of convictions disqualify applicants from licensure.

Mr. Brooks asked that the Licensing Committee work with staff and legal counsel on clarifying the criminal conviction questions.

b. Update on Discussion of the Pharmacist Intern Hour Requirements from Business and Professions Code section 4209 and 16 California Code of Regulations Section 1728 and the Intern Hours Affidavit Form 17A-29

Relevant Statutes

Business and Professions Code section 4209 establishes the requirements for intern pharmacists to earn 1500 hours of experience as qualification to take the pharmacist licensure exams.

California Code of Regulations section 1728 further specifies the types of practice environments and experience areas where intern hours must be earned prior to eligibility to take the pharmacist licensure examinations.

To confirm compliance with the above requirements, the board uses a pharmacy intern hours affidavit (form 17A-29), which includes two areas where the intern hours earned can be recorded:

- 1) Number of hours of pharmacy practice experience obtained in a pharmacy (where 900 hours are required, and
- 2) Number of hours of pharmacy practice experience substantially related to the practice of pharmacy (where up to 600 hours may be reported).

Background

Historically, usually in response to inquiries from the public, the board has scheduled discussions on the intern hours requirement and how this information is reported to the board as a requirement for admission to the California pharmacist licensure examinations. At the October 2013 Board Meeting, President Weisser requested that intern hours be added to the agenda of the Licensing Committee at the request of Board Member Law.

Committee Discussion and Action

The committee discussed the process currently used by board staff to substantiate intern experience and was advised that the board will also accept a letter from the dean of a school of pharmacy as sufficient documentation of completion of the hours earned under the auspices of the program.

The committee was advised that representatives from California Northstate University have expressed concern about the current process used to verify intern experience, but have not submitted any written information.

The committee discussed the current legal requirements and considered if changes should be made to the current internship requirements or how the board confirms this information.

Public comment received during the meeting included that the board should consider rescinding the affidavit requirement.

The committee did not take formal action on this item, but requested that the topic be included on the agenda for a future meeting. The committee requested that staff extend invitations to the California schools of pharmacy to participate in the discussion and also requested that board staff research internship requirements in other states.

Board Discussion

President Weisser directed the board and the public's attention to Attachment 1 of the board meeting materials for further details on internship hours.

Ms. Veale noted that while the board is willing to look for ways to simplify the intern hours process, the board's main goal is to protect the public and make sure that quality pharmacists are coming out of the schools ready to serve consumers.

c. Update on the Implementation Schedule for SB 809 (DeSaulnier, Chapter 400, Statutes of 2013)

Relevant Statutes

Health and Safety Code Sections 11165 – 11165.3 establish and define the parameters and use of the CURES Program which is housed within the California Department of Justice. Included within these provisions are requirements that have existed for a number of years, including the requirement for prescribers and pharmacies to report dispensing information each week into the CURES system.

Background

In 2013, the CURES Program received additional funding through SB 809 to rebuild and replace its aging computer system and provide minimal, but essential, staffing to support the program in the future. (This funding was needed because CURES had been housed in the DOJ's Bureau of Narcotic Enforcement, a unit that was totally defunded several years ago in response to General Fund budget cuts made by Governor Brown in response to the state's fiscal crisis.)

The new CURES funding source identified for this system is from licensees of the several healing arts boards that regulate prescribers and dispensers. Beginning in April 2014, every practitioner eligible to prescribe (e.g., physicians, nurse practitioners, optometrists, veterinarians, dentists) or dispense (pharmacists, pharmacies), and wholesalers and clinics will pay an ongoing fee of \$6 per year fee as part of their renewal. Additionally, before January 1, 2016, every pharmacist (and each of the prescriber classifications) will be required to submit an application to obtain approval to access CURES data as part of the renewal process. This process is intended to ensure widespread eligibility for prescribers and pharmacists to access CURES data on an individual patient – when the practitioners so choose – at the time of prescribing or dispensing.

Additionally, due to a trailer bill to the 2013/14 California State Budget, the board is funding for two years (2013/14 and 2014/15) an additional \$215,000 (in addition to ongoing annual funding of \$92,000 that we have been providing for approximately 10 years) that will be used to replace the aging CURES computer and replace it with a more robust system, capable of providing better access to the state's prescribers and dispensers, who are checking the controlled substances dispensed to specific patients as part of the prescription drug monitoring program (PDMP). The prescriber boards are also contributing sizeable amounts to secure a new computer system.

Collection of CURES funding from board licensees will begin with renewals due April 1, 2014 and thereafter. The department's Legal Office has approved the following language to be added to impacted renewal notices from the board:

FOR ANNUAL RENEWALS:

Pursuant to SB 809 (DeSaulnier, Chapter 400, Statutes of 2013), you are assessed \$6 ANNUALLY which is collected at the time of renewal to cover the operation and maintenance of the Controlled Substance Utilization Review and Evaluation System (CURES).

FOR BIENNIAL RENEWALS:

Pursuant to SB 809 (DeSaulnier, Chapter 400, Statutes of 2013), you are assessed \$6 ANNUALLY which is collected at the time of renewal to cover the operation and maintenance of the Controlled Substance Utilization Review and Evaluation System (CURES). The amount of \$12 per renewal cycle is hereby added to the renewal fee.

Meanwhile, senior board staff members are participating in development of the parameters for the new CURES computer system. They are also involved in establishing a simplified mechanism by which pharmacists will be able to sign up for CURES without needing documents certified by notary publics as part of the approval process.

Committee Discussion and Action

The committee discussed the CURES system and SB 809. The committee did not take action on this item.

Board Discussion

President Weisser commented that the board is very committed to a new CURES computer system that will be user friendly and provide useful information to pharmacists.

Ms. Herold provided an overview of the IT purchasing process that the DOJ is currently using.

Dr. Gutierrez and Ms. Veale commented on the difficulty of registering for the CURES system and asked if there is anything the board can do to increase pharmacists' access to the current CURES system by making it easier for licensees to register.

Dr. Gutierrez suggested that perhaps the board could share the licensee database with the DOJ to simplify the registration process. Ms. Herold responded until now the DOJ has not been receptive to this idea, but she is willing to approach them again.

Dr. Gutierrez suggested that Mike Small from DOJ be invited to the next Prescription Medication Abuse Subcommittee Meeting so that they can discuss the challenges of the system.

Steve Gray, representing Kaiser, commented that Kaiser supports the use of the CURES system. Dr. Gray commented that if you get at least 20 people together Mr. Small will come and sign-up the participants in the system without all the additional paperwork. Dr. Gutierrez again

expressed her concern and frustration that even with the in-person option, the registration process and ongoing access to the system is too difficult.

d. Update on the Implementation Schedule for SB 493 (Hernandez, Chapter 469, Statutes of 2013)

Background

Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) establishes an “advanced practice pharmacist” (APP) category of licensure, allowing such pharmacists to perform advanced patient care functions, such as to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers. In addition, this legislation provides for expanded duties all pharmacists can perform.

The APP provisions include the ability to:

- write or issue a prescription in specific settings under 4052.2(a)
- issue an order for controlled substances in specific settings
- Perform patient assessments
- Order and interpret drug therapy related tests
- Refer patients to other health care providers
- Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers
- Initiate, adjust or discontinue drug therapy; must provide notification back to diagnosing prescriber or enter info into patient record shared with the prescriber

Further, depending on the services provided, a pharmacist may require registration with DEA to issue an order for controlled substances.

The law also establishes the following general requirements for an APP including:

- An active CA pharmacist license (in good standing) as a pharmacist
- Submission of an application and fee (maximum of \$300)
- Issuance of a license good for 2 years linked to RPh renewal
- Completion of additional 10 units of CE each renewal cycle in an area of practice relevant to the pharmacist’s clinical practice
- Satisfy two of the following qualifying requirements:
 1. Earn certification in a relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, psychiatric practice recognized by ACPE or another entity recognized by the board)
 2. Complete a postgraduate residency in accredited postgraduate institution

where 50 percent of experience includes direct patient care with interdisciplinary teams

3. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, APP, a pharmacist practicing collaborative drug therapy management, or health system

Regulations will be needed to implement multiple provisions in SB 493 including the parameters for the education requirements provided above.

The legislation also established expanded duties for all pharmacists. Under these provisions a pharmacist may perform all of the following when appropriately qualified:

- Administer drugs and biological products that have been ordered by a prescriber
- Independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older as specified
- Furnish nicotine replacement products in accordance with a state treatment protocol to be developed jointly by the Pharmacy and Medical boards, provided:
- Records are retained of drugs and devices furnished for at least 3 years so as to notify health provides or monitoring of the patient
- The pharmacist notifies the patients' primary care provider of drugs and devices furnished or directly enters these into a patient record.
- Furnish self-administered hormonal contraceptives in accordance with a state protocol developed by the Pharmacy and Medical Boards of California pursuant to the guidelines of the CDC.
- Furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the US (travel medications)

Some of these provisions will also require the board to implement regulations.

Committee Action and Discussion

The committee discussed the legislation and was provided with a brief presentation by the California Pharmacists Association (CPhA) and California Society of Health System Pharmacists (CSHP). The associations have joined together with some of their members and multiple California schools of pharmacy to develop components to comply with some of the provisions in SB 493. The board has not been involved in this process.

The committee was reminded that the board is charged with the implementation of SB 493 and the development of the necessary regulations will need to be done publicly. The committee or board may choose to use the work product of the CPhA/CSHP workgroups as one source of consideration in development of the requirements.

Several participants expressed interest in working with the board and committee as it moves forward with development of the necessary regulations.

The committee did not take formal action on this item, but will reconvene on February 12, 2014, to focus efforts on implementation.

Board Discussion

President Weisser stated that it is the board's responsibility to create the regulations and this will be done publically so that stakeholders can provide input.

e. Update on the Implementation Schedule for SB 294 (Emmerson, Chapter 565, Statutes of 2013)

Background

SB 294 was the board's sponsored legislation to strengthen the board's ability to regulate specialized pharmacies within and outside California that compound sterile drug products – that is, those that are compounded for injection, administration to the eye or for inhalation. The provisions provide for implementation of the requirements beginning July 1, 2014.

Committee Discussion and Action

The committee discussed the legislation and was advised of the implementation efforts being made by staff to ensure full implementation by July 1, 2014 as the legislation calls for. The committee was advised that inspector staff members received specific and extensive training and are beginning to complete inspections that are necessary as a condition of licensure and annual renewal. The board's inspections will include nonresident sterile compounding pharmacies and those located in California.

The committee did not take action on this item.

Board Discussion

Ms. Herold reported that all of the board's inspectors have received 53 hours of training and will be receiving training from the FDA and ventilation specialists. Ms. Herold added that the board will continue to provide training to ensure staff are up to the task of inspecting these pharmacies and to avoid deaths from sterile compounding and will seek ongoing funding for training to accomplish this.

Dr. Gutierrez noted that that schools of pharmacy have not focused much on sterile compounding, so inspector staff needs to be trained in this area so they can become experts.

Ms. Herold commented that as the board's inspectors are expert witnesses, so they need credentials that are impeccable.

f. Report on the New Pharmacy Technician Accreditation Commission (PTAC)

Relevant Statutes

Business and Professions Code section 4202 establishes the requirements for licensure as a pharmacy technician.

California Code of Regulations section 1793.6 further defines the requirements for a technician training course, which is one of the pathways to licensure.

Background

The board learned that the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) have announced their collaboration to accredit pharmacy technician education and training programs, beginning in late 2014. The collaboration will result in the creation of the Pharmacy Technician Accreditation Commission (PTAC), which will be tasked with assuring and advancing the quality of pharmacy technician education and training programs.

The PTAC will conduct document reviews and site surveys and advise the ASHP/ ACPE boards of directors, which will then agree on final accreditation actions. The establishment of the PTAC expands upon ASHP's 31-year history as a national accrediting body for pharmacy technician training programs. The ACPE also accredits educational programs involving pharmacy – specifically all schools of pharmacy in the US are accredited by ACPE.

According to information provided to the board, there are currently 258 programs in the ASHP accreditation process. Through the work of its Commission on Credentialing, ASHP will continue to accredit pharmacy technician programs until the PTAC officially begins its work in the fall of 2014. ASHP will also provide ongoing accreditation support for the PTAC.

Committee Action/Discussion

The committee briefly discussed this item. No public comment was provided and the committee did not take formal action. They did, however, request that staff research and provide more information at a future meeting about the new ASHP technician program approval process so the committee can determine if action is necessary, including possible changes to CCR 1793.6.

Board Discussion

Dennis McAllister, representing ACPE, reported that the PTAC is live now and the surveys will start within the next 30-60 days.

g. Report on the Pharmacy Compounding Accreditation Board (PCAB) Pharmacy Technician Certification Requirement Changes

Background

The board was advised by the Pharmacy Compounding Accreditation Board (PCAB) that as a result of concerns raised by their applicants regarding technician certification, the PCAB's Standards Committee reviewed the interpretation of PCAB Standard 1.20.

After review the Standards Committee recommended no change in Standard 1.20 to the PCAB Board of Directors. Instead, the recommendation was to continue with the current interpretation of Standard 1.20 and cancel the pending January 1, 2015, recommended change.

Consequently, a proposed requirement for pharmacy technician certification that had been slated to begin on January 1, 2015, has been eliminated. Thus, PCAB will continue with their current interpretation of Standard 1.20 directing that pharmacy technicians will be certified or otherwise credentialed by an appropriate certifying agency only when required by the state(s) in which they practice.

The item was brought to the committee for informational purposes only. No committee or public comments were provided and the committee took no action.

Board Discussion

Ms. Veale noted that pharmacists are ultimately responsible for the technician's actions.

President Wiesser noted that in light of the compounding issues this might be an opportunity for the board to tighten up its education requirements for technicians who are compounding.

Dr. Gutierrez noted that having technicians who have been trained in compounding would be helpful to the pharmacists in compounding pharmacies. Dr. Gutierrez and Ms. Veale asked that technician credentialing for sterile compounding be discussed at the next compounding subcommittee meeting.

h. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Effective December 1, 2013, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that there is currently a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board expects to release the scores in February 2014, however, will release exam scores more quickly if the review is completed.

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

Board Discussion

No comments from the board or from the public.

i. Licensing Statistics

The board renewed the second quarter's licensing statistics. During the first half of the fiscal year, the board received more than 8,900 applications and issued more than 7,500 licenses. The number of applications received increased almost 14 percent and the number of licenses issued decreased almost 5 percent when compared to the same time periods last fiscal year.

Board Discussion

No comments from the board or from the public.

j. Second Quarterly Report on the Committee's Goals for 2013/14

The board is meeting the acceptance parameters for Success Indicators 2C – Review Received Deficiency Items to Determine Application Completeness within five working days of receipt and 2E – Update Information Changes to Licensing Records within five working days.

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

- 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, board staff is working to move towards the goal parameters. As vacancies are filled and training is completed additional progress will be made in these three areas.

Board Discussion

Dr. Wong asked if the board could create a “fast track” process for applications, specifically for sites licensed. Ms. Herold responded that this would have to be done through the Legislature and she did not feel that it would be advantageous as eventually everyone would opt for the fast track and the process would not be any faster.

Mr. Schaad noted that there were 10 out of state compounding applicants, and he asked if the board had been able to inspect those locations. Ms. Herold responded that we cannot inspect out of state locations until July 1, 2014.

Mr. Brooks asked if the board could contract with other states to do the inspections in locations outside of California to save the board money. Ms. Herold responded that we cannot contract out for inspections and noted that the board will get reimbursed for travel costs by the applicant for those out-of-state. Mr. Room added that due to the compounding deaths, California decided that we could not count on other boards or accreditation agencies to inspect these facilities.

Mr. Brooks asked if the board has enough staff to conduct these inspections. Ms. Herold responded that the board received 5 inspector positions. Ms. Sodergren noted that the board will also redirect staff to help with the applications.

Dr. Gutierrez asked how many out of state facilities the board expects to apply. Ms. Herold responded that the board estimates 120 locations will apply.

Dr. Gutierrez asked if the board could prioritize large facilities so there is not a stoppage of medications to patients. Ms. Herold responded that the board will inspect California facilities first and is working with the Administrator on streamlining the out of state travel approvals to make it easier for inspectors to travel for inspections.

Dennis McAllister, representing Express Scripts, provided that a number of states are doing similar inspections however they are allowing NABP to conduct the inspections. Ms. Herold responded that statute does not currently provide for the use of outside contractors.

VIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

President Weisser noted that the Organizational Development Committee did not meet last quarter and provided the following report to the board.

a. Budget Update/Report

Budget Report for 2013/14

President Weisser provided an overview of the board's expenditures and revenue and directed the board and the public to view the graphs in the meeting materials for more details on the board's budget.

Fund Condition Report

President Weisser reported that the board is in the process implementing a fee increase to improve the board's fund.

Update on BreEZe

Anne Sodergren reported that the board is redirecting two staff to work full time on the BreEZe project for six weeks.

Updates on Board Member Attendance, Reimbursement and Mail Votes

President Weisser noted that board member attendance and mail vote participation have been reported in the meeting materials.

b. Personnel Update

President Weisser reported that Randy Kajioka recently resigned from the board and again welcomed Mr. Schadd and Mr. Murphy to the board.

Ms. Herold reported that the board has a new public information officer, Joyia Emergard. Ms. Herold added that the board has had two inspectors retire; the board is in the process of recruiting to fill the positions. Additionally, Ms. Herold reported the board's recruitment efforts in the licensing and criminal conviction unit.

c. Discussion and Possible Action on Recommendation for Board Policy to Delegate Hearing of Petitions for Reinstatement of a License and Petitions for Modification of Penalty to a Committee of the Board

President Weisser provided an overview of how the board currently handles petitions for license reinstatement and modification of penalties. Currently petitioners have to wait many months to be heard due to the board's full schedule. President Weisser proposed two options. The first option is to have an administrative law judge hear the petitioners without board members present. The second option is for the board to create a committee to review (with an administrative law judge) petitions and make recommendations to the full board for the board to ratify.

Mr. Brooks expressed his concern that the committee structure would not actually streamline the process as the committee's recommendation would still have to be ratified by the board.

Mr. Santiago noted that using the committee structure would actually lengthen the process time required to make corrections to the decisions. Mr. Room noted that a few years ago the board had more problems with errors in the decisions, they have since changed the procedures and have had fewer errors.

Mr. Room noted that the he sees more quality decisions come from administrative law judges when they sit with the full board rather than conducting the hearing alone. President Weisser agreed and expressed his preference to have the judge sit with the committee to hear petitioners.

Ms. Sodergren provided that there are currently about 15 petitioners waiting to be heard by the board. Currently the board hears two to three petitioners per board meeting.

Ms. Veale said that she feels that a committee structure could be advantageous as they could have set meeting dates to allow staff to schedule petitioners as they make requests to seek modification. Ms. Veale added that using a committee may also help add consistency in the decisions.

Mr. Brooks expressed that he would not support the use of the committee structure as he feels the full board has such diverse backgrounds and experience it adds value to the decision making process. Mr. Brooks recommended that extra full board meetings be conducted to handle petitioners.

Dr. Law commented that perhaps simple cases could be brought before the committee and more complex cases could come before the full board for consideration.

Mr. Brooks and Mr. Lippe commented that the current petition process allows for the board to judge the character of the petitioner in a face to face forum.

Mr. Room responded that he was not aware of any boards that used a committee structure for petitions and reinstatements.

Dr. Wong commented that he would like to see the full board schedule additional meetings to hear petitioners.

Steve Gray, individual, commented that he would like to make sure that the committee meetings would be public meetings. Mr. Room confirmed that if two or more board members are present in a meeting it is required to be public. President Weisser added that the purpose of creating a committee is to reduce processing time not to hinder the board's transparency in any way.

Mr. Room added that the Registered Nursing Board schedules 9-12 petitioners for each of their board meetings.

Motion: Create the committee and evaluate the efficiency of the committee process after one year (or sooner if problems become apparent).

M/S: Veale/Gutierrez

Support: 0

Oppose: 10

Abstain: 0

President Weisser commented that he had another item to bring before the board for consideration. He reported that currently the Organizational Development Committee is made up of the board president and vice president. As the board expands and takes on additional responsibilities, President Weisser recommends that the board consider changing the committee so that it is comprised of the current president and the past president. In his opinion this will allow for the past president to provide history and experience to the Organizational Development Committee.

Ms. Veale commented that she believes it is beneficial for the committee to be comprised of the vice president and current president because typically the vice president will become president and it is an opportunity for them to receive guidance and knowledge from the current president.

The board concluded that this item should be discussed in the future when the current president's term ends.

The board recessed for break at 3:34 p.m. and resumed at 3:46 p.m.

IX. EXECUTIVE OFFICER REPORT

a. Update on Activities of the Medical Board of California –Kimberly Kirchmeyer, Interim Executive Director

Ms. Kirchmeyer, Interim Executive Director for the Medical Board, provided the board with an update of the Medical Board's activities as follows.

- The Medical Board is in the middle of transition. Due to SB 304, the Board's investigative staff will be transitioning to the Department of Consumer Affairs. Due to the logistics of this move, staff has been very busy working to ensure this is a smooth transition.
- At a prior meeting, Ms. Kirchmeyer spoke about movement of some investigative staff to a Prescribing Strike Force. The overall goal was to develop a team of investigative staff that could be assigned specifically to some of the egregious overprescribing cases in order to take action as quickly as possible. The Strike Force has been extremely successful. This specialized unit has made 5 arrests, issued 7 search warrants, done over 15 undercover operations, and has procured thousands of physical prescriptions since its implementation in late June. Local law enforcement and the DEA have been very willing to assist the Board in these cases. In addition, the actions of the Strike Force have been picked up by the media, which is a deterrent for physicians who are inappropriately prescribing to patients.
- The Medical Board is still working on educational materials from its Prescribing Task Force meeting on September 23, 2013. Due to other priorities, the board has not been able to complete a document that can be shared with physicians regarding communication between physicians/pharmacists, but hopes to complete it soon. Ms.

Kirchmeyer noted that she will be working with Ms. Herold prior to submitting the document to the Pharmacy Board for review and finalization.

- The Board's Prescribing Task Force is also preparing for its second meeting that will be held February 19th here in Sacramento. This meeting is going to be dedicated to looking at the Board's pain management guidelines.
- In discussions with Ms. Herold, the board does not believe that it would be prudent to begin activity on another Joint Forum until such time that the board revises its pain management guidelines.
- The Medical Board would like to work with the Board of Pharmacy on is a campaign for the month of March. Senator DeSaulnier authored Senate Concurrent Resolution 8 that proclaims the month of March, each year, as Prescription Drug Abuse Awareness Month and encourages all citizens to participate in prevention programs and activities and to pledge to "Spread the Word....One Pill Can Kill." The board's Public Information Officer is working on an outreach plan for March.

Board Discussion

Mr. Brooks offered to help create a Public Service Announcement via the radio.

Dr. Gutierrez commented that the Board of Pharmacy is taking a strong stand a pharmacist's corresponding responsibility and asked what the Medical Board doing to hold doctors responsible for their part in the opioid epidemic. Mr. Kirchmeyer responded that the Medical Board created their Prescribing Strike Force and is educating their licensees about corresponding responsibility.

Mr. Law asked if there a hotline someone can call if it is suspected that a doctor is overprescribing. Ms. Kirchmeyer responded that that Medical Board does have an 800 number and added that with the new BreZE system complaints can be filed anonymously online.

Ms. Herold asked Ms. Kirchmeyer to if the Medical Board had any concerns with how the DOJ is implementing the CURES system. Ms. Kirchmeyer responded that that she has been in the same meetings as Ms. Herold and she shares the Pharmacy Board's desire to see access to CURES be improved as it is an important tool for doctors. She added that when the Medical Board used the current system for investigations they found the information to be outdated.

Ms. Kirchmeyer confirmed that the Medical Board is contributing 1.638 million dollars.

Mr. Brooks asked if pharmacists could receive continuing education to conduct education on drug abuse. Ms. Herold responded that an ACPE requirement for pharmacy students is for them to provide community education and noted that one CA school of pharmacy actually has partnered with a high school to educate them on drug abuse. Ms. Herold added that it would be difficult to award CE for pharmacists who conduct educational programs, but the Prescription Drug Abuse Committee can look into ways that pharmacists can actively educate the public.

Steve Gray, individual, commented that he would encourage the Medical Board and the Board of Pharmacy to work jointly on creating the pain management guidelines.

Pierre Del Prado, individual, commented that there is a nationwide program sponsored by the American Pharmacist Association that is designed to send student pharmacist to a variety of public venues (including schools) to discuss the problems of prescription drug abuse. Mr. Brooks asked board staff to research programs such as this that the board could advocate.

b. Settlement with CVS for Violation of California Business and Professions Code Section 17200 (unfair Business Practices) by the San Diego, Alameda and Riverside District Attorney's Offices for Failure to Consult Patients

Ms. Herold reported that the board recently worked with three district attorney's offices to conduct an undercover investigation into pharmacies' failure to consult. In particular the investigation focused on the practice of screening patients for consultation that occurs in many chain pharmacies, which violates pharmacy law. Ms. Herold expressed that she was pleased with the investigation and settlement as it sadly has become the general public opinion that if you walk into a pharmacy in California you may not receive a consultation.

Mr. Lippe commented that whenever he goes into a Rite Aid they have a check off box saying that he does not want to receive a consultation. Ms. Herold responded that this practice is screening for consultation and is a violation of pharmacy law. Mr. Room commented that sign-off sheets or logs are not a substitute for an actual consultation with a pharmacist.

Dr. Guterrez asked if the drug store chain has changed their corporate policies in response to this settlement. Ms. Herold reported that the chain has changed their policies in response to the settlement and the board has been into their locations and has not seen any more of these types of violations.

President Weisser and Dr. Gutierrez discussed that they have heard that some chain pharmacies are discouraging pharmacists from exercising their corresponding responsibility. Ms. Herold responded that complaints should be submitted so that the board can investigate.

Steve Gray, individual, commented that the board should publicize this settlement as much as possible to educate the industry and the public about consultation practices.

Mr. Room commented that there are other ongoing investigations so the board is waiting for the conclusion of these cases to widely publicize the settlement.

Mr. Law asked if the pharmacists in the stores were cited by the board. Ms. Herold responded that the stores have received fines as well as the pharmacist-in-charge and in some cases the pharmacist who did not consult.

c. Program Growth at the Board of Pharmacy in Recent Years

Ms. Herold reported that in three years the board has gone from having an overall budget of \$14.6 million to a \$19.6 million starting July 1, 2014. Ms. Herold also reported that board has gone from 74 positions to 101 positions in the last three years.

d. Sterile Compounding Training for Inspector Staff

Ms. Herold restated that the board is training its inspector staff in sterile compounding.

X. PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE REPORT

In Chair Castellblanch’s absence, Ms. Herold provided a reported on the Prescription Medication Drug Abuse Subcommittee meeting that was held on December 4, 2013.

a. Possible Action to Adopt the Mission Statement for the Subcommittee

Background

During the December meeting, the subcommittee refined the draft of its mission statement.

Ms. Herold reported that the committee would like the board to adopt its mission statement.

Board Discussion

No comments from the board or from the public.

Committee Recommendation (Motion): Adopt as the mission statement of the subcommittee:

The mission of the Prescription Drug Abuse Subcommittee is to promote the prevention and treatment of prescription drug abuse, particularly the abuse of controlled substances; provide education to practitioners and the public regarding prescription drug misuse; and optimize the widespread use of tools such as CURES.

Support: 11 Oppose: 0 Abstain: 0

b. Review of Statistics Documenting the Issues of Prescription Medication Abuse in California

Background

The subcommittee reviewed statistics on the prevalence of prescription drug abuse in California and in the US. Some statistics and additional background were provided in the meeting materials.

Statistics gathered from CURES about the number of controlled drugs dispensed to patients in California indicate that:

From the CURES System: 7/1/12 – 6/30/13

	Number of Prescriptions Filled	Total Quantity	Pills Prescribed Per Prescription	Pills Per Californian
Oxycodone & Combinations	3,164,677	286,706,709	90.6	8.2
Hydrocodone & Combinations	15,950,799	1,061,658,195	66.5	30.36
Alprazolam	3,646,130	205,983,740	56.5	5.89
Codeine Cough syrups	385,269	80,576,572	209 mL Per Rx	2.4 mL

Discussion

Ms. Veale asked if there was data on Soma. Ms. Herold responded that it was not reported here because it has not been scheduled long enough.

c. Review of the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain*

Background

The Medical Board of California has *Guidelines for Prescribing Controlled Substances for Pain*. This document was developed in 1994 and revised in 2007.

As stated earlier in the meeting by Interim Executive Officer Kimberly Kirchmeyer, the Medical Board plans on another modification to these guidelines later in 2014, and will begin this process in late February at its next Prescription Drug Task Force Meeting.

At the December subcommittee meeting, Renee Threadgill, Medical Board Chief of Enforcement, commented that the Medical Board is currently in the process of convening its second Prescription Drug Task Force meeting. Threadgill noted that the pendulum for prescribing controlled substances has swung from under prescribing to over prescribing.

President Weisser noted that the Board of Pharmacy is planning to continue its collaboration with the Medical Board by attending their task force meetings. Dr. Fujimoto added that other prescribing boards and consumers were present at the Medical Board's first task force meeting.

Board Discussion

No comments from the board or from the public.

d. Report on the Presentation by National Association of Boards of Pharmacy regarding the Parameters of the National Prescription Drug Monitoring Program Currently in Use

The subcommittee heard a presentation by Scotti Russell from the National Association of Boards of Pharmacy regarding its prescription monitoring program for controlled substances that shares data across state lines called PMP InterConnect. This program provides another piece of the monitoring program for state regulators, prescribers and dispensers about what controlled substances patients may be receiving across state states.

Ms. Russell described that matching of patient data is made typically by use of patient name, date of birth, and address (can be part of the address). Ms. Russell added that there are data matching techniques that allow the system to pull the patient even if there are slight variations (example: St. vs. Street).

There was a lengthy discussion about the system. Included in the discussion was a comparison of the data in the Surescripts System vs. NABP system. Ms. Russell responded that Surescripts has a lot of data, however it does not show cash transactions like the NABP system does. Ms. Russell added that the Surescripts system includes more than just controlled substances. Cash is a big issue when looking at red flags for potential drug abuse.

Ms. Russell said that about half of the states collect Schedules II through IV medications in their prescription monitoring programs, but there has been a move to collect Schedules II through V medications.

Chairperson Castellblanch asked if NABP had shown their system to California. Ms. Russell responded that NABP has talked to representatives from California multiple times, however right now the CURES system is so outdated that it cannot work with the NABP system.

Ms. Russell concluded the presentation by stating that the bottom line is NABP will work with any state that is willing to share data with other states through this program.

Board Discussion

Ms. Herold noted that Ms. Russell offered to appear before the full board as they get closer to implementing the new CURES system. President Weisser responded that it would be advantageous for Ms. Russell to come before the board. Dr. Gutierrez added that it is important that the CURES system be interoperable with NABP's system. Ms. Herold told the board that she would reach out to Ms. Russell to see if she could attend a future board meeting.

Steve Gray, individual, commented that it is important for the board to determine if it is allowed to share data across state lines. He added that the board should look if there are federal grants available to help fund the system.

Dr. Gutierrez commented that Ms. Russell provided a map during her presentation that broke down state-by-state who had control over the "CURES" program. The map illustrated that, in the majority of states the Board of Pharmacy had control of the system, not the DOJ. Ms. Herold responded that the DOJ will have oversight of the system in California, despite the board's request otherwise.

e. Report on the Discussion and Identification of Effective Ways to Educate Pharmacists about Prescription Drug Abuse and Corresponding Responsibility

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, has been the subject of a subscriber alert, and was discussed recently at the October Board Meeting.

At the subcommittee meeting the members discussed ways to educate pharmacists on corresponding responsibility.

The board will highlight this decision in its next newsletter, *The Script*. A PowerPoint presentation has been specifically developed on corresponding responsibility to educate pharmacists about this concept. This program runs 1.5 -2 hours, for which continuing education credit is available.

Staff will also add this decision as a topic in prescription drug abuse presentations made to the public, and specifically call it to the attention of prosecuting DAGs when seeking discipline for a licensee's failure to adhere to corresponding responsibility.

Another approach to educate pharmacists about prescription drug abuse is to foster the development of continuing education courses in this area.

The board also is proposing changes in its continuing education requirements in regulation to mandate CE in specific topics.

The subcommittee discussed if continuing education should be required not only for "substance abuse" but also for corresponding responsibility or specifically *prescription* drug abuse. The subcommittee will discuss continuing education topics on prescription drug abuse be placed on the next meeting's agenda.

The subcommittee will discuss at a future meeting possible replacement materials to further educate licensees on current pain management guidelines and their corresponding responsibility.

Board Discussion

Dr. Gutierrez commented that in addition to required CE in any or all of the following topics, emergency/disaster response, patient consultation, maintaining control of a pharmacy's drug inventory, ethics and substance abuse, she would like to add sterile compounding to the regulation language.

Motion: Add sterile compounding to the continuing education regulation language.

M/S: Brooks/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

Motion: Direct the executive officer to take all steps necessary to initiate rulemaking process.

M/S: Brooks/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

f. Summary of Presentations by San Diego Task Force to Educate Parents, Teens, Educators, Law Enforcement, Medical and Pharmacy Professionals About Prescription Drug Abuse

At the December meeting, very comprehensive and moving presentations were made by members of the San Diego parent/community task force to combat prescription drug abuse. A brochure developed to promote a recent project of this task force was provided in the meeting materials. The following individuals traveled to the meeting and provided presentations:

- Tom Lenox Supervisory Special Agent, Tactical Diversion Squad, DEA San Diego Field Division
- Nathan Painter, PharmD, CDE, Health Sciences Associate Clinical Professor, UCSD , Skaggs School of Pharmacy and Pharmaceutical Science

- Sherrie Rubin, Parent Advocate and founder of Heroin, OxyContin, Prescription Education (HOPE)

A substantial portion of the meeting was focused around this well-developed group and the type of information they provide to Southern Californians.

- Mr. Lenox of the DEA provided highlights of how the program has developed over the last several years, and the type of data they share during the various events.
- Dr. Painter described how UCSD School of Pharmacy students are working with high school students on issues related to prescription drug abuse, and other projects involving health care providers. Dr. Painter shared additional information about his work with prescription drug abuse.
- Sherry Rubin provided moving information about her son who was seriously injured by prescription drugs and the dramatic effect Aaron has on high schools students when he is able to present to them

Meeting attendees were highly interested in the presentations. The subcommittee will consider the work of this group in the development of a statewide response to their efforts to develop materials on prescription drug abuse. Copies of the presentations were provided in the meeting materials.

Board Discussion

Dr. Gutierrez commented that the presentations were very moving.

Gary Cacciatore, Cardinal Health, commented that Cardinal had developed two brochures on corresponding responsibility. Dr. Gutierrez asked if the brochures were available to the public. Mr. Cacciatore responded that there is information available to the public, however these two brochures were created for Cardinal customers.

g. Summary of Presentation by the County of Orange Health Care Agency on Its Public Education Program about Prescription Drug Abuse

Background

Della Lisi Kerr, Prevention Specialist from Orange County Health Care Agency, provided a presentation on their public education campaign for prescription drug abuse. The presentation has numerous elements and Ms. Kerr encouraged the board to collaborate with them on sharing the information. This review will occur in the future at a subsequent meeting.

The subcommittee greatly benefited from the work and enthusiasm of the two presentations provided at this meeting.

Board Discussion

No comments from the board or from the public.

h. Report on Public Outreach to Address Prescription Drug Abuse

During the April Board Meeting there was discussion on the success of the February 2013 Joint Forum on Appropriate Prescribing and Dispensing with the Medical Board. The need for

greater public activity with respect to prescription drug abuse led the board to form this subcommittee.

The Medical Board of California has expressed interest in cohosting another forum with this board on appropriate prescribing and dispensing practices. Such an event is tentatively focused at the late spring or summer 2014. Planning has not yet begun on this subsequent event by the staff of the two boards. However, it would seem logical to convene such a conference following the development by the Medical Board of new pain treatment guidelines.

Meanwhile, the US Department of Justice is interested in duplicating and hosting its own version of the Pharmacy Board/Medical Board Forum perhaps in March 2014 in the Bay Area. We have no other information about this conference.

Over the last two years, the board has hosted several highly popular 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. Six hours of CE is awarded for this training, which is well attended and receives high evaluation scores.

Two such sessions were provided in June and July 2013. Another training event was provided in Orange County on January 22, 2014, and another in Sacramento will be provided on January 31. Agendas for these two presentations were provided in the meeting materials.

Board Discussion

Ms. Herold reported that over a year ago, the board approved the provision of board-approved CE for these presentations. Since it has been over one year, staff requests the board's reconsideration of this CE, and award the six units if still appropriate.

Motion: Approve 6 hours of continuing education for the January 22, 2014 and January 31, 2014 training events.

M/S: Lippe/Murphy

Support: 11

Oppose: 0

Abstain: 0

XI. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Mr. Brooks provided a report on the Communication and Public Education Committee meeting held on January 6, 2014.

a. Update on the Approved Requests from California Pharmacies Related to Title 16 California Code of Regulations Section 1707.6

Wal-Mart's Request to Use an Alternate "Notice of Interpreter Availability" Format in all Wal-Mart and Sam's Club Pharmacies

Board regulation at 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. On this notice, the words *"Point to your language. Interpreter services will be provided to you upon request at no cost."* are to appear in English and in twelve additional, specific languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog and Vietnamese.

The committee approved a request from Walmart to use an alternate format of the board's "Notice of Interpreter Availability" poster in all Walmart and Sam's Club pharmacies. In addition to the regulatory requirements, Walmart Stores, Inc. included that the notices are required to be posted by the California State Board of Pharmacy.

Safeway's Request for Approval to Use an Alternate Display Methodology for the "Notice to Consumers" Poster

Board regulation at section 1707.6(a) requires every pharmacy to prominently post, in a place conspicuous to and readable by prescription drug consumers, a *Notice to Consumers* as made available by the board. The regulation allows a pharmacy to also or instead display the notice on a video screen that is located in a place conspicuous to and readable by prescription drug consumers, so long as:

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

The committee approved a request from Safeway to use an alternate display methodology of the board's "Notice to Consumers" poster. Specifically, Safeway will display the board's (yellow) "Notice to Consumers" poster on 24" video screens, mounted vertically. The English version of the poster will rotate in five minute intervals, and other non-English language versions may be rotated within that five minutes as well. Safeway will display the notices in accordance with the above requirements and will also use the screens to display the non-English Notice to Consumers posters available on the web site, as well as to display other health and pharmacy related information. Safeway pharmacies will continue to have hard copy "point to your language" notices available to the consumer, and will also have a copy of the board's (hard copy) Notice to Consumers poster available to consumers.

Board Discussion

Chair Brooks asked that the board approved both Safeway and Wal-Mart's requests as one motion.

Dr. Wong expressed his concern with the translations on the posters. Chair Brooks thanked Mr. Wong for expressing his concerns and asked Ms. Herold to look at the translations to ensure they are correct. Ms. Herold added that a certified translator was used she will research it.

Motion: Approve requests for both Safeway and Walmart and give the executive officer the authority to review and approve future requests and report back to the committee.

M/S: Lippe/Weisser

Support: 11 Oppose: 0 Abstain: 0

b. Update on the Status of the Updated Emergency Contraception Fact Sheet, as Required by Title 16 California Code of Regulations Section 1746

Background

The board used the interpreter services used by the Department of Consumer Affairs to have the board's Emergency Contraception Fact Sheet translated into six languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. The translated Fact Sheets are now available on the board's website for download and are available in the following languages: English, Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. Copies of these Fact Sheets were provided in the meeting materials.

Board Discussion

No comments from the board or from the public.

c. Report on the Research Project on Prescription Container Labels by Amir Zargarzadeh and Anandi Law, Titled "Design and Test of Preference for a New Prescription Medication Label"

Anandi V. Law, Professor and Chair of Pharmacy Practice and Administration of the College of Pharmacy, Western University of Health Sciences, presented the committee with findings of her research published in March 2011 related to the design of patient-centered prescription labels. In 2009-2010 when the board was developing parameters for patient-centered prescription container labels, Dr. Anandi Law attended several of the meetings and provided information about a research project she was working on to design patient-centered prescription labels.

Board Discussion

No comments from the board or from the public.

d. Continued Assessment of California's Patient-Centered Labeling Requirements as Required by Title 16 California Code of Regulations Section 1707.5(e)

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 began a review of the regulations in April 2013, and the board began its full review and discussion of the committee's recommendations at the October 2013 Board

Meeting. In October 2013, the board voted on two modifications related to the patient-centered requirements, and directed the remainder of the review back to the committee for additional discussion.

Board Approved Change 1: To require that ONLY the four items listed in 1707.5(a)(1) be within the 50 percent of the label designated for the patient-centered items.

1707.5(a)(1) Each of the following items, and only these 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:

A. Name of the patient

B. Name of the drug and strength of the drug. For the purposes of this section, name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.

C. The directions for use

D. The condition or purpose, if it is indicated on the prescription.

Board Approved Change 2: Require 12 point font

*1707.5(a)(1) Each of the following items, and only these 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:*

A. Name of the patient

B. Name of the drug and strength of the drug. For the purposes of this section, name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.

C. The directions for use

D. The condition or purpose, if it is indicated on the prescription.

The committee has continued its discussion of the elements contained in the patient-centered labels, to include:

- Should Section 1707.5(a)(1)(B) be modified to remove the requirement that the manufacturer’s name be listed in the patient-centered clustered area of the label when a generic is dispensed?
- Should changes be made to 1707.5(a)(1)(B) regarding the “name of the drug and strength of the drug”?
- When a generic drug is dispensed, should the brand name of the generic equivalent be included on the label phrased as “generic for _____”?
- Should Purpose or Condition be in the patient-centered clustered items? Should it be a requirement for labels generally?
- Should the existing requirements for “added emphasis” in the patient-centered area of the prescription label be modified?
- Translations on Labels -- Translated directions for use are available on the board’s website. Should the board require use of them to aid patients with limited or no

- English proficiency understand the information on the prescription label? Should there be additional requirements?
- Should the board consider technology standards to enhance the patient-centered requirements?

The committee discussed translations on labels at length, and requested that staff gather additional information for the next committee meeting.

The committee also discussed at length whether or not the purpose or condition should be in the patient-centered clustered items, and whether it should be a required element for labels generally. The committee will discuss this topic in greater depth at its next committee meeting.

Board Discussion

The board discussed the potential benefits and problems that could arise by requiring “generic for _____” on the patient centered label. Ms. Herold noted that Missouri Arizona both require “generic for” to be on their labels. Ms. Veale commented that while it is beneficial, she would not recommend that the board make it a requirement. Ms. Butler expressed that she feels listing both the generic and brand on the label is very helpful for patients.

Chair Brooks reported that the committee was concerned about patient confidentiality if the board requires purpose to be listed on the labels and added that the committee asked counsel to research any potential HIPPA violation.

Ms. Veale commented that while she understands the concern for potential HIPPA violation, purpose is a very useful tool for patients to discern what medication they are taking. Mr. Santiago provided that B&P code 4076(a)10 states that the condition or purpose has to be on the label if the condition or purpose is on the prescription, therefore if the board wanted to require this information on the label it would require a statutory change.

Dr. Gutierrez noted that a lot of medications have more than one use, so in her opinion the prescriber should be the one to indicate what the purpose of the medication is.

Mr. Murphy asked if there was any way the board could require the Medical Board to include purpose on the prescription when they write it. Ms. Herold responded that the Medical Board has begun discussing the importance of including purpose on prescriptions; however the medical community as a whole still has reservations.

Chair Brooks concluded that the committee will wait for counsel to provide a memo on potential HIPPA violations that could arise from requiring purpose on the label and discuss it further at future committee meetings.

Chair Brooks noted that the committee considered if the existing requirements for “added emphasis” in the patient-centered area of the prescription label be modified to allow for items in the patient centered portion to be in printed in bold or italics. Ms. Veale replied that she did not feel that any additional emphasis was needed in the patient centered portion of the label.

Ms. Veale and Mr. Law expressed their opinion that the board should not require the patient centered information to take up 50 percent of the label. Mr. Santiago responded that this requirement is in existing regulation.

President Weisser commented that the board made this requirement in response to some pharmacies crowding the label so much that patients couldn't find important information. He added that changing this requirement would be contrary to the board's work on patient centered labels.

Mr. Lippe asked if the board wanted to remove the 50 percent requirement if it would have to go through the entire regulation process again. Mr. Santiago confirmed and noted that because the board is changing the regulation to require 12 point font, they will have to go through the entire regulation process again. Mr. Lippe responded that changing the font size to 12 point will not receive any opposition from the public, however, removing the 50 percent requirement will.

Dr. Steve Gray, representing Kaiser, reminded the board of the long process it went through to develop a patient centered label with *much* input and compromise with consumers. He warned that if the board makes too many changes to the patient centered label the consumer groups will go back to the legislature to create labels without the board.

Chair Brooks thanked the board and the public for their input on patient centered labels and stated that the committee would discuss these items in more depth at its next meeting.

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

As part of the committee's goals for the 2012-2017 Strategic Plan and development, the committee will include a commitment to issue *The Script* at least two times a year. The board now has a new public information officer, who also is the new editor of the board's newsletter. The committee will also incorporate into its goals the activities of the new Prescription Drug Abuse Subcommittee.

Board Discussion

No comments from the board or from the public.

f. Update on *The Script*

The most recent issue of *The Script* was released in November. Work has begun on the next issue of the newsletter which will focus on new 2014 laws. Staff is working to issue the newsletter sometime in February. Staff has also added to the board's website a summary of new laws affecting the board that went into effect in 2014.

Discussion

No comments from the board or from the public.

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

The board will be conducting the two public outreach activities described below.

1. Public Continuing Education Training Session Provided by the California State Board of Pharmacy, the Los Angeles Field Division of the Drug Enforcement Administration and County of Orange Health Care Agency: January 22, 2014 in Brea, CA
2. Public Continuing Education Training Session by the California State Board of Pharmacy and Federal Drug Enforcement Administration Scheduled for January 31, 2014 in Sacramento

This six-hour CE presentation will feature Federal DEA Diversion Program Manager Joseph Rannazzisi and the board's strengthened corresponding responsibility component. It is the first time this presentation will be provided in Sacramento.

Board Discussion

No comments from the board or from the public.

h. Report on the Public Outreach Activities Conducted by the Board

Background

The committee was provided with an update on public outreach activities conducted by board staff in the past quarter

Board Discussion

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

The board recessed to closed session at 5:56 p.m.

THURSDAY, JANUARY 30, 2014

The board resumed open session at 8:04 a.m.

President Weisser conducted a roll call. Board members present: Gregory Lippe, Deborah Veale, Lavanza Butler, Amy Gutierrez, Victor Law, Gregory Murphy and Stanley Weisser.

Note: Albert Wong arrived at 8:11 a.m. and Ramon Castellblanch arrived at 8:46 a.m.

XI. ENFORCEMENT COMMITTEE REPORT

Chairperson Gutierrez provided a report on the Enforcement and Compounding Committee meeting held on January 10, 2014 as follows.

a. 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 Sections 1735 et seq. and 1751 et seq. Relating to Pharmacy Compounding

At the October 2013 Board Meeting, the board moved to initial notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45 day comment period ran from November 29, 2013 – January 13, 2014. A regulation hearing was held on January 16, 2014 to provide the public with an opportunity to provide comments in another forum.

The meeting materials contained the board's documents that are required to release a regulation for the 45 days of public comment – the notice, the initial statement of reasons and the proposed text. During the notice period, the board received many written comments. These comments were provided in a separate attachment, "Regulation Comments Supplement"

Discussion

Dr. Gutierrez noted that many of the comments received asked for clarification of terms and the allowance of electronic records. Dr. Gutierrez recommended that the comments be given back to the staff to work with herself and Allen Schaad to revise the regulation as needed.

Julie Lenhart, president of CSHP, commented that CSHP would like the enforcement committee to consider separating the regulatory provisions into two domains – outpatient and acute hospital.

Motion: Allow the sterile compounding workgroup to work through the comments received.

M/S: Lippe/Law

Support: 9 Oppose: 0 Abstain: 0

Chairperson Gutierrez asked Ms. Herold to report what the board is currently doing in anticipation of the implementation of SB 294. Ms. Herold reported that the board worked with The Department of Public Health to get the locations of all CA hospitals and is conducting unannounced inspections of the locations in anticipation of sterile compounding licensure. She added that the board is not enforcing the proposed regulations, rather existing regulations that pharmacies are already supposed to be in compliance with.

Chairperson Gutierrez asked if satellite pharmacies needed to submit applications. Ms. Herold reported that there will be a revised application within the next two weeks. The application allows a hospital to list all of the locations in the hospital where sterile compounding takes place rather than submitting separate applications for each satellite pharmacy within the hospital. When the updated forms are available, Ms. Herold stated that the board would use its subscriber alert system to notify its licensees.

Ms. Veale noted that USP 797 was referenced multiple times in the comments, and asked if we were going to align ourselves with it. Chairperson Gutierrez said that the goal is to align ourselves with 797 in some areas; however, legal counsel had indicated that we could not reference USP 797 in the regulation. Mr. Room responded it is much easier to enforce a regulation that does not depend on an outside body's standard. He added that the board can create regulations that are consistent with USP 797.

Dr. Wong asked what happens if a hospital's accreditation expires in March, three months prior to the July implementation date. Ms. Herold responded that the hospital is not required to become licensed with the board for sterile compounding until July 1, 2014. However if they choose to wait to submit their application will be put in a queue to be inspected. That is why

the board is making efforts to preemptively inspect hospitals to ensure there is no interruption of services.

Ms. Herold reported that the board is hiring additional inspector staff specifically with sterile compounding experience and the current inspectors are doing sterile compounding training. Additionally the board is working with the Governor's Office to secure approvals for inspectors to travel out of state to conduct inspections prior to July 1, 2014. However she noted that board's first priority are inspecting facilities in California. Chairperson Gutierrez added that the Enforcement Committee will be taking the same training the inspectors are currently doing.

Steve Gray, CSHP, commented that committee should consider defining a satellite pharmacy and should address the fact the non-pharmacist staff (such as nurses and doctors) compound in hospitals. Dr. Gray added that the committee should consider dividing the regulation between hospitals and non-hospitals as they are such different environments.

Bruce Vincent, Cedar Sinai Medical Center, expressed his support of Dr. Gray's comments.

William Stewart, sterile compounding pharmacist, expressed his concerns with the way USP 797 defines beyond use dates and asked the committee to carefully consider what parts of 797 it wants to incorporate into its regulation.

Gary Catchatory, Cardinal Health, noted that nuclear pharmacies are unique and USP 797 actually creates problems for these pharmacies.

b. Enforcement Matters

1. Discussion and Possible Action on the Preemption of California's e-Pedigree Requirements, as Required by California Business and Professions Code Section 4034.1 and Enacted HR 3204, the Federal Drug Quality and Security Act

On November 27, 2013, President Obama signed HR 3204, establishing a track and trace system for the US. This legislation contains language that immediately upon enactment preempts any state's track and trace systems. This exemption is:

In California's Business and Professions Code section 4034.1, there are additional provisions that preempt California's e-pedigree requirements should federal legislation be enacted. The law also requires that the board post action about the inactivation of California's standards with section 4034.1.

At this Board Meeting

During the Compounding and Enforcement Committee, the committee discussed these requirements and voted to recommend that the board take specific action on three items regarding California's e-pedigree law:

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1. To provide and publish a notice of preemption to the public

Committee Recommendation (Motion): The board will provide and publish a notice of preemption to the public as follows:

Pursuant to Business and Professions Code section 4034.1, which provides in pertinent part that “[u]pon the effective date of federal legislation . . . addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163(c) – (g), 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative,” and which requires that within 90 days of the enactment of such legislation the board publish a notice regarding the invalidation of these statutes, the California State Board of Pharmacy is hereby publishing notice that federal legislation meeting the requirements of section 4034.1 has been enacted, and that Business and Professions Code sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 became inoperative as of November 27, 2013.

The board will publish this notice in the California Regulation Notice Registry, include in a subscriber alert, and post on the board’s website as a notice. It will also be included in a newsletter article to be published in the next *The Script*.

Support: 9 Oppose: 0 Abstain: 0

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2. To seek a legislative repeal of California’s provisions via 2014 proposed legislation

To provide for clear understanding to licensees and the public about components in California law, inactive/preempted sections of law should be removed so that California Pharmacy Law contains only sections of law that are in effect. As such the committee recommends that the board sponsor legislation to remove the inactive/preempted provisions dealing with e-pedigree in California law.

Board Discussion

No comments from the board or from the public.

Committee Recommendation (Motion): The Board will seek legislative repeal of California’s e-Pedigree provisions via 2014 Board-Sponsored legislation.

Support: 9 Oppose: 0 Abstain: 0

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3. Stop the adoption of and withdraw pending regulations to implement California's e-pedigree requirements.

There are currently two noticed rulemakings in progress regarding implementation of e-pedigree requirements. The committee recommends that the board withdraw and or stop action on the following two rulemakings:

1. Pedigree Requirements – Unique Identifier; Identification of 50 Percent of Product Serialized for Sale in California; Grandfathering – Adoption of sections 1747 -1747.1
Status: Disapproved by the Office of Administrative Law received on October 31, 2013 (the disapproval would have been corrected via addition of documents to the rulemaking file for 15 days)
2. Drop Shipment; add section 1747.2 to Title 16 California Code of Regulations
Status: Regulation noticed for 45 days of public comment, hearing held 10/29/13

Committee Recommendation (Motion): Enforcement and Compounding Committee: Recommend that the Board Stop the Adoption of and Withdraw Pending Regulations to Implement California's e-pedigree provisions

Support: 9 Oppose: 0 Abstain: 0

2. Discussion and Possible Action on Federal Legislation that Eliminated Licensure of Third Party Logistics Providers as Wholesalers, Pursuant to the Enacted HR 3204, the Federal Drug Quality and Security Act

The federal legislation enacted to eliminate California's e-pedigree requirements also contained provisions to establish national standards for wholesalers and establish specialized regulation of third party logistics providers (3PLs). The new federal law requires the FDA to establish regulation provisions regarding national standards for wholesalers and 3PLs over the next one to two years. If a state does not regulate wholesalers and 3PLs, the national registration will be required.

California has regulated wholesalers for more than 25 years. In recent years, the board has regulated 3PLs as wholesalers, in fact, California law defines 3PLs as a subdivision of wholesalers.

The federal provisions which took effect November 27, 2013, however, prohibit the regulation of 3PLs as wholesalers, which is exactly what California's current law does. Consequently effective November 27, 2013, neither the state nor federal government is requiring licensure

(and regulation) of 3PLs until the federal requirements are put in place. Since 3PLs are vital members of the supply chain who store, select and ship prescription drugs, the committee recommends to the board that legislation be pursued in California to restore licensure of 3PLs as a separate category of licensee, but to include them in California Pharmacy law everywhere wholesalers are mentioned. Proposed legislation to do this was provided in the meeting materials.

During the committee meeting, Mr. Room stated that the new federal law does not allow states to license 3PLs as wholesalers. Therefore, for the board to maintain regulatory oversight of 3PLs, a new license type for 3PLs has to be created.

Ms. Herold commented that 3PLs control the flow of drugs and the board sees it as a dangerous hole in the supply chain to leave unregulated.

Dr. Steve Gray, individual, commented that he supports the board's work in this area and encouraged the board to consider if they will require common carriers to be licensed. Ms. Herold responded that there is a definite difference in the type of service a common carrier provides and a 3PL provides.

Ron Bone, McKession, thanked the board for their leadership to help create federal standards.

Committee Recommendation (Motion): The board will sponsor 2014 legislation to regulate third party logistic providers and include them everywhere wholesalers are mentioned in the California pharmacy law

Support: 9 Oppose: 0 Abstain: 0

Dr. Ramon Castellblanch arrived after the vote at 8:40am.

3. Update on Implementation of AB 1136 (Levine, Chapter 304, Statutes of 2013) Regarding Warning Labels on Prescription Container Labels

CA Business and Professions Code 4074 requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug (1.) if the drug poses a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and (2.) the drug is determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136, signed by the Governor on September 9, 2013, amended Business and Professions Code section 4074 to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

The specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle may be impaired are found in 16 California Code of Regulations Section 1744.

Committee Discussion

Dr. Gutierrez raised concerns that the list of medications in Section 1744 doesn't list every drug that is potentially harmful. President Weisser opined that it might be better to rely on the judgment of pharmacist rather than an incomplete list when determining what is harmful for a patient.

However, current law would have to be amended in order to eliminate the current list because the statute directs the board to develop a list. Mr. Lippe suggested adding language such as "including, but not limited to" to the list so a pharmacist can use his or her professional judgment.

Steve Gray, representing himself, spoke in support of the recommendation. He believes that the change will let pharmacists use their own professional judgment and will probably result in more warnings being affixed to the prescription bottles. Dr. Gray also stated he believes the word "vessel" needs further clarification.

Board Discussion

Dr. Wong expressed that he felt this legislation was unnecessary. Ms. Herold answered that the board could choose to repeal the legislation but it would be an uphill battle and would be viewed as working against consumer protection.

Michael Santiago commented that the Office of Administrative Law (OAL) might argue that "including but not limited to" is not specific enough and would require a list of medications, therefore he recommends putting in a list of specific drugs. Dr. Gutierrez commented that keeping the drug list would be very difficult and it should be up to the professional judgment of the pharmacist.

Mr. Santiago commented that statute already makes the allowance for a pharmacist's professional judgment to decide if a drug could impair a patient's ability to operate a vehicle or vessel so the regulation does not need to say "including but not limited to."

Ms. Veale asked if the board could take what's in the statute and include it in the regulation. Mr. Santiago commented that OAL may view this as duplicative.

President Weisser asked Mr. Santiago if in his opinion the statute already accommodates the language "including but not limited to" so the board does not need to include it in the regulation. Mr. Santiago confirmed that the "pharmacists professional judgment" language in the statute accomplishes the same thing as placing "including but not limited to" in the regulation.

Ms. Veale and Dr. Gutierrez again expressed their concern of providing a list of specific drugs in the regulation.

Ms. Veale recommended that the board modify the language in the regulation so that it points a pharmacist back to the statute on a pharmacist's professional judgment.

President Weisser asked Mr. Santiago to work with the committee to create language that would be approved by OAL.

Dr. Gray commented that the current law only requires that the warning be given verbally, the new requirement is that the warning must be placed on the label. He added that the legislation came about when people were injured and killed as the result of someone driving a boat under the influence of prescription medication. The prosecution failed because the argument was made that the person did not know the prescription medication made it dangerous to operate a vessel.

4. Report on the Request for Comments from the DEA on the Possible Scheduling of Tramadol into Federal Schedule IV

Tramadol was approved for marketing as a non-controlled analgesic in 1995 based on information related to its low potential for abuse and very weak narcotic effect. Recent data, however, indicates that tramadol produces effects, including adverse, analgesic, and other effects, similar to opioids in Scheduled III and IV.

It has become one of the most prescribed opioids in the United States and numerous reports have surfaced regarding its misuse, abuse, and diversion.

On November 4, 2013, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPR) to place tramadol in Schedule IV of the Controlled Substances Act. If tramadol is placed in schedule IV, entities that handle it by the effective date of the final rule, will be subject to registration, security, labeling, packaging, inventory, recordkeeping, reporting, prescription, and import and export requirements required for substances placed in Schedule IV.

During the committee meeting, Ms. Herold stated that the board has seen cases in which tramadol has been abused like other controlled substances and feels it is appropriate to place Tramadol in Schedule IV.

This will also mean that tramadol dispensed to patients in California will be tracked by CURES.

President Weisser and Executive Officer Herold submitted a letter to the DEA supporting the classification. A copy of the letter was provided in the meeting materials.

Board Discussion

Mr. Law thanked the Ms. Herold and President Weisser for the letter.

5. Update on Presentation from MedAvail for a Waiver of Title 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines

The committee saw a demonstration by MedAvail, a group advocating specific automated technology for a new form of kiosk machine to dispense medications to patients. This presentation was for informational purposes only, although in the future, the proponents of this technology have advised that they may seek a waiver of section 1713(d).

During the meeting, the committee watched a short video and heard a brief presentation that included the existing use of the technology and possible its use in California.

Information provided included:

- The kiosk is linked to a pharmacy licensed by the state in which the kiosk is located. The pharmacy would own and operate the kiosk and be responsible for its use.
- The kiosk is pre-loaded with room temperature medications that are found to be used/needed most often. At a kiosk, a patient may submit a prescription, consult with a pharmacist, pay for the medication, and have it dispensed. Licensed pharmacists staff a call center 24 hours daily.
- If a patient needs a medication that is not pre-loaded or is out-of-stock, the patient is directed to another nearby pharmacy or kiosk.

Board Discussion

Ms. Veale asked if the kiosk would need to be licensed as a pharmacy. Dr. Gutierrez and President Weisser responded that MedAvail is not requesting a waiver at this time; the presentation was for information only.

6. Discussion and Possible Action on the Request from UCSD and Sharp Healthcare for a Waiver of Title 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines

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

Phil Burgess and Sara Lake representing Asteres and Kim Allen representing Sharp HealthCare made a brief presentation and offered their formal written proposal to request a waiver of the provisions of Section 1713 for purposes of conducting a study with UCSD to determine if use of the technology improves medication adherence in the targeted audience.

The proposal has changed since July, where the kiosk would have been located in an unlicensed corporate office. The prior plan was to license the kiosk as a pharmacy and return with a more robust study proposal. However, upon closer examination of the law, the board's staff could not license a kiosk in a corporate office as a pharmacy.

Instead, the new proposal is to place the kiosk in the lobby area of a licensed hospital owned by Sharp. The kiosk would be serviced by a Sharp retail pharmacy located less than a mile away and the kiosk would include new prescriptions as well as refills.

Prescriptions would first come to the retail pharmacy, be processed and filled by pharmacy staff and verified by a pharmacist. Patients who chose to have their prescriptions delivered to the kiosk would have their medications segregated for delivery to the kiosk. Pharmacy staff would take the medications to the kiosk and fill the machine. The kiosk would read the barcodes on the new medications and send an email to the patient that the medication was ready for pick up. To avoid errors, the computer system would alert to any discrepancy between the original prescription and what was placed in the kiosk. The system would generate a report with an audit trail.

For new prescriptions, a pharmacist would consult with the patient prior to the medication being released from the kiosk. The kiosk would be available to Sharp employees and their families.

The committee had a lengthy discussion regarding the first-time fills from the kiosk, where patient consultation would be required. The proposal would require patient counseling to be done via telephone located near the kiosk. Ms. Allen stated that once the patient is counseled via telephone, the pharmacist would make a note in the computer that the patient was counseled and then electronically release the medication to the patient via the kiosk.

The minutes of this meeting detail the discussions of the committee. Some of the concern involved why a retail pharmacy located a short distance outside the hospital would be responsible for the machine, when the hospital where the kiosk would be located had a onsite inpatient pharmacy.

Another major concern of the committee involved the after-hours release of medication requiring counseling when the outpatient pharmacy that supports the kiosk would be closed. Additionally concern was expressed that a six-month pilot is too short a period to collect usable data. Staff suggested that the request should be for a longer period with a progress report to the board detailing data after six months. Meanwhile, the researchers could continue to collect data on an ongoing basis and provide periodic reports thereafter.

Ms. Herold also asked for clarification on what will be measured in the study because the documentation seemed to indicate most of the measurements would be made to determine consumer satisfaction. Ms. Allen stated that they would collect data and measure anything the board would like to see.

Dr. Gutierrez indicated she would be more comfortable with the study moving forward with only refills. Mr. Lippe stated that if the concern is new prescriptions, collecting six months of data on only refills isn't going to put the board in a better position to make a decision about whether new prescriptions should be included. He believed both refills as well as new prescriptions should be included in the pilot study. He suggested that Asteres/Sharp report to the board once a month instead of once after the six month study had concluded.

Committee members asked many other clarifying questions regarding the process.

Public comment included that the study include formal outcomes, and have the patients enroll into the study. There were also comments regarding consultation being difficult to provide in such a manner.

Mr. Lippe restated that when the prescription is called in, the consultation by a pharmacist be performed during the pharmacy's normal business hours.

At the last board meeting where this proposal was discussed, the board asked that Dr. Castellblanch provide assistance in developing a more traditional research protocol. Following the meeting, Dr. Castellblanch did provide this review and his comments were sent to the lead researcher at UCSD, Charles Daniels, for incorporation into a more robust research proposal.

Board Discussion

Charles Daniels, Associate Dean of UCSD School of Pharmacy, commented that the goal of the study to look at how electronic kiosks effect medication adherence as well as patient behavior during the consultation process.

Dr. Daniels provided a brief presentation on the goals and process of study. Dr. Daniels noted that the study would need to be conducted for 18 months to allow for a sample size that is statistically valid.

Ms. Veale asked if there would be a control group in the study. Dr. Daniels confirmed there would be.

Dr. Castellblanch noted that the proposal that he reviewed did not contain a discussion of risks for patients involved in the study. He also added that he did not see anything about informed consent of the patients involved in the study.

Dr. Castellblanch also commented that he was unable to find any information regarding the qualifications of the principle investigator for the study, and it did not seem that UCSD was very involved in the study.

Ms. Herold commented that after the enforcement committee meeting she provide the materials on the study to Dr. Castellblanch so that he could provide some initial feedback. Ms. Herold and Dr. Daniels discussed the concerns, and Dr. Daniels is attending the meeting so that he can address the concerns in a public forum.

Ms. Veale noted that the documents provide to the board stated that the sample size would be 300 and in the presentation it stated that it would need to be 800. Dr. Daniels responded that further review by statisticians have required them to change the sample size to 800.

Ms. Veale asked who the control group would be. Dr. Daniels responded that the control group would be those people who choose not to participate and go to the traditional pharmacy.

Dr. Daniels clarified that he is the principle investigator for the study and he could provide his qualifications to the board.

Mr. Room stated that the board's regulation requires that any person who uses an electronic kiosk to have signed a written consent form. Dr. Daniels responded that those who use the kiosk will be signing consent forms, they are still determining if the people who choose to not use the kiosk also need to provide consent.

Mr. Santiago commented that 1706.5 requires that the board receive a letter from the Dean with the study parameters so that it can be reviewed and approved. Dr. Daniels responded that he thought the letter had been provided. Mr. Santiago noted that the letter provided did not include the most current requirements that the committee discussed.

President Weisser stated that he would like to give Dr. Castellblanch more time to review the documents and report back to the committee. Dr. Castellblanch commented that he would be happy to review them.

Mr. Room noted that part of the reason UCSD had not submitted a complete study proposal was that there were waiting to see if the board would approve the study before they invested time and money into creating it. President Weisser commented that he could not guarantee that the board would approve the study, but based on recent discussions it seemed that the board was open to the idea.

Mr. Law asked how the kiosk would ensure that the person at the kiosk was in fact the patient. Kim Allen, manager for the Sharp pharmacies, responded that the pharmacist would ask for the date of birth for the patient and noted that currently a patient can send an agent to pick up a prescription for a patient. She added that currently the law allows for a note to be given stating that consultation is available and provided a phone number. Mr. Room interjected that he disagreed with her statement that a note could be given in the place of a consultation by a pharmacist. He stated that a large chain had just been fined for this same type of practice. The law requires that a pharmacist initiate consultation with the patient - not provide a note or prescreen for consultation.

Ms. Veale asked if the law actually requires for in person consultation. Mr. Room and Ms. Herold responded that it requires the patient or the patient's agent to be present. Ms. Veale stated that perhaps the committee should require that in the study the pharmacist initiate the consultation by calling the patient. Dr. Gutierrez noted that this requirement was already outlined in the study documents.

Ms. Butler if consultation would be given during business hours. Ms. Allen confirmed this.

Mr. Room asked how the study would measure the *quality* of the consultation provided with the kiosk vs. in the pharmacy. Dr. Daniels responded that they are still determining how to quantitatively measure the quality of the consultation.

Ms. Herold asked if the board would receive a report on the study in June 2015. Dr. Daniels responded that a formal report would be provide at the conclusion of the study, but there would be progress reports given monthly, or as the board sees fit.

Ms. Herold asked how long the study would need to be conducted for Dr. Daniels responded that 12 months of operation to obtain a sample size that is statistically significant.

Ms. Herold noted that the board should consider if at the end of the 12 month study they would require the machine to be removed or become inoperable. Ms. Herold stated that perhaps USCD should consider tracking patients after the machine shuts down to see if they return to a pharmacy to pick up their medications more frequently.

Mr. Law commented that he supports new technology however he wants to be sure the patient consultation is not impaired.

President Weisser asked that a complete study packet be provided to the committee to be discussed at the next meeting.

Ms. Allen asked if they could work with Dr. Castellblanch directly. Ms. Herold stated that she would help facilitate their communication. Dr. Castellblanch asked that Dr. Gutierrez work with him on the review so that she could provide him a pharmacist's perspective.

Ms. Butler commented that she still has some concerns about the patient consultation piece.

Dr. Gray, CSHP, expressed CSHP's support of this study.

Brian Warren, California Pharmacists Association, would like to see more information on how initial fills and consultations will be handled to ensure patient safety.

The board recessed for a break at 10:05 a.m. and resumed at 10:21 a.m.

7. Discussion and Possible Action on the Requests from Scripps Health San Diego and Sharp Health System for Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Sections 4128 et seq.

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are bar coded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012). Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read.

The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals.

Recently board staff was advised that Scripps Health San Diego had limitations in its software that prohibit full compliance with the barcode requirements specified in section 4128.4. Scripps Health System is requesting that the board interpret the meaning of the provisions more broadly to allow additional time following licensure to fully comply with the requirements. Scripps indicated that it does have a bar code that is readable at the bedside that identifies the drug, dosage and strength.

Sharp Health Care also notified the board that it was unable to affix a barcode to each container to read the specific information identified in section 4128.4.

In preparing for this meeting, board staff conferred with counsel on the applicability of such a waiver given the specificity of the language in Business and Professions Code section 4118. This request is being brought to the board for consideration and to provide direction to staff on the waiver request as well as interpretation and application of section 4118.

Bob Miller stated that Scripps became aware that the provision in section 4128.4 that speaks to the retrieval of patient information at the patient's bedside was being interpreted by the board differently than what they had expected. Their expectation was that if they put a barcode on all their doses which included the lot number, then based on the lot number, they would be able to retrieve the patient information at the bedside. Their barcoding system, however, doesn't actually pull up that information and show it to the nurse. The purpose of the appearance before the board is to ask the board to adopt a broader interpretation of the provisions of the new law and make the case as to why their system is in compliance, or alternatively, to ask the board for a waiver until the technology becomes available to permit the reading of the additional bar code information.

Ken Scott explained that all the required patient information is actually retrievable from the label of each unit dose medication container, it is not encoded into the barcode.

Mr. Room provided information regarding Business and Professions Code section 4128.4 which states that upon reading the barcode, the six data elements shall be immediately retrievable. In his opinion, one of the conditions of licensure is that the licensee has the ability to perform that technological service.

Mr. Room presented three different options with which the board could deal with this situation.

1. Pursuant to Business and Professions Code section 4118, the board has the ability to waive a requirement for licensure.
2. The board could exercise enforcement discretion and allow a specified time period to come into compliance. This option would have to be applied to all licensees.
3. The board could return to the legislature and to clarify which data elements, if any, have to be retrievable at the bedside.

Dr. Gutierrez stated the data elements need to be retrievable in case of a recall. She asked for an explanation of Scripps' process if a medication is recalled. Ms. Benner stated that the batch record is an electronic record and they capture all data elements including the lot number,

expiration date, and all components of the compound. The recalled medication could be traced back to a patient by conducting a search.

Mr. Room stated that although the data elements are readable (on the label), he thinks the intent of the law was to link the data elements on the barcode to a database where the elements would be present and retrievable.

Mr. Santiago stated that it was arguable whether the board could grant a waiver pursuant to Business and Professions Code section 4118 because the language is a waiver for a requirement of licensure. Ms. Herold clarified that Scripps had not been issued a license based on their inability to meet the law's requirements.

Mr. Santiago also stated that the board could not use its enforcement discretion across the board because that would constitute an underground regulation. Mr. Room agreed. Steve Gray, representing the California Society of Health-System Pharmacists (CSHP), stated that CSHP was the sponsor of the bill and he was personally involved in developing the language. He stated that the board's interpretation of the law is incorrect and that the intent was not to have the data readable at the bedside. He didn't believe that a waiver was necessary, but he offered to work with the CHA to create some clarifying language.

Perry Flowers, representing Kaiser Permanente, spoke in support of Scripps and Sharp.

Board Discussion

Ms. Veale asked if the board waives this requirement for Scripps and Sharp they would open it up for anyone to seek waiver. Mr. Room confirmed that the board would have to review and approve each request for waiver and added that CSHP has already created some language and is searching for an author.

Jonathan Nelson, CSHP, commented that currently they are working with the legislature to get this issue resolved.

Committee Recommendation (Motion): Approve a five year waiver for Scripps Health and Sharp Health Care that as long as the lot number is provided on the label and the required data elements are otherwise retrievable, waive the requirement that the data elements in section 4128.4 be retrievable at the patient's bedside by way of a barcode.

Support: 10 Oppose: 0 Abstain: 0

Jonathan Nelson, CSHP, commented that they will be including the lot number requirement in their proposed legislation language.

8. Summary of the Presentation from K. Scott Guess, Pharm.D., RPh - Proposal for Safe, Effective Dispensing of Controlled Substances

Background

Dr. K. Scott Guess requested the opportunity to appear before the Enforcement Committee to discuss his proposal for safe, effective dispensing of controlled substances. Dr. Guess indicated that pharmacies cannot get an adequate supply of controlled substances and patients are being affected negatively. Wholesalers are reducing or eliminating supplies due to pressure from the

DEA who say they're just enforcing the Controlled Substances Act. There is increased pressure on everyone in the supply chain to reduce the number of controlled substance prescriptions due to an increase in prescription drug-related deaths.

Dr. Guess proposed creating a "Controlled Substances Advanced Practice Pharmacy" registration which could be regulated at the state level. This new registration would allow pharmacies that meet the requirements to safely, consistently, and effectively dispense controlled substances to patient in need of pain management. A copy of Dr. Guess's presentation follows the meeting minutes. No action was taken by the committee, nor were public comments made.

Board Discussion

Dr. Castellblanch commented that a Controlled Substances Advanced Practice Pharmacy is an interesting idea but he would like to see them also consider the use of alternatives to controlled substances for pain management.

Misty Guess, nurse, commented that when Dr. Guess's pharmacy was unable to obtain controlled substances last summer three patients died, they believe as the result of being unable to obtain pain medication.

Mr. Lippe asked to confirm if Dr. Guess believes that the three patients died as the result of not receiving pain medications. Ms. Guess responded that one of the patients was already medically frail and ended up having to be admitted to the hospital where the patient died.

Ms. Butler remarked that there is still an obligation to make sure that patients receive their legitimate pain medications.

Dr. Gutierrez asked if any patient complaints regarding this. Ms. Herold responded that complaints were received regarding a specific pharmacy asking the board to require the wholesaler to sell the drugs to the pharmacy that wholesalers had cut off. However, the board does not require wholesalers to sell drugs to a pharmacy nor does it require a pharmacy to dispense specific medications.

Dr. Castellblanch provided statistics on the opioid epidemic and noted that while he appreciates the need for patients to receive pain medications, he wants to be sure that the board does not lose sight of the overall opioid epidemic.

William Steward, pharmacist, commented that as a pharmacist who deals with pain patients he is under a great deal of scrutiny.

9. Enforcement Statistics

Background

The enforcement workload statistics for the first two quarters of the fiscal year as well as SB 1441 Program Statistics were provided in the meeting materials.

Board Discussion

Dr. Gutierrez briefly reviewed the enforcement statistics provided in the materials.

Dr. Gutierrez noted that only one sterile compounding license was surrendered and given the scrutiny they are under, she was surprised there was not more. Ms. Sodergren responded that while the license surrenders are low, the board issues cease and desists and they can begin breaking out these numbers for the enforcement statistics.

There were no public comments.

10. Second Quarterly Report on the Committee's Goals for 2013/14

Materials in the board meeting packet display that the board is not meeting its success indicators for its enforcement related activities. This is due in part to a number of vacancies within the office as well as the training of new inspector staff, when the board received a significant number of new staff. Through ongoing efforts to complete the oldest cases as well as fill vacant positions, staff expects gradual improvement in all areas.

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

c. Compounding Matters

1. Update on Implementation of New California Sterile Compounding Laws: Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva)

Senate Bill 294 (Chapter 565, Statutes of 2013) strengthens the board's ability to regulate and monitor pharmacies that compound sterile drug products. This law prohibits a pharmacy from compounding or dispensing to patients in this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license. Such licensure must follow a board-performed inspection. The law also eliminates accreditation by designated agencies as an alternative to board licensure.

Assembly Bill 1045 (Chapter 302, Statutes of 2013) 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 also requires 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 12 hours of the recall notice.

Since enactment of these bills, board staff has been taken steps to implement the provisions of both measures including education of our licensees, revisions to application and renewal forms, and advocating for the necessary staff and training resources. Board staff estimates that about 612 sterile compounding pharmacies will require inspection prior to July 1, 2014 when enactment of these provisions takes effect. In addition staff estimates another 150 site will require inspection before the end of the calendar year. Inspections will be conducted on a random, unannounced basis.

The committee reviewed the proposed sterile compounding application. The law requires every location where sterile compounding is preformed to be licensed as a sterile

compounding pharmacy. In the case of a hospital, the board may need to issue several sterile compounding licenses to “satellite” locations throughout the hospital where sterile compounding is performed. In such cases, it is the staff’s intent to only require a single hospital pharmacy license and link each separate sterile compounding location via a separate compounding license to the main hospital’s pharmacy license.

Ms. Herold indicated the board has initiated inspections ahead of the July 1, 2014 license requirement.

Ms. Herold also stated that the board is going to be communicating to all interested parties via subscriber email list in the next few months as details are finalized and as the July 1, 2014 deadline approaches.

Steve Gray, representing California Society of Health-System Pharmacists, verified that if an application was made now, an inspection would be based on current regulations. Secondly, he verified that each separate area in which compounding takes place, needs a separate license. He pointed out that there is no definition of a satellite pharmacy in law or regulation.

In response, Mr. Room explained, for example, that if a hospital has four locations with varied conditions, the board can’t state that the hospital meets the requirements in the regulations if the requirements are not being met in all locations. There is no way to capture all the conditions and issues that might be taking place at different locations under one sterile compounding license.

A question was also raised regarding whether records would need to be kept in the main pharmacy or at each satellite pharmacy. Mr. Room stated that for immediate use it would be best to keep records in the satellite pharmacy, but for long term storage it is perfectly acceptable to keep he records in the main hospital pharmacy.

Board Discussion

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

2. Discussion and Possible Action Regarding Extension of Board Approval of Accreditation Agencies for Sterile Injectable Compounding Pharmacies until July 1, 2014

Business and Professions Code sections 4127 – 4127.8 provide for the regulation of pharmacies that compound sterile injectable drug products in a pharmacy. Pharmacy law currently creates an exemption from the licensure requirements for a pharmacy that is accredited by a private accreditation agency approved by the board (B&PC 4127.1 (d) and 4127.2 (c).) This exemption will be repealed July 1, 2014 when the provisions of SB 294 take effect.

There are currently five accreditation agencies approved by the board. As a matter of process, the board approved such entities for a specified period to allow for periodic review. Approval of four accrediting entities listed below will expire in February 2014 unless the board grants an extension.

- A. Accreditation Commission for Health Care, Inc. (ACHC) Currently Approved Through February 2014
- B. Community Health Accreditation Program (CHAP) Currently Approved Through February 2014
- C. Pharmacy Compounding Accreditation Board (PCAB) Currently Approved Through February 2014
- D. American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) Currently Approved Through February 2014.

Board Discussion

Ms. Veale asked if JACHO was also an accrediting agency. Ms. Herold responded that SB 294 eliminates JACHO as an accrediting agency July 1, 2014.

Ms. Veale asked how many sites are JACHO accredited. Ms. Herold responded that we do not know how many out of state sites are accredited as the agency will not provide that information.

Committee Recommendation (Motion): Approve extensions of accreditation agencies through June 30, 2014 for ACHC, CHAP, PCAB and HFAP.

Support: 10

Oppose: 0

Abstain: 0

3. Update on Compounding Provisions Enacted by HR 3204, the Federal Drug Quality and Security Act

Included as part of the federal Drug Quality and Security Act (HR 3204) are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by “outsourcing facilities.” The federal law sets forth voluntary requirements for licensure and enforcement, future fees and future regulation.

During the committee meeting Supervising Deputy Attorney General Joshua Room provided a high level overview of the requirements of this new law and its potential to impact California’s regulation of compounding pharmacies. California’s law is more restrictive than the federal law in several areas.

California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with our board and comply with California’s requirements, even if the entity becomes licensed with the FDA as an outsourcing facility.

Mr. Room stated that if and until the FDA says otherwise, he believes California should continue to enforce the sterile compounding and regular pharmacy licensing requirements against both in-state and out-of-state facilities that dispense compounded medications to California patients.

Representatives of McGuff Compounding Pharmacy asked whether the board could provide any direction regarding the California allowance for prescriber office use and the apparent federal disallowance of compounding for prescriber office use.

Mr. Room stated that the board had not addressed the question and that it would be up to the FDA to decide whether they will to enforce in a way that is contrary to California state law. California state law permits prescriber office use.

Mr. Blair from McGuff Compounding Pharmacy said that it was his understanding that California will have to enter into a memorandum of understanding (MOU) with the federal government to regulate interstate distribution. The MOU is supposed to define an inordinate amount of compounding and make sure that California will follow up on complaints. In his view, California already defines an inordinate amount of compounding and he hoped the board would use that as a basis for discussions when entering into an agreement. He also hoped that the MOU would not restrict interstate compounding. He felt that limiting interstate compounding to a percentage would hurt California pharmacies as well as patients.

Mr. Room stated that previous attempts to define an amount which would establish a line between compounding and manufacturing were unsuccessful. He indicated that the FDA has not yet initiated talks to enter in to an MOU.

Ms. Herold indicated that the FDA has always taken the position that pharmacy compounding is only pursuant to a prescription. Although California law has allowed anticipatory compounding by pharmacies as well as compounding for prescriber office use for over 25 years, the FDA doesn't recognize pharmacy compounding for prescriber office use at all. Any compounding pharmacy could be declared a manufacturer by the FDA at any time. Without a prescription in hand, compounding pharmacies are running a risk of being declared a manufacturer.

Ms. Herold stated that the FDA issued a letter on January 9, 2014, that they expect to only see patient-specific compounding from pharmacies. Presumably outsourcing facilities will perform some amount of non-patient specific compounding.

A suggestion was made that when the board begins talks to enter into the MOU that the board consider using the language in 16 CCR 1735.2 which concentrates on control over safety in quality without restricting interstate trade.

Rich Kruzynski, President of Pharmedium Services, stated Pharmedium has registered as an outsourcing facility with the FDA and indicated that they will be under much more scrutiny from the FDA than they would be from any state regulator. He believes federal registration is a better way to getting oversight for a large-scale sterile compounding operation.

George Suarez, retail pharmacist, asked whether federal section 503(B) and the registration of outsourcing facilities pertains just to sterile products. Mr. Room answered that it applies to all pharmacy compounding – sterile and non-sterile.

Tony Park, on behalf of the California Pharmacists Association, asked if the board has considered some sort of reporting mechanism to facilitate the reporting of out-of-state compounding pharmacies who continue to engage in illegal activities.

Mr. Room stated that this is actually a violation of state law, and the board would investigate these as complaints.

Board Discussion

Mr. Room explained that under the Federal Food Drug and Cosmetic Act (FFDCA), compounded drugs are considered a “new drug” and have to go the entire new drug process and meet specific requirements before they can be produced and sold in interstate commerce. Newly enacted HR 3204 reiterates the 503A exception (which had been invalidated in the 9th circuit), that allows licensed pharmacies to compound patient specific medications and without meeting all of the FFDCA requirements. It also creates a new registration category in section 503B which allows an outsourcing facility to not meet *all* of the FFDCA’s requirements. So far outsourcing facilities have not yet been inspected by the FDA and the fees will not be collected until October 2014. The federal law does not have any direct impact on the state’s impact to regulate.

Dr. Gutierrez asked if outsourcing facilities can use wholesale distributors. Mr. Room responded that they cannot use a distributor, they must ship directly.

President Weisser asked what the board’s position would be on federal regulations that do not allow for compounding to supply for prescribers’ offices. Mr. Room responded that California is one of the states that allows for non-patient specific compounding for use by a doctor’s office. He added that he had been provided with copies of warning letters that the FDA has sent to pharmacies that identify compounding for prescriber office use as a violation of 503A. Ms. Herold commented that the board has a number of enforcement cases pending where facilities are taking advantage of the prescriber office use exception.

William Blair and Damon Jones, from McGuff Compounding Pharmacy, expressed their concerns that California law only allows for the compounding of medications for prescriber office use so they cannot supply to hospitals or clinics. This is problematic as many of the drugs hospitals are requesting are on the FDA shortage list and McGuff is unable to supply them.

Rich Kruzynski, President of Pharmedium Services, stated that Pharmedium was the first to register with the FDA as an outsourcing facility. Ms. Herold noted that many of the requirements the FDA has are also requirements in California and stated that the board can consider formatting their reporting requirements similar to the FDA so that facilities are not having re-format their FDA reports to submit to California.

Steve Gray, CSHP, reported that CSHP members are very concerned about their ability to obtain the medications that they have come to rely on from these facilities especially as even basic things, such as saline, are in short supply.

4. Summary of Recalls of Compounded Drugs Throughout the United States

Copies of subscriber alerts sent regarding the recall of compounded drugs were provided in the meeting materials.

Dr. Gutierrez commented that many of the recalls were the result of pharmacies not using large enough sample sizes for their testing.

Damon Jones commented that the FDA is not only looking test results, they are looking at the testing method. Some pharmacies unknowingly use testing labs that are not USP recognized labs and cannot show the testing methods to the FDA. This causes the FDA to issue a recall even if the medications were sterile.

d. Summary of September 10, 2013, Presentation From Da Vita Rx Regarding Prescription Drugs Dispensed to Renal Clinics for Administration to Specific Patients

Background

DaVita RX could not attend the October 2013 board meeting, and requested that this matter be postponed for review at this board meeting. A summary of their presentation and committee discussion from the September Enforcement Committee is provided below.

Presentation and Discussion

The committee heard the presentation from representatives of DaVita Rx regarding the return and reuse of unused prescription medications that were previously dispensed to renal patients but never received by the patient. These medications are transported to renal centers via common carriers.

Ned Milenkovich stated that DaVita Rx is a full service pharmacy specializing in renal care. All medications are sent to the dialysis centers in a controlled locked box and the medication rests in a sealed tamper-proof evident packaging. In many cases the medication is returned to the pharmacy for various reasons and this medication is then destroyed and not reused. These medications could be reprocessed when received back in the pharmacy. The integrity of the medication is maintained throughout each step of the delivery process and DaVita Rx is confident that the medication has never been received or administered to the patient nor left the tamper evident packaging. This is similar to what happens in a pharmacy when the patient never picks it up their medications and the medication is put back on the shelf. These medications would then be reused. This medication maintains its integrity and not touched by the original patient and hasn't been opened. Mr. Milenkovich also indicated that Florida and Texas currently allow this activity to occur.

Mr. Milenkovich is requesting to work with California to permit DaVita Rx to reprocess the unused medications that were properly handled and returned to the pharmacy, and then provide and use on other patients in the future. DaVita Rx sees this as a very important way to reduce health care costs where medications must be unnecessarily thrown away that could be used on other patients.

Dr. Gutierrez asked for clarification on the type of medications to be reprocessed and whether they are oral medications, sterile compounds, or solutions and was advised that these were primarily manufactured and in sealed containers.

Mr. Milenkovich stated that currently DaVita Rx is operating in Florida, Texas and California and that Florida and Texas permit this activity. Mr. Milenkovich stated that the definition of dispensed is whether the patient received the medication or didn't receive the medication, that if the patient didn't receive the medication then the prescription wasn't dispensed.

Dr. Gutierrez asked where the California pharmacy was located and was advised that there is one pharmacy located in San Bruno which dispenses about 4,000 – 5,000 prescriptions a day.

Dr. Gutierrez asked if this proposal was legal. Ms. Shellans stated that the issue is whether you can restock and resell such medication that has been shipped to a administration location and then returned for re-dispensing. There is no assurance that the drug is safe and has not been somehow damaged or adulterated. The law states you cannot transfer a drug, and cannot return drug products. The pharmacist can no longer be assured about the integrity of the drugs in such a system. Ms. Shellans does not recommend the returning and restocking of the drugs.

Mr. Lippe asked if there is some ability to verify if the drug was not adulterated. Mr. Room commented that you can never be sure that the drugs weren't adulterated.

The board should bless this practice but stated that DaVita Rx is on the hook if there is actual patient harm or a patient receives adulterated drugs.

Mr. Room applauded the general thinking and benefit to the healthcare system but noted that if something goes wrong, the pharmacy and pharmacist-in-charge are going to be responsible. Mr. Room cautioned the board in blessing this practice as the board can't say if those drugs have been adulterated.

Mr. Milenkovich stated that the definition of dispensing means furnishing of drugs or a device. Mr. Milenkovich maintains that the patient would never personally possess the medication, and the medication would always be in a tamper-resistant pouch. He stated that it doesn't sound like the board is saying it's not permitted, but instead to proceed with caution and that the pharmacy and pharmacists would be responsible for problems.

Mr. Milenkovich indicated that the medications are handled by the pharmacist, pharmacy technician, physicians, nurses, social workers, and FedEx. The drugs are temperature controlled during shipment.

Ms. Shellans asked if they have received feedback from FDA and was advised that they aren't aware of any requirements that FDA has regarding returned and reuse of medications. Ms. Shellans suggested that they look at FDA compliance guidelines section 7132.09.

Ms. Shellans stated that the Health and Safety Code prohibits someone from holding a drug that is adulterated and it really is about whether the drug is adulterated or not. Ms. Shellans stated that the general guidance and position of the board should be to say that you shouldn't return and reuse the medication.

Mr. Room stated that there is no action the board can or should take.

There were no comments received by the public.

Board Discussion

Ben DeMarco, assistant general legal counsel for DaVita Rx, provided a brief explanation of DaVita's services. Mr. DeMarco explained that in many cases the medication is returned to the pharmacy for various reasons and this medication is then destroyed and not reused. These medications could be reprocessed when received back in the pharmacy as they are in tamper evident containers. A sample of the tamper-evident prescription container was provided to the board.

Mr. Schaad asked what type of medications would most frequently be returned for resale. Typically binders are returned.

Dr. Gutierrez asked Mr. Room to provide information on the legal considerations for this type or return practice. Mr. Room responded that there is nothing in pharmacy law that permits pharmacies to receive returned medications for the purpose of destruction. DaVita is proposing taking back returned medications not for the purpose of destruction, but to redistribute to other patients. The risk is that these drugs could have been adulterated prior to their return. Mr. Room added that dispensing adulterated drugs would result in enforcement action by the board; DaVita needs to decide if it is willing to assume this risk.

Ms. Veale stated that she supports improving efficiencies and saving patients money; however she is unsure that DaVita could really ensure that the drugs are not adulterated.

Mr. Schaad asked how large of a geographic area this take back practice would occur in. Mr. DeMarco responded that they already do this in Florida and Texas but tack backs would only occur between a California pharmacy and a California dialysis center.

Mr. Room stated that he did not feel that the board could state that this practice is authorized by law. Mr. Room added that historically the board's policy position has been that returns inherently introduce complications in the supply chain that could potentially harm consumers.

Dr. Wong asked what happens when a mail order pharmacy receives a returned prescription medication from a patient. Ms. Herold responded that the mail order pharmacy cannot re-dispense a medication after it has been returned to them.

Dr. Gutierrez asked how unused medications are handled in nursing homes. Dr. Ratcliff and Mr. Room responded that only in skilled nursing facilities, where the medication is always under the supervision either a registered nurse or above, does the board allow for the return of unused medications.

The representatives from DaVita asked if in the absence of express prohibition, if the board would be able to provide some informal guidance to the general public so that it can understand better what the board's intent is. Mr. Room responded that the California's underground regulations prohibitions would prevent the board from doing so, as any interpretation of law that is not case specific would be deemed an underground regulation.

Mr. DeMarco asked to clarify that the board is not taking any action at this time to prohibit this return program. The board stated no action is currently planned.

XII. LUNCH

The board recessed for a lunch break at 12:15 pm.m and resumed at 1:15 p.m.

XIII. LEGISLATION AND REGULATION COMMITTEE REPORT

Mr. Lippe provided a report on the Legislation and Regulation Committee meeting that was held on January 29, 2014.

Dennis McAllister, representing the Arizona Board of Pharmacy, invited the board to attend the May 17th NABP annual meeting. Ms. Herold stated that the Governor's Office has to approve all out-of-state travel, even if there is no cost to the state.

a. Legislation Report

1. Status of Board-Sponsored Provisions

A. Issuance of a Public Reprimand for Violations That Would Not Warrant License Denial or Issuance of a Probationary License

Background

In May 2012, the board voted to sponsor a statutory provision to authorize the board to issue a public reprimand for violations that may not warrant license denial or issuance of a probationary license. Any such reprimand issued with a license would constitute discipline, and would be reported to the National Practitioner Data Bank. Staff continues to work to secure an author to carry the proposal. A copy of the board-approved text was provided in the meeting materials.

Board Discussion

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

B. Designated Representatives – Minimum Age Requirement

Background

In 2012, the board voted to amend Business and Professions Code Section 4053 to amend requirements related to designated representatives. The board-sponsored provisions were included in the Senate Committee on Business, Professions and Consumer Protection's 2013 omnibus measure, SB 821. Following introduction of Senate Bill 821, the board voted to also require that a designated representative meet a minimum age requirement of 18 years of age. This amendment will be provided for inclusion in the 2014 omnibus committee bill. A copy of the approved language was provided in the meeting materials.

Discussion

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

2. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

A. AB 467 (Stone) Prescription Drug Collection and Distribution Program

Assembly Bill 467 will require prescription drug collection and distribution program "intermediaries" to be licensed with the board. Within the scope of that license, these intermediaries may facilitate the donation and distribution of donated medications to and from participating repository programs. The bill requires renewal of the license yearly.

The fee for such an intermediary license and renewal is \$300 but provisions allow non-profit organizations, as defined, to be fee exempt. The bill has an "urgency clause" which means that upon signature by the Governor, the provisions would be effective.

The committee is recommending that the board ratify the "Support" position taken by the Messrs. Weisser and Lippe taken January 10, 2014.

Board Discussion

Ms. Herold provided an example of an intermediary to the board. Dr. Castellblanch asked if a police department would be considered an intermediary. Mr. Room clarified that in this bill an intermediary is only referring to a drug broker who is facilitating action between entities who are donating unused drugs to redistribute medications to medically indigent. Ms. Sodergren added that this bill is not intended to create a drug take back program.

Committee Recommendation (Motion): Ratify the "Support" position taken by the Messrs. Weisser and Lippe taken January 10, 2014.

Support: 10 Oppose: 0 Abstain: 0

B. SB 506 (Hill) Retail Sales of Ephedrine Products: Pilot Project

Under current law, pseudoephedrine and related products (PSE) are available without a prescription in limited quantities. These drugs must be kept behind the pharmacy counter, and pharmacies are required to maintain logs related to purchases. Retailers cannot sell in a single transaction more than three packages, or 9 grams of a product that contains PSE products. These limitations and requirements do not apply to the dispensing a PSE product pursuant to a valid prescription.

Senate Bill 506 would repeal existing statutory provisions for over-the-counter sales of PSE products and replace them with new sales limits consistent with federal law. The bill would impose restrictions on sales of PSE products, and require retailers to store them in a locked cabinet behind the counter.

The bill also would authorize a pilot project (until 2019) to require the electronic recording of PSE sales (those not related to a prescription). The bill provides that retailers would be required to immediately transmit specified information regarding PSE purchases to the National Precursor Log Exchange (NPLEx), a privately funded out-of-state data base. This information would include the individual's name, date of birth, address and the product sold, the quantity of packages, and the total gram amount of PSE products involved in the sale. This system

would also provide retailers with a real-time alert if an individual attempts to purchase PSE products in excess of the sale limits. This pilot project would sunset January 1, 2019.

The board does not have a position on SB 506. Staff continues to monitor this two year bill.

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

C. SB 727 (Jackson) Medical Waste: Pharmaceutical Product Stewardship

Last Amend: April 3, 2013

Board Position: *None*

Status: 2-Year Bill

The board was advised that the author's office is no longer moving the bill.

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

b. Regulation Report

1. Discussion and Possible Initiation of Rulemaking to Amend Section 1707.5 of Title 16 California Code of Regulations Regarding Patient-Centered Labeling Requirements

At the October 2013 Board Meeting, the board voted to modify the board's patient-centered prescription label requirements at Section 1707.5 (a) (1) to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(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:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

The language reflects the board's decision to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label, and to require these items be printed in 12-point sans serif typeface.

Board Discussion

Ms. Veale asked if it was best to approve the agreed-upon changes to section 1707.5 (a), and initiate the rulemaking and then go back and discuss the additional items remaining with patient-centered labels. Ms. Herold confirmed that initiating the rulemaking now to establish 12

point font is in the public's best interest.

Ms. Veale asked what the timeline would be for 12 point font to be in use in pharmacies. Ms. Herold responded that January 2015 would be the earliest the rulemaking would be complete and added that the board could choose a more specific effective date. Ms. Sodergren recommended that the board establish an effective date when the board adopts the recommendation.

Committee Recommendation (Motion): Direct the executive officer to initiate a rulemaking to modify the text of Section 1707.5 of Title 16 California Code of Regulations as presented at this meeting. Authorize the executive officer to make any non-substantive changes to the rulemaking package and issue a notice and proposed language for 45 day public comment period.

Support: 10

Oppose: 0

Abstain: 0

2. Board-Approved – Undergoing Administrative Review (Information Only)

A. Fee Schedule –Proposal to Amend Title 16 California Code of Regulations Section 1749

Background

On April 24, 2013, the board approved a proposal to amend Title 16 California Code of Regulations Section 1749 to increase the board's fees to the statutory maximum. The rulemaking was initiated on June 14, 2013, and the 45-day public comment period concluded July 29. A regulation hearing was held at 1:00 p.m. on July 30, 2013.

At the July 2013 Board Meeting, the board approved the motion to direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the executive officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at Section 1749 as noticed on June 14, 2013.

The final rulemaking file was submitted to the Department of Consumer Affairs for review on October 21, 2013. The board was advised that the rulemaking file was submitted to the Business, Consumer Services and Housing Agency on January 14, 2014.

Board Discussion

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

B. Combined Rulemaking – Proposal to Amend Sections 1745 and 1769, and to add Section 1761 to Title 16 California Code of Regulations Related to Partial Fill of a Schedule II Prescription, Criteria for Rehabilitation, and to Further Define Unprofessional Conduct

At the February 2013 Board Meeting, the board voted to modify the text of its proposal at Section 1762. Staff prepared a notice of modified text that was issued for a 15-day public comment period.

The final rulemaking file was submitted to the Department of Consumer Affairs for review on October 10, 2013. In accordance with Business and Professions Code section 313.1, the director of the Department of Consumer Affairs may request an extension in the one-year notice period to promulgate regulation in the event that the one-year notice period lapses during the director's 30-day review period. Board staff was advised on October 17, 2013, that the director of the Department of Consumer Affairs signed an extension letter for the review of rulemaking file as the one-year notice lapsed October 18, 2013, during the Director's 30-day review period.

On January 10, 2014, the rulemaking file was delivered to the Office of Administrative Law for review.

Board Discussion

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

3. Board-Approved – Discussion and Possible Action

A. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1732.2, 1732.5, and 1732.05 related to Continuing Education

The board previously approved a 45-day public comment period for three proposals related to continuing education. Due to the significant changes in pharmacy law as a result of SB 294 (Emmerson, Chapter 565, Statutes of 2013) and SB 493 (Hernandez, Chapter 469, Statutes of 2013), board staff recommends revisiting the three continuing education regulation proposals.

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education

Proposed amendments to section 1732.2 would specify additional methods of obtaining board-accredited continuing education. Pharmacists are required to complete 30 hours of continuing education per renewal period. Specifically, the board's proposal would specify that a pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) may annually be awarded up to six hours of CE hours for conducting a review of exam test questions; would specify that a pharmacist or pharmacy technician may be awarded up to six hours of CE for attending a full-day board meeting and up to two hours of CE for attending a full committee meeting of the board; and would specify that an individual may be awarded three hours of CE for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas

The board's proposal would require continuing education in specific content areas for pharmacists. Specifically, the proposed text would require six of the 30 units required of continuing education for a pharmacist renewal to be in specified content areas.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education

The board's proposal would amend section 1732.05(a)(2) to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

Board Discussion

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

4. Board-Approved – Awaiting Notice

A. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.6 Related to Renewal Requirements

At the July 2013 Board Meeting, the board voted to amend sections 1702, 1702.1, 1702.2, and 1702.5 to Title 16 of the California Code of Regulations. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

Proposal to Amend Section 1702 – Update Pharmacist Renewal Requirements

The board's proposal would amend section 1702 to add as a condition of renewal, the pharmacist must disclose on the renewal form any disciplinary action against any license issued to the individual by a government agency, the proposal also defines disciplinary action.

Proposal to Amend Section 1702.1 – Update Pharmacy Technician Renewal Requirements

The board's proposal would amend section 1702.1 to add as a condition of renewal a fingerprint requirement for pharmacy technicians who do not have an electronic record of the licensee's fingerprints in the Department of Justice's criminal offender record identifier. Additionally, this proposal adds as a requirement for a licensee to disclose specified convictions and disciplinary actions on license renewal applications.

Proposal to Amend Section 1702.2 – Update Designated Representative Renewal Requirements

The board's proposal would amend section 1702.2 to require designated representatives who do not have an electronic record of the licensee's fingerprints in the Department of Justice's criminal offender record identifier to resubmit their fingerprints. Additionally, this proposal adds the requirement for a licensee to disclose specified convictions and disciplinary actions on renewal applications.

Proposal to Amend Section 1702.5 – Update Nonresident Wholesaler or Nonresident Pharmacy Requirements

The board’s proposal would amend section 1702.5 to add as a condition of renewal, a requirement for a nonresident wholesaler or nonresident pharmacy to disclose on the renewal license form any disciplinary action against any license issued to the licensee by a government agency as well as establishing a definition of a disciplinary action.

Board Discussion

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

C. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to “Section 100” Regulatory Actions

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 change, the executive officer shall report to the board at its next regularly scheduled board meeting any regulation changes made under this authority. This delegation expired December 31, 2013.

At the October 2013 Board Meeting, staff proposed language 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.” At the October 2013 Board Meeting, the board voted to direct staff to initiate the formal rulemaking process, issue the amended text for a 45-day public comment period. The board also directed that if no negative comments are received, staff shall take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law. The board also delegated to the executive officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process.

Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking. The approved language was provided in the meeting materials.

Discussion

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

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

No comments from the board or from the public.

ADJOURNMENT

1:47 p.m.