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

DATE: July 17 – 18, 2012

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

BOARD MEMBERS PRESENT:
Stanley C. Weisser, RPh, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Neil Badlani, RPh
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Amy Gutierrez, PharmD,
Rosalyn Hackworth, Public Member
Deborah Veale, RPh
Shirley Wheat, Public Member
Albert C.M. Wong, PharmD
Tappan Zee, Esq. Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Miller, Staff Analyst (July 17 only)
Jan Jamison, Information Officer

Note: The webcast for this meeting is available at:

http://www.dca.ca.gov/publications/multimedia/webcast_archive.shtml

Call to Order

President Stan Weisser called the meeting to order at 11:04 a.m.

I. General Announcements

President Weisser welcomed two new professional members to the board.

Amy Gutierrez is the pharmacy director and chief pharmacy officer for Los Angeles County Department of Health Services.

Albert Wong is a co-owner of Oakland Pharmacy Inc.

President Weisser recognized and congratulated Rosalind Hackworth, Gregg Lippe and Ryan Brooks for their reappointments to the board.

President Weisser conducted a roll call. Board members present: Neil Badlani, Greg Lippe, Rosalyn Hackworth, Deborah Veale, Tappan Zee, Randy Kojioka, Shirley Wheat, Ryan Brooks, Ramon Castellblanch, Amy Gutierrez, Albert Wong and President Weisser.

II. Approval of the Full Board Meeting Minutes of May 1 and 2, 2012

MOTION: Approve the minutes of the May 1 and 2, 2012, board meeting.

M/S: Veale/Hackworth

Support: 9 Oppose: 0 Abstain: 3

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

No public comment was provided.

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

President Weisser recognized and congratulated three pharmacists for being licensed in California for 50 years. David Bendahan, Al Takahashi and Jody A. Stewart, in attendance at the meeting, were presented with 50 year pins.

V. SUMMARY OF THE SUNSET REVIEW ISSUES IDENTIFIED BY THE SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT THAT WERE ADDRESSED BY THE BOARD DURING ITS MARCH HEARING

Executive Officer Herold discussed that the Sunset Review is a very important milestone for the Board of Pharmacy's continued existence. Ms. Herold explained that the Business, Professions and Economic Development Committee posed a series of questions to the board which were answered in great detail in the 900-page Sunset Review Report. The report was submitted to the Legislature on November 1, 2011, and is available on the website. It has been nine years since the previous Sunset Review was conducted.

Ms. Herold summarized the timeline for the process following submission of the report as:

- February 23 - Senator Price authored and introduced SB 1237, which would extend the board's sunset date for four years. Without adoption of the bill, the board would lose its statutory authority on January 1, 2013.

- March 5 -The Senate Business, Professions and Economic Development Committee advised the board of 12 issues that the committee would like discussed.

- March 19 - President Weisser and Ms. Herold testified before the committee.

- April 19 – Formal written comments were submitted.

http://www.pharmacy.ca.gov/publications/sunset_2011.pdf

Issues addressed by the Senate Business, Economic and Professional Development Committee for Sunset Review:

Issue #1 – Quorum problems

The committee asked about the difficulty of conducting business due to board vacancies and the potential for the lack of a quorum. Ms. Herold explained that the board has 13 member positions, and seven board members are needed for quorum. To date, the board has not been required to cancel any meetings due to lack of a quorum.

Issue #2 – Budgetary problems

The committee expressed concern about overspending in the AG line item and asked how the board would address this matter in the future. Ms. Herold explained that AG costs are necessary and consistent with the board's consumer protection mandate and

that despite hiring and spending freezes, the board hasn't compromised expenditures in the enforcement area. Ms. Herold reiterated that the board would not curtail enforcement activities in the future and that a future budget change proposal would probably be initiated to increase the line item for AG spending to reflect past years' expenditures.

Ms. Herold provided that in 2015 or 2016, a fee increase may be initiated for Board of Pharmacy licensees. At the current time, the board's fees are at the statutory minimums.

Issue #3 – Statutory Reporting Requirements

Ms. Herold provided that the California Pharmacy Law "Section 800 reports" requires licensees or their legal representatives to report to the board any settlement or arbitration award over $3,000 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services. Additionally, a clerk of a court that renders a judgment for an amount over $30,000 where the licensee has committed a crime, or is liable for any death or personal injury, as specified, be reported to the board within 10 days after the judgment is entered.

Over the last two years, the board has advised licensees through its newsletter that these reports are required. In January 2012 the board sent a letter to all headquarters of chain retail pharmacies operating in California, informing them that Section 800 reports were due. That action triggered a slight increase in the number of reports received, and board staff was able to absorb the workload.

Issue #4 – Proof of Intern Hours Earned

The committee asked about the board's plans to address the difficulty out-of-state graduates experience in submitting intern hours in order to qualify for the California licensing exam. Such applicants are required to secure separate affidavits from every pharmacy in which they gained intern experience, years after getting the experience. This is also time consuming for the board to process the paperwork.

The omnibus bill currently pending in the Senate will fix this problem by allowing the State Board of Pharmacy in another state to transfer intern hours to the California board.

Issue #5 – Unlicensed Activity or the Underground Economy

Ms. Herold provided that this issue specifically dealt with unlicensed activity and the steps the board was taking to address it. Ms. Herold explained that there are two major areas of unlicensed activity that the board typically deals with and these were highlighted to the committee.

a. Purchasing from an Internet Site that Is Not a Licensed Pharmacy.

Ms. Herold explained that the National Association of Boards of Pharmacy has reported that 96 percent of Internet pharmacy sites are not operating legally, and only 4 percent are licensed and operating legally. Ms. Herold provided that one of the provisions the board has had on the books since early 2000 allows the board to cite and fine $25,000 per prescription for medication dispensed via the internet without an appropriate exam.

Mr. Brooks inquired about the possibility of hiring additional inspectors who would be dedicated to internet pharmacy investigations and whose salaries would be paid via fines assessed by the board. Ms. Herold provided that this may be a possibility and was confident that such a program would fund itself.

b. Unlicensed Wholesaler/Pharmacy Doing Business in California

Ms. Herold stated that the counterfeit Avastin found in California was being purchased by 16 doctors' offices in California from an unlicensed, out-of-state wholesaler.

The Board of Pharmacy has re-instituted the practice of conducting inspections for all new pharmacies to ensure they are legitimate enterprises.

Issue #6 – Pharmacist Recovery Program

The committee inquired about the board's Pharmacist Recovery Program (PRP). More specifically, the committee asked if it was necessary for the board to continue to maintain this program and whether the program should be audited.

Ms. Herold explained that the board's philosophy doesn't support diverting substance abusing practitioners from discipline. The board does encourage practitioners who have been identified as having substance abuse problems to enroll in the PRP as the board continues the investigation. Statistics show that only 7 percent of enrollees in the PRP are *not* known to the board, or not the subject of an investigation.

Ms. Herold provided that after addressing the committee's questions regarding the program, she felt that many of their concerns had been alleviated.

Issue #7 – Drug Diversion and CURES

The committee asked the board to address the CURES Program and its role in drug diversion and enforcement efforts, and to provide recommendations for future success and viability of the program.

Ms. Herold provided that prescription drug abuse is an escalating problem. There is a very high street value on many prescription drugs and the pharmacy staff is often targeted because of their ability to access and divert drugs.

Ms. Herold explained that drug diversion is a very high priority for the board and that the board strongly supports the CURES program and wants to help ensure its continuing operation.

Pending legislation will allow the board the opportunity to take a support position on finding an alternative source of funding for the program. The program is currently funded by California's General Fund, but the Department of Justice may discontinue funding for the program in the near future.

Options for funding in the future would include the continuation of federal grants, instituting a surcharge on drug manufacturers for each controlled substance sold in California, requiring specialized registration for prescribers and pharmacies, and increasing registration fees for various health care professionals. The board presented the following options for continuation of the program:

1. Keep the program with the Department of Justice

2. Transfer the program to another agency such as the Board of Pharmacy

3. A combination of #1 and #2

Issue #8 – Workforce Development

The committee asked the board if California has a pharmacist shortage and if so:

1. What is the impact to the Federal Patient Protection and Affordable Care Act?

2. What is the impact on the pharmacist workforce and healthcare delivery?

3. How do delays in the licensing process impact the pharmacy workforce in California?

Ms. Herold explained to the committee that pharmacy workforce experts believe that there is no shortage of pharmacists now, nor is there expected to be one in the immediate future. However, if a large number of pharmacists are needed to provide direct services due to the Affordable Care Act, there could be a shortage.

Issue #9 – Implementation of Requirements for ePedigree

Ms. Herold explained that the board was asked to provide an update on ePedigree.

The board is now actively engaged in implementing requirements for the ePedigree requirement. The Senate Business, Professions and Economic Development Committee has been the primary supporter of ePedigree since early 2004, when the chair of the committees sponsored each of the three bills (also 2006 and 2008).

Ms. Herold explained that in late 2010 the board resumed quarterly public meetings for the supply chain. At the time the board submitted the Sunset Review report in 2011we had already provided future meeting dates. Our next meeting date is scheduled for September 11, 2012, with another one scheduled for December.

Ms. Herold further provided that action would be taken at this board meeting to address the activation of a serialized number and the issue of grandfathering. The board is also ready to receive surveys from interested parties on elements for inference.

In the near future, the board will start working on drop shipment pedigrees and the linkages between invoices and shipping notices.

We are still looking at a federal solution that would provide meaningful security for the supply chain and remove California's role.

Issue #10 – Prescription Label Standards

Ms. Herold explained that at the time of the Sunset Hearing in March, the board of Pharmacy had its patient centered label and interpreter requirements in effect. Since the beginning of the year, board inspectors were actively assessing the quality of the labels and ensuring that interpreters were available for the public when requested.

The board is in the final stages of development for the new notice to consumers poster and the interpreter advisory poster. In addition, a consumer survey has been developed and administered to solicit consumer feedback regarding the new labeling requirements.

Ms. Herold provided that a legislative report is due on these items on January 1, 2013. In addition, the board has committed that by December 2013 it will fully evaluate whether there are additional legislation or regulation requirements needed to improve these requirements.

Issue #11 – Drug Take Back Programs

The committee asked about the board's involvement in drug take-back programs.

Ms. Herold provided that since the board regulates the entities that dispense drugs in California, that we would take an active role in the development of drug take-back programs. She explained that there is currently a tremendous prescription drug abuse problem in the country. California does not have a legislative solution, but there is currently a bill in the legislature that addresses drug distribution and reuse programs.

Issue #12 – Continuance of Board of Pharmacy

Ms. Herold provided that the committee recommended that the board be continued as a regulatory agency with a consumer protection mandate.

Recognition of Meeting Guests

President Weisser introduced and welcomed Holly Strom, past president of the Board of Pharmacy, and Dennis McCallister, past president of the National Association of Boards of Pharmacy.

Dennis McCallister introduced Regina Mendez Harper, a member of the New Mexico Board of Pharmacy.

VI. LICENSING COMMITTEE REPORT

There was no meeting of the Licensing Committee in the past quarter.

Mr. Lippe introduced the following items for discussion:

a. Implementation of Self Query Reports from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank for All Applications for Initial Licensure in California

Relevant Statutes

Business and Professions Code Section 4053 authorizes the board to issue a license to a designated representative. A designed representative is a person responsible for protecting the public health and safety in the handling, storage and shipment of dangerous drugs and dangerous devices in a wholesaler or veterinary food-animal retailer.

Business and Professions Code Section 4112 provides that any pharmacy located outside this state that ships, mails or delivers dangerous drugs or devices or controlled substances into California shall be considered a nonresident pharmacy. Further, this section specifies that no person may act as a nonresident pharmacy unless first licensed by the board.

Business and Professions Code Section 4161 specifies that any person located outside this state that either ships, sells, mails or delivers dangerous drugs or devices; or sells or brokers such sales to practitioners or to other businesses must be licensed as a nonresident wholesaler prior to providing such services.

Business and Professions Code Section 4207 requires the board to make a thorough investigation to determine whether an applicant is qualified for the license being sought and specifically mandates that the board investigate all matters directly related to the issuance of the license that may affect the public welfare. In addition, subdivision (d)

authorizes the board to request any information it deems necessary to complete the application investigation required and specifies that such information deemed necessary by the board in carrying out this section shall not be required to be adopted by regulation.

Background

The National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank (HIPDB) are two federal data banks that have been created to serve as repositories of information about health care providers in the United States. Federal law requires that adverse actions taken against a health care professional's license be reported to these data banks.

The board currently reports information regarding its licensees who have been disciplined or otherwise had an adverse action to the NPDB/HIPDB required by law. In addition to our reporting, all adverse actions taken by federal or state agencies, exclusions of health care practitioners in federal or state programs, criminal convictions, and civil judgments are also required to be reported to the NPDB/HIPDB. NPDB/HIPDB serves as the repository of data for all such actions taken against healthcare practitioners.

As part of the application requirements for the pharmacist exam, as well as for licensure as a pharmacist intern or pharmacy technician, the board now requires a self-query from the HIPDB/NPDB. This requirement was implemented via the regulation process. At the conclusion of the rulemaking process to add this as a requirement for the pharmacist licensure exam and pharmacy intern license, board staff was advised by the Office of Administrative Law, given the authority established in B&PC 4207, that a regulation is not necessary to implement such a requirement.

Staff Recommendation

Board staff recommends that the application form and requirements for nonresident wholesalers, nonresident pharmacies and designated representatives be updated to include a self-query report as part of the application. Requiring such a search will ensure that the board has all relevant information when making a licensing decision and does not inadvertently issue to an individual or entity that has been disciplined in another state unless, after review of the information, the board determines that an issuance is consistent with the board's consumer protection mandate. Should the board deem this necessary, staff recommends that these provisions be implemented for applications received on or after September 1, 2012.

MOTION: Support the staff recommendation that the board require a self-query as part of the application process for non-resident wholesalers, non-resident pharmacies and designated representatives of wholesalers.

M/S: Lippe/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

Ms. Veale was not in attendance.

b. Competency Committee Report

(1) California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

The committee was advised that the board instituted a quality assurance review of the CPJE effective 4/1/2012. This process is done periodically to ensure the reliability of the examination. This review concluded on 6/27/2012.

(2) Examination Development

The Competency Committee will hold its annual meeting of all subject matter experts in August 2012. Each of the two workgroups will also convene one meeting in the fall of 2012 as well.

c. Reporting of Quarterly Data for Future Strategic Plan Reports on Committee Goals

Chairperson Lippe stated that as the board transitions to its new strategic plan, it is time to also evaluate how information is presented to conform to the new plan outline. During this portion of the meeting, the board will discuss one possible implementation strategy. Should the board approve this reporting mechanism, similar reporting will be used for the board's other strategic objectives.

President Weisser referenced the new reporting structure that was developed by Assistant Executive Officer Anne Sodergren.

Ms. Sodergren explained that as the board transitions to the new strategic plan, one of the goals is to develop a better way to demonstrate where the board is with respect to meeting performance standards. As such, the proposal is to make it easier for board members and the public to quickly identify where success indicators are being met and where the board is falling short. The new reporting structure was created for the Licensing Division, but Ms. Sodergren explained that if the board approves it, it will be rolled out to the other divisions.

Discussion

After reviewing the committee's objections, Mr. Lippe offered that many of the people applying for licenses have previous drug histories, and made a suggestion that the situation be addressed earlier in the licensing application process. Mr. Lippe suggested moving the issue to the Licensing Committee.

Mr. Badlani provided that the board doesn't currently license pharmacy clerks, but they are often responsible for diversion so the board may want to consider the idea.

DCA Staff Counsel Kristy Shellans offered that the discussion would be more appropriately addressed at the next Licensing Committee meeting.

d. Fourth Quarterly Report on the Committee's Goals for 2011/12

Mr. Lippe referenced the last quarterly report of the committee's goals in the board packet.

There no public comments.

Lunch Recess

President Weisser adjourned the meeting for lunch at 12:17 p.m.

Resumption of Meeting

President Weisser reconvened the meeting at 1:34 p.m.

VII. LEGISLATION AND REGULATION COMMITTEE REPORT

Licensing Committee Chair Shirley Wheat provided the Legislation and Regulation Committee Report as follows:

PART I – REGULATIONS

a. Approved by the Office of Administrative Law

1. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

2. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination - Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

Background

Committee Chair Shirley Wheat provided that in 2011, the board initiated a rulemaking to add section 1727.2 and to amend section 1728 to require a pharmacist intern applicant and an applicant for the pharmacist examination to submit with his or her application a self-query report from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-

HIPDB). The board determined this information was necessary and pertinent to the board's pre-licensure review of an applicant and will allow the board to determine if an applicant has been the subject of discipline in another state prior to making a decision on an application. This is the same type of self-query report that was approved in 2011 for pharmacy technician applicants.

During review of this regulation, the Office of Administrative Law reviewing attorney contacted staff to remind the board that pursuant to Business and Professions Code Section 4207(d), the board may request any information it deems necessary to complete an application investigation. For the purposes specified in § 4207 the board is not *required* to adopt such a requirement by regulation.

Ms. Wheat provided that both regulations would be effective July 18, 2012.

There was no board discussion or public comment.

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

1. Proposed Amendments to Title 16, California Code of Regulations, Section 1735.1 - 1735.3 and 1751.2 Related to Compounding Drug Products (*15-day comment period will be closed on July 20).*

Background

On March 9, 2012, the board noticed for a 45-day public comment period, proposed to Title 16 California Code of Regulations beginning at section 1735.1 relating to compounding drug products. The 45-day comment period concluded on April 23, 2012, and the board conducted a Regulation Hearing on May 1, 2012.

At the board meeting held May 1-2, 2012, the board considered comments received during the 45-day public comment period and at the regulation hearing and voted to modify the text of section 1735.3(a)(6) to incorporate by reference USP 797 related to "Redispensed CSPs," and to amend Section 1751.2(d) modifying the text of the special label used for cytotoxic agents. The board directed that the modified language be made available for a 15-day public comment period.

A Notice of a 15-Day public comment period was issued on July 5, 2012; this public comment period concluded on July 20, 2012.

Committee Chair Wheat noted that because this notice period was still open for comment, the board will review and consider any comments received during the 15-day comment period at a future meeting. She noted, however, that if no negative comments are receive during the 15-day comment period, the board

has authorized the Executive Officer to complete the rulemaking process without bringing it back to the board for further consideration, including filing it with the Office of Administrative Law.

There was no board discussion or public comment.

2. Proposed Amendments to Title 16, Section 1746 – Emergency Contraception Protocol

Relevant Statutes
Business and Professions Code section 4052.3 authorizes a pharmacist to initiate emergency contraception therapy in accordance with either (1) standardized procedures or protocols developed by the pharmacist and an authorized prescriber, or (2) standardized procedures or protocols developed and approved by both the Medical Board of California and the board of Pharmacy.

The current state protocol was developed by the Medical board in 2004 and was adopted by the Board of Pharmacy that same year. Title 16 CCR § 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication and a typographical error was identified in the final protocol that requires correction.

Background
In 2011 the Medical Board of California approved language to update the emergency contraception protocol at section 1746 and at the October 2011 board meeting, the board approved that language for a 45-day public comment period. The proposed regulation was noticed on January 6, 2012, and the board received one comment in response to the notice.

At the board meeting held on May 1, 2012, Dr. Kathleen Hill-Besinque, a women's health specialist designated by the California Pharmacists Association, appeared before the board to answer questions related to the proposed protocol. At that meeting, the board rejected the comment received. The Board voted that upon concurrence by the Medical Board, to authorize the Executive Officer to finalize the rulemaking, adopt the language and file the rulemaking with the Office of Administrative Law for final review.

Recent Update
Committee Chair Wheat explained that following the board meeting in May 2012, Dr. Hill-Besinque suggested that staff modify the Table of Dedicated Emergency Contraception for the purpose of clarifying the dosing instructions and to use the word "tablet" instead of "dose," and to add a generic one-tablet EC regimen that was approved by the FDA on July 13, 2012. Staff initiated and prepared draft modified language reflecting the recommendations of Dr. Hill-Besinque, and the modified language is being brought before the board for consideration and

possible action at this meeting. Ms. Wheat noted that before this modified language could be noticed, the Medical Board of California must first consider the comment made by the 45-day comment period, and may also consider the modified language recommended by staff.

Staff Recommendation
Board staff developed modified language for the board's consideration and possible action at this meeting. The modifications made by staff are to the Table of Dedicated Emergency Contraception and would (1) clarify the dosing instructions, (2) change the word "dose" to "tablet," and (3) would add a new generic, one-tablet EC regimen to the table.

Motion: Direct staff to take all steps necessary to modify the text of Title 16 California Code of Regulations in Section 1746 as described at this meeting and upon concurrence and approval of the modified text by the Medical Board of California, direct staff to take all steps necessary to complete the rulemaking process, including issuing the modified text for a 15-day public comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process and adopt the regulations in Title 16 Section 1746 as noticed in the modified text notes.

M/S: Veale / Kajioka

Favor: 11 Oppose: 0 Abstain: 0

Ms. Wheat announced that the Medical Board of California would be meeting July 19 and 20, and would be adopting the regulations.

There were no comments from the board or the public.

Board Approved Regulations – Awaiting Formal Public Notice

1. **Proposed Addition of Section 1762 – Additional Grounds for Unprofessional Conduct**

Background
Ms. Wheat provided that in October 2010, the board began discussions to add 16 CCR section 1762 to implement components of the DCA's consumer protection enforcement initiative relative to unprofessional conduct. In February 2011 the board addressed draft language and moved to initiate the rulemaking process to amend Section 1762 to specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or

subpoena for records; and authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Staff is working to prepare a rulemaking package for a 45-day public comment Period for this proposal which will be pursued together with proposed amendments to sections 1745 and 1769.

There were no comments from the board or the public.

2. Proposed Addition of Section 1769 – Addition of Application Review to Criteria for Rehabilitation

Background

Ms. Wheat explained that this proposal would authorize the board to request that, in specific situations, an applicant for licensure undergo an examination to determine if the applicant is safe to practice. The board directed staff to initiate the rulemaking process to amend 16 CCR § 1769, specifying that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board.

Staff is currently working to prepare a rulemaking package for a 45-day public comment period, together with proposed amendments to sections 1745 and 1762.

There were no comments from the board or the public.

3. Proposed Amendments to Section 1745 – Partial Filling of Schedule II Controlled Substance Prescriptions

Background

Ms. Wheat provided that at the October 2010 board meeting, the board voted to initiate a rulemaking to amend Section 1745(c)(2) to allow pharmacies to maintain electronic records or document the original prescription when partially filling a Schedule II controlled substance.

Staff is working to prepare a rulemaking package for a 45-day public comment period, together with proposed amendments to sections 1762 and 1769.

There were no comments from the board or the public.

4. Proposed Addition of Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies

Background

At the May 2012 meeting, the board considered a recommendation from the

Licensing Committee to adopt requirements to specify standards for agencies that accredit licensed sterile injectable compounding pharmacies. At that meeting the board voted to initiate a formal rulemaking to add section 1751.9 to Division 17 of Title 16 of the California Code of Regulations.

Staff is currently preparing a rulemaking package for a 45-day comment period.

There were no comments from the board or the public.

5. Proposed Amendments to Section 1732.2 – Board Accredited Continuing Education

Background

At the board meeting held January 31, 2012, the board considered amendments to the continuing education regulation. At that time, a rulemaking to amend section 1732.2 related to continuing education was pending final review at the Office of Administrative Law. The board voted to withdraw from OAL its rulemaking to amend Section 1732.2 and refer the matter to the Licensing Committee.

At the May 2012 board meeting, the board considered proposed language to amend Section 1732.2 in a different manner and voted to initiate a rulemaking. Staff is in the process of preparing a notice package for this rulemaking.

There were no comments from the board or the public.

6. Credit in Specific Content Areas

Background

The board has considered requirements related to continuing education in certain areas. At the February 2012 board meeting, the board determined it would proceed with a rulemaking to require six of the 30 units required for a pharmacist license renewal every two years to be in specified content areas. At the May 2012 board meeting, the board voted to initiate a rulemaking to amend section 1732.5 of the California Code of Regulations.

Staff is in the process of preparing a notice package for this rulemaking.

There were no comments from the board or the public.

7. Proposed Amendment of Section 1732.05 to Update Accreditation Agencies for Continuing Education

Background

At the May 2012 board meeting, the board considered a request from the California Pharmacists Association requesting a modification to section 1732.05 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. At that meeting the board voted to amend Section 1732.05 and to initiate a formal rulemaking.

Staff is in the process of preparing a notice package for this rulemaking.

There were no comments from the board or the public.

a. Under Development

1. Proposed Amendments to Section 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers) [referred to subcommittee]

Relevant Statutes
Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the most recent version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

Discussion
Because of concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 board meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

The board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change. Board President Weisser encouraged board members Badlani, Kajioka and Gutierrez to be part of the subcommittee and begin work in this area soon.

There were no comments from the board or the public.

2. Proposed Amendments to Section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Ms. Wheat provided that this item is currently under consideration and has been referred to the Licensing Committee. This proposal has not been further developed due to other board priorities.

The Licensing Committee has not yet initiated a program review of the veterinary food-animal drug retailer program. Until the committee completes a review, no language will be brought back to the board for reconsideration.

There were no comments from the board or the public.

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

Relevant Statutes
California Code of Regulations section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Business and Professions Code section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

Chapter 9, Division 2, Chapter 19 (Business and Professions code Sections 4300-4315) defines disciplinary proceeding for the board as well as the grounds for taking such discipline.

Background
Last year the board directed staff to restructure and update its *Disciplinary Guidelines*. Subsequent to this, in April 2011, the SACC finalized the uniform standards required in B&PC section 315. At that time it was understood that the standards needed to be incorporated into the board's disciplinary guidelines to facilitate implementation.

During the July 2011 meeting, staff was directed to incorporate the uniform standards into the *Disciplinary Guidelines* for consideration by the board at a future meeting. During the September 2011 board meeting, the board voted to pursue a regulation change to *Disciplinary Guidelines* which were noticed in October 2011 and later modified during the January 2012 board meeting.

During the May 2012 board meeting, the board was advised of a recent advice provided to the department from the Government Law Section of the Attorney General's Office as well as a legal opinion from the Legislative Counsel Bureau. Based on these opinions, the department sent a memorandum clarifying that the board has no discretion on how to implement the standards. The board was advised of two options – proceeding as is or rescinding the current regulation. Two areas where the board has discretion were identified including: (1) whether

the uniform standards should be placed in a regulation separate from the *Disciplinary Guidelines*; and (2) if the regulation should include a definition of (or criteria by which to determine) what constitutes a "substance abusing licensee." Based on this information the board voted to rescind the current rulemaking file and requested that counsel craft language to facilitate implementation of the standards as well as language to define "substance-abusing licensee."

However, the scope of the proposed changes to the *Disciplinary Guidelines* includes more than just the uniform standards. As such, a regulation change is necessary to implement those additional changes.

Ms. Wheat provided that Staff Counsel Shellans is preparing the language requested by the board regarding the definition of "substance abusing licensee" as well as language to incorporate SB 1441 standards.

Discussion

Ms. Shellans stated that in April of this year the Deputy Director of Legal Affairs for the Department of Consumer Affairs issued a memo to all healing arts boards, taking the position that a separate document may be required to contain the standards for dealing with substance abusing licensees.

Ms. Shellans presented the following three options that were discussed in this memorandum:

Option #1 - Burden shifting option

This option identifies a violation for self-use of drugs and alcohol. Ms. Shellans expressed concerns that the option would shift the burden of proof to a licensee, which could be problematic.

Option #2 – Clinical Diagnostic Evaluation

The board's proposal would require that a respondent undergo a clinical diagnostic evaluation. If the evaluator recommends restrictions or conditions on the respondent's practice, the board may adopt these restrictions or conditions. Then if the respondent violated them, it would be a violation of probation.

Ms. Shellans expressed concern that this standard could come into play after a licensee is already on probation.

Option #3 – Establishment of Proof

This option requires an "establishment of proof" that an individual is a substance abuser. The board would have to prove substance abuse first, and then apply the standards.

Discussion followed regarding the definition of “substance abuser” and what types of offenses would trigger that description.

President Weisser asked that Ms. Shellans and Ms. Sodergren collaborate on the options presented and that Deputy Attorney General Room produce a definition. Mr. Weisser directed that enough information be collected by the end of August to forward to a subcommittee, and that the subcommittee will then propose a recommendation at the October board meeting.

There were no comments from the public.

PART II – LEGISLATION

a. Board-Sponsored Legislation for 2012

SB 1575

Committee Chair Shirley Wheat provided that SB 1575 contains two omnibus proposals sponsored by the board:

1. Section 4209 of the Business and Professions Code would provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned for pharmacist applicants (section 23 of the bill).

2. Section 4300.1 of the Business and Professions Code would ensure the board can put discipline on record even if the license is cancelled (section 24 of the bill).

No provisions related to the Board of Pharmacy have been modified since they were amended into the bill on April 16.

The board established a position of SUPPORT, which was affirmed at the May 1 board meeting.

Committee Recommendation: *None (no changes needed)*

There were no comments from the board or the public.

Mr. Brooks and Mr. Castellblanch left the room at 2:46.

b. Regulation of Dangerous Drugs and Devices

1. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Background

AB 389 establishes the Standards for Service for Providers of Blood Clotting Products for Home Use Act by imposing specified requirements on providers of blood clotting products for home use. The bill has been signed by the Governor.

The board has opposed this bill since introduction, citing concerns regarding jurisdiction and challenges in enforcing some of the provisions. The January 17, 2012, version of the bill removed references to home nursing services being under the supervision of pharmacists, one source of the board's opposition. The board reaffirmed its position of Oppose at the January 2012 board meeting and again at the May 2012 board meeting. Since that time, the bill was passed by both houses of the Legislature, and was signed by the Governor.

Committee Recommendation: *None*

Oppose position. The bill has been enacted.

2. AB 1442 (Wieckowski) Common Carriers to Transport Pharmaceutical Waste

Background

AB 1442 amends the Medical Waste Management Act (which is under the jurisdiction of the CDPH) to define, for purposes of the act, "pharmaceutical waste" and "common carrier"; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste.

During the May 2012 board meeting, members discussed this measure and some of the concerns the bill posed in the current form. These concerns involved the need for controls in the movement of the drugs that are picked up and shipped. After discussion the board established an Oppose Unless Amended position.

Staff has worked with the author's office requesting changes to the legislation that will provide for the security of the pharmaceutical waste. The bill in its current form incorporates many of the changes requested. In light of the changes incorporated at the request of the board and the author's office commitment to working with the board, staff recommended that the committee consider changing its position on this bill to a neutral position.

During the committee meeting, members discussed the measure as well as the amendments incorporated at the request of the board. After discussion the committee voted to recommend a change in the board's current position on this measure from an Oppose Unless Amended to a Neutral position.

At the request of the author's office, board staff recently testified before the Senate Committee on Environmental Quality expressing gratitude to the author's office and sponsor for working with the board to address its concerns and indicated that the board would be reconsidering its position during the July 2012 board meeting and could be moving to a Neutral position.
There were no commends from the public or the board.

Motion: Ms. Wheat provided that the committee moves to change the board's current position on AB 1442 from an Oppose Unless Amended to a Neutral position.

Favor: 10 Oppose: 0 Abstain: 0

Mr. Brooks & Mr. Castellblanch were out of the room.

3. **AB 2348 (Mitchell) Registered Nurses: Dispensing Oral Contraception in Clinics**

Background
Ms. Wheat explained that The Nursing Practice Act authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic. This bill would, in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse- midwife, nurse practitioner, or physician assistant. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures (without having to be in a specified clinic setting).

On May 1, 2012, the board took a "Watch" position. Since that time, the bill has been amended to specify the standardized procedure / protocol under which a registered nurse may dispense self-administered hormonal contraceptives and also administer injections of hormonal contraceptives, and makes other changes specific to the Nursing Practice Act. The most recent version of the bill specifies that nothing shall be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed under Pharmacy Law.

The committee did not recommend a position on this measure.

There were no comments from the public or the board.

4. **SB 419 (Simitian) Solid Waste: Home Generated Sharps**

Ms. Wheat provided that there has been no change in this measure since the last committee meeting or the May 1, 2012, board meeting.

There were no comments from the board or the public.

5. SB 616 (DeSaulnier) CURES Program

The Legislation and Regulation Committee did not discuss this measure at its meeting held June 25.

This bill would establish the CURES Fund within the State Treasury to receive contributions to be allocated, upon appropriation by the Legislature, to the DOJ for the purpose of the CURES program. This bill was amended to affect CURES after the Legislation and Regulation Committee met in June. Staff recommends the board take a support position on this bill.

Motion: To establish the CURES Fund within the State Treasury

M/S: Lippe/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

Mr. Brooks was not in attendance.

6. SB 1301 (Hernandez) Prescription Drugs: 90-Day Supply

Background
This measure would specify conditions under which a pharmacist may dispense a 90-day supply of a dangerous drug, as specified, without first receiving authorization from the prescriber. The board established a position of Support on May 1. Since that time, the bill was amended to specify that a pharmacist shall not dispense a greater supply of a dangerous drug if the prescriber indicates "dispense as written" or words of similar meaning.

Committee Recommendation: The committee did not recommend a change in the board's position from support-unless-amended to support.

Public Comment
Mary Staples, National Association of Chain Drug Stores, explained that her organization is cosponsoring SB 1301. She provided that with recent amendments the bill would limit the amount of drugs dispensed at one time, based upon the prescriber's direction. "Dispensed as written" is new language.

Board member Kajioka indicated that this wording would be confused with the same wording which indicates "do not generically substitute another drug from that written on the prescription form."

Steve Gray from Kaiser Permanente commented that he reviewed corresponding language from 50 states, and that most computer companies have defaulted to "DAW" (dispense as written). Mr. Gray strongly encouraged the members to ask the author to define quantity differently.
Dennis McCallister, representing Express Scripts, agreed that the "DAW" reference would be confusing for pharmacies. He provided that the language in the bill isn't clear and should be further defined.

The board recommended that the committee's position on the bill be left as is, and Ms. Wheat and Ms. Sodergren will work with the author to further amend the language.

7. **SB 1329 (Simitian) Prescription Drugs: Collection and Distribution Program**

Summary
Ms. Wheat provided that under current law a county may establish a repository and distribution program under which a pharmacy may distribute donated/surplus medications to medically indigent persons. Currently, skilled nursing facilities, manufacturers, or pharmacy wholesalers may donate medications to a drug dispensary program. Under these programs, donated drugs must be (1) dispensed to an eligible patient, (2) destroyed as pharmaceutical waste, or (3) returned to a reverse distributor.
Those who donate medications to these programs are not subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program. SB 1329 would expand repository and drug distribution programs by allowing a county health officer to establish a program, and would expand the pool of defined entities that can donate drugs to the program. SB 1329 would also allow donated drugs to be transferred from one program to another. The bill would require certain information to be reported to the county, and would allow the board to request this information. The bill specifies entities, including the Board of Pharmacy, that may prohibit a pharmacy or clinic from participating in a program.

At the May 1, 2012 board meeting, the board established a position of Support if Amended. Since that time, staff has worked with the author's office to address the board's concerns. The current version of the bill contains some amendments that address the board's concerns, but there are a few areas that remain outstanding. Staff is continuing to work with Senator Simitian to address the board's concerns.

Ms. Wheat provided that the committee was working with the author's office and did not recommend a change in the board's position.

Ms. Gutierrez provided that the board should not support the bill unless there are enough provisions in the bill to safeguard public safety. She further offered that it would not be feasible to expect a county facility to monitor the safety requirements.

There were no comments from the public.

c. Sunset Review and Legislative Oversight

1. SB 1237 (Price) Sunset Extension to 2017

Ms. Wheat provided that the board took a Support position.

There were no comments from the board or the public.

d. Licensing and Pharmacy Operations

1. SB 377 (Solorio) Hospital Central Fill Pharmacies

Background

AB 377 provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership. The board's concerns were conveyed to the author and the sponsors indicated they plan to amend the bill back to a 2009 version that the board previously supported.

At the June 25 meeting of the Legislation and Regulation Committee, the chair reported that the measure has not changed since the board established its position in April 2011. Representatives from the California Society of Health System Pharmacists addressed committee and thanked the executive officer and the board for working with the sponsor and other stakeholders – adding that they expect amendments to be out any time. The committee did not make a recommendation to change the board's position.

Public Comment

Jonathan Nelson, California Society of Health System Pharmacists, offered that his association was working with Assemblyman Solorio's office on a couple of changes to the bill, as follows:

- Change the radius defined in the bill from 100 miles to 75 miles;
- Establish a definition for "common ownership."

Mr. Nelson explained that those changes would be made as soon as possible so the board could change its position on the bill from Support if Amended to Support.

Ms. Herold provided that she has seen the amendments, which are very similar to those that the board created in 2009. The amendments set up a dedicated license specifically for this repackaging function.
Ms. Herold explained that the board's goal is to ensure that hospital patients receive bar coded product before they have medication administered to them. This practice would ensure that the right drug is being administered to the right patient.

2. AB 1588 (Atkins) Reservist Licensees: Fees and Continuing Education

Background
AB 1588 would require a licensing board to waive renewal fees and continuing education for a member of the California National Guard or member of the U.S. Armed Forces while they are on active duty.

At the June 25 meeting of the Legislation and Regulation Committee, the committee discussed the prior version of the bill. At that time, staff counsel advised that the bill did not specify what the 'status' of the license should be (while waived) nor did the bill define "good standing". The committee asked that staff clarify the intent of the bill and report back to the board.

Since that time, the bill has been amended. The new version denotes a license is to be "current and valid" – not "in good standing." However, the newly amended version still; does not specify what the status of the license is to be while "waived." Because the bill authorizes a board to adopt regulations to implement the provisions, the board could specify what status the license is to be through regulations.

Committee Recommendation: The committee did not recommend a position on this measure.

Discussion
Discussion clarified that the licensee or registrant would be on inactive status during the period of the waiver. If the licensee is acting as a pharmacist in the military, he or she must have an active license and thus continue to renew the license.

Motion: Move to support the bill as is.

M/S: Tappan/Veale

Support: 12 Oppose: 0 Abstain: 0

3. AB 1896 (Chesbro) Tribal Health Programs: Health Care Practitioner

Background
This measure seeks to codify into state law existing federal law (the Patient Protection and Affordable Care Act). This bill would specify that a healthcare professional employed by a tribal health program is exempt from state licensure if that health professional holds a license from another state.

Recently, it was brought to staff's attention that under the Federal provisions of the Indian Health Care Improvement Act, non-Indian patients may be extended health care at all tribal facilities. According to the California Rural Indian Health Board, Tribal Health Programs (THPs) have the authority *and desire* to serve the non-Indian population. The CRIHB notes that other non-California licensed providers also serve California residents (University of California, Veterans Administration). The CRIHB states that in many rural parts of California, THPs are the only providers in these regions and they operate as part of an integrated rural health care delivery system. They state the purpose of AB 1896 is to assist in remedying the shortage of doctors, dentists, nurses, and other providers by conforming State law to Federal law.

The board did not take a position on AB 1896 at the May 1, 2012, board meeting.

The Legislation and Regulation Committee met on June 25 and discussed the March 27 version of the bill. Counsel noted it is unclear what legal standing the board may have to address concerns that Tribal Health Programs and populations they serve.

The committee made a recommendation that the board take a position of Oppose Unless Amended, and offer the author amendments that would require a Tribal Health Program to be licensed by the board if they wish to provide services to Californians off of tribal lands. Unfortunately, prior to the board meeting the bill was enrolled and presented to the Governor. The board did not take any further action on this bill.

4. AB 1904 (Block) Military Spouses: Temporary License

Background
As amended, this measure authorizes a board to expedite the licensure of an applicant who is a military spouse, and authorizes a board to adopt regulations to administer the provisions. Staff anticipates that this may impact two primary license types: pharmacist, and pharmacy technician.

The former version of the bill provided for *temporary* licensure of applicants, as specified, and would have required the board to expedite the processing for the purpose of issuing the temporary license, specified the term of a temporary license, and authorized the board to promulgate regulations. The board established a position of "Support" for the prior version.

The Legislation and Regulation Committee met on June 25, and discussed the term "current license" as reflected in subdivision (a). The committee asked staff to clarify

the meaning of this term. The committee did not recommend that the board change its current position on the measure.

Discussion
Ms. Shellans provided that the board should ensure that applicants who are expedited have current, active and unrestricted licenses. In order to comply with the statute, the author should consider adding the definitions “active” and “unrestricted” to the bill, since these are the applications that will be expedited. She further explained that the applications from other states that have a restriction of any kind would not be expedited.

Ms. Shellans suggested including a side letter suggesting a clarification.

Ms. Wheat provided that the board has currently taken a Support position.

There were no public comments.

5. AB 2570 (Hill) Licensees: Settlement Agreements

Ms. Wheat provided that there has been no change in this measure since the board established its position of “Oppose Unless Amended” at the May 1, 2012 board meeting.

Background
This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board. The board supported this provision.

The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action. The board opposed this provision.

Since the May board meeting, staff has had discussions with the author’s staff who do not share the board’s perspective.

The committee did not recommend a change in the board’s position.

There were no comments from the public or the board.

6. SB 1095 (Rubio) Pharmacy: Surgical Clinics

Background

Ms. Wheat provided that SB 1095 would expand the definition of a clinic in section 4190 to include not only surgical clinics licensed by the CDPH under H&SC section 1204, but also to accredited outpatient settings and to Medicare certified ambulatory surgical centers, as specified. SB 1095 would provide that board licensure is optional, and that the board is authorized to inspect those clinics which are licensed by the board. A clinic licensed by the board would be able to comingle the drug stock of the clinic and would authorize the clinic to purchase drugs at wholesale. SB 1095 would provide that nothing in the article shall preclude a physician and surgeon from dispensing dangerous drugs as provided in B&PC Section 4170. As Introduced, the board established a position of Oppose Unless Amended (May 2012).

Since that time, staff has been working with the author's office and the sponsors to resolve concerns among the stakeholders. Amendments sought by the board have been made. At the June 25 meeting of the Legislation and Regulation Committee a recommendation was made to change the board's position from Oppose Unless Amended to Support. This followed action by the board president and Legislation and Regulation Chair on July 2 to change the board's position from OUA to Support.

Recommendation of Committee: Ratify the position of "Support" taken on July 2, 2012.

Motion: Ratify the position of "Support" taken on July 2, 2012.

M/S: Veale/Zee

Support: 12 Oppose: 0 Abstain: 0

7. SB 1481 (Negrete McLeod) Clinical Laboratories: Community Pharmacies

Background

This bill would permit a community pharmacy to provide blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA, and approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test kit. The current version also would require a pharmacy that obtains a CLIA certificate of waiver to notify the public health officer of the county in which the pharmacy is located that the pharmacy is performing those tests.

The board established a Support position at the May 1 board meeting.

Committee Recommendation: *(No change in position recommended.)*

There were no comments from the board or the public.

d. Other

1. AB 2369 (Valadao) Prisoners: Pharmacy Services

Background
Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for facilities under the jurisdiction of the DCR that is cost effective and efficient, and that may incorporate a requirement to use "less expensive" medications. AB 2369 does not seek to modify existing Pharmacy Law. The board considered the introduced version of the bill (2/24/12) which required that "generic" medications be specified; however, the amended version of the bill specifies that "less expensive" medications be used.

Committee Recommendation: Chairman Wheat provided that the board did not take a position on this bill.

There were no comments from the board or the public.

2. SB 1185 (Price) Centralized Intelligence Partnership Act (DCA)

Background
This bill would create a Centralized Intelligence Partnership ("partnership") as a pilot program – until January 1, 2018 – for the purpose of combating the underground economy. This partnership would institutionalize collaboration among state agencies, with a key element being to authorize and facilitate data and intelligence sharing among the partnership and state agencies. The partnership shall consist of the Employment Development Department, the Franchise Tax Board and the State Board of Equalization.

The Department of Consumer Affairs is one of six state agencies designated that may participate in the pilot program in an advisory capacity. Should the DCA wish to participate, the DCA may provide a representative to the advisory committee, which shall meet at least quarterly. The bill in its current form authorizes participating agencies to exchange intelligence, data, documents, information, complaints, leads, etc. SB 1185 specifies that the partnership shall report to the Legislature, and specifies the frequency and content of those reports.

The Legislation and Regulation Committee did not discuss this bill at its meeting held June 25, nor did the board take a position on it.

There were no comments from the board or the public.

e. <u>Additional Legislation Impacting the Board or Its Regulatory Jurisdiction</u>

PART III – LEGISLATION AND REGULATION COMMITTEE

Fourth Quarterly Report on the Committee's Goals for 2011/12

Chairwoman Wheat announced that the Fourth Quarterly Report was included in the board packet.

There were no comments from the board or the public.

<u>Recess</u>

President Weisser called a recess at 3:51 p.m.

<u>Resumption of Meeting</u>

President Weisser resumed the meeting at 4:10 p.m.

VII. Presentation on a Proposed Amendment to the Alameda County Ordinance Code by Adding Chapter 6.53, Sections 6.53.010 through 6.53.120 to Require Any Person Who Produces a Drug Offered for Sale in Alameda County to Participate in an Approved Drug Stewardship Program for the Collection and Disposal of Unwanted Drugs from Residential Sources; Provide for Implementation, Enforcement, Fees, and Penalties; and Making Environmental Findings.

<u>Public Comment</u>
Dr. Joel Kreisberg, Executive Director of the Teleosis Institute, provided that the proposed ordinance would require pharmaceutical manufacturers to pay for drug disposal programs in Alameda County. The program is based on a CalRecycle program, which currently has 24 disposal sites in the county that use lock boxes but are not staffed. Mr. Kreisberg provided that the amendment had been approved during the first round of discussion and is due to come up for final approval in a couple of weeks.

President Weisser invited members of the public to testify in support or against the proposed amendment to the Alameda County Ordinance.

Marjorie Powell, Sr. Asst. General Council for PhARMA, urged caution with the proposal. She provided that there was no provision for public safety and that 53 percent of the existing disposal programs were located inside pharmacies, some of which have open disposal bins. She also urged caution with the disposal guidelines. PhARMA urges

that unused or expired pharmaceuticals be mixed with undesirable substances and thrown away.

ADJOURNMENT FOR THE DAY

The board meeting was recessed at 4:47 pm.

Wednesday, July 18, 2012

IX. CLOSED SESSION 8:00 a.m.

Pursuant to Government Code Section 11126(c) (3), the meeting convened in Closed Session to Deliberate on Disciplinary Matters

Call to Order -- RESUMPTION OF THE OPEN SESSION 10:00 a.m.

X. EXECUTIVE OFFICER'S REPORT

Ms. Herold welcomed Linda Whitney, Executive Director of the Medical Board of California, and Kim Kirschmeyer, Assistant Executive Director of the Medical Board.

Ms. Whitney provided that the Medical Board is looking forward to collaborating with the Board of Pharmacy on a number of important issues, including:

- **Pain Management Summit** - Ms. Whitney provided that the summit will focus on the use and misuse of controlled substances. A former program specialist from the Medical Board will be planning the two-day session. The Board of Pharmacy will be using books by Dr. Fishman from the Medical Board, who has examined the issue of controlled substances and has been an expert in addiction medicine for quite some time. The summit is currently being planned for January 2013.

- **CURES Program** - The Board of Pharmacy and the Medical Board will continue to work together to secure continuation of the CURES Program.

- **Board of Pharmacy Newsletter** – The Medical Board has been distributing the Board of Pharmacy newsletter to all of its physician members. Ms. Whitney provided that the Medical Board recognizes the importance of educating its physician members and consumer audience about pharmaceutical industry news.

  Ms. Whitney explained that the Medical Board meeting was scheduled to begin the next day and the board would be reviewing the Emergency Contraception Protocol. The Medical Board was also scheduled to review their strategic plan and would be moving into the Sunset Review in the near future.

President Weisser commended Ms. Herold and Ms. Whitney for developing and enhancing the important relationship between the Board of Pharmacy and the Medical board.

Discussion

Mr. Weisser announced that the October 25 and 26 Board of Pharmacy meeting would be held in Sacramento and that a technology summit was being planning for October 24, the day before the board meeting starts. The summit will provide an opportunity to review different type of technology in use, or proposed for use, in pharmacies, hospitals and skilled nursing facilities.

Mr. Weisser commended Assistant Executive Officer Anne Sodergren and Board Analyst Laura Hendricks for their hard work in coordinating the move into expanded office space that affected some Board of Pharmacy staff.

Discussion followed about the proposal to move the October board meeting from San Diego to Sacramento. The decision to relocate to Sacramento was based on the Governor's travel freeze. Ms. Herold announced that the board was also in the process of establishing a video conference room to provide for easy teleconferencing with inspectors. The facility will further cut down on travel costs.

Ms. Herold provided that the board would implement the Governor's Furlough Plan, with a one day furlough each month, on August 1st. She explained that there would be a reduction of staff presence on Fridays, but that the plan was expected to have minimal impact.

XI. ENFORCEMENT COMMITTEE REPORT

Discussion and Possible Action Items From the Meeting Held June 12, 2012

a. Presentation and Discussion on the Use of the Pharmacist Assessment for Remediation Evaluation (PARE) Examination as an Optional Enforcement Tool to Assess Pharmacist Practice Deficiencies

Background

In years past, the National Association of Boards of Pharmacy had an examination that could be used to assess the knowledge and deficiencies in a pharmacist's education and training. This was an assessment that the board would periodically require in disciplinary matters where the skills of the pharmacist were in question. The NABP discontinued this examination several years ago.

In July 2011, representatives of the NABP attended the board meeting to discuss, among other items, a new pharmacist assessment process that could be used to

assess a pharmacist's knowledge. This assessment was called the Pharmacist Assessment for Remediation Evaluation (PARE). At that time the PARE was undergoing pilot testing by NABP.

Committee Meeting Discussion

According to the NABP, the PARE was developed to be used when an objective measure is needed to assist in decisions regarding pharmacist practice. The assessment is comprised of approximately 210 questions involving issues related to medication safety (50 percent), professional ethics (25 percent), and pharmacy practice (25 percent). It will take approximately 4.5 hours to complete and will cost $250.

Public Comments

Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy, presented information on the PARE exam and explained that it is a new assessment tool. The exam was developed to help with decision making to determine if a practitioner who has been out of practice needs additional training or exams. The exam would cover three primary areas: 1) Medicine Safety and the Practice of Pharmacy; 2) Professional Ethics/Pharmacist Judgment; and 3.) Clinical Pharmacy.

Mr. Catizone explained that the exam would be a pass/fail format and would require a grade of 80 percent to pass. Scores would be delivered to the Board of Pharmacy office, as well as to the examinee. The exam would be given four times a year and technical assistance would be available for test-takers between 9:00 a.m. and 5:00 p.m. Central Time.

Discussion

Discussion centered around how monitoring and security systems for the exam would work. Mr. Catizone provided that the exam would be administered at the board's offices, and if the exam was taken off-site, there would be controls in place to monitor the exam.

Mr. Catizone further explained that all practice areas would be covered in the exam and that the content would not be state-specific, but more general in nature. He suggested that state-specific questions would be more appropriate in the jurisprudence exam.

The cost of the exam would be $250 per applicant, and all applicants would be provided an exam study guide.

Ms. Herold provided that the Board of Pharmacy needs to assess the competency of pharmacists. An example would be a pharmacist who is making a lot of medication errors. She explained that this type of exam would give the board an opportunity to identify areas of deficiency and further protect the public.

President Weisser and Ms. Herold will forward this issue to a committee for further review and have the results available at the October board meeting.

Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

b.The Presence of Counterfeit Avastin and Altuzan Found in California Physician Offices and Clinics

Summary

In January, the FDA notified the board and the Medical Board of California about the identification of counterfeit Avastin discovered in California. Avastin is a cancer-treatment medication that is typically administered to patients (rather than dispensed to them) and high priced. The counterfeit Avastin contained no active ingredient.

The counterfeit drugs have been traced to a Tennessee wholesaler who sold the product to 19 physician offices through the US; 16 of these physician offices are located in California. This wholesaler is not licensed to do wholesaling or pharmacy sales in California.

In April, the board learned that an additional 42 California physician offices had purchased unapproved foreign drugs from various unlicensed entities.
These cases remain under investigation by various entities, including the FDA. .

More recently, counterfeit Adderall has been also discovered in the US, some of the origin has been from Internet sales initially, but there has been concern expressed that the drug could find its way into the US supply chain.

The board released a subscriber alert in early April reminding subscribers about the dangers of buying unapproved drugs from unlicensed sources. In January, the board developed an earlier alert about buying drugs from unlicensed entities.

1. **Dysfunction in California's Supply of Prescription Medication Discovered During Board of Pharmacy Investigations**

Summary

Ms. Herold explained that during inspections of California pharmacies and wholesale facilities, the board's inspectors have been encountering numerous serious violations involving "redispensing" of previously dispensed medication.

Ms. Herold provided a presentation to the board which included photos of the violations which were taken during pharmacy inspections. Some photos indicated secret rooms in pharmacies which were being used to sort and bottle previously dispensed medications.

Discussion

President Weisser offered that the board has been focused on e-Pedigree and prescription drug take-back programs to help alleviate these egregious violations.

Ms. Herold provided that the greatest driver of these illegal operations is to obtain drugs at a cheap price. The e-Pedigree program would help prevent this type of activity by providing a chain of custody for all prescription medications which identifies where each lot comes from.

2. Board of Pharmacy's Letters to Federal Representatives and Senators on Elements Needed in any Proposal for Federal Legislation

Summary
Ms. Herold explained that at the May board meeting, the board directed that a letter explaining California's e-pedigree requirements be sent to certain federal legislators who, throughout May and June, were deliberating on a possible federal system for drug chain security. This letter was sent in early May. A copy of the letter was in the board packet and the result was some congressional support for at least some of California's requirements.

3. Colloquy from Senators Enzi and Harkin in Support of Retaining Protections in California Law in Future Federal Requirements for Tracking Prescription Medications Through Pharmaceutical Supply Chain

Senators Enzi and Harkin released a colloquy on May 22, 2012, supporting California's serialization requirements as elements needed in a federal supply chain system for prescription drugs.

4. Presentations from Supply Chain Companies

1. Robert Celeste, Director, Healthcare, GS1 US, gave a presentation on the work of GS1 and supply chain companies to prepare for California's e-pedigree laws.

Lunch Recess and Resumption of Meeting

President Weisser adjourned the meeting for lunch and reconvened the meeting at 1:35 p.m.

Mr. Brooks did not return to the meeting.

XIV. PETITION FOR EARLY TERMINATION OF PROBATION

a. Shauna Weaver, RPH 49557
b. Annette Patterson, RPH 42732
c. Valerie Gaurano, RPH 38852

XV. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the board convened to deliberate on disciplinary matters at 2:54 p.m.

Resumption of Open Session
Open Session was resumed at 3:40 p.m.

Continuation of Enforcement Committee Meeting

Committee Chair Randy Kajioka asked if there were additional presentations regarding the e-Pedigree program.

There were no additional presentations.

5. **Discussion Regarding Proposed Regulation Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California's e-Pedigree Requirements**

6. **Discussion and Possible Action to Initiate a Rulemaking to Adopt Proposed Section 1747 to Title 16, California Code of Regulations -- Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California's E-Pedigree Requirements**

Summary
At the May board meeting, the board directed the Enforcement Committee to reconsider the proposed parameters for a serialized numeric identifier that will be the tracking number for each prescription container, and aggregated groups of containers in cases.

Proposed regulation text has been developed that mirrors a guideline developed by the FDA -- the FDA's "Guidance for Industry Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages."

Discussion
Chairman Kajioka explained that the committee reviewed and slightly modified the proposed text developed by the staff in reference to the FDA's guidelines.

Enforcement Committee Recommendation: Initiate a rulemaking to add Section 1747 to Title 16 of the California Code of regulations to specify a unique identification number for prescription medication pursuant to California's e-Pedigree requirements, authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide the proposed language for a 45-day public comment period.
There were no comments from the public or the board.

Favor: 11 Oppose: 0 Abstain: 0

Mr. Brooks was not in attendance.

Proposal to Add a New Article 5.5 and Article Title, and Add New Sections 1747 and 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than twenty (20) digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Authority: 4005, 4034, 4163 Business and Professions Code. Reference: Sections 4005, 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, 4163.5 Business and Professions Code.

7. Discussion Regarding Proposed Regulation Provisions for Non-pedigreed Dangerous Drugs Pursuant to Section 4163.2 of the California Business and Professions Code

Discussion Regarding Proposed "Grandfathering" Provisions for Non-Pedigreed Dangerous Drugs Pursuant to Section 4163.2 of the Business and Professions Code

Also at the May board meeting, the board directed the enforcement committee to reconsider the proposed parameters for "grandfathering" non-serialized products so that they may remain in California commerce after the e-pedigree requirements take effect.

During the Enforcement Committee meeting, the committee reviewed revised draft language. After review and discussion the committee voted to recommend the board initiate a rulemaking to adopt this language and recommended that the board take action to initiate a rulemaking to adopt this requirement.

8. **Discussion and Possible Action to Initiate a Rulemaking to Adopt Proposed Section 1747.1 to Title 16, California Code of Regulations – Establishing "Grandfathering" Provisions for Prescription Drugs in California Commerce After Activation of e-Pedigree Requirements**

Discussion

Mr. Room provided that the term "grandfathering" with respect to e-Pedigree refers to drugs that may be in stock as of the date of implementation of the program. These would not necessarily have an e-pedigree. California law at Business and Professions Code section 4163.2 would allow pharmacies to identify what drugs are in stock at the time of e-Pedigree implementation, through a declaration provided for the Board of Pharmacy.

The other part of the regulation deals with manufacturers, who must serialize 50 percent of their products by January 2015. This regulation defines the mechanism for which manufacturers will inform the Board about which 50 percent of their stock has been serialized.

Mr. Room provided that he worked with Staff Counsel Shellans to produce a definition that has subsequently been approved by the Enforcement Committee.

Enforcement Committee Recommendation: Initiate a rulemaking to add Section 1747.1 to Title 16 of the California Code of regulations, authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide the proposed language for a 45-day public comment period.

Favor: 11 Oppose: 0 Abstain: 0

Mr. Brooks was not in attendance.

Proposal to Add a New Article 5.5 and Article Title, and Add New Sections 1747 and 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 5.5. Pedigree Requirements.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board, by December 1, 2014, but no later than December 31, 2014, a declaration

signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board, by December 1, 2015, but no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no

later than August 1, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) A statement that specifies the means and source of acquisition; and,

(3) A statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Authority: 4005, 4034, 4163, 4163.2, 4163.4, 4163.5 Business and Professions Code. Reference: Sections 4005, 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, 4163.5 Business and Professions Code.

9. Discussion Concerning Elements for Inference as Provided by California Business and Professions Code Section 4163.3

The Enforcement Committee discussed the topic of inference. Inference would allow a read of a single serialized number on a case or pallet to link with every serialized package within the case or pallet, without having to separately read and confirm the presence of each individual container.

Mr. Room explained that the term “inference” describes the act of assuming that the contents of a drug container or box contains the product that is supposed to be inside, without having to scan each and every bottle or package. Mr. Room further explained that the board will need to define when inference would be appropriate and what risks may be involved.

Mr. Room provided that he would develop a written request to solicit feedback from industry regarding inference and would ask for that feedback by September 1, 2012.

Public Comment

Steve Tattevich, representing McKesson, explained that it might be difficult to solicit feedback from industry by September 1, 2012.

Mr. Kajioka provided that the information solicited would be simply a description of the process that the manufacturer, wholesaler or pharmacy would take for instances of inference.

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

10. Meeting Minutes of the June 12, 2012 Enforcement Committee Meeting

Mr. Kajioka provided that the minutes from the June 12, 2012, meeting were available to the board members in Attachment 7.

Mr. Kajioka referenced the following items not discussed during the Enforcement Committee meeting:

11. Board of Pharmacy's Letter to Federal Representatives and Senators on Proposed PDSA Amendments for Possible Inclusion in Pending 2012 Prescription Drug User Fee (Re-Authorization) Act

Immediately after the committee meeting in mid-June, the board was asked to provide comments on pending amendments to federal law that would have established supply chain requirements for prescription drugs.

The proposed amendments were not included in the pending 2012 Prescription Drug User Fee Act. A copy of the letter was provided in the meeting materials.

Mr. Room added that there are still efforts underway to enact federal legislation in this area in 2012.

12. Enforcement Statistics

There were no comments on these statistics provided in the board meeting materials.

13. Fourth Quarterly Report on the Committee's Goals for 2011/12

There were no comments from the board or the public.

XII. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

Committee Member Deborah Veale provided that the Communication and Public Education Committee met on July 17, 2012, immediately before the start of this board meeting.

a. Discussion on the Design of New Notice to Consumers Posters (as Required by Title 16 California Code of Regulations Section 1707.6)

Committee Member Veale provided that since the beginning of 2012, the Communications and Public Education Committee has been working on the design for the new Notice to Consumers poster.

The board viewed new poster designs and selected a design they felt would be appropriately differentiated from other posters and advertisements displayed in pharmacies. Ms. Veale explained that the final poster will be printed and mailed to all pharmacies in California. The poster will also be translated into additional languages and will be available from the board's office upon request.

b. Discussion about the Video Display Format Option for Notice to Consumers (as Required by Title 16 California Code of Regulations Section 1707.6)

Ms. Veale explained that the video version of the notice to consumers has been edited to allow each slide to remain on the screen for a minimum of 60 seconds as specified in the requirements. In addition, the board logo and state seal have been incorporated at the bottom of each slide.

The video will be available in DVD format for any pharmacy that requests it and will be available on the board's website. The next edition of The Script will also describe the requirements and how to obtain a copy.

The video will be presented in its final form to the committee at the next committee meeting to be held on August 29.

c. Discussion on the Format for Notice of Interpreter Availability (as Required by Title 16 California Code of Regulations Section 1707.6)

The "Point to Your Language" mini poster was slightly modified to improve the overall design. It is ready for release publicly, once the board's brand is added to the bottom of the poster. The poster provides translations into 12 primary languages in use in California and provides that interpreters will be provided for each of those languages if desired.

The notice is being finalized and will be ready for release.

d. Discussion on Securing Consumer Comments on the Board's Regulation Requirements for Patient-Centered Labels and Translations for Limited English Speaking Individuals

Ms. Veale reported that the board has a mandated report to the Legislature due January 1, 2013, on implementation of the patient-centered labels. Efforts to collect data for this report began in January 2012, and have focused on information collected during board inspections on labels in use and availability of interpreters.

One additional post-implementation piece of patient-centered labels will be collecting and reviewing consumer comments on prescription labels, and whether additional changes would be beneficial. Consumer surveys will be used to solicit consumer feedback.

The board will encourage pharmacies and others to assist with having consumers complete the surveys.

The board also committed that by December 31, 2013, it would reconsider all requirements put in place as part of the patient-centered labeling and interpreter requirements to evaluate if changes in the requirements are needed.

e. Update on an Assessment of the Board's Public Education Materials

Ms. Veale provided that board staff has begun an assessment of the board's current public education materials. This process includes updating existing consumer education materials and fact sheets, as well as identifying new materials needed to address current and relevant public pharmaceutical issues.

There are several new consumer education brochures in the works. These include *Teen Prescription Drug Abuse*, *Teen Abuse of Synthetic Cannabinoids*, *Prescription Drug Abuse* and *Purchasing Pet Meds Safely from Online Pharmacies*. Several more topics have been identified and brochures will be developed on an ongoing basis.

As part of the design process for the notice to consumers, board staff has been working with the Department of Consumer Affairs Office of Publications, Design and Editing to develop a brand identity for the Board of Pharmacy. This will include the development of a standardized menu of logo blocks and a consistent design look-and-feel for all printed publications and consumer education materials. The intent is to design brochures and fact sheets into a tri-fold format to allow for easier handling and better presentation.

Two national events are planned in coming months that will provide an opportunity for public relations and consumer outreach activities. Wake up to Medicine Abuse Week is a week-long collaboration sponsored by the Partnership at Drugfree.org and Cardinal Health, scheduled for September 23-29. American Pharmacists Month is scheduled for the month of October, where in prior years, the focus of the campaigns has been on "talk to a pharmacist." These public campaigns may be a good time for the board to

promote the new notice to consumers, interpreter availability and new prescription label requirements. There is also another DEA-sponsored consumer drug back day planned for the end of September that could be part of the promotions.

A new board website design is currently in the planning stages that will be consistent with the new design selected by the Governor. The color palette has been selected from a menu of approved state templates and new site architecture is being developed. The new architecture will be simplified and designed to be intuitive and easy to navigate. All content will be updated and refreshed as necessary.

f. Update on *The Script*

The August 2012 issue of *The Script* is currently undergoing legal review. The issue will focus on application of laws and the forthcoming e-Pedigree requirements. It also lists the multiple disciplinary decisions taken by the board since the beginning of 2012.

The issue will focus on items related to the patient-centered labeling project; specifically:

- the new notice to consumers poster that should be released and mailed to pharmacies later this summer,
- the option to use the video format of the notice to consumers (and how to obtain the video),
- the mini-poster notice of the availability of interpreters, and
- how to request an exemption to display a pharmacy's own video or interpreter availability mini-poster.

g. Public Outreach Activities Conducted by the Board

State government continues to be subject to a travel freeze that restricts all but the most essential travel. Moreover, the Department of Consumer Affairs must still preapprove all travel where a travel claim will be submitted. This has restricted board operations in all areas, including public and licensee outreach.

Public and licensee outreach activities performed during the fourth quarter of fiscal year 2011/12 include:

- April 13 – Executive Officer Herold provides a presentation on the board's enforcement program and consumer protection initiatives to UCSF students

- May 9 – Executive Officer Herold provides a presentation on the board's enforcement program to Ralphs' pharmacy managers

- May 17 – Executive Officer Herold provides a webinar training on California's e-pedigree laws for RfXcel

- June 13 – Supervising Inspector Hunt, Association Analyst Sue Durst and Public Information Officer Jan Jamison attend a Senior Scam Stopper Seminar in Stockton. Dr. Hunt provided a presentation on consumer awareness involving pharmacy services, and Ms. Durst and Jamison staffed an information booth.

- June 19 --- Executive Officer Herold provides a webinar training on California's e-pedigree laws for Axway

- June 20 – Inspector De'Bora White presents information about the board's enforcement program to pharmacists attending at CE program in Pasadena.

There were no comments from the board or the public.

h. Fourth Quarterly Report on the Committee's Goals for 2011/12

There were no comments from the board or the public on the materials provided in the meeting packet.

XIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

There was no meeting of the Organizational Development Committee in the past quarter.

Committee Chair Weisser provided a report on the following:

a. Budget Update/Report

1. Budget Report for 2011/2012
The final FY 2011/12 numbers will not be available until the beginning of August 2012.

Expenditures (as of May 2012): $11,768,117

Maximum spending authority for year: $14,400,000

Revenue Collected (as of May 2011): $12,506,718
The board has overspent its AG budget because the budget line item for several years has been insufficient to cover all of the legal services needed by the board. The board's budget currently authorizes $1,568,863 in AG expenditures. In 2010/11 the board overspent its Attorney General budget by almost $700,000. Although final budget figures are not yet available, board staff believes that the AG's budget will again far exceed our authorized expenditures, by roughly $600,000. The board may need to seek a budget augmentation or face difficult choices and curtail its administrative cases.
Budget Report for 2011/12

2. Fund Condition Report

According to a fund condition report prepared by the department (Attachment 2), the board will have the following fund conditions at the end of the identified fiscal years: 2010/11	$13,678,000	11.5 months in reserve (actual)
2011/12	$11,484,000	9.1 months in reserve
2012/13 2013/14	$8,405,000 $5,035,000	6.6 months in reserve 3.9 months in reserve

3. Budget Report for 2012/13

The budget year began July 1, 2012, and will end June 30, 2013. The governor signed the budget June 28, 2012, which provides a $15,289,000 spending authorization for the board.

The administration remains very focused on reducing state spending. One of the cost saving areas identified was a strict restriction on travel. Recently the department released at memo to all Executive Officers and Bureau Chiefs reminding all of the current travel restrictions and the exemptions to such restrictions. Board staff remains cognizant of the travel restrictions and follows the exemption process developed by the DCA. After a cost analysis, it was decided that the October 2012 board meeting will be moved to Sacramento, which will result in a cost savings of at least $1500.

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

Previous board Discussion

The staff continues to commit a significant amount of resources to implement BreEZe to ensure the board's operational needs are met. The executive officer continues to serve as an executive sponsor of this project and was recently nominated to serve on a change control board, part of the established governance plan for this project. Two board staff have been working part-time for this project, assisting the department in documenting system requirements that meet the needs of our board as well as others throughout the project. As the implementation date approaches, there will be a need to redirect other staff to ensure the necessary transition plans and data clean-up are in place to mitigate problems during the transition.

It is anticipated that the board will transition in late Spring of 2013 to this new system.

5. Reimbursement to board Members

Mr. Weisser noted that expenses and per diem payments to board members are provided in the board packet.

There were no comments from the board or the public.

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

Since July 2005, the board has acknowledged 1262 pharmacists with 50 or more years of licensure as pharmacists in California. There were 73 pharmacists who reached this milestone between April and July 2012. When a pharmacist reaches this milestone, the board sends a certificate and an invitation to attend a future board meeting for public recognition.

b. Personnel Update

Ms. Herold provided that the Governor's budget included a slight reduction in authorized positions, down from 84.4 authorized positions to 83.9 positions. This reduction reflects the elimination of a half-time, two-year limited term position the board received as part of the Consumer Protection Enforcement Initiate. In addition, pursuant to Budget Letter 12-03 (Attachment 5), the board is required to reduce its authorized position by an additional 3.9 positions no later than the end of July. The board will be achieving this reduction through attrition and elimination of vacant positions. This reduction is unfortunate as previous budget restrictions including hiring freezes prevented the board from filling mission-critical positions.

Below is a breakdown of the number of vacant positions.

.5 Office technician responsible for receptionist duties

.8 Office technician responsible for application review and back-up receptionist duties

1 analyst responsible for corresponding with consumer complainants and helping track complaints through the investigative and review process.

7 inspector positions primarily responsible for investigating complaints and conducting inspections.

1. **Board Member Vacancies**

Since the last board meeting, two new members were appointed to the board and two members were reappointed.

Ryan Brooks was reappointed by Governor Brown as a public member.

Amy Gutierrez was appointed by Governor Brown to the acute care pharmacist position on the board.

Gregory Lippe was reappointed by Governor Brown as a public member.

Albert C. M. Wong was appointed by Governor Brown as a professional member.

With these appointments the board has 12 board members and one vacancy. The vacant position is a Governor appointee and is for a professional member representing labor.

ADJOURNMENT

President Weisser adjourned the meeting at 4:35 p.m.