



California State Board of Pharmacy
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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE: April 21 and 22, 2010

LOCATION: Loma Linda University
Damazo Amphitheater, Centennial Complex
24760 Stewart Street
Loma Linda, CA 92354

BOARD MEMBERS

PRESENT: Kenneth Schell, PharmD, President (April 22, 2010)
Randy Kajioka, PharmD, Vice President
Stanley C. Weisser, RPh, Treasurer
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Roselyn Hackworth, Public Member
Greg Lippe, Public Member
Shirley Wheat, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joan Coyne, Supervising Inspector (April 21, 2010)
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Fraga, Staff Analyst

CLOSED SESSION

I. Closed Session

At 8:30 a.m. on April 21, 2010, the board convened in closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary decisions.

OPEN SESSION

II. Petition for Reinstatement

At 9:21 a.m. on April 21, 2010, the board convened in open session to hear a petition for reinstatement from Evan Stein.

CLOSED SESSION

III. Closed Session

At 12:52 on April 21, 2010, the board again convened in closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary decisions and the petition for reinstatement.

CALL TO ORDER

Vice President Randy Kajjoka called the public board meeting to order at 1:43 p.m.

General Announcements

Dr. Kajjoka recognized former board members Stan Goldenberg and Rich Palombo who were attending the meeting and in the audience. He also recognized Arizona Board of Pharmacy Member and former National Association of Boards of Pharmacy (NABP) President, Dennis McAllister, who was in the audience.

Stan Weisser thanked the board, board staff, and Loma Linda University, School of Pharmacy Dean, Billy Hughes, for their efforts. He welcomed the audience to Loma Linda University.

IV. Recognition of Pharmacists Licensed with the Board for 50 Years

Dr. Kajjoka provided that the recognition of pharmacists in service for 50 years was a program initiated by former board member Stan Goldenberg several years ago. He noted that it is the board's honor to be able to continue the tradition.

Dr. Kajjoka recognized Donald Sabol. Mr. Sabol was licensed in 1959. He spent five years in the Air Force and is a graduate of Drake University. Mr. Sabol's career in pharmacy began at Horton and Converse Pharmacy. He later became the pharmacy director at Conejo Valley Hospital, opened three pharmacies, and

is now currently with CVS. Mr. Sabol highlighted some of the changes he has seen throughout his career as a pharmacist. Ryan Brooks presented Mr. Sabol with a 50-year pin.

V. Approval of the Full Board Meeting Minutes of January 20 and 21, 2010

MOTION: Approve the minutes of the January 20 and 21, 2010 Board Meeting.

M/S: Weisser/Brooks

Support: 9 Oppose: 0 Abstain: 0

VI. Approval of the Full Board Meeting Minutes of February 17, 2010

MOTION: Approve the minutes of the February 17, 2010 Board Meeting.

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

VII. Communication and Public Education Committee Report and Action

There has been no meeting of the Communication and Public Education Committee during this quarter.

a. Board of Pharmacy Video on Steps Consumers Can Take to Prevent Receiving Med Errors

Mr. Brooks provided that throughout 2009, there were a number of media inquiries and stories about pharmacies making medication errors and the resulting impact on patients.

Mr. Brooks stated that the board investigates medication errors when it learns of them. Additionally, during all inspections, the board looks at the quality assurance program components and reporting to ensure the pharmacy is performing a quality assurance review after any error (however, the board does not look at the quality assurance program as a source of complaints to investigate).

Mr. Brooks provided that part of the board's mandate is to educate consumers so they can represent themselves in the marketplace. One way the board does this is to require the posting of two Notice to Consumers posters in all community pharmacies. The information on these posters can educate patients, at the time

they are in the pharmacy, with important information that can aid them in receiving better health care.

Mr. Brooks provided that in December 2009, the board partnered with the Department of Consumer Affairs and contracted with a private firm to produce a three-minute video for consumers on how patients can prevent receiving a medication error. The video is available on the board's Web site.

The board viewed the video.

No public comment was provided.

The board had no comment on the following agenda items.

b. Update Report on *The Script*

The February 2010 issue of *The Script* was published and mailed to pharmacies and wholesalers in March. This was the first issue published since February 2009 – budget and other workload priorities were the primary reasons for the delay.

This issue will be the last issue that will be printed and mailed as has been done in the past. In the future, the newsletters will be released online to the board's licensee subscriber list. (Note: effective July 1, 2010, all sites licensed with the board must join the board's subscriber alert system.) Only a few issues will be printed for distribution at public outreach events and from the board's office.

c. Update on Public Outreach Activities

Since the last report to the board on public outreach activities, board members and staff have performed the following:

- January: Supervising Inspector Dang did a CE presentation hosted by USC on surviving a board inspection.
- February: The board staffed an information booth at CPhA's annual meeting. Inspector Roger Toevs did a presentation on surviving a board inspection, EO Giny Herold provided an update on 2010 pharmacy law changes, and EO Herold and Board President Schell provided an update on Board of Pharmacy activities underway and during 2009.
- February: Inspector Toevs did a CE presentation on surviving a board inspection to the San Mateo Pharmacists Association.
- February: EO Herold did a Webinar on California's e-pedigree requirements hosted by IBS.
- February: EO Herold and Assistant EO Anne Sodergren did a presentation to 200 California Northstate School of Pharmacy students on the board's enforcement program.

- February: Supervising Inspector Judi Nurse provided a presentation on surviving a board inspection to the Indian Pharmacists Association.
- February: SI Nurse provided information to 50 consumers about medication discount plans, Internet purchase of drugs, counterfeit drugs and obtaining medication safety.
- March: President Schell provided information about the practice of pharmacy at the UCSF Career Day.
- March: SI Nurse provided a presentation on pharmacy law to Loma Linda University students.
- March: SI Dang did a presentation on the responsibilities of a Pharmacist-in-Charge (PIC).
- April: President Schell provided a presentation on the future of pharmacy to 200 students at CAL.

d. Third Quarterly Report on Committee Goals for 2009/10

The third quarterly report on the Communication and Public Education Committee's goals was provided in the board packet.

VIII. Licensing Committee Report

There has been no meeting of the Licensing Committee during this quarter.

a. Report Released: Addressing Drug and Device Recalls in Hospitals

Greg Lippe provided that during the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. He stated that the board cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. Mr. Lippe advised that because several of these hospitals and one PIC still have appeals of the citations and fines pending, board members cannot yet discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future should they be appealed to the Office of Administrative Hearings.

Mr. Lippe provided that throughout 2009, the board convened a two-board member task force to work with relevant associations, regulators, hospitals, wholesalers and patient advocates on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. He indicated that three public meetings were held statewide. Mr. Lippe stated that a document establishing the parameters for recalls in hospitals was one major outcome of these meetings.

Mr. Lippe provided that at the January 2010 Board Meeting, the board approved the text of this report. He stated that since the meeting, the board has reformatted the report into a format more befitting a report.

No public comment was provided.

b. Review and Possible Approval of Accreditation Agencies for Sterile Injectable Compounding Pharmacies

Mr. Lippe provided that California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are 1) already licensed pharmacies, and 2) compounding injectable sterile drug products. He stated that these specialized pharmacies may be either hospital pharmacies or community pharmacies. Mr. Lippe explained that as a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. He advised that this is the only category of board licensure that requires annual inspections as a condition of renewal.

Mr. Lippe provided that currently the board has 243 such licensed facilities in California, and 93 nonresident pharmacies with such permits.

Mr. Lippe explained that there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

- the pharmacy is licensed by the board or the Department of Public Health

AND

- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Mr. Lippe provided that currently there are two accreditation agencies approved by the board: 1) Accreditation Commission for Health Care, Inc (ACHC), and 2) Community Health Accreditation Program (CHAP).

Mr. Lippe provided that the board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. He stated that recently the board modified its regulations for pharmacies that compound medication. Mr. Lippe explained that included in these requirements are modified requirements for pharmacies that compound sterile injectable medication. He indicated that these regulations were approved and filed with the Secretary of State on January 6, 2010, and pursuant to the board's directive, will take effect July 6, 2010. (The board also directed an

additional six months of “educational” enforcement for the new requirements to facilitate compliance.)

Mr. Lippe provided that the board periodically reviews its approval of the accreditation agencies it has the authority to approve. He advised that under need for review are ACHC and CHAP.

Mr. Lippe provided that since 2003 when both ACHC’s and CHAP’s accreditation were approved by the board, board inspectors have not identified a problem with the accreditation standards used to accredit any pharmacy in California. He stated that in 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. Mr. Lippe explained that it was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1. should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law, good professional practice standards and the specific factors. He advised that both agencies were last reviewed by the board in 2006.

1. Periodic inspection -The accrediting entity must inspect and re-accredit the pharmacy at least every three years.
2. Documented accreditation standards -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payers - Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.
7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

Mr. Lippe provided that staff believes that a meaningful review of the two agencies and a third accreditation agency seeking board approval involves the agencies’ incorporation of the new sterile injectable compounding requirements and ability to accredit against these standards into their accreditation inspections. He advised that at the current time, the board has not initiated this review of the

accreditation standards (although all three agencies have been advised of the modified requirements).

Mr. Lippe provided that assessment of the agencies is very detailed (nearly 300 pages have been submitted by the two agencies already accredited), and the board was unable to have its designated supervising inspector perform this review due to an extended absence (which has just ended). He stated that the criteria the board has used in the past to assess the accreditation processes of these agencies has been drafted into a proposed regulation, currently awaiting action by the board.

Mr. Lippe provided that board staff made the following recommendations: 1) extend the approval of the two already approved accreditation agencies, ACHC and CHAP, for one year until April 2011; 2) direct board staff to review and assess the three accreditation agencies seeking board approval as an accrediting agency for sterile injectable compounding pharmacies; 3) provide a staff report to a future Licensing Committee Meeting (the next meeting is scheduled for June 16, 2010); and 4) bring the committee's recommendations to the board for action at a future meeting.

No public comment was provided.

MOTION: Accept board staff's position to 1) extend the approval of the two already approved accreditation agencies, ACHC and CHAP, for one year until April 2011, 2) direct board staff to review and assess the three accreditation agencies seeking board approval as an accrediting agency for sterile injectable compounding pharmacies, 3) bring staff's report to a future Licensing Committee Meeting (the next meeting is scheduled for June 16, 2010), and 4) bring the committee's recommendations to the board for action at a future meeting.

M/S: Lippe/Weisser

Support: 9 Oppose: 0 Abstain: 0

c. Processing Timelines and Work Flow of the Board

Executive Officer Virginia Herold provided that in late June 2009, the Governor issued an Executive Order imposing a third furlough day each month on state employees. She advised that this order also closes state offices three Fridays each month through June 2010.

Ms. Herold provided that board staff continue to evaluate the board's most mission-critical functions for the licensing unit. She explained that even with priority changes, and since February 2009 when furloughs were initiated,

processing times have extended to well beyond the board's strategic objectives detailed in the strategic plan.

Ms. Herold provided that in March 2010, the board learned about the potential to modify the furloughs of staff performing licensing functions to achieve fulfillment of an initiative pursued by the Governor called the Job Creation Initiative. She explained that the goal is to reduce the backlog of licensing applications for all DCA special fund licensing agencies (including the board) by 50 percent from a December 2009 assessment.

Ms. Herold provided that since March 2010, some board staff worked on weekends to perform licensing functions that will lead to licensure of new individuals and firms (this also allowed those staff members to 'bank' their furlough days for use in the future). She stated that once staff work 40 hours in a week, they are able to be paid for overtime hours in excess of 40 hours.

Ms. Herold reported that as a result, pharmacy technician application processing times were reduced to a 60-day turnaround in March, from a 90-day turnaround three months prior.

Assistant Executive Officer Anne Sodergren reviewed the current applicant and renewal processing timelines and workflow of licensing categories.

Ms. Herold encouraged licensees to renew timely so as to avoid delays – as the efforts related to the Jobs Creation Initiative applied to new applicants – not those renewing.

Dr. Ramón Castellblanch sought clarification on the status of furloughs given the recent decision regarding the lawsuits.

Joshua Room, Deputy Attorney General, advised that the lawsuit is ongoing and the furloughs remain in place.

No public comment was provided.

d. Competency Committee Report

Mr. Lippe provided that effective April 1, 2010, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). He stated that the board hopes to complete this review and release examination results once the review is complete sometime in June 2010.

1. Action to Review and Approve a New Content Outline for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Mr. Lippe provided that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the CPJE examination. He explained that to complete this analysis, the committee recently developed a job analysis survey with the board's contracted psychometric firm. Mr. Lippe stated that the survey was offered to specific, randomly selected California pharmacists (via postcard and a link to the board's Web site) and to California pharmacists generally in December 2009. He indicated that there were 692 pharmacists who provided responses.

Mr. Lippe provided that according to the board's contracted psychometric firm, the results were sufficient for a statistically reliable sample.

Mr. Lippe provided that the information learned from this job analysis survey resulted in the need to slightly change the content outline of the CPJE to ensure it remains valid for California. He stated that the content outline identifies specific subject areas for the CPJE that will be generated into any examination, and serves as a study guide for students.

Mr. Lippe stated that since the beginning of the year and under the leadership of the board's psychometric consultant, the Competency Committee worked on revising the CPJE content outline, and that the committee's work is now complete.

Mr. Lippe advised that the board needs to review and ultimately approve the new content outline which will be used to construct examinations administered after April 1, 2011. Mr. Lippe stated that Board Member Kajioka and Supervising Inspector Dang participated in this process.

Ms. Herold reviewed the three major sections for the examination and the proposed modifications provided below:

Current:

I.	Provide Medication to Patients	25 questions
II.	Monitor and Manage Patient Outcomes	25 questions
III.	Manage Pharmacy Operations	25 questions

Proposed:

I.	Patient Medications	25 questions
II.	Patient Outcomes	30 questions
III.	Pharmacy Operations	20 questions

Ms. Herold reviewed the following items identified for deletion from the current content outline:

- 1A1. Interpret prescription/medication order
- 2B2: Prepare IV admixtures
- 2A3. Determine the need for a referral
- 2A4. Communicate the therapeutic plan to the patient/patient's representative, the prescriber and other health care professionals
- 3A4. Store pharmaceuticals, durable medical equipment, devices and supplies under proper storage conditions

Ms. Herold provided that the items proposed for addition to the content outline include:

- 1A7. Assess prescription/medication order for insurance coverage
- 1B2. Select specific product(s) to be dispensed for a prescription/mediation order
- 1B8. Use automated dispensing equipment (e.g., Pyxis, Omnicell, Accu-Dose, ScriptPro)
- 1B9. Prepare finished dosage forms for dispensing (e.g., measure, count, reconstitute, compound, repackage, unit dose)
- 2A3. Assess changes in health status (e.g., onset of new disease states, changes in clinical condition)
- 2A7. Resolve problems that arise with patient's therapy (e.g., ADRs, drug interactions)
- 2B10. Respond to consumer inquiries (e.g., internet searches, media information, FDA patient safety alerts, radio/television commercials)
- 2B11. Provide supplemental information as indicated (e.g., medication guides, computer-generated information, videos)

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, sought clarification regarding the removal of an item regarding the preparation of IV admixtures.

Ms. Herold indicated that this item has been redirected to another area of the exam content.

Ms. Sodergren indicated that the North American Pharmacist Licensure Examination (NAPLEX) content outline also includes this item.

Dr. Kajioka provided that the committee worked to avoid duplication of NAPLEX content.

There was no additional board discussion or public comment.

MOTION: Approve the new content outline for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

M/S: Lippe/Weisser

Support: 8 Oppose: 0 Abstain: 1

2. New English Language Proficiency Requirements for NABP's Foreign Pharmacy Graduate Examination Committee

Mr. Lippe reported that in March 2010, the board was advised that the NABP's Foreign Pharmacy Graduate Examination Committee (FPGEC) had revised its requirements for foreign-educated pharmacists seeking certification by the FPGEC. He stated that the California law (Business and Professions Code section 4200) requires certification of foreign-educated pharmacists by the FPGEC as a condition of application for licensure as a California pharmacist.

Mr. Lippe provided that according to the FPGEC, effective April 1, the TOEFL iBT will be the sole English proficiency examination accepted for new candidates seeking certification. He indicated that the TOEFL iBT, a computer-based exam, will replace the paper-based TOEFL and the Test of Spoken English.

No public comment was provided.

e. Third Quarterly Report on Licensing Committee Goals for 2009/10

The third quarterly report on the Licensing Committee's goals was provided in the board packet.

IX. Legislation and Regulation Committee Report and Action

There has been no meeting of the Legislation and Regulation Committee during this quarter.

LEGISLATION REPORT

a. Board-Sponsored Legislation

1. Discussion Regarding the Executive Staff's Written Response to the Chair of the Assembly Business and Professions Committee For a Report on Board-Sponsored Legislation for 2009-10

Mr. Weisser provided an overview of AB 977 and a request from Assembly Member Mary Hayashi, Chair of the Assembly Business, Professions and Consumer Protection Committee to provide information about board-sponsored legislation for 2009 and 2010. He indicated that the request from Ms. Hayashi expressed concern that "legislative efforts of dubious merit to consumers is taking priority over licensing and enforcement" and asked the board to explain

how consumer protection drives the board's activities. Mr. Weisser provided that the report was completed and submitted to Chair Hayashi in February 2010.

Ms. Herold highlighted the contents of the report including details about the board's consumer protection mandate and legislative program. She stated that board executive staff has met with Chair Hayashi to address the report as well as her concerns.

Dr. Castellblanch provided comment regarding the board's support position for AB 977 and Chair Hayashi's concerns. He stated that the board's position could appear to be on the side of industry.

Mr. Brooks provided that the board evaluates legislation and provides support to bills that are good policy.

No public comment was provided.

2. AB 977 (Skinner) Pharmacists: Immunization Administration - Proposal to Amend B&PC §4052.8

Background

Last year, the board approved a legislative proposal to expand the conditions under which a pharmacist could administer certain immunizations. This proposal also strengthened the training requirements for such pharmacists and established reporting requirements. The proposal, as introduced, was defeated early on because of strong objections by the California Medical Association (CMA) and was significantly amended to only include intent language. In early December 2009, board staff resumed work on this proposal and provided amendments to the author's office for consideration. The amendments resulted in a scaled-back version of the original proposal, but still provided improved patient access to life-saving flu vaccinations.

In its current form, this bill establishes a pilot project to allow a pharmacist to administer flu vaccines to any person 18 years of age or older pursuant to a protocol developed by the Medical Board of California in consultation with public health officers. The bill specifies that the protocol must be consistent with the requirements for flu vaccination approved by the Advisory Committee on Immunization Practices (ACIP). The bill retained the training and continuing education requirements from previous versions of the bill as well as the record keeping requirements and requires the board in concert with the Medical Board, to evaluate the effectiveness of the pilot. The measure included a sunset date of January 1, 2015.

Ms. Herold provided that the administration has an oppose position on this bill. She recommended to the board that they may wish to release its sponsorship of the bill given the administration's opposition and, instead, take a support position.

Dr. Castellblanch provided comment on the significant modifications to the bill. He stated that the bill has changed substantially since it was first introduced.

Public Comment

Guy Diasqua, representing Target, asked how the bill changes current access or programs for providing immunizations if the bill is opposed.

Ms. Herold provided that the current provisions would be left unchanged. She indicated that new protocol would be developed by the Medical Board that would allow pharmacists to administer immunizations to adults for flu only.

Mr. Room advised that this would be a statewide protocol instead of an individual prescriber to pharmacist protocol.

Dr. Steve Gray, representing Kaiser Permanente, indicated that Kaiser took a support position on the bill and will be providing a support letter. He discussed factors affecting access to immunizations for people living in urban and rural areas of the state.

Billy Hughes, representing Loma Linda University, provided that Loma Linda University School of Pharmacy students receive certification in immunizations and provide immunizations to the student body.

Stan Goldenberg applauded the board for its efforts in this area. He discussed the needs of populations in under-served communities.

The board discussed possible implications for withdrawing its sponsorship of the bill. It was reiterated that the bill has changed substantially since its introduction.

There was no additional board discussion or public comment.

MOTION: Move from sponsorship to a position of support on AB 977.

M/S: Lippe/Castellblanch

Support: 7 Oppose: 0 Abstain: 2

3. SB 1489 Omnibus Provisions (Senate Committee on Business, Professions and Economic Development)

Mr. Weisser provided an overview on SB 1489 and its amendments.

Background

On January 20, 2010, the board voted to support the inclusion of the following amendments in the Senate Business Professions and Economic Development Committee's Omnibus measure for 2010. SB 1489 was introduced on March 11, 2010 and included the board's requested proposals. The April 5, 2010, amendment of the bill did not modify any pharmacy-related provisions.

(A) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative in Charge

At its October 2008 Board Meeting, the board approved provisions to be included in the 2009 Omnibus Bill (Senate BP&ED, SB 821). The chaptered version of SB 821 contained a drafting error and this section requires clarification (to be amended as previously approved by the board).

(B) Add §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4 Time Failure)

In October 2008, the board approved that the sunset provision within §4200.1 be eliminated, making permanent the requirements that those who fail either licensure exam four times must take 16 units of education from a school of pharmacy. Though the Senate BP&ED committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. This language has, again, been included in the Senate BP&ED Committee's 2010 Omnibus bill.

(C) General Provisions Correcting a Name Change from the Department of Health Services to the State Department of Public Health.

- Amend §4017 – Authorized Officers of the Law
- Amend §4028 – Definition of Licensed Hospital
- Amend §4037 – Definition of Pharmacy
- Amend §4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations
- Amend §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- Amend §4072 – Oral or Electronic Transmission of Prescription – Health Care Facility
- Amend §4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

- Amend §4127.1 – License to Compound Injectable Sterile Drug Products Required
 - Amend §4169 – Prohibited Acts (also, strike operative date of 2008)
 - Amend §4181 – License Requirements; Policies and Procedures; Who May Dispense
 - Amend §4191 – Compliance with California Department of Public Health Requirements; Who May Dispense Drugs
- (D) Provision to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)
- Amend §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- (E) Provisions to update references to the Department of Health Care Services (formerly known as the Department of Health Services)
- Amend §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
 - Amend §4426 – Department of Health Care Services to Study Reimbursement Rates
- (F) Provisions to Correct a Transposition Error in Terminology “Food-Animal Drug Retailer” (current Law States “Food Drug Animal Retailer”)
- Amend §4101 – Designated Representative-in-Charge of a Wholesaler or Veterinary Food-Animal Drug Retailer

No public comment was provided.

4. Board-Sponsored Provisions Not Included in 2010 Legislation

Background

Over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet.

The board voted on January 20, 2010, to sponsor legislation to distinguish between a reverse distributor and an integrated waste hauler. Following the board’s approval, staff proposed these provisions for inclusion in the Senate Committee on Business, Professions and Economic Development’s omnibus measure, but they were declined by the committee. Likewise, staff was not able to secure an author or identify any measure in which these provisions could be included in the current session.

Staff will again pursue these board-approved provisions in the next legislative session.

Mr. Weisser reviewed the following provisions:

- (A) Reverse Distributors – Provisions to Specify the Operations of Reverse Distributors
 - Amend §4040.5 Reverse Distributor
 - Amend §4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
 - Amend §4126.5 Furnishing Dangerous Drugs by a Pharmacy
- (B) Changes Proposed by the Board for Enhancement of the Board's Enforcement Program
 - Amend §4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
 - Amend §4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures
 - Amend §4112 - Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
- (C) Changes for the Pharmacist Recovery Program
 - Amend §4362 – Pharmacists Recovery Program

No public comment was provided.

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

1. Board of Pharmacy

AB 2104 (Hayashi) – California State Board of Pharmacy

Mr. Weisser provided that this bill would require the Governor to appoint the executive officer and would authorize the Governor to determine whether the executive officer may or may not be a member of the board. He stated that this bill would require the board to receive approval from the DCA prior to sponsoring or taking positions on legislation and would define ex parte communications and the reporting requirements for board members that engage in such communications.

Ms. Sodergren provided that the department has taken an oppose unless amended position on this bill and has offered amendments to Assembly Member Hayashi. She indicated that the bill has passed out of the Assembly Committee on Business, Professions and Consumer Protection.

Ms. Sodergren reviewed the scope of the amendments offered by the department.

Mr. Room clarified that the board's position would only apply to the current form of the bill and not the amendments that have been offered.

Mr. Brooks recommended that the board reevaluate the bill at a later date after it has had more time to go through the legislative process.

Mr. Zee provided comment in opposition to the bill.

Public Comment

Stan Goldenberg encouraged the board to not add a layer of politics when promoting its mission to protect the public.

There was no additional board discussion or public comment.

MOTION: Establish a position of oppose on AB 2104.

M/S: Lippe/Zee

Support: 8 Oppose: 0 Abstain: 1

SB 1390 (Corbett) – Prescription Container Labels

Mr. Weisser provided that this bill will allow the board to exempt from the labeling requirements established in regulations, prescriptions dispensed to patients in specified health care facilities if the prescriptions are administered by a licensed health care professional.

Ms. Sodergren provided that this bill has passed out of committee as amended. She indicated that the scope of these amendments is unknown at this time.

Public Comment

Sarah Mason, representing the Senate Committee on Business, Professions and Economic Development, stated that the amendments accepted in committee are technical and provide clarification regarding the specific type of in-patient facilities involved.

Discussion continued regarding the specific health care facilities involved and the possible implications for granting exemptions in this area.

Dr. Steve Gray, representing Kaiser Permanente and California Pharmacists Association (CPhA), provided comment on the history and intent of the bill. He provided clarification on the various types of facilities involved. Dr. Gray requested support for SB 1390.

Ms. Herold recommended that the board either defer taking action on this bill until final language is provided or take a position that specifies the board's concerns.

It was the consensus of the board to delay taking action on this bill until further clarification is provided.

There was no additional board discussion or public comment.

2. Pharmacy Practice

AB 1869 (Anderson) – Pharmacy (spot bill)

Mr. Weisser provided that the current version of AB 1869 is a spot bill (intent language only) related to the scope of practice of pharmacists. He indicated that this is a spot bill. Mr. Weisser advised that based on information received by the author's office, there are no immediate plans for this bill.

No public comment was provided.

AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors

Mr. Weisser provided that as amended, AB 1916 would require a pharmacy to report to the board any occurrence known by the pharmacy of a prescription being furnished to a person other than the patient named on the prescription or that patient's representative. He stated that the bill would also require the pharmacy to report any known adverse reaction that may have occurred as a result of the person to whom the prescription was furnished using the prescribed drug.

Mr. Weisser provided that this bill was re-referred to the Assembly Committee on Business, Professions and Consumer Protection.

Ms. Sodergren reported that the bill recently did not pass out of committee.

No public comment was provided.

3. Sunset Review and Legislative Oversight Proposals

AB 1659 (Huber) – State Government, Agency Repeals

Mr. Weisser provided that as amended, the bill established a Sunset Review Committee charged with conducting a comprehensive analysis of every agency

to determine if it is still necessary and cost effective. He explained that it also establishes reporting elements that must be addressed by the agencies including its purpose, budget information, programs and projects under its control; as well as its successes, failures, and recommendations for changes to better fulfill its mission. Mr. Weisser stated that the bill defines the committee composition and appointment authorities.

Mr. Weisser provided that this bill was double referred. He advised that it is scheduled to be heard in the Assembly Health Committee on April 13, 2010, and should it pass out of committee, it will be referred to the Assembly Committee on Business, Professions and Consumer Protection.

No public comment was provided.

AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection

Mr. Weisser provided that this bill is the implementation bill for AB 1659 (Huber). He explained that it abolishes the Joint Committee on Boards, Commissions and Consumer Protection and refers the charge of that committee to the proposed Sunset Review Committee established by AB 1659.

Mr. Weisser provided that this bill passed out of the Assembly Committee on Business, Professions and Consumer Protection (11-0) on April 6, 2010, and was referred to the Assembly Appropriations Committee.

No public comment was provided.

SB 954 (Harmon) – Legislative Procedure, Committee Referrals

Mr. Weisser provided that this bill would enact the Jobs Protection Act. It would rename the Joint Committee on Boards, Commissions, and Consumer Protection as the Joint Committee on Boards, Commissions, and Consumer or Business Protection, and would create a new legislative procedure with regard to any bill, as defined, that may have a statewide economic impact affecting business. The bill would require the Assembly Committee on Rules and the Senate Committee on Rules to refer any bill that may have a statewide economic impact affecting business, as specified, to the joint committee for the preparation of an economic impact analysis, hearing and approval. The bill would require the joint committee to move a bill with an estimated fiscal impact of \$10,000 or more on small business, as defined, or \$50,000 or more on any other business, to the suspense file of the joint committee for further consideration, subject to specified procedural requirements. The bill would also require the joint committee to make an annual report in that regard.

Mr. Weisser provided that Senator Harman's staff has indicated that they are working to determine how best to move forward to achieve the goals of the Jobs Protection Act. He stated that this bill is not yet scheduled for hearing.

No public comment was provided.

SB 1171 (Negrete McLeod) – Regulatory Boards, Operations

Mr. Weisser provided that this bill is needed to update and streamline the sunset review process. He explained that it specifies that when a professional licensing board in the Department of Consumer Affairs becomes inoperative or is repealed, a successor bureau is created to succeed it, and is vested with all of powers and duties of the prior board. Mr. Weisser stated that the bill makes reconstitution of a licensing board automatic and allows for standing policy committees of the Legislature to conduct sunset review hearings.

Ms. Sodergren provided clarification regarding the scope of this bill. She explained that under current law, the board is subject to a sunset review every four years. She indicated that if the sunset date is not extended, the board would become a bureau within the department. Ms. Sodergren stated that as amended, this bill makes reconstitution of a licensing board automatic, rather than having the board transform into a bureau. She advised that this bill also establishes reporting requirements for board's undergoing sunset review and requires that a review be completed by the appropriate policy committees of the Legislature.

Ms. Schieldge expressed concern regarding the potential for conflicting recommendations from each house of the Legislature. She also discussed possible implications if the term limits for all board members begin and expire at the same time. Ms. Schieldge recommended the implementation of staggered term limits.

Sarah Mason, representing the Senate Committee on Business, Professions and Economic Development, stated that the goal of recreating the Sunset Review process is to reconcile any competing recommendations and to increase efficiency.

Ms. Sodergren provided that this bill mirrors many of the provisions contained in SB 638 (Negrete McLeod, 2009). She advised that the board had a support position on the bill.

No public comment was provided.

SB 1172 (Negrete McLeod) – Sunset of Diversion Program

Mr. Weisser provided that in its current form, this bill requires a board contracting for monitoring services, such as the Pharmacists Recovery Program, to require an audit at least once every three years and specifies that the audit will be provided to the legislature. He stated that this bill would require a healing arts board to order a licensee to cease practice if the licensee tests positive for any prohibited substance as specified.

Ms. Sodergren provided that this bill passed out of committee. She advised that it is the vehicle being used to facilitate implementation of the SB 1441 Uniform Standards for Substance Abusing Healing Arts Professionals.

No public comment was provided.

3. Regulation of Dangerous Drugs and Devices

AB 1455 (Hill) – Pseudoephedrine

Mr. Weisser provided that this bill implements a statewide electronic tracking program in retail outlets that monitors all California over-the-counter pseudoephedrine (PSE) purchases in real-time to prevent individuals from exceeding legal purchase limits. He stated that this system would allow retailers to be alerted immediately when a consumer is about to exceed purchase limits, and requires the retailer to deny the sale.

Ms. Sodergren provided that this is a two-year bill. She advised that it has been granted reconsideration as it did not pass out of the Public Safety Committee last year.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, sought clarification regarding the implementation timeframe for the provisions of this bill. He requested that the board do some further research in this area and provide clarification regarding when compliance is required.

There was no additional board discussion or public comment.

AB 2548 (Block) – CURES – Prescription Drug Monitoring Program

Mr. Weisser provided that this bill seeks to provide authority to the Prescription Drug Monitoring Program (PDMP) within the DOJ to monitor and report any suspicious behavior by PDMP Subscribers and would establish a system for issuing citations for PDMP Subscribers who violate any provision of the Uniform Controlled Substances Act.

Mr. Weisser provided that the bill passed out of committee.

Ms. Herold provided that this bill would provide regulatory screening and monitoring of prescriber or pharmacist access and possible misuse including the mining of confidential data.

Dr. Kajioka stated that he does not believe that there is a need for AB 2548 as there are existing laws regarding the inappropriate use of personal health information such as HIPAA violations.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente and the California Pharmacists Association (CPhA), provided support for the intent of this bill. He expressed concern that the potential for discipline may deter prescribers or pharmacists from enrolling in the program.

Ms. Herold provided comment on patient confidentiality in light of recent breaches involving celebrity patient records. She stated that the board will discipline its licensees who violate patient confidentiality.

There was no additional board discussion or public comment.

SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

Mr. Weisser provided that this bill, sponsored by the Hemophilia Council of California, establishes the “Standards of Service for Providers of Blood Clotting Products for Home Use Act.” He stated that as amended on April 7, 2010, the bill sets forth requirements for entities that deliver blood clotting products and related equipment, supplies and services for home use. Mr. Weisser indicated that it authorizes the Department of Health Care Services to promulgate regulations necessary for the implementation of these standards, and specifies that the Board of Pharmacy shall enforce the provisions established.

Mr. Weisser provided that the bill was double-referred to Senate Health and to Senate Committee on Business, Professions and Economic Development and is scheduled for hearing in the Senate Committee on Business, Professions and Economic Development on April 19, 2010.

Ms. Sodergren stated that the bill passed out of Senate BP&ED 'do pass as amended.'

Public Comment

Sarah Mason, representing the Senate Committee on Business, Professions and Economic Development, provided clarification on the amendments. She stated that the amendments clarified the definitions for "provider of blood clotting products at home" and "sufficient knowledge." Ms. Mason advised that this bill would remove the requirement that the board enforce physician prescribing of blood clotting products.

Ms. Herold indicated that this bill is changing quickly and may not be a bill the board needs to watch at this time.

There was no additional board discussion or public comment.

SB 1071 (DeSaulnier) – CURES

Mr. Weisser provided that as amended on March 24, 2010, this bill creates the CURES Fund in the State Treasury and imposes a yearly fee, as determined by the Department of Justice (DOJ), on manufacturers and importers of Schedule II, Schedule III, and Schedule IV controlled substances. He stated that this measure specifies what these funds may be used for as it relates to the CURES program.

Mr. Weisser stated the bill was double-referred to both the Senate Committee on Revenue & Taxation, and to the Senate Committee on Health. He advised that the Senate Revenue & Taxation hearing set for April 14, 2010 was postponed by the committee.

Carolyn Klein, Legislation and Regulation Manager, added that a hearing in Senate Health has been set for May 5, 2010.

Dr. Kajjoka asked if the fund will be rolled into the general fund or dedicated solely for CURES use.

Ms. Klein provided that the fund is only to be used for certain purposes including investigations. She stated that the maintenance of CURES is contingent upon

available funds from the Pharmacy Board Contingent Fund and that of four other DCA boards.

Ms. Herold provided that the bill specifies that the reporting of Schedule III and Schedule IV controlled substances to CURES is contingent upon available funds from the Department of Justice and not the five specified boards.

No public comment was provided.

SB 1106 (Yee) – Prescribers – Dispensing of Samples

Mr. Weisser provided that this bill will require a prescriber dispensing sample prescription drugs to either (1) provide the patient with a copy of the FDA approved package insert for the drug sample or starter kit or (2) ensure that the manufacturer's warnings are affixed to the package containing the drug sample or starter kit.

Ms. Sodergren provided that the bill has been re-referred to Senate Appropriations and has not yet scheduled.

Ms. Herold encouraged the board to support this bill as it strongly promotes patient safety.

Deborah Veale sought clarification regarding responsibility and the dispensing of samples.

Ms. Herold indicated that pharmacists do not dispense samples.

Rosalyn Hackworth asked if this bill would apply to practitioners other than physicians.

Ms. Sodergren provided that the provisions would apply to any prescriber dispensing a drug sample or starter kit.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, expressed concern regarding the technical language of the bill. He advised that the language including "manufacturer's insert" is unclear and requires clarification.

There was no additional board discussion or public comment.

MOTION: Support SB 1106 if amended to clarify the drug informational material that would be required to be provided to patients by a practitioner dispensing

samples is the same that a pharmacy must currently provide to patients when dispensing a drug.

M/S: Castellblanch/Hackworth

Support: 8 Oppose: 0 Abstain: 1

5. Pharmacy Licensing Issues

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

Mr. Weisser provided that AB 2077 makes findings and declarations regarding unit dose packaging and centralized packaging functions, and 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. He stated that 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, as specified.

Ms. Sodergren advised that the California Department of Public Health (CDPH) license would require that a pharmacy be on the hospital premises.

Robert Ratcliff, Supervising Inspector, provided that the amended form of the bill creates more problems than the original bill. Specifically, he stated that the bill is unclear with regards to consolidated or common ownership, responsibility of the compounded product, and the elimination of bar codes.

Mr. Room expressed concern that the original intent of the bill has been lost as it was originally intended to facilitate bedside bar coding through repackaging.

Ms. Herold reviewed the scope of the original bill. She stated that bar coding is an essential step in the prevention of med errors. Ms. Herold expressed concern that this requirement has been removed in the current form of the bill.

Ms. Veale asked for clarification on the current requirements for licensure in this area.

Mr. Ratcliff provided that under existing law, each hospital has their own hospital pharmacy that is responsible for the repackaging of its own individual supply of medications. He advised that a hospital pharmacy would need to obtain a manufacturer license if it repackages supply for purposes other than its own use.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided comment on the background of this bill and discussed the importance of bedside bar code information.

Robert Miller, representing Scripps, clarified that the revised language was not intended to make it possible for a hospital to move its pharmacy operation and staff offsite.

Ms. Herold provided that the board took a support position at the January 2010 Board Meeting on the provisions in the previous version of the bill.

Discussion continued regarding the provisions of AB 2077 and adherence to pharmacy law.

There was no additional board discussion or public comment.

AB 2292 (Lowenthal) – Pharmacy: Clinics

Mr. Weisser provided that current law allows the board to issue a clinic license only to an entity licensed by the Health and Safety Code section 1204. He stated that the ruling in the Capen v. Shewry decision, the California Court of Appeal interpreted the Health and Safety Code to exclude physician owned and operated surgical clinics from licensing by the Department. Mr. Weisser explained that as a result, the board cannot issue permits to ambulatory surgical clinics with physician ownership.

Mr. Weisser provided that AB 2292 amends pharmacy law to modify the licensing requirements for a board-issued clinic license for a surgical clinic to include (1) licensure by the California Department of Public Health under §1204 of the Health and Safety Code; (2) an outpatient setting accredited by an approved agency as defined in §1248 of the Health and Safety Code; and (3) an ambulatory surgical center certified to participate in the Medicare Program, as specified.

Mr. Weisser provided that the bill was passed out of Assembly Health (19-0) on March 23, 2010, and was re-referred to Assembly Appropriations.

Ms. Sodergren added that AB 2292 would address the concerns presented to the board at the February 2010 Board Meeting regarding consequences of the Capen decision. She reviewed the history of the bill and advised that the board has historically supported its provisions.

Ms. Herold provided that this bill has been vetoed in the past in part because the Department of Public Health and the Governor's Office want physician operated surgery centers to be licensed by the Department of Public Health. She advised that the Department of Public Health continues to seek a veto of this until standards to this effect are developed.

Ms. Schiedge provided comment on the public policy shift initiated by this bill.

Discussion continued regarding the legislative intent of this bill and the impact it will have on the board.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided that the comingling of drugs at surgery centers is occurring. He stated that this bill would legitimize the comingling of drugs, provide pharmacist oversight, and allow for inspection ability.

There was no additional board discussion or public comment.

MOTION: Support AB 2292.

M/S: Zee/Veale

Support: 4 Oppose: 1 Abstain: 4

AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program

Mr. Weisser provided that as introduced, AB 2551 states the Legislature's intent to establish a new fee structure for loan repayment of various health professions development programs. He stated that staff has been advised that the bill will be amended to create a scholarship fund for pharmacy technicians.

Mr. Weisser provided that the bill was referred to the Assembly Committee on Business, Professions and Consumer Protection but has not yet been scheduled for hearing.

No public comment was provided.

6. Distribution of Needles and Syringes

AB 1701 (Chesbro) – Hypodermic Needles and Syringes

Mr. Weisser provided that AB 1701 removes the 2010 sunset date of the Disease Prevention Demonstration Project (a pilot launched in 2004) within the California Department of Public Health which allows a pharmacist, if authorized by a county or city, to furnish or sell 10 or fewer hypodermic needles or syringes at any one time, as specified.

Mr. Weisser provided that the bill passed out of the Assembly on April 5, 2010.

Ms. Sodergren provided that the bill is now in the second house. She explained that historically the board has been in support of needle exchange programs.

Public Comment

Dr. Steve Gray, representing California Pharmacists Association (CPhA) encouraged the board to support this bill.

MOTION: Support AB 1701.

M/S: Castellblanch/Hackworth

Support: 9 Oppose: 0 Abstain: 0

AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services

Mr. Weisser provided that AB 1858 expands provisions related to needle exchange programs (NEPs) to allow the California Department of Public Health (CDPH) to authorize NEPs in addition to those currently authorized by counties and cities and specifies other requirements of CDPH related to NEPs (Web site information, reports, etc.). He indicated that the author states that the measure is intended to compliment the efforts of SB 1029 (Yee).

No public comment was provided.

SB 1029 (Yee) -- Hypodermic Needles and Syringes

Mr. Weisser provided that this bill is an incremental move away from complete prohibition of sale and possession of syringes, allowing an adult to possess 30 or fewer syringes for personal use.

Mr. Weisser provided that as amended on April 7, 2010, SB 1029 is scheduled for hearing in Senate Business Professions and Economic Development on April 19, 2010.

Mr. Room provided comment on technical provisions of the bill. He stated that this bill would repeal the general prohibition against possession of hypodermic needles and syringes.

Mr. Schieldge clarified that this would be a change in current law. She provided that current law includes an exemption which allows a person to possess, for personal use, 10 or fewer hypodermic needles and syringes if acquired from an authorized source. She stated that SB 1029 would remove the requirement that a person provide proof of legitimate medical need in order to acquire these items.

Public Comment

Sarah Mason, representing the Senate Committee on Business, Professions and Economic Development, provided that the bill would create a statewide program that would not require any local authorization.

Discussion continued regarding the scope and provisions of SB 1029.

Dr. Steve Gray, representing California Pharmacists Association, stated that previous bills in this area may not have passed because they required statewide authorization. He provided comment on the availability of needles and syringes across the state. Dr. Gray advised that pharmacies are requesting that the limit of 10 needles and syringes be increased to 30 or a more reasonable quantity.

Ms. Herold expressed concern regarding the repeal of Section 4140.

There was no additional board discussion or public comment.

AB 2139 (Chesbro) – Solid Waste: Product Stewardship

Mr. Weisser provided that AB 2139 establishes the Product Stewardship Program within the Department of Resources Recycling and Recovery and proposes an Extended Producer Responsibility (ERP) framework for the purpose of establishing one law to address a wide range of toxic products, including home-generated medical waste (including hypodermic needles, pen needles, intravenous needles and lancets), household pesticides, and other hazardous waste found around the home. He stated that the bill requires a producer or product stewardship organization, on or before September 30, 2011, to submit a product stewardship plan to the department. Mr. Weisser indicated that the bill makes declarations and findings related to product stewardship, defines terms, requires reports, and specifies other requirements.

Mr. Weisser provided that the April 6, 2010, version of the bill passed out of Assembly Environmental Safety and Toxic Materials on April 13, 2010 (6-3) and was re-referred to the Assembly Committee on Natural Resources.

Ms. Sodergren provided that the bill has been referred to Assembly Appropriations.

No public comment was provided.

7. General / Other

AB 2112 (Monning) – Prescription Record Privacy Act

Mr. Weisser provided that this bill has been pulled.

No public comment was provided.

8. Other Legislation Impacting the Board's Jurisdiction

Ms. Herold provided that the board may wish to empower the president and the chair of the Legislation and Regulation Committee to take positions on bills of an emergent nature in order to be responsive prior to the deadline of the second house.

Mr. Brooks suggested that board meetings be rescheduled in order to coincide with bill progress.

Dr. Castellblanch provided that he would like to retain the option to vote on bills and would support the rescheduling of meetings to allow for this.

MOTION: Delegate the power to the board's president and chair of the Legislation and Regulation Committee to take board positions on emergent bills between board meetings.

M/S: Zee/Lippe

Support: 9 Oppose: 0 Abstain: 0

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

No public comment was provided.

Recess for Day

The board meeting was recessed at 5:25 p.m.

Thursday, April 22

XI. Closed Session

At 8:09 a.m. on April 22, 2010, the board convened in closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary decisions.

The board reconvened for the public board meeting at 9:04 a.m. on April 22, 2009.

General Announcements

President Ken Schell acknowledged Loma Linda University, its staff, and the pharmacy students in attendance.

President Schell recognized DCA Director Brian Stiger and former board member Richard Mazzoni who were in attendance.

XII. Possible Action on Proposed Regulation Section 1707.5

- a. Discussion Regarding Adoption of New Section at Title 16 California Code of Regulations Section 1707.5 – Requirements For Patient-Centered Prescription Container Labels

Background

Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board was also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. These forums and one-on-one surveys of consumers were conducted over a period of 17 months.

Since July 2009, the board has dedicated a portion of every meeting to develop this regulation and convene two special board meetings in August 2009 and February 2010 principally to focus on the regulation.

Here is an overview of the timeline since the board initiated the rulemaking:

October 22, 2009:	Board initiates rulemaking and directs staff to release the language for 45 days
Nov. 20, 2009 – Jan. 4, 2010:	Initial (45-day) comment period
January 20, 2010:	Board hearing on regulation. Text is proposed to be modified and released for a 15-day comment period.
February 17, 2010:	Board reviews all initially submitted comments and testimony provided at January Board Meeting, modifies text and releases for 15-day comment period
February 22 – March 10, 2010:	15-day comment period

Focus of SB 472's Requirements

Senate Bill 472 directed the board to focus on five items in developing its patient-centered label regulation (4076.5(c)):

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

President Schell advised that the board will discuss the comments received in response to the 15-day comment period, which took place between February 22 and March 10, 2010. He noted that a large number of written comments have been received from individuals and associations regarding this regulation.

Dr. Castellblanch referenced to a letter to the board from Senator Corbett regarding the regulation. He noted that 12-point font is essential to the board's mission to improve the patient-centered label. Dr. Castellblanch indicated that the 12-point font is the preferred standard. He provided statistics on visual impairment as it relates to age and the correlation to the number of prescription taken by this population.

Ms. Hackworth provided comment in favor of 12-point font in the interest of patient safety.

Ms. Herold underscored the significant number of consumer responses received. She stated that this issue is very important to consumers as well as the pharmacy profession.

Mr. Brooks stated that he thinks that the 10-point font standard is an improvement on current prescriptions. He discussed the unintended consequences of larger vial sizes.

Dr. Kajjoka discussed difficulty in legibility for senior populations. He stated that a 10-point font standard increases the standard currently used in pharmacy practice. Dr. Kajjoka provided comment on elements that can help to emphasize important elements on the label including highlighting and use of white space. He suggested that only specified information be printed in a larger font size on the label as a means to add emphasis and to avoid increasing the font size for all information.

Ms. Veale provided that the objective before the board is to create a standardized label with a minimum standard that improves the current situation and prevents med errors. She stated that the 10-point font standard accomplishes this goal. Ms. Veale expressed concern about being overly prescriptive and the potential for unintended consequences.

Tappan Zee provided that this issue includes a diverse range of opinions and consequently requires compromise. He stated that while the 10-point font standard is a step forward, a 12-point standard may be a significantly better step forward to address the needs of consumers.

b. Public Comment

Ron Belville, representing Ron's Pharmacy Services, the Long Term Care Management Counsel and the California Pharmacists Association (CPhA), stated that everyone has the right to read their label. He suggested that a flexible standard be created to allow a person to select an appropriate font size to meet their needs. Mr. Belville discussed SB 1390 and supported labeling exemptions for skilled nursing facilities and long term care facilities.

Harriet Baker, representing the California Alliance for Retired Americans (CARA), expressed concern that the current regulation disregards the comments provided in support of the 12-point font standard. She discussed the needs of the senior population and encouraged the board to implement the requirements for 12-point font and translations.

Natalie Nodos requested clarification regarding the benefit of larger font sizes and improved readability for senior populations.

Stan Goldenberg, representing Bravo Pharmacy, commended the board for its efforts in this area. He requested that the board create flexibility for the assisted living market. Mr. Goldenberg cautioned that the regulation should not inhibit the development of future technology.

Marty Martinez, representing California Pan-Ethnic Health Network (CPEHN), provided comment in support of the 12-point font standard. He expressed concern that the regulation does not comply with the mandate and does not address the needs of the limited English proficient population.

Victor Vercammen, representing Supervalu, presented current company labels and sample labels to the board. He discussed implementation and development challenges that will be encountered in order to comply with the regulation.

Alfred Floyd, representing Costco, discussed implementation challenges including the amount of time that will be needed for compliance. He indicated that Costco supports the intent of the regulation but will require more time to implement and comply with the changes.

Syed Sayeed, representing Consumers Union, provided that the comments submitted support the need for a 12-point font standard. He discussed available research in this area. Mr. Sayeed requested that the board reconsider the translation requirements.

Al Carter, representing Walgreens, provided comment in support of the 10-point font standard. He stated that a minimum font with a standardized label is the correct approach.

Dan Luce, representing Walgreens, stated that pharmacists can't control how much information is on the label. He stated that pharmacists need the flexibility to individualize the font size to meet the needs of the patient. Mr. Luce asked that the board consider unintended consequences when being overly prescriptive.

Doreena Wong, representing the National Health Law Program, discussed procedural defects in the board process for developing this regulation. She requested that the board allow for an additional public hearing. Ms. Wong provided support for the 12-point font standard and stronger translation requirements. She encouraged the board to reconsider this regulation.

Don Gilbert, representing Rite Aid, provided support for the 10-point font standard to prevent the decanting of medicine. He thanked the board for its efforts in this area.

Bruce Wiswell, representing Rite Aid, discussed challenges with maintaining the bar code when using larger labels. He stated that the elimination of bar codes may consequently increase prescription errors.

Peter Kellison, representing Walgreens and the California Pharmacists Association (CPhA), provided support for the current proposed regulation. He stated that the requirements adhere to the board's mandate.

Bob Hansen, representing Safeway, stated that the 12-point font requirement will substantially increase the bottle size and will have significant environmental resource implications.

Kim Holden recommended that the board consider a waiver that consumers can sign if they do not want a larger font size on their label.

Angela Blanchard, representing Target, commended the board for its efforts throughout the development of the regulation. She presented labels currently being used by Target. Ms. Blanchard asked the board to focus on flexibility and readability instead of a particular font size. She underscored the importance of the directions for use on the label.

Douglas Barcon, provided comment on current limitations impacting the ability of acute care facilities to provide 12-point font on the label. He stated that flexibility is needed in this requirement.

DCA Director Brian Stiger provided that this regulation has a strong interest and importance for the Department of Consumer Affairs. He stated that the most important information on the label should be in 12-point font. Mr. Stiger indicated that he is encouraged that there may be flexibility in this area. He urged the board to consider the comments that have been provided and produce a regulation that adheres to the spirit of the law.

Dr. Steve Gray, representing Kaiser Permanente, provided support for increased readability of labels. He stated that the essence of filling a prescription is custom packaging to meet the needs of the individual patient. Dr. Gray recommended that the board build flexibility into the regulation to allow the patient to choose their desired font size.

Mary Staples, representing the National Association of Chain Drugstores, provided that the regulation will have a dramatic impact on the industry. She asked the board to give industry a year to come into compliance after adoption.

Missy Johnson, representing the California Retailers Association (CRA), thanked the board for its efforts in this area and for the ability for the public to offer comments. She provided comment in support of the 10-point font requirement

and indicated that industry will be able to comply. Ms. Johnson encouraged the board to move forward with the current regulation.

There was no additional public comment.

c. Possible Action to Adopt or Amend Proposed Text at Title 16 California Code of Regulations Section 1707.5 – Requirements For Patient-Centered Prescription Container Labels

Ms. Schieldge reviewed the following options before the board:

1. Adopt the text of the regulation as modified during the February-March 15-day comment period.
2. Modify the text and release for a second 15-day comment period (where action would be taken at the next board meeting).
3. Modify the language and start the entire process again with a 45-day comment period.

The board discussed a motion to increase the 10-point font requirement to 12-point.

Mr. Brooks expressed concern that there may be unintended consequences if the board chooses to move forward with the 12-point font requirement for all information on the label. He suggested that a 12-point font be used only for the directions for use.

Dr. Castellblanch provided that research in this area indicates that all four elements on the label are important. He discussed the board's mission to protect and promote the health and safety of Californian's. Dr. Castellblanch reviewed available research and the comments that have been provided that support the use of a 12-point font and urged the board to adopt this requirement.

Ms. Wheat provided comment in opposition to the 12-point font requirement. She stated that 10-point is a minimum standard that will improve current practice standards. Ms. Wheat advised that there will be an opportunity to reassess this requirement to make modifications in the future.

Ms. Veale provided that the 12-point font requirement may potentially create other problems and unintended consequences. She stated that a 10-point font minimum standard will improve current practice and will allow for flexibility and the use of larger fonts if needed.

Dr. Kajjoka stated that a 10-point font requirement will meet the needs of consumers and will address the results of the consumer surveys conducted by the board for SB 472. He reviewed other elements that will be used to increase

readability including use of white space, highlighting, and bolding. Dr. Kajioka advised that the board should avoid being too prescriptive.

Mr. Zee provided that the font size on the label should be a consumer choice. He stated that allowing the consumer to request a 12-point font is a compromise for all involved parties that will help to promote the safety of the consumer.

President Schell provided comment in support of the 12-point font requirement. He discussed various med errors that occur when a consumer or caregiver is unable to read and understand the information on the label.

Public Comment

No public comment was provided.

MOTION: Amend the modified text in section 1707.5 (a)(1) to read as follows:
Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, 10-point, 12-point, sans serif typeface, and listed in the following order:

M/S: Weisser/Castellblanch

Support: 4 Oppose: 5 Abstain: 1

The board discussed a proposal offered by Mr. Brooks to require a 10-point font for three elements including the name of the patient, name and strength of the drug, and the purpose or condition and a 12-point font for the directions for use for up to 48 characters. Additionally, the clustering requirement in section (a)(1) would be removed.

Mr. Lippe asked why there would be a 48 character maximum.

Mr. Brooks provided that he believes this maximum to be the industry standard.

Ms. Wheat asked why the 50% percent clustering requirement is being eliminated.

Ms. Veale provided that it will be difficult to comply if the requirement is too prescriptive. She stated that the elimination of this requirement promotes flexibility.

Mr. Zee provided that he believes this requirement may give less flexibility to the professional. He stated that all four elements are important to the consumer.

Ms. Wheat reviewed why the cluster requirement was originally added to the regulation. She stated that clustering important information into one area of the label in a check-book template format would ensure that a patient can easily locate label information.

Dr. Castellblanch stated that the motion does not adhere to the findings of the available research in this area. He encouraged the board to stay in line with the research.

Mr. Brooks reminded the board that they have already voted to reject the 12-point font requirement for the entire label. He stated that his motion would be a good compromise and would help to eliminate unintended consequences.

Mr. Zee reiterated that the consumer should have the right to request their desired font size.

Public Comment

Missy Johnson, representing the California Retailer's Association (CRA), asked whether the research that has been cited by Dr. Castellblanch was included in the rulemaking materials. She stated that the public would like the opportunity to review this material. Ms. Johnson indicated that industry would be able to comply with the clustering requirement. She indicated that it will be difficult to comply with the 50% requirement.

Dr. Steve Gray, representing Kaiser Permanente, spoke in opposition to the removal of the 50% requirement. He discussed possible conflicts between regulation requirements for manufacture information that is required on the label.

President Schell provided that information brought forward at today's meeting will not be considered during the deliberations at this meeting.

Stan Goldenberg stated that the volume of prescriptions used by seniors is in excess to the senior population. He indicated that the ability to have options is highly important for industry. Mr. Goldenberg provided that the name of the drug is the most important label element for the long term care industry.

Douglas Barcon suggested that the board evaluate the number of characters on a typical prescription label with 12-point font.

Syed Sayeed, representing the Consumers Union, provided that there is confusion on some of the background information and research on this issue as well as confusion on the parliamentary process. He encouraged the board to take additional time to consider its action.

Ms. Wheat and Dr. Castellblanch reiterated their opposition for the motion.

There was no additional board discussion or public comment.

MOTION: Amend the modified text in section 1707.5 (a)(1) to read as follows:

Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, 10-point, sans serif typeface, and listed in the following order. Items (a), (b), and (d) shall be printed in at least a 10-point, sans serif typeface. Item (c) shall be printed in at least a 12-point, sans serif typeface, up to 48 characters.

M/S: Brooks/Veale

Support: 2 Oppose: 7 Abstain: 1

The board discussed a motion to maintain the 10-point font requirement. However, a provision would be included to allow a consumer to request at least a 12-point font.

Dr. Castellblanch stated that industry has indicated that they already provide this option for consumers. He expressed that he believes this requirement is not different than the 10-point standard.

Mr. Room provided that this requirement would make it mandatory for all pharmacies to provide 12-point font if requested.

Dr. Castellblanch expressed concern that consumers will not be adequately informed to make this request.

Ms. Herold suggested that the board require a Notice to Consumers posting requirement to inform patients of this option.

The board discussed the patient-education element of this option. It was suggested that consumers be informed of this option during patient consultation. Concern was expressed regarding a pharmacy's ability to alter font sizes at the point of care.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided that Kaiser will be able to provide complete label formatting options at the user level.

Peter Kellison, representing Walgreens, asked what a pharmacy would be required to do if the information does not fit on the label in 12-point font.

It was clarified that the pharmacy would need to use a larger label on a larger bottle in order to accommodate the information in a 12-point font.

Bruce Wiswell, representing Rite Aid, provided that Rite Aid would be able to implement this requirement.

Doreena Wong, representing the National Health Law Program, provided that this requirement puts the burden on the consumer. She stated that the consumer will need to be appropriately informed regarding this option or the burden should be placed on the pharmacist to ask their patients if they would like the 12-point font.

Missy Johnson, representing the California Retailers Association, indicated that retailers will be able to accommodate the 12-point font requirement if the 50% provision is removed from the regulation.

Marty Martinez, representing the California Pan-Ethnic Health Network, expressed concern that consumers will not know that they have this option. He stated that 12-point font should be the standard unless the patient wants a smaller bottle.

Dr. John Cronin, representing the California Pharmacists Association, provided that consumers need to take a more active role in their own care. He stated that the board bears the responsibility to educate consumers about their rights and what information they need to know about their medications. Dr. Cronin advised that pharmacies will need more time than what is provided during the 15-day comment period in order to provide feedback regarding their ability to comply.

Victor Vercammen, representing Supervalu and Albertsons, provided comment on the role of chain pharmacies in communities and discussed their ability to comply. He requested flexibility in this area.

Stan Goldenberg spoke in support of the idea of consumer choice. He indicated that his pharmacies would be able to comply with this requirement.

Alfred Floyd, representing Costco, provided that it is possible to comply with this requirement and advised that implementation time will be needed.

DCA Director Brian Stiger provided that this requirement is a good compromise that preserves the intent of the law. He urged the board to support the motion.

Syed Sayeed, representing the Consumers Union, discussed the need for a Notice to Consumers to advertise this option.

Peter Kellison, representing Walgreens, indicated that Walgreens will find a solution in order to comply.

Ms. Herold thanked everyone involved and engaged in this process. She advised that the board will rely on everyone to help educate consumers. Ms. Herold indicated that she will encourage the board to require a Notice to Consumers as well as refill reminders regarding this option. She indicated that the Communication and Public Education Committee will conduct public outreach in this area.

Dr. Castellblanch expressed concern that a notice requirement is not included in the regulation and stated that the 15-day comment period may be insufficient.

The board discussed the time needed for implementation and was reminded of the statutory mandate that the regulation be effective January 1, 2011. It was clarified that the board can allow time for implementation before the regulation becomes effective.

There was no additional board discussion or public comment.

MOTION: Amend the modified text in section 1707.5 (a)(1) to read as follows:
Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, 10-point, sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order.

M/S: Zee/Brooks

Support: 5 Oppose: 4 Abstain: 1

The board discussed a motion to strike subdivision (d) regarding oral language translations.

Ms. Veale expressed concern regarding the ability for pharmacies to comply with a translation services requirement.

Mr. Lippe suggested that the requirement apply to certain available languages.

Dr. Castellblanch provided comment on the Medi-cal standard languages.

Mr. Zee discussed the financial burden that providing translation services may pose for pharmacies.

Discussion continued regarding the accessibility of translation services.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, expressed concern regarding limiting the translations to specific languages. He stated that pharmacies are already obligated under state and federal law to provide language services.

Mr. Room reviewed potential perceived risks with regards to this issue. He stated that if the language is stricken, the board will have an additional element of proof when determining whether or not a pharmacy had available services and failed to provide those services.

Dr. John Cronin, representing the California Pharmacists Association (CPhA), provided that this language was included at the request of CPhA. He stated that providing these services will be an expensive enterprise for independent pharmacies to undertake.

Dr. Castellblanch withdrew his motion.

The board discussed a motion to strike "if interpretive services in such language are available" from subdivision (d).

Public Comment

Marty Martinez, representing the California Pan-Ethnic Health Network, spoke in support of the motion. He stated that the language "if available" leaves too much ambiguity.

Doreena Wong, representing the National Health Law Program, provided comment regarding a pharmacy's obligation to provide oral services if it receives specific funding. She suggested that the board invite a representative from the Office of Consumer Rights to speak at the next board meeting.

MOTION: Amend the modified text in section 1707.5 (d) to read as follows:

The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

M/S: Castellblanch/Hackworth

Support: 2 Oppose: 7 Abstain: 1

Ms. Herold provided that the California Medical Association (CMA) has indicated that the purpose provision of the regulation violates the clarity standard of the Administrative Procedure Act by allowing the purpose or condition of a medication to be placed onto a label without the purpose or condition being stated on the prescription by the prescriber. She stated that CMA is requesting that the purpose language in the regulation be amended so that, if the condition or purpose is to be included on the container label, it must first be specified by the provider.

The board discussed a motion to strike “if otherwise known to the pharmacy and its inclusion on the label is requested by the patient,” in section (a)(1)(D).

Dr. Kajjoka provided comment in support of the motion.

Dr. Castellblanch discussed privacy issues involved with providing the purpose on the label when it is not requested by the patient.

Mr. Room provided that current law requires this information to be on the label if the prescriber includes it on the prescription.

President Schell provided that the patient has the right to request the removal of the purpose on the label. He stated that the pharmacist is required to contact the physician for approval of this request.

Ms. Sodergren clarified that section 4040 contains the prescription provision that states the condition or purpose is included on the prescription if requested by the patient. She explained that section 4076 requires the purpose to be included on the label if it is included on the prescription.

Mr. Weisser provided comment in support of the inclusion of purpose on the label. He stated that providing the purpose benefits the patient and helps to eliminate confusion.

Ms. Herold encouraged the board to ensure that the regulation is consistent with current law in order to avoid rejection by the Office of administrative Law (OAL).

Public Comment

Steve Gray, representing Kaiser Permanente and the Board of Pharmacy Association of California, provided that the purpose is one of the most important elements that consumers have indicated that they want on the label. He encouraged the board to retain this element and to not support the motion.

Dr. John Cronin, representing the California Pharmacists Association, provided comment in support of the inclusion of the purpose on the label.

The board discussed the possible rejection of the regulation if the purpose provision is included. It was stated that the rejection will further delay implementation.

Mr. Room provided that he believes rejection by OAL is unlikely. He stated that this provision would expand upon the current statutory minimum and does not conflict with this minimum.

Ms. Schieldge provided that current law specifies that the purpose is to be included on the label only if it is included on the prescription. She stated that inclusion of the purpose provision in the regulation may be a consistency issue for OAL and can cause rejection of the entire regulation.

The board discussed the possibility of noticing a separate regulation for the purpose provision after the finalization of the current regulation.

There was no additional board discussion or public comment.

MOTION: Amend the modified text in section 1707.5 (a)(1)(D) to read as follows:

Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is desired requested by the patient.

M/S: Zee/Lippe

Support: 7 Oppose: 2 Abstain: 1

MOTION: Establish a 15-day comment period for the proposed modifications to the text of section 1707.5.

M/S: Weisser/Zee

Support: 8 Oppose: 1 Abstain: 1

MOTION: Direct staff to take all steps necessary to complete the rulemaking process including preparing modified text for an additional 15-day comment period which includes the amendments previously approved by the board at this meeting. If after the 15-day public comment period no adverse comments are received, authorize the executive officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process and adopt section 1707.5 of the proposed regulations with the modified text.

M/S: Weisser/Zee

Support: 9 Oppose: 0 Abstain: 1

MOTION: Direct staff to develop a protocol for a Notice to Consumers regarding the availability of 12-point font.

M/S: Lippe/Castelblanch

Support: 7 Oppose: 0 Abstain: 1

Ms. Herold asked the board to consider scheduling a one day board meeting prior to the July 2010 board meeting.

It was the consensus of the board to schedule an additional one day board meeting in June 2010.

REGULATION REPORT

- a. For Board Discussion - Discussion Regarding Possible Regulation Specifying Consumer Notice for Language Assistance Interpretative Services Provided in Pharmacies

Mr. Weisser provided that at the last two board meetings during discussions to develop the requirements for patient-centered medication container labels, it was strongly suggested that a written notice requirement for pharmacies be established to provide notice to patients regarding the availability of interpretative services.

Ms. Herold highlighted the initial language prepared by staff for board comment and input. She stated that in New York City, the Department of Consumer Affairs is considering the following language to advise patients about their rights to interpretive services in pharmacies. This language is below (with the exception of the first paragraph which was developed for CA) and provides one way to phrase such a notice.

1707.6 (a) The pharmacy's policies and procedures required by section 1707.5(d) to notify patients with limited or no English proficiency about the availability of interpretative services shall include development and display of a written reference list of languages for which translation services are available, in the specific written language of interpretation. Such a list will enable a non-English speaker to identify his or her language by pointing to the desired language on the reference list of languages.

(b) A pharmacy shall provide the following statement in English and in each of the languages for which interpretative services are available: "Point to your language. Language assistance will be provided at no cost to you."

(c) The statement in each of the required languages shall be in 18-point, bold-face type in a color that sharply contrasts with the background color of the sign. Each such statement shall be enclosed in a box, and there shall be at least a ¼ inch clear space between adjacent boxes.

(d) The statements in all of the required languages shall be printed on one sign that shall be conspicuously displayed on or at each counter near every cash register where prescription drugs are sold and shall be positioned so that a consumer can easily point to the statement identifying the language in which such a person is requesting assistance.

President Schell exhibited an example notice to the board.

Ms. Herold provided that if the board is interested in pursuing a regulation about this consumer notice, after comments during this meeting, staff will bring more refined language to the July 2010 board meeting with the intent that the board finalize it into the text of a proposed requirement, and then initiate a rulemaking and release the proposal for 45 days of public comment.

Mr. Weisser stated that the proposed language is adequate.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, expressed concern regarding the limited space available to post the notice and the selection of the languages included on the notice. He suggested that the board allow pharmacies to install flat screens to communicate information via a scrolling notice.

Ms. Herold discussed the current notices that are supplied and required to be posted by all pharmacies. She indicated that use of flat screens could be permitted in the regulation.

Doreena Wong requested that the board provide guidance as to how pharmacies should display the notice.

Ms. Herold indicated that this issue will be brought before the board for further discussion at the next meeting.

There was no additional board discussion or public comment.

b. Board Approved – Undergoing Administration Review

1. Adopt Sections 1721 and 1723.1 in Division 17 of Title 16 of the Code of Regulations Regarding Dishonest Conduct During a Pharmacist's Licensure Examination/Confidentiality

Mr. Weisser provided that the approved amendments to 16 CCR §1721 and §1723.1 will strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

Mr. Weisser provided that the board adopted this regulation during the January 2010 Board Meeting. He indicated that this rulemaking file was compiled and submitted to the department in March 2010.

No public comment was provided.

2. Adopt New Section at Title 16 California Code of Regulations Section 1702 – Fingerprint Submissions for Pharmacists

Mr. Weisser provided that at the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file.

Mr. Weisser provided that the board adopted this regulation during the February 2010 Board Meeting. He stated that the rulemaking file was compiled and submitted to the department in February 2010.

No public comment was provided.

c. Board Approved – Awaiting Notice

1. Title 16 of the California Code of Regulations, Amendments to Section 1746 of – Emergency Contraception Protocol (including Correct Typographical Error: Mcg Instead of Mg)

Mr. Weisser provided that in 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. He indicated that the regulation became operative on December 2, 2004.

Mr. Weisser provided that staff recommends that an error be corrected in the 'chart' of Dedicated Emergency Contraception that is specified in 16 CCR §1746(b)(11) to correct the heading of "Ethinyl Estradiol per Dose (mg)." He explained that the heading should designate micrograms – not milligrams. Mr. Weisser stated that while the board deems this to be a typographical error, the regulation (as originally adopted) specified milligrams, not micrograms. Mr. Weisser indicated that as a result, a formal regulation proposal is required to correct this heading.

No public comment was provided.

2. Title 16 CCR Section 1732.2 – Board Issued Continuing Education Credit

Mr. Weisser provided that the Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. He stated that at the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete review of examination questions if the committee member is not seeking reimbursement for their time.

Mr. Weisser proved that this was included into the board's continuing education policy, but was never formally amended into regulation.

Mr. Weisser provided that during the February 2010 Board Meeting, the board voted to initiate the formal rulemaking process. He advised that board staff anticipates initiating this rulemaking for action at either the July or October 2010 board meeting.

Public Comment

Douglas Barcon asked whether the annual award is based by the calendar year or by the renewal cycle.

Ms. Herold provided that the award was based on one calendar year when the policy was developed. She indicated that this issue will be addressed.

There was no additional board discussion or public comment.

- d. Board Approved Regulations – Under Development
 - 1. Title 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Background

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period. Subsequent to these actions however, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

Mr. Weisser provided that the Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. He stated that board staff does not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

No public comment was provided.

- 2. Title 16 CCR Section 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Background

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

The proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.

Mr. Weisser provided that staff will be working with counsel to draft language that will be discussed at a future Legislation and Regulation Committee Meeting.

No public comment was provided.

3. Title 16 CCR Section 1780 – Update the USP Standards Reference Material

Mr. Weisser provided that CCR §1780 sets minimum standards for drug wholesalers. He stated that section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. Mr. Weisser indicated that the USP Standards is updated and published annually. He explained that consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Mr. Weisser provided that because of stated concerns about whether referencing the 2005 USP standards is 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.

Mr. Weisser provided that President Schell may wish to consider filling the subcommittee vacancy created when former board member Jim Burgard's term concluded. He advised that this subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

No public comment was provided.

Third Quarterly Report on Legislation/Regulation Committee Goals for 2009/10

Mr. Weisser referenced to the third quarterly report on the Legislation/Regulation Committee's goals that are contained within the board packet.

Public Comment

Stan Goldenberg offered to arrange for a presentation from representatives from long-term care committees to discuss labeling in skilled nursing facilities and assisted living facilities.

There was no additional public comment.

XIII. Enforcement Committee Report and Action

There has been no meeting of the Enforcement Committee During this Quarter

- a. Discussion and Possible Action Regarding the Drug Enforcement Administration's Proposed Regulations for the E-Prescribing of Controlled Substances

Dr. Kajioka provided that the federal Drug Enforcement Administration (DEA) released on March 22, 2010 proposed requirements to enable e-prescribing of controlled drugs. He stated that current federal law prevents the electronic prescribing of written prescriptions for controlled drugs. Dr. Kajioka indicated that the comment period on these requirements will close in 60 days from publication in the Federal Register (which occurred on March 31, 2010). Thus, the comment period should end on or about May 31, 2010.

Dr. Kajioka provided that this is an important and significant change for prescribers, for pharmacy and for patients. He indicated that the volume of material released by the DEA for this regulation is extensive – 334 pages, and was provided initially to individual board members via a link in late March. Dr. Kajioka explained that not all these pages are text of the requirements. He advised that the regulation is very technical and is difficult to readily digest.

Dr. Kajioka highlighted the regulation content.

Dr. Kajioka reviewed the following options for the board:

- Provide comments to the DEA on these regulations.
- Empower a subcommittee of the board to provide comments on behalf of the board (in which case the subcommittee will need to be appointed and meet).
- Dedicate a portion of a future meeting on discussion of the requirements, and not proceed with comments to the DEA during the short time-frame available for comment.

Mr. Room provided that the review is very technical. He advised the board that if they chose to provide comment, it would require a technical capability that is beyond his ability.

Ms. Herold suggested that the board convene a summit or schedule time at a future meeting for further review of this area.

President Schell recommended that the board not take action at this time and instead consider dedicating time at a future board meeting for discussion.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided comment on the importance of these regulations. He offered comments and analysis from one organization's analysis to aid the board with this issue. Dr. Gray recommended that the board request an extension for the comment period.

There was no additional board discussion or public comment.

MOTION: Request an extension of 120 days beyond the 60-day comment period to submit comments to the DEA.

M/S: Lippe/Veale

Support: 7 Oppose: 0 Abstain: 1

b. Review of the Federal Food and Drug Administration's Guidance on the Standardized Numeric Identifier for Prescription Drugs

Dr. Kajioka provided that on March 26, 2010, the federal FDA released its guidance (not requirements) on the serialized numeric identifier for prescription drug packages. He stated that the FDA was directed to develop a standard for the unique identifier that could be used for identifying and tracking prescription drugs at the saleable unit throughout the supply chain. Dr. Kajioka explained that this is an identifier that could be used under California's e-pedigree requirements, or if preempted by federal legislation, used federally to uniquely identify and track prescription drugs through the supply chain from manufacturer to the pharmacy.

Dr. Kajioka stated that the FDA guidance provides that a serialized identifier be comprised of:

1. Up to 20 characters
2. Any character may be a number or an alphabetic letter

Dr. Kajioka provided that the FDA estimates that this will allow the tracking of billions of units without duplication. He stated that the FDA's guidance for the serialized numeric identifier would allow and support the use of existing standards already in place by industry.

No public comment was provided.

c. Discussion and Possible Action Regarding Provisions of the Department of Consumer Affairs New Enforcement Model Contained in SB 1111 (Negrete-McLeod)

Dr. Kajioka provided that since July 2009, the Department of Consumer Affairs has been working with the health care boards to upgrade their capabilities to investigate and discipline errant licensees to protect the public. He stated that the proposed changes have taken various forms. Dr. Kajioka advised that the goal is to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. He explained that formal discipline means those cases which are the most serious, and for which license removal or restriction is being sought.

Dr. Kajioka provided that some of the recommended changes involve statutory modifications. He stated that after the January 2010 Board Meeting, the department released its refined list of statutory modifications. Dr. Kajioka indicated that these proposals are contained in SB 1111. He advised that the department has asked that this item be placed on the agenda of every health care board's public board meeting, with the goal of obtaining the board's support for the legislation.

Dr. Kajioka provided that the April 2010 Board Meeting affords this board its first opportunity to discuss the proposals. He stated that the department has previously convened a separate meeting with board presidents of the health care boards, and convened another meeting with stakeholders for each of these boards. Dr. Kajioka indicated that the pharmacy stakeholders had their meeting several weeks ago.

DCA Director Brian Stiger notified the board that SB 1111 did not pass out of committee earlier in the day. He highlighted a press release issued from the Governor regarding enforcement policies. Mr. Stiger indicated that there was a lot of opposition from professional associations and unions particularly regarding due process and diversion programs.

Ms. Herold commended Mr. Stiger for his efforts to implement the new enforcement model as well as for his support of the board.

Mr. Weisser discussed several capabilities available to the board that are not afforded to other boards including a dedicated inspection team.

No public comment was provided.

- d. Discussion and Possible Action Regarding Changes to Current Regulations and Statutory Requirements to Implement the Uniform Standards Recommended by DCA's Substance Abuse Coordination Committee (per SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)

Dr. Kajioka provided that in 2008, SB 1441 was enacted to direct health care boards with so called "diversion programs" for health care licensees to establish department-wide minimum standards for participation. (Technically, a diversion program stops discipline in favor of rehabilitating a licensee with a substance abuse problem, so long as he/she remains abstinent.) He stated that these mandatory standards would apply to those in a diversion program as well as those licensees who are on probation for substance abuse violations.

Dr. Kajioka provided that the board has its Pharmacists Recovery Program (PRP), which serves the board's public protection mandate by closely monitoring those with substance abuse or other specified conditions. He advised that the

PRP is not a diversion program. Dr. Kajioka explained that instead, the board encourages a licensee under investigation for a substance abuse program to enter the program in advance of the board's formal discipline. He stated that the licensee enters a strict monitoring program while the investigation and enforcement processes continue.

Dr. Kajioka provided that there are 16 standards under development by a committee comprised of board executive officers. He stated that the standards are not yet finalized, but are nearing completion.

Dr. Kajioka provided that the department has asked that each of the health care boards review and begin necessary actions to implement these standards. He indicated that Board Counsel Schieldge has identified whether each standard needs statutory and/or regulation modifications.

Dr. Kajioka provided that some of the statutory modifications needed will be inserted into a Negrete McLeod bill later this year. He stated that the regulations needed by the board will mostly involve modifications of the board's disciplinary guidelines.

Dr. Kajioka provided that the board may wish to refer detailed work on these standards to staff to bring a future committee meeting of the Enforcement Committee.

Ms. Sodergren provided an overview on SB 1441 and the 16 standards. She identified standards that will require changes to current regulations and statutory requirements for implementation.

Ms. Herold provided that Substance Abuse Coordination Committee is scheduled to meet in mid-June 2010. She stated that the board may wish to direct staff to initiate work on the uniform standards to bring to a future committee meeting of the Enforcement Committee.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, asked whether the Attorney General's Office has conducted a comparison on the standards and the current federal requirements.

There was no additional board discussion or public comment.

MOTION: Direct staff to perform detailed work on the uniform standards to bring to a future committee meeting of the Enforcement Committee.

M/S: Schell/Kajioka

Support: 7 Oppose: 0 Abstain: 1

e. Update on California Drug “Take Back” Programs from Patients

Dr. Kajioka provided that since 2008, the board has been working on guidelines for entities to take back unwanted prescription drugs from patients. He stated that in February 2009, the California Integrated Waste Management Board released statutorily-required guidelines for the take back of pharmaceuticals from patients. Dr. Kajioka indicated that the board participated in the development of these guidelines.

Dr. Kajioka provided that in the February 2010 *The Script*, the board promoted these guidelines to licensees for the first time. He stated that the board is aware that some pharmacies developed take-back programs before the adoption and awareness of the state guidelines. Dr. Kajioka indicated that in the coming months, board inspectors will take pictures and collect basic information regarding how California pharmacies are taking back drugs from patients, whether and how any program complies with the guidelines, and encourage compliance with the guidelines. He stated that this information will be provided to the board at a future time.

No public comment was provided.

f. Enforcement Statistics 2009-10

Dr. Kajioka referenced to the statistics contained within the board packet.

No public comment was provided.

g. Third Quarterly Report on Enforcement Committee Goals for 2009/10

Dr. Kajioka referenced to the third quarterly report on the Enforcement Committee’s goals contained within the board packet.

No public comment was provided.

h. Public Comment

Dr. John Cronin provided comment regarding the drug take-back programs. He asked if inspectors intend to also evaluate city programs and non-pharmacy programs. Dr. Cronin expressed concern that only looking at this issue within pharmacies may drive these programs into other areas.

Ms. Herold provided that the board does not intend to regulate other programs beyond its jurisdiction. She advised that the DEA is becoming heavily involved with the operations of drug take-back programs.

Dr. Steve Gray, representing Kaiser Permanente, sought clarification regarding the drug-take back guidelines and the board's policy in this area.

Ms. Herold provided that the guidelines do not carry any statutory authority.

Mr. Room provided that there is no statutory authorization for drug take-back programs in pharmacies.

XIV. Organizational Development Committee Report and Action

There has been no meeting of the Organizational Development Committee During this Quarter

a. Budget Update/Report

1. Budget Reports for 2009/10

Background

Early this fiscal year, the Governor directed that no new purchases or contracts could be executed until a 15% spending reduction plan is in place. Board staff submitted a reduction plan that was approved which allowed us to resume purchasing supplies and securing vendors for contracts. With such a significant reduction in operating expenses, board staff are adapting to new ways of processing information and organizationally we are looking into cost saving measures.

For 2009-10, estimated budget figures (including the 15% reduction) are:

- Revenue: \$10,555,000
- Expenditures: \$9,812,000

Also, after releasing his proposed budget for 2010-11, the Governor issued Executive Order S-01-10. This order calls for a 5% current year reduction in salary savings, as well as similar ongoing savings in future budget years.

Ms. Herold highlighted California's current deficit and the impact it has had on the board.

No public comment was provided.

2. Fund Condition Report

Ms. Herold provided that according to a fund condition report prepared by the department, the board will have the following fund conditions at the end of the identified fiscal years:

2008/09	\$11,001,000	13.5 months in reserve (actual)
2009/10	\$11,744,000	10.4 months in reserve
2010/11	\$ 9,312,000	8.1 months in reserve
2011/12	\$ 6,619,000	5.6 months in reserve
2012/13	\$ 3,500,000	2.9 months in reserve

No public comment was provided.

3. Budget Change Proposals for the 2010/11 Budget

Ms. Herold provided that on January 8, 2010, the Governor released his proposed budget for 2010-11. She stated that if enacted as proposed, the board would gain two licensing technicians to address the significant growth we have experienced in applications over the past several years.

Ms. Herold provided that also included in this budget is an augmentation to implement the Consumer Protection Enforcement Initiative. She stated that in the case of this board, this is 22.5 enforcement positions to review and investigate complaints. Ms. Herold discussed that the loss of SB 1111 may impact these positions.

Ms. Herold provided that the board will also be subject to a 5 percent reduction in personnel expenditures that is being assessed on all state agencies. She stated that to comply with this reduction, the board will:

- Leave positions vacant for 4-5 months to generate salary savings
- Where possible, reallocate vacant positions to lower classifications
- Reduce the board's temporary spending and expenditures

Ms. Herold requested that the board consider deferring paying board members their per diem (not reimbursement for expenses) until the end of the year to ensure the board has sufficient funding.

No public comment was provided.

4. Reimbursement to Board Members

Ms. Herold referenced to the expenses and per diem payments to board members are provided in the board packet. These are hours and expenses claimed by board members during the indicated periods. Board members are paid for each day of a board meeting, but in accordance with board policy, may also submit hours for work performed doing additional board business.

No public comment was provided.

5. BreEZe Progress

Ms. Herold provided that for a number of years the department has worked to replace and/or enhance the legacy licensing and enforcement tracking systems. She stated that a few years ago, the department initiated an i-Licensing project which would offer online application and renewal of licenses (a much needed relief from mail-in renewals).

Mr. Herold provided that this project was recently replaced as a component in DCA's proposed Enforcement System upgrades with a new proposal (called BreEZe) that will allow for the online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System. Ms. Herold advised that implementation is still 3 years away.

No public comment was provided.

b. National Association of Boards of Pharmacy Annual Meeting in May 2010 in Anaheim

Ms. Herold provided that on May 22-25, 2010, the National Association of Boards of Pharmacy is holding its annual meeting in California.

No public comment was provided.

c. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

Ms. Herold provided that since July 2005, the board has acknowledged 937 pharmacists with 50 or more years of licensure as pharmacists in California. She stated that as pharmacists reach this milestone, they are sent a certificate and invited to a future board meeting for public recognition.

No public comment was provided.

d. Personnel Update

1. Board Member Changes

Ms. Herold provided that there are currently ten board members, and three board member vacancies. She stated that the vacant positions are Governor appointments of pharmacist members.

No public comment was provided.

2. Staff Changes

Ms. Herold provided that the board currently has two inspector vacancies. She stated that two board supervising inspectors conducted civil service interviews in March to compile a new list of pharmacists who would be eligible for hiring as board inspectors. Ms. Herold indicated that the budget analyst position was filled this week.

No public comment was provided.

e. Third Quarterly Report on the Committee's Goals for 2009/10

President Schell referenced to the third quarterly report on the Organizational Development Committee's goals contained within the board packet.

No public comment was provided.

XV. Election of Board Officers for 2010-11

President

MOTION: Elect Stan Weisser as president of the Board of Pharmacy.

M/S: Zee/Lippe

MOTION: To close further nominations.

M/S: Schell

Support: 7 Oppose: 0 Abstain: 1

Vice President

MOTION: Reelect Randy Kajioka as vice president of the Board of Pharmacy.

M/S: Weisser/Veale

MOTION: To close further nominations.

M/S: Schell

Support: 7 Oppose: 0 Abstain: 1

Treasurer

MOTION: Elect Greg Lippe as treasurer of the Board of Pharmacy.

M/S: Zee/Weisser

MOTION: To close further nominations.

M/S: Schell

Support: 7 Oppose: 0 Abstain: 1

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

No public comment was provided.

The meeting was adjourned at 3:27 p.m.



SB 1441

Uniform Standards
Regarding Substance-Abusing
Healing Arts Licensees



Diagnostic Evaluation

- Licensee in a diversion program or on probation.
- Qualifications for the licensed practitioner
- Required elements of the evaluation.
- Provides for timeframes



Temporary removal of practice for clinical evaluation

- Cease practice during the evaluation.
- Random drug testing at least two times per week.
- Evaluation criteria for return to work conditions.



Communication with Licensee's Employer

- Notification of the names, addresses and telephone numbers of all employers.
- Requires written consent for the board and employers to communicate.



Drug testing

- Requires 104 random drug tests per year for the first year
- Requires a minimum of 50 random drug tests from then on
- Observed testing
- Daily check-in and same day testing
- Criteria for collection sites and labs processing the results



Group Meeting Attendance

- Evaluation criteria used to determine meeting frequency
- Qualifications and reporting requirements for facilitator



Type of treatment

- Criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.

Worksite monitoring

- Criteria for a worksite monitor
- Methods of monitoring used by monitor
- Reporting requirements by the worksite monitor
 1. Specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day
 2. Specifies that a written report must be provided to the board within 48 hours of the occurrence
- Completion of consent forms to allow for communication.



Positive drug test

- Temporary cease practice
- Determine if the positive drug test is evidence of prohibited use
- Criteria used to make the determination.



Ingestion of a banned substance

- A confirmed positive drug test is evidence of use of a prohibited substance
- Constitutes a major violation.

Consequences for major and minor violations

- Major Violation Defined
 1. Failure to complete a board ordered program or undergo a clinical diagnostic evaluation
 2. Treating patients while under the influence of drugs/alcohol
 3. Any drug/alcohol related act which would constitute a violation of the state/federal laws,
 4. Failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
- Consequences for a major violation
 1. Cease practice order
 2. Requiring a new clinical evaluation
 3. Termination of a contract/agreement
- 1. Referral for disciplinary action.

Consequences for major and minor violations

- Minor violation includes
 1. Untimely receipt of required documentation
 2. Unexcused group meeting attendance
 3. Failure to contact a monitor when required
 4. Any other violations that does not present an immediate threat to the violator or the public.
- Consequences for a minor violation
 1. Removal from practice
 2. Practice restrictions
 3. Required supervision
 4. Increased documentation
 5. Issuance of a citation and fine or working notice
 6. Re-evaluation/testing
 7. Other actions as determined by the board.



Return to full time practice

- Criteria to return to full time practice
 1. Demonstrated sustained compliance
 2. Demonstrated ability to practice safely
 3. Negative drug screens for at least six months
 4. Two positive worksite monitor reports
 5. Compliance with other terms and conditions of the program.



Unrestricted practice

- Criteria for a licensee to request unrestricted practice
 1. Sustained compliance with a disciplinary order
 2. Successful completion of the recovery program
 3. Consistent and sustained participation in recovery activities
 4. Demonstrated ability to practice safely
 5. Continued sobriety of three to five years, as specified.



Private-sector vendor

- Reporting any major violation to the board within one business and any minor violation within five business days
- Approval process for providers or contractors that work with the vendor
- Discontinue the use of providers or contractors that fail to provide effective or timely services as specified.



Confidentiality

- Requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed for participants in a diversion program whose been issued a cease practice order or has practice restrictions
- Disclosure will not include that the restrictions are as a result of the participation in a diversion program



Audits of private-sector vendor

- Requires an external independent audit every three years
- Audit must assess the vendor's performance in adhering to the uniform standards
- Requires the reviewer to provide a report to the board by June 30 of each three year cycle
- Requires the board and department to respond to the findings of the audit report



Measurable criteria for standards

- Establish annual reporting to the department and Legislature
- Details the information that must be provided in the report
- Establish criteria to determine if:
 1. The program protects patients from harm
 2. Is effective in assisting licensees in recovering from substance abuse in the long term.

Consumer Protection Enforcement Initiative (CPEI)

SB 1111 (Negrete McLeod)

Department of Consumer Affairs

CPEI Goal

Improved Consumer Protection

Reduce the average timeframe for investigating and prosecuting violations of was to between 12 and 18 months.

CPEI

Comprehensive Approach

1. Statutory Changes (SB 1111)
 2. New Integrated Computer System
 3. Staff Augmentation
-

Required Internet Information

- License status including active, canceled, revoked
 - Suspensions and revocations taken
 - Other enforcement actions - -citation and fines, letters of admonishment
 - Cannot include personal information – including the address of record
-

Audits by DCA Director

- Enforcement Activities including, opening, conduct and closing of investigations
 - Does not include formal disciplinary action.
 - Recommendations to the legislature based on findings of audit
-

Cost Recovery Awarded by ALJ

- Applies To:
 - Administrative Case
 - Citation and fine
 - Probation Monitoring costs
 - Restricts board action for failure to pay
 - Restricts conditions for reinstatement
 - Includes other costs - expert witness fees & administrative filing fees
-

Collection Agency

- Fees, fines and cost recovery
 - Provide personal information including SSN
 - Decision must be final prior to collection
-

Citation and Fine Appeals

- ❑ Require at minimum 2 Board Members to hear appeal, one must be a professional member
 - ❑ Licensee can appeal that decision to the full board
 - ❑ Authorizes telephonic meetings if acceptable to the licensee
-

Investigative Services

- Allows board to contract with DOJ for services
 - Makes changes to DOI
 - Peace officers for RN board
-

Delegations to EO

- Default Decisions
 - Stipulated revocations
 - Stipulated surrender
-

Stipulations prior to pleading

- Settlement must include findings of fact
 - Must include statutes or regulations violated
 - Applies to Licensees and applicants
-

Temporary Cease Practice Order

- EO can petition when licensee poses imminent risk
 - Hearing before the director
 - 90 days or ISO is granted or denied
 - Fine and administrative action for licensee that fails to comply
 - Immediate notification to director if condition changes
 - Post cease practice orders on the web site
 - Defines imminent risk
-

Automatic Suspension

- Felony incarceration
 - Dangerous drug and controlled substances violation automatically considered substantially related
 - Check on other codes
 - Board may set aside suspension in the interest of justice
 - Matter cannot be resolved until conviction is final
-

Mandatory Revocation

- Sexual contact with patient
 - Committed or convicted of sexual offense
-

Sex Offenders

- deny any application for licensure
 - revoke any license
 - prohibits reinstatement of a license
 - does not apply to misdemeanor offenses
-

Gag Clause Prohibition

- Civil dispute resolution cannot prohibit a person from contacting or filing a complaint with the board.
-

Access to Records

- 10 days to produce certified copies of requested information
 - Subject to fines for failure to provide records
 - Applies to:
 - Other state agencies
 - Law Enforcement
 - Licensees
 - Health Care Facilities
-

Employer Notification

- Suspensions or terminations due to:
 - Controlled substances or alcohol
 - Unlawful sale of controlled substances or prescription items
 - Patient neglect, abuse or harm or sexual contact
 - Gross negligence or incompetence
 - Theft from a patient, employer or another employee
 - Established fines for noncompliance with reporting
-

Annual Reporting to the Legislature

- Enforcement activity data
 - Processing time data
 - Caseload for staff
-

Internet Posting

- Licensee status for current and prior licensees
 - Discipline in CA or another state
 - Felony convictions
 - Accusations
 - Malpractice judgments
 - Hospital disciplinary actions
 - Misdemeanors that result in administrative actions
 - Disclaimers adopted by regulation
-

Timelines for AG's Office

- Accusations drafted within 60 days
 - Default decisions drafted within 5 days
 - Hearings requested within 3 days
-

Application Denial

- Based on evaluation substantiating a mental or physical illness.
-

Limited Licenses

- Authority to issue a limited license
-

HIPDB

- Mandatory reporting
 - Search prior to issuing or renewing a license
 - Authorizes a fee to cover search
 - Automatic suspension in CA for suspension in another jurisdiction
-

Emergency Health Care Enforcement Reserve Fund

Allows for intradepartmental loans

Midyear Budget Augmentation

- To cover enforcement related costs
 - DOF can approve
-

Sexual Misconduct

- Unprofessional Conduct
 - Substantially related to the licensee's practice
-

Unprofessional Conduct – Drug Related

- Conviction of state or federal law regulation dangerous drugs or controlled substances
 - Violation of state or federal law regulating dangerous drugs or controlled substances
 - Self prescribing for or administration of controlled substances
 - Impairment caused by use or drugs or alcohol
 - Misdemeanor or felony involving use, consumption or self-administration
-

Unprofessional Conduct – Other

- Failure to provide information as requested
 - Failure to cooperate in investigation or other regulatory or disciplinary proceeding
-

Mandatory Reporting

- Indictment or information charging a felony
 - Arrests
 - Convictions
 - Disciplinary action taken by another jurisdiction
 - 30 day time frame for reporting
-

Self Identification

- ❑ Licensee must identify him/herself as a licensee to law enforcement and court upon arrest or charging
-

Court Clerk Reporting

- Notice of crimes
 - Death or personal injury judgment over \$30,000
-

DA, City Attorney or Prosecuting Agency Reporting

- Felony
 - certified documents
 - preliminary hearing transcripts
 - Probation reports
-

DOJ Reporting

- Subsequent arrest, convictions and other updates

Unlicensed Practice

- \$100,000 public fine
 - Practicing without a license
 - Fraudulently buys, sells or obtains a license
-

Diversion Programs

- ❑ Sunsets diversion programs January 1, 2013.

Health Quality Enforcement Section

- Option to use for DOJ services – Vertical Enforcement

Peace Officers

- RN Board investigators
-

New IT System

- Integrated System to support licensing and enforcement functions