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

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

DATE: April 30 and May 1, 2009

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

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, President
Stanley C. Weisser, RPh, Treasurer
Ryan Brooks, Public Member
James Burgard, Public Member
Randy Kajioka, PharmD
Greg Lippe, Public Member
Robert Swart, PharmD
Andrea Zinder, Public Member

BOARD MEMBERS NOT PRESENT:
Susan L. Ravnan, PharmD
Shirley Wheat, Public Member

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

Call to Order

President Schell called the meeting to order at 9:10 a.m.

Salvadore Biondolillo and Brian Gluadil from the Drug Enforcement Agency thanked board inspector, Lin Hokana, for his commitment and service and presented him with a certificate of appreciation for work on a joint investigation.

I. Approval of the Full Board Minutes of January 21 and 22, 2009

Board Discussion

President Schell requested that modifications be made to the first paragraph on page 11.

Public Comment

Steve Gray, representing Kaiser Permanente, requested that clarification be provided to comments on page 4.

There was no additional board of public comment.

MOTION: To approve the minutes of the January 21 and 22, 2009 Board Meeting as amended.

M/S: JB/SW

Support: 6 Oppose: 0

II. Legislation and Regulation Committee Report and Action

Part 1: Regulation Report and Action (*Note: CCR as used below means California Code of Regulations)*

A. Action to Repeal Title 16 CCR Sections 1716.1 and §1716.2, Amend and Adopt Sections 1751 through 1751.8, and Adopt Sections 1735 through 1735.8 – Pharmacies that Compound Medicine

Andrea Zinder provided that pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. She stated that as required in Business and Professions Code § 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. Ms. Zinder indicated that there are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. She provided that this proposal would establish guidelines to provide uniformity in compounding for California consumers.

Ms. Zinder provided that the 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. She stated that at the conclusion of the regulation hearing, the board voted to create a subcommittee of two

board members to work with staff and fully consider all comments received both orally and in writing.

Ms. Zinder provided that during the January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt some of the record keeping requirements detailed in § 1735.3 for sterile products that are compounded on a one-time basis for administration within 2 hours as specified. She stated that in response to this 15-day comment period, the board received a significant amount of comments.

Ms. Zinder provided that executive staff of the board, after reviewing the comments submitted, suggests that the board has several options to potentially further modify Section 1735.3 (a)(6):

(1) exempt compounded solutions made pursuant to a patient order for administration within 24 hours,
(2) use 12 hours or
(3) keep as noticed, at 2 hours.

Ms. Zinder provided that the staff did not provide a recommendation.

Assistant Executive Officer Anne Sodergren provided that the board will need to pursue a15-day public comment period based on board action. She indicated that comments submitted should be directed specifically to the proposed changes.

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 following amendment: amend the exemption to § 1735.3(a)(6) for sterile products compounded on a one-time basis for administration within 24 hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the following changes with the modified text: repeal sections 1716.1, 1716.2, 1751.01. 1751.02; add sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8; and amend sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, and 1751.8 of Division 17 of Title 16 of the California Code of Regulations.

M/S: SW/RK

Support: 6 Oppose: 0

B. Approved Regulations

Section 100 Changes

1. Amendment of 16 CCR §1715 Self Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law; and related updates to Forms 17M-13 and 17M-14

Ms. Zinder provided that §1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. She stated that these self-assessment forms are designed to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Ms. Zinder added that the forms make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their PICs. She advised that the law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the pharmacist-in-charge occurs.

Ms. Zinder provided that at the October 2008 Board meeting, the board voted to pursue section 100 changes to update the forms. She stated that board staff was recently advised that these forms were approved by the Office of Administrative Law. Ms. Zinder advised that the revised forms are on the board's Web site and that a notice was provided in the recently published issue of *The Script* advising readers of the change.

No board or public comment was provided.

2. Amendment of 16 CCR §1784 Self Assessment of a Wholesaler by the Designated Representative-in-Charge to Update for Changes in Pharmacy Law; and related updates to Form 17M-26

Ms. Zinder provided that §1784 of the California Code of Regulations establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge (DRC) to complete this form to ensure compliance with pharmacy law. She stated that this self-assessment form is designed to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Ms. Zinder added that the forms make the inspection process more meaningful and provide relevant information to wholesalers and their DRC. She indicated that the law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the designated representative-in-charge occurs.

Ms. Zinder provided that at the October 2008 Board meeting, the board voted to pursue section 100 changes to update this form. She stated that board staff was recently advised that it was approved by the Office of Administrative Law. Ms. Zinder indicated that the revised form is on the board's Web site and that a notice was provided in the recently published issue of *The Script* advising readers of the change.

No board or public comment was provided.

C. Board Approved Regulations – Undergoing Administrative Review

1. Proposed Adoption of 16 CCR §1760 – Disciplinary Guidelines

Ms. Zinder provided that at the April 2008 Board Meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. She stated that after receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. Ms. Zinder advised that while the department did approve this regulation, State and Consumer Services Agency was concerned about the optional language relating to automatic revocation when a probationer fails to submit cost recovery as mandated. She provided that as a result, the matter was referred back to the board at the January 2009 Board Meeting.

Ms. Zinder provided that during the October 2008 meeting the board considered the option to withdraw the rulemaking and begin over, or to modify the language removing the specific term and notice the modification through a 15-day comment period. She stated that at the conclusion, the board directed staff to modify the text to remove the specific term/optional language discussed above and to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period. Ms. Zinder explained that the board further stated that if, after the 15-day public comment period, no adverse comments are received, the Executive Officer is authorized to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to 16 CCR §1760 – Disciplinary Guidelines.

Ms. Sodergren provided that the rulemaking has been approved by the Office of Administrative Law and that it will take affect May 27, 2009.

No board or public comment was provided.

2. Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course

Ms. Zinder provided that in April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. She stated that the subcommittee recommended to the full board that it vote to create a program similar to the program used by the Medical Board. Ms. Zinder advised that this proposal would establish in regulation the minimum requirements for the ethics program. She indicated that these minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. Ms. Zinder added that this proposal will provide licensees with the necessary information to assist in their rehabilitation.

Ms. Zinder provided that the board determined the requirements necessary, based on testimony received during the October 2007 Board Meeting. She stated that during the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. Ms. Zinder indicated that the board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. She added that, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. Ms. Zinder provided that this self-reflection includes completing questions as part of a background assessment. She advised that the two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

Ms. Zinder provided that during the October 2008 board meeting, the board held a regulation hearing on the proposed changes. She stated that at the conclusion, the board directed 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 following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). Ms. Zinder explained that if after the 15-day public comment period, no adverse comments were received.

Ms. Zinder provided that this rulemaking is currently undergoing review by the department.

No board or public comment was provided.

D. Board Approved Regulations – Awaiting Notice

1. Title 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Ms. Zinder provided that 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. She explained that 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.

Ms. Zinder provided that the draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. She stated that during the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Ms. Zinder provided that the Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. She stated that board staff do 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 board or public comment was provided.

2. Title 16 CCR Sections 1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination / Confidentiality

Ms. Zinder provided that at the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and 1723.1 that would 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 the licensing examination.

Ms. Zinder provided that this recommendation was generated from the board's competency committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. She discussed that compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Ms. Zinder provided that this rulemaking is awaiting notice.

No board or public comment was provided.

3. Title 16 CCR Section 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Ms. Zinder provided that Business and Professions Code §4127.1 requires a separate license to compound sterile injectable drug products. She stated that §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. Ms. Zinder indicated that since the inception of this statute, the board has approved two such agencies.

Ms. Zinder provided that this proposed regulation would specify the criteria the board uses to evaluate these agencies.

Ms. Zinder provided that this rulemaking is awaiting notice.

No board or public comment was provided.

E. Regulations Under Development

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

Ms. Zinder provided that CCR §1780 sets minimum standards for drug wholesalers. She stated that § 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. Ms. Zinder indicated that the USP Standards is updated and published annually. She discussed that 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.

Ms. Zinder 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.

Ms. Zinder provided that President Schell and Jim Burgard are serving in the subcommittee and will be working with board staff and industry. She indicated that this subcommittee has not held any meeting.

No board or public comment was provided.

2. Title 16 CCR Section 1732.2 – Continuing Education for Competency Committee Members

Ms. Zinder provided that at the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Ms. Zinder 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. She indicated that a committee member's term is generally about eight years.

Ms. Zinder provided that, annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. She explained that each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Ms. Zinder added that committee members also participate in 2-4 writing assignments based on the examination development need. She indicated that committee members spend approximately 50-80 hours preparing for and attending

committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

Ms. Zinder provided that one of the core functions of this committee is to complete an on-line review of all test questions prior to administration. She discussed that as the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Ms. Zinder stated that the committee requests that the board award up to six hours of CE annually for members that complete this on-line review.

Ms. Zinder provided that current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Ms. Zinder provided that the board will also award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Ms. Zinder provided that board staff will be drafting regulation language for board consideration.

No board or public comment was provided.

9:40 a.m. – No quorum was present. The board acted as a subcommittee of the board and discussed the following legislation until a quorum was established.

Part 2. Legislative Report: Discussion and Action on Pending Legislation

A. Board Sponsored Legislation:

1. SB 819 (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).

Ms. Zinder provided that at the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. She discussed that

many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

Ms. Zinder provided that these omnibus provisions were categorized into four types of changes:

a. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.
b. General omnibus provisions.
c. Use of mobile pharmacies.
d. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.

(a) Changes Based on Recodification of B&PC §4052

Ms. Zinder provided that in 2006 Business and Professions Code section 4052 was recodified into four sections. She stated that as a result, the following B&PC sections and H&SC section reference 4052 and require technical updates.

Section 733 – Dispensing Prescription Drugs and Devices
Section 4027 – Skilled Nursing Facililty – Intermediate Care Facility – Other Health Care Facilities
Section 4040 – Prescription; Content Requirements
Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
Section 4060 – Controlled Substance – Prescription Required, Exceptions
Section 4076 – Prescription Container – Requirements for Labeling
Section 4111 – Restrictions on Prescriber Ownership
Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
H&SC 11150 – Persons Authorized to Write or Issue a Prescription

(b) General Omnibus Changes

Ms. Zinder provided that the following proposals were also approved as omnibus provisions for 2008:

Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions.
A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Section 4081 – Records of Dangerous Drugs or Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
This section requires amendment to replace the term “representative-in-charge” with “designated representative-in-charge.”

Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation initiated by the board.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

(c) Omnibus Changes to Allow for the Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

(d) Omnibus Changes Specific to the PIC and Designated Representative in Charge Requirements

Section 4022.5 – Designated Representative; Designated Representative-in-Charge
This section requires amendment to clarify the definition of “designated representative-in-charge” as well as the responsibilities of a licensee serving as such.

Section 4036.5 – Pharmacist-in-Charge
A new section is needed to define the term “pharmacist-in-charge” as well as the responsibilities of a pharmacist serving as such.

Section 4161 – Non-Resident Wholesaler; Requirements
This section requires amendment to further clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC § 4043.

Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

Section 4329 – Nonpharmacists; Prohibited Acts
This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

Section 4330 – Proprietors; Prohibited Acts
This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

No board or public comment was provided.

(2) SB 820 (Senate Business, Professions & Economic Development Committee) New Omnibus Provisions

Ms. Zinder provided that late last year, board staff was advised that the Office of Examination Resources (OER) was being renamed to the Office of Professional Examination Resources. She discussed that SB 820 (Senate Business, Professions & Economic Development Committee) make conforming changes throughout the Business and Professions Code to reflect this name change.

No board or public comment was provided.

(3) SB 821 (Senate Business, Professions & Economic Development Committee) New Omnibus Provisions specific to PIC and DRC Requirement

Ms. Zinder provided that at the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions. She indicated that these provisions are contained in SB 821.

Add Section 4146 – Disposal of Returned Sharps by a Pharmacy
This section needs to be added to allow a pharmacy to accept returned sharps containers from consumers for disposal.

Add Section 4013 – Subscriber Alert
This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Amend Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.
This section requires amendment to clarify when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she ceased to serve in such a capacity.

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Amend Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition, this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days as required.

Amend Section 4160 – Wholesaler Licenses
This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Amend Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked
This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

No board or public comment was provided.

(4) SB 470 (Corbett) Prescription Labeling to Add “Purpose” -- Proposal to Amend B&PC §4040 and §4076

Ms. Zinder provided that at the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the “condition” for which a prescription is prescribed, with the “purpose” for which the medicine is prescribed. She stated that this change will clarify a pharmacist’s authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the “purpose” of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. Ms. Zinder discussed that this proposal is consistent with the results of the board’s prescription label survey where many consumers suggested that the purpose of the medicine be included on the label.

Ms. Zinder provided that Senator Corbett is authoring this bill for the board. She stated that this bill will amend Business and Professions Code sections 4040 and 4076 to include the “condition or purpose” for which a medicine is prescribed.

Ms. Zinder provided that board staff has been working to establish a broad base of support for this proposal. She stated that the California Medical Association recently submitted a letter advising the author's office that it has taken a Support If Amended position and offered amendments. Ms. Zinder indicated that Senator Corbett's office has advised CMA that they will be accepting the amendments offered. She added that Senator Corbett's office is also working with the California Retailers Association and National Association of Chain Drug Stores who submitted an Oppose Unless Amended position.

Ms. Zinder provided that board staff continues to advocate for this proposal and continue to work with the Senator Corbett's Office as well as stakeholders who may have concerns.

Ms. Sodergren reviewed the proposed amendments and provided that this bill recently passed out of the Senate Business, Professions and Economic Development Committee and was referred to the Committee on Appropriations.

No board or public comment was provided.

(5) AB 977 (Skinner) Pharmacists: Immunization Administration -- Proposal to Amend B&PC §4052 and §4052.8

Ms. Zinder provided that at the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Ms. Zinder provided that Assembly Member Skinner is authoring this bill for the board. She indicated that this bill will amend Business and Professions Code section 4052 and add 4052.8 to allow a pharmacist to administer immunizations as specified. Ms. Zinder explained that, as introduced, this bill would have allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP), however with the approval of the board president, this proposal will be amended to allow a pharmacist to administer influenza and pneumococcal vaccinations or any other immunization pursuant to a prescriber protocol. She stated that the National Vital Statistics Report published by the U.S. Department of Health and Human Services reports that combined, influenza and pneumonia are the eighth leading cause of death in people of all ages, and the sixth leading cause of death in people over 65.

Ms. Zinder provided that board staff has been working with stakeholders to establish a broad base of support.

Ms. Zinder provided that this bill failed passage in the Assembly Business and Profession Committee; reconsideration was granted. She indicated that Assembly Member Skinner's Office will be amending the bill.

Executive Officer Virginia Herold provided that the new amendment tasks the California Pharmacists Association (CPhA) with developing a study on protocols for immunizations. She stated that the California Medical Association (CMA) continues to oppose the bill, even with the proposed amendments.

No board or public comment was provided.

(6) AB 1071 (Emmerson) Pharmacy Fees -- Proposal to Amend B&PC §4110, §4127.8, §4160, §4400, and §4127.5

Ms. Zinder provided that at the January 2009 Board Meeting, the board voted to pursue a statutory change increase to its fees.

Ms. Zinder provided that Assembly Member Emmerson is authoring this proposal for the board. She stated that AB 1071 adjusts application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. Ms. Zinder indicated that this bill also builds in a cap to increase future fees by no more than 30 percent.

Board Discussion

Ms. Herold provided that during the January 2009 Board Meeting, significant discussion occurred regarding the best way to determine fees. She stated that the board voted to pursue the statutory fee increase, but did not reach consensus on the fees themselves. Ms. Herold explained that with approval of the board president, board staff drafted language that begins to reduce the current subsidy that exists between individual and site licenses.

Kristy Schieldge, DCA Staff Counsel, provided that there is no legal prohibition barring the board from subsidizing pharmacy fees. She noted that any public policy issues will need to be addressed by the board.

Joshua Room, Deputy Attorney General, provided that he is unaware of any restrictions on the board's ability to have one license category fees subsidize another license category fees.

Ms. Zinder expressed concern regarding the higher percentage of increase for pharmacy technician fees.

Ms. Herold provided that pharmacy technician fees are increasing at a larger percentage because this fee is currently lower than other license categories.

Discussion continued regarding the fee increase with respect to the pharmacy technician salary.

There was no additional board discussion. No public comment was provided.

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

President Schell reiterated that the following legislation was for discussion only until a quorum was reestablished.

AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License

Ms. Zinder provided that this bill would require a state governmental licensing entity, as defined, issuing professional or occupational licenses, certificates, registrations, or permits to provide to the Franchise Tax Board the name and social security number or federal taxpayer identification number of each individual licensee of that entity. She stated that the bill would also require the Franchise Tax Board, if a licensee fails to pay taxes for which a notice of state tax lien has been recorded, as specified, to mail a preliminary notice of suspension to the licensee.

Ms. Zinder stated the committee did not provide a recommendation for this bill.

Ms. Sodergren provided that this bill failed passage.

No board or public comment was provided.

AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012

Ms. Zinder provided that this bill would require every licensed prescriber, or prescriber's authorized agent, or pharmacy operating in California to have the ability, on or before January 1, 2012, to transmit and receive prescriptions by electronic data transmission.

Ms. Zinder stated that the committee provided a recommendation to support AB 718.

No board or public comment was provided.

AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice

Ms. Zinder provided that this bill would declare the intent of the Legislature to enact legislation authorizing the Director of Consumer Affairs to appoint a specified committee of 7 members to perform occupational analyses, as specified, and to prepare written reports on any bill that seeks to expand the scope of a healing arts practice.

Ms. Zinder provided that the committee did not take a position on this bill.

No board or public comment was provided.

AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container

Ms. Zinder provided that this bill would increase the number of oral dosage form and suppository dosage form drugs for storage within this container to limit to 48. She indicated that the current limit is 24.

Ms. Zinder provided that the committee did not take a position on this bill.

No board or public comment was provided.

AB 1370 (Solorio) “Best Before” Date on a Prescription Label

Ms. Zinder provided that this bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug or device.

Ms. Zinder provided that the committee did not take a position on this bill.

Ms. Sodergren provided that this bill was referred to the Assembly Health Committee; but, was not scheduled for hearing.

No board or public comment was provided.

AB 1458 (Davis) Drugs: Adverse Effects Reporting

Ms. Zinder provided that this bill would mandate that licensed health professionals report to the FDA's MedWatch system when serious adverse reactions occur as specified.

Ms. Zinder provided that the Legislation/Regulation Committee did not discuss this bill.

No board or public comment was provided.

SB 26 (Simitian) Home-Generated Pharmaceutical Waste

Ms. Zinder provided that this bill would require the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical waste and the disposal of devices. She added that this bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Ms. Zinder provided that the committee did not take a position on this bill.

No board or public comment was provided.

SB 238 (Calderon) Medical Information

Ms. Zinder provided that this bill would allow a pharmacy to mail specified written communications to a patient, without the patient's authorization under specified conditions.

Ms. Zinder provided that the Legislation/Regulation Committee did not discuss this bill.

Ms. Sodergren provided that this bill is similar to SB 1096 from the previous legislation cycle.

No board or public comment was provided

SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs

Ms. Zinder provided that this bill would require the department to make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate the safety and effectiveness of prescription drugs in California as specified.

Ms. Zinder provided that the Legislation/Regulation Committee did not discuss this bill.

No board or public comment was provided.

SB 364 (Florez) Pharmacies

Ms. Zinder provided that this bill would declare the intent of the Legislature to enact legislation authorizing the imposition of specified penalties on a pharmacy that fails to safeguard controlled substances.

Ms. Zinder stated that the committee did not provide a recommendation for this bill.

Ms. Zinder provided that this bill was amended and is no longer related to the practice of pharmacy.

No board or public comment was provided.

SB 762 (Aanestad) Professions and Vocations; Healing Arts

Ms. Zinder provided that this bill would make it unlawful for a city, county, or city and county to prohibit a healing arts licensee from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee, but would prohibit construing this provision to prohibit the enforcement of a local ordinance effective prior to January 1, 2010, as specified.

Ms. Zinder stated that the committee did not provide a recommendation on this bill.

SB 484 (Wright) Ephedrine Products to Schedule V

Ms. Zinder provided that this bill would classify ephedrine, pseudoephedrine, and specified related drugs as Schedule V controlled substances, able to be possessed or dispensed only upon a lawful prescription.

Ms. Zinder stated that the committee did not provide a recommendation for this bill.

Public Comment

Terri Thomas, president of Thomas Advocacy Inc., provided that SB 484 has been amended to eliminate any references to classifying ephedrine and pseudoephedrine products on a schedule. She indicated that the bill now requires a prescription for obtaining these products. Ms. Thomas expressed to the board that Thomas Advocacy Inc. strongly opposes this bill. She asked that the board consider the significant consumer impacts that the amendment to the bill creates.

Mandy Hagen, State Government Relations Director for Consumer Healthcare Products Association (CHPA), reviewed the current restrictions on ephedrine products in California. She discussed the issue of meth labs and pseudoephedrine sales in California and at the national level. Ms. Hagen stated that CHPA would like California to

enforce the current restrictions mandated by federal law and encouraged the board not to support SB 484.

Stan Weisser sought clarification regarding CHPA's position on alternative products for ephedrine and pseudoephedrine products.

Ms. Hagen responded that consumer demand for pseudoephedrine products is a strong indicator for its effectiveness and consumer preference over alternative products. She also discussed similar legislation enacted in Oregon and its impacts.

Kent Shaw, representing the Office of the Attorney General, discussed the dramatic increase in methamphetamine labs in California. He explained that pseudoephedrine is the essential precursor for making methamphetamine. Mr. Shaw provided that pseudoephedrine purchased (smurfed) from retail outlets in California is the exclusive source of the precursor used by methamphetamine manufacturers. He indicated that the best way to combat the smurfing problem is to require a prescription for pseudoephedrine and to only have it available from a pharmacy. He discussed that Oregon has successfully implemented such a regulation and provided that the results have been dramatic. Mr. Shaw encouraged the board's support on SB 484.

Discussion continued regarding the development of new pseudoephedrine products and the smurfing epidemic.

Steve Gray, representing the California Pharmacists Association (CPhA) board of trustees, suggested a "middle ground" that would allow pseudoephedrine products to be sold in pharmacies upon the interview and authorization of a pharmacist. He indicated that this optional service may result in an additional fee. Mr. Gray provided a summary of comments that have been submitted to the bill's author by the CPhA board of trustees and offered support for SB 484 if amended.

Discussion continued regarding the responsibilities and implications involved with the interview and authorization process for obtaining pseudoephedrine drugs. A distinction was made between a consultation and a pre-sale interview and authorization.
Bryce Docherty, representing the California Society of Health-System Pharmacists (CSHP), provided support for SB 484 in its current form. He expressed concern regarding the implementation and time limitations for conducting pre-sale interviews and authorizations for pseudoephedrine drugs.

Greg Lippe discussed the prescription requirement of the bill and how this could affect a pharmacist's choice to dispense pseudoephedrine products.

Mr. Docherty provided that pharmacists can refuse to dispense any medication based on their scope of practice and professional judgment.

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), provided that the NACDS is opposed to SB 484. She indicated that the NACDS will continue to oppose this bill in its amended form.

10:45 a.m. – The quorum was reestablished. The board continued to discuss SB 484.

Dr. Kajioka sought clarification on why the bill is seeking to add pseudoephedrine to Schedule V as opposed to a schedule that would be tracked through CURES.

Mr. Shaw provided that a higher schedule was considered. He stated that the bill was amended in response to the Receivership/Overcrowding Crisis Aggravation (ROCA) policy.

President Schell provided that the board has reestablished a quorum and suggested that the board take action on the items that were previously discussed.

There was no additional board or public comment.

MOTION: To establish a board position of support on SB 484.

M/S: SW/JB

Support: 4 Oppose: 1 Abstain: 1

AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements

Ms. Zinder provided that this bill would alter the requirements for licensure as a pharmacy technician as well as establish continuing education requirements as a condition of renewal.

Ms. Zinder stated that the committee provided a recommendation to support AB 418.

Public Comment

Bryce Docherty, representing the California Society of Health-System Pharmacists (CSHP), provided that the bill is consistent with licensing requirements for other health professionals in the Business and Professions Code. He stated that this bill will help to raise the minimum standard for licensure of pharmacy technicians to better protect California consumers. Mr. Docherty thanked the committee for its recommendation to support the bill and urged the board to honor that position.

Steve Gray, representing Kaiser Permanente, provided that Kaiser Permanente does not support this bill in its current form. He stated that pharmacy technicians do not require the training proposed in the bill and that it would result in increased costs to healthcare administrators.

There was no additional board or public comment.

MOTION: To establish a position of support on AB 418.

Support: 5 Oppose: I

AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012

Board Discussion

The board discussed the purpose and necessity for this bill.

There was no additional board discussion. No public comment was provided.

MOTION: To table this motion.

M/S: RB/SW

Support: 6 Oppose: 0

AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid

Ms. Zinder provided that this bill would replace various drug compendia references with compendia approved by the federal Centers for Medicare and Medicaid Services.

Ms. Zinder stated that the committee provided a recommendation to oppose AB 830.

Board Discussion

Carolyn Klein, Legislation and Regulation Manager, reviewed the technical changes that have been made to the bill.

President Schell provided that this bill will be too restrictive on the practice of pharmacy.

Ms. Herold provided that the purpose for the bill is unclear. She recommended that the board take no position until further clarification is provided from the author's office.

Discussion continued regarding the intent and clarity of the bill.

Ms. Schieldge informed the board that it will need to act on the committee's recommendation.

There was no additional board discussion. No public comment was provided.

MOTION: To establish a position of oppose on AB 830.

Support: Zinder, Weisser, Kajioka, Burgard Oppose: Lippe, Burgard

AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)

Ms. Zinder provided that this bill would require specified healing arts boards to add and label as "mandatory" specified fields on an application for initial licensure or a renewal form for applicants applying to those boards and would require the board to select a database and to add some of the data collected in these applications and renewal forms to the database and to submit the data to the clearinghouse annually on or before January 1.

Ms. Zinder provided that the committee did not take a position on this bill.

Board Discussion

Ms. Sodergren provided that this bill alters the application and renewal process to require that personal data be collected. She stated that concern has been expressed regarding whether or not collecting this personal information would be appropriate.

Ms. Herold reviewed the data that would be collected including information regarding race, ethnicity, date, and place of birth.

Ms. Zinder sought clarification on whether the bill would result in additional costs and staff requirements.

Ms. Herold provided that additional staff will be required and that the renewal process will need to be amended.

Ms. Schieldge expressed concern regarding the broad nature of the bill and indicated that the bill does not include public disclosure restrictions. She recommended that the board pursue other options for obtaining this information.

Public Comment

Steve Gray, representing Kaiser Permanente, expressed concern regarding the requirement to collect work hour information. He discussed that this requirement will create additional workload for board staff and may put applicants in a self incriminating position due to pharmacist labor restrictions.

There was no additional board or public comment.

MOTION: To establish no position on AB 1310.

MS: RB/SW

Support: 7 Oppose: 0

AB 1458 (Davis) Drugs: Adverse Effects Reporting

Board Discussion

Ms. Sodergren provided that this is a constituent sponsored bill. She discussed that the bill is intended to encourage increased reporting to the system.

Mr. Room provided that the board will have the authority to enforce this mandatory reporting.

Ms. Herold provided that the bill does include an exemption that would protect violations from penalty.

Robert Swart expressed concern regarding the broad definition for 'serious adverse reactions.'

There was no additional board discussion. No public comment was provided.

MOTION: To establish a position of support on AB 1458.

M/S: GL/AZ

Support: 5 Oppose: 1

SB 26 (Simitian) Home-Generated Pharmaceutical Waste

Board Discussion

Stan Weisser sought clarification on the committee's recommendation.
Ms. Herold expressed concern with several of the requirements of the bill and sought clarification regarding its scope and the responsibility placed on the board. She stated that these requirements would require additional staff and would create added costs. Ms. Herold urged the board to request that specific amendments be added into the bill to conform to the existing take-back policy provided in the model guidelines.

There was no additional board discussion. No public comment was provided.

MOTION: To establish a position of oppose unless amended, with the following amendments: (1) provisions are to be effective January 1, 2011; (2) include reference in Business and Professions Code 4068; and (3) include reference to Business and Professions Code 4146.

M/S: AZ/SW

Support: 6 Oppose: 0

SB 43 (Alquist) Cultural and Linguistic Competency

Ms. Zinder provided that this bill would authorize the healing arts boards, as defined, to collect information regarding the cultural and linguistic competency of persons licensed, certified, registered, or otherwise subject to regulation by those boards.

Ms. Zinder stated that the committee provided a recommendation to support SB 43.

Board Discussion

Ms. Schieldge provided that this bill is voluntary. She indicated that the board will determine what information it will collect.

Ms. Sodergren provided that the information collected is to remain confidential and is not subject to public disclosure.

There was no additional board discussion. No public comment was provided.

MOTION: To establish a position of support on SB 43.

Support: 6 Oppose: 0

SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs

Board Discussion

Randy Kajioka sought clarification regarding the bill as it relates to the FDA.

Ms. Sodergren responded that bill is intended to enhance the efforts of the FDA.

There was no additional board discussion. No public comment was provided.

MOTION: To establish no position on SB 341.

M/S: AZ/SW

Support: 6 Oppose: 0

SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus

Ms. Zinder provided that this bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. She stated that the bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

Ms. Zinder stated that the committee provided a recommendation to support SB 389.

No board or public comment was provided.

MOTION: To establish a position of support on SB 389.

Support: 6 Oppose: 0

SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews

Ms. Zinder provided that this bill would redefine the sunset review process.

Ms. Zinder stated that the committee provided a recommendation to support SB 638.

Board Discussion

President Schell expressed concern regarding specific language in the bill that details terms of office for board members.

There was no additional board discussion. No public comment was provided.

MOTION: To establish a position of support on SB 638.

Support: 6 Oppose: 0

SB 762 (Aanestad) Professions and Vocations; Healing Arts

Board Discussion

Ms. Schieldge clarified the intent of the bill and provided background on the issue that served as the impetus for its establishment.

Ms. Zinder asked if the bill is applicable to the pharmacy profession.

President Schell responded that this bill might pertain to pharmacists who take back sharps.

Discussion continued regarding the scope of the bill and its applicability to the pharmacy profession. Comments were made regarding the authority of cities and counties and whether it is appropriate for these entities to determine limitations on a scope of practice.

There was no additional board discussion. No public comment was provided.

MOTION: To establish a position of support on SB 762.

M/S: AZ/GL

Support: 6 Oppose: 0

C. Other Legislation Introduced

Ms. Zinder introduced the following legislation:

1. AB 832 (Jones) Clinic Licensing
2. AB 1094 (Conway) Disposal of Personal Information
3. AB 1201 (Perez) – Immunizations -- Physician Reimbursement

No board or public comment was provided.

D. Summary of the Legislation and Regulation Committee Held April 16, 2009

Ms. Zinder provided that the minutes of the Legislation and Regulation Committee are contained within the board packet provided.

E. Third Quarterly Report on Legislation/Regulation Committee Goals for 2008/09

Ms. Zinder referenced to the third quarterly report on the Legislation/Regulation Committee's goals contained within the board packet.

F. Public Comment

No public comment was provided.

President Schell recognized former board members Hank Hough and Ruth Conroy. He thanked Mr. Hough and Dr. Conroy for their service and presented them with a token of gratitude.

Recognition of Pharmacists Licensed with the Board for 50 Years

President Schell 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, as will be done today.

Stanley Weisser recognized Thomas Barnett. Mr. Barnett followed his farther into the profession. He has been a pharmacist his whole adult life and has worked for Drug Fair, Thrifty, and Vons. Mr. Barnett owned his own pharmacy in Oakhurst, California for 10 years and has participated in a variety of civic activities. Mr. Barnett was honored with a pin.

Mr. Barnett thanked the board for its recognition.

III. Communication and Public Education Committee Report and Action

A. Report of the SB 472 Medication Label Subcommittee Meeting Held March 12, 2009

1. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472

President Schell provided that in May 2008, board staff developed a prescription label survey for distribution at public outreach events. He indicated that the survey is available in English and Spanish.

President Schell provided that since late May, board staff has been using the survey to interview attendees at public events. He stated that consumers have been invited to complete surveys on-site during the events, or mail them to the board using the self-addressed envelopes provided. President Schell indicated that this method of soliciting information has proved less intimidating to consumers than individually speaking at

public hearings. He provided that board staff attending the community events has also reported positive feedback when discussing this initiative with the public. President Schell stated that in October 2008, pharmacist and pharmacy associations agreed to share the surveys with their members to aid the board in data collection

President Schell provided that the board has also provided consumers with one-page fact sheets entitled, “Do you understand the directions on your Rx medicine label?” He stated that the fact sheet provides background information related to SB 472, and printed samples of faux prescription labels as a visual aid.

President Schell provided that a total of 646 consumers completed board surveys as of April 21, 2009. He stated that not every consumer provided an answer to each question, while others provided multiple answers to individual questions. President Schell explained that many consumers gave the same response (i.e., larger font) to more than one question.

President Schell provided that trends have been identified in the answers provided thus far. He explained that many responses suggest that the purpose of the drug be printed on the prescription label, and that a larger or bolder type font be used.

President Schell provided the following survey results:

When asked what would make prescription labels easier to read, the top two responses were:

- Larger or bolder print
  (324 of 541 responses = 60.0%)
- Highlighting directions for use and other information in colors other than black
  (62 of 541 responses = 11.5%)

When asked what to change on the prescription label, the top three responses were:

- Print should be larger or darker
  (177 of 583 responses = 30.4%)
- No changes should be made to label – references were made to Target, Raley’s, CVS and Kaiser labels
  (143 of 583 responses = 24.5%)
- Include purpose of the drug – state what condition the medication is intended to treat
  (70 of 583 responses = 12.0%)

When asked what information on the label was most important, the top three responses were:

- Directions for use
- (233 of 1,1,256 responses = 18.6%)
- Name of drug; if generic, brand name and generic
- (233 of 1,256 responses = 18.6%)
- Dosage prescribed
- (223 of 1,256 responses = 17.8%)

When asked for other suggestions, the top two responses were:

- Easy-open lids should be used; no child-proof caps for seniors
    - (25 of 146 responses = 17.1%)
- Include purpose of the drug – state what condition the medication is intended to treat
    - (19 of 146 responses = 13%)

President Schell provided that the board is sponsoring legislation to add the purpose of the drug to the label if requested by the patient. He stated that this bill is SB 470 and the author is again Senator Corbett. President Schell indicated that having the purpose of the drug listed on the label was stated as a response to the following three questions:

What information is most important to you:
86 of 1,256 responses = 6.9 percent
or 86 of 646 individuals submitting surveys (13.3 percent)

What would you change on the label:
70 of 583 responses = 12.0 percent
or 70 of 646 individuals submitting surveys (10.8 percent)

Other suggestions for improving the label:
19 of 146 responses = 13 percent
or 19 of 646 individuals submitting surveys (2.9 percent)

No board or public comment was provided.

2. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472

President Schell provided that the board worked with the Pharmacy Foundation of California to develop a multiple choice survey of four questions that were available via a radio-sponsored survey. He explained that the goal was to identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels.

President Schell provided that the survey was conducted via Entercom Broadcasting – and was made available during January 2009 on radio station Web sites that stream their audio. He stated that there were 1,357 responses to the following questions:

1. How often do you read the label on your prescription containers?
2. When you need to obtain information from the label, what do you have the most trouble with?
3. Which parts of the label are most important to you?
4. What would you change on the prescription label?

President Schell provided the following key results:

1. How often do you read the label on your prescription containers?
    a. Every time I take the drug 30.9 percent
    b. Once in a while 16.7 percent
    c. Only the first time I take it 42.8 percent
    d. Almost never 12.5 percent

2. When you need to obtain information from the label, what do you have the most trouble with?
    a. Finding it 44.3 percent
    b. Reading it –too small 37.5 percent
    c. Reading it –style hard to read 11.3 percent
    d. Understanding it – too technical 26.5 percent
    e. Understanding it – wrong lang. 5.8 percent
3. Which parts of the label are most important to you?
    Directions: 64.5 percent
    Exp. Date: 34.6 percent
    Strength: 31.2 percent
    Brand name: 24.9 percent
    Refill number: 21.3 percent
    Generic name: 19.7 percent
    Purpose: 17.2 percent
    Plus other responses

4. What would you change on the prescription label to improve it?
    Bigger print size for drug names & directions
    Clarity in directions
    Purpose placed on label
    Side effects/interactions on labels versus “sticker
    “Chunking” info into identifiable sections

No board or public comment was provided.

3. Presentation of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance

President Schell provided that in 2003, California enacted provisions that require health care service plans to ensure access of their enrollees to language assistance services when obtaining health care services.

President Schell provided that at the committee meeting, Marty Martinez provided a presentation on the requirements of this law.

Presentation to the Board

Marty Martinez, representing California Pan-Ethnic Health Network (CPEHN), provided an overview of SB 853 (Statutes of 2003). He stated that the bill mandates that all California health plans provide language assistance services to their enrollees. Mr. Martinez explained that the legislation stipulates that all vital documents must be translated into threshold languages and interpretation services made available to enrollees.

Mr. Martinez provided that the requirements of the bill will greatly impact the pharmacy profession. He discussed specific issues that will be impacted including oral translations of medication labels, mandatory consultations, and pharmacist interactions and communication with health plans and health care providers.

Board Discussion

Mr. Weisser sought clarification on the pharmacists' role and obligation to contact a health plan on behalf of a patient.

Mr. Martinez suggested that CPEHN work with the board to determine this responsibility. He indicated that the ultimate burden is placed on the health plans to initiate the communication process with the providers. Mr. Martinez clarified that pharmacists will be responsible for communicating information regarding medication, not the terms of a patient's health plan. He explained that a pharmacist can request a health plan to act on the pharmacist's behalf to provide information to the consumer regarding details about their plan and their medication.

The board discussed the interaction between all necessary parties and the confusion that may occur when determining the appropriate language and services needed by a particular patient.

Dr. Swart sought clarification regarding whether or not a timeframe exists for this process and how a pharmacist will identify the language of a patient. He expressed concern regarding the logistical implementation of this process.

Mr. Martinez responded that resources are available to limit any significant wait time. He provided that the requirements provide pharmacists with tools to better communicate with their patients.

Hope Tamraz, the board's Newsletter Editor, provided that health plans may provide their members with an insurance card that will clearly indicate the patient's language. She explained that pharmacists would be able to use this card as a resource when contacting the correct health plan to request the appropriate translator for the patient.

Mr. Swart suggested that this card indicate an expiration date to ensure that the information provided on the card is current.

President Schell expressed concern regarding several issues including the fact that pharmacies do not contract with the health plans, pharmacists' accountability, and family members providing translation services to a patient.

Mr. Martinez responded that requirements to prohibit the use of a minor to provide translation services for a family member will need to be clarified.

Mr. Martinez provided that CPEHN is eager to continue working with the board to address issues regarding SB 853.

Public Comment

Steve Gray, representing Kaiser Permanente, recommended that the board conduct further research on this issue in order to provide clear information to pharmacies in the board's newsletter. He discussed several complex issues with the bill and suggested the board contract with a law firm specializing in this area to address these issues.

There was no additional board or public comment.

4. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)

President Schell provided that the board is directed by SB 472 (Chapter 470, Statutes of 2008) to develop patient-centered prescription labels. He stated that at the January 27, 2009 Committee Meeting, the committee reviewed each prescription label requirement specified in California Business and Professions Code section 4076 and selected those with the greatest importance to consumers.

President Schell provided that the committee generated a basic list that identified three key items of most importance to a patient using a medication and the container's label:

- trade name/ generic name,
- directions
- strength

President Schell provided that, concurrently, the board's executive officer has participated as a member of a National Association of Boards of Pharmacy (NABP) task force in developing model guidelines for patient-centered labels for all states. He stated that the report of this task force will be given at the NABP Annual Meeting in May 2009. President Schell indicated that the NABP has recently released the list of key prescription label requirements from a patient's perspective in advance of their May meeting.

President Schell provided the following key recommendations of the task force report with respect to patient-centered labels: (page 49):

> The task force agreed that the following information is critical and must appear on the label with emphasis (either highlighting or bolding)

in a sans-serif font, with a minimum point size of 12, and which must never be truncated:

- patient name
- directions for use and, if included on the prescription drug order, the purpose/indication
- drug name and strength
- date by which the medication should be used

President Schell provided that in developing California's regulation, the board will need to consider the general format of prescription container labels to maximize value to patients, while considering the diversity of containers in use by pharmacies. He stated that the NABP task force report on pages 4 and 5 show two sample labels that highlight essential consumer information and minimize other information. President Schell indicated that the board's staff also developed sample labels based on the elements identified as most important for consumers at the January meeting.

Presentation to the Board (Via Conference Call) – Anandi Law, PharmD

Dr. Anandi Law, representing the Western University of Health Sciences College of Pharmacy, provided an overview of a study conducted by Western University that compared existing label formats with a modified label on content, convenience and cosmetics from the perspective of relevant stakeholders including patients, pharmacists, and physicians. She indicated that the modified labels were designed to include a time table for taking medications, the addition of warning labels to the label and removal of auxiliary labels, the addition of indication in the directions, increased font size, and the addition of color highlights. Dr. Law stated that the study found that the modified labels were preferred over existing labels in terms of content, convenience, and cosmetics.

No board or public comments were provided.

5. Directions for Use Used on Prescription Labels

President Schell provided that board staff has collected information about research in standardizing directions for use on prescription labels. He explained that this will be important for securing translations of the directions into key languages used in California.

President Schell referred to a list that was developed by researcher Michael Wolf, PhD, who is an expert in the area of label design. He provided that Dr. Wolf states that about 90 percent of all directions for use will fit into one of these statements.

Presentation to the Board – Michael Wolf, Ph.D.

Dr. Michael Wolf, representing Northwestern University, highlighted findings from a study that focused on a patient-centered approach to designing prescription labels and providing prescription instructions. He provided that there is a significant improvement in patient comprehension when using a particular patient-centered format.

Dr. Wolf encouraged the board to continue its efforts in this area and strongly supported setting uniform standards.

No board or public comment was provided.

B. Update Report on *The Script*

President Schell provided that the February 2009 issue of *The Script* was actually distributed in early April.

President Schell provided that work is now centered on the July issue. He stated that this issue will focus on issues involving pharmacy law and emerging new federal polices for pharmacies. President Schell indicated that there will also be an article on the Model Guidelines of the California Integrated Waste Management Board on drug-take back programs.

No board or public comment was provided.

C. Update on Public Outreach Activities

President Schell listed the following public and licensee outreach activities performed during the third quarter of Fiscal Year 08/09:

- January 5, 2009: Board President Schell provided a presentation to UCSD School of Pharmacy on careers paths in pharmacy.
- January 22, 2009: Board President Schell provided a presentation to UCSF School of Pharmacy on ethics and integrity in pharmacy.
- January 23, 2009: EO Herold provided an update on board activities to the California Society of Health-Systems Pharmacists Board of Directors.
- January 27, 2009: Board President Schell provided a presentation to undergraduate students of UCSD on career paths in pharmacy.
- February 5, 2009: Supervising Inspector Ratcliff provided a presentation to the South Bay Pharmacists Association on “Surviving and Inspection.”
- February 7, 2009: Board President Schell provided a presentation at the California Science Museum.
- February 20, 2009: EO Herold made a presentation at the Pharmacy Foundation of California’s Award Ceremony honoring a patient education advocate.

- February 21, 2009: EO Herold and President Schell presented a 1.5 hour CE lecture on the Board of Pharmacy at that CPhA's annual meeting.
- February 21, 2009: EO Herold served as one of three judged for patient education videos produced by students as part of the CPhA's annual meeting. The winning videos will be promoted by the board.
- February 20 – 21, 2009: SI Ratcliff and AEO Sodergren staffed a booth at the CPhA's annual meeting answering pharmacy law and licensing questions.
- February 22, 2009: EO Herold and President Schell discussed the role of a regulatory agency in investigating and preventing medication errors as CPhA's annual meeting.
- February 24, 2009: EO Herold made a presentation to UCSF and UCSD students in a first year pharmacy school law class.
- February 25, 2009: President Schell made a presentation to students at the USC School of Pharmacy.
- March 14, 2009 - President Schell spoke at an Eagle Scout ceremony in Sacramento.
- March 19, 2009 - SI Ratcliff did a CE presentation on board inspections to 80 pharmacists at a Vietnamese Pharmacist Association.

D. Third Quarterly Report on Committee Goals for 2008/09

President Schell referenced to the third quarterly report on the Communication and Public Education Committee's goals contained within the board packet.

E. Public Comment

No public comment was provided.

IV. Licensing Committee Report and Action

A. Meeting Summary of the Subcommittee to Evaluate Drug Distribution within Hospitals, held March 2, 2009, and Discussion of the Board

Mr. Weisser provided that during the spring of last year, 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. Weisser advised that because many of these hospitals and PICs have appealed the citations and fines, board members cannot 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. Weisser provided that the recall system is not working, and staff is pursuing

identification of problems with the recall system with the California Department of Public Health, the California Society of Health-System Pharmacists, The California Hospital Association and the FDA. He stated that the board is hoping to develop California-specific solutions.

Mr. Weisser provided that to facilitate this process, the board contracted with a facilitator. President Schell established a two-board member task force to work with these agencies on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. He stated that the first meeting of this subcommittee was March 2, 2009, at the Crowne Plaza Hotel in Irvine, California and was well attended. Mr. Weisser indicated that the FDA and Department of Public Health discussed recall requirements at both the state and federal level and participants discussed best practices related to drug recall process within hospitals. He provided an overview of the meeting's agenda.

Mr. Weisser provided that the next meeting is scheduled for June 2, 2009, at University of California, San Francisco. He stated that board staff will work with the facilitator to develop an agenda that will be more outcome oriented.

No board or public comment was provided.

B. Summary of March 24, 2009 Meeting of the Licensing Committee

1. Emergency and Disaster Response Planning: EMS Authority Looking for Pharmacists and Other Health Care Volunteers

Mr. Weisser provided that the Emergency Medical Services Authority (EMSA) has notified the board and other agencies that it is seeking service providers in three areas:

1. Maintenance of state-owned disaster readiness equipment and state-run warehouses
2. Management and deployment of licensed medical and support personnel for disaster response
3. Development and implementation of disaster response training program.

Mr. Weisser provided that the EMSA has asked that we share this information to the "widest possible distribution" of potential service providers. He stated that this information was shared with the Licensing Committee, however because of the scheduling of the committee date; it was after the response date.

No board or public comment was provided.

2. Review of the Professional Competency Statement for Pharmacy

Mr. Weisser provided that, for nearly 40 years, the board has had a competency statement for pharmacy. He stated that since the early 1990s, it has been printed in the front of the published lawbook, but does not appear anywhere else.

Mr. Weisser provided that pharmacy historian and USCF Pharmacy School Dean Bob Day has advised that the statement was created in 1971 when clinical pharmacy was under creation and there was no definition of what a pharmacist does. Mr. Weisser explained that the professional competency statement was used to construct exams prior to the advent of job analyses and content outlines which have been in use since the late 1980s at the board.

Mr. Weisser provided that the committee discussed if the statement accurately reflects pharmacy practice today and whether such a statement is necessary. He advised that, based on discussion and advice from staff counsel, the board will no longer distribute this statement.

No board or public comment was provided.

3. National Association of Boards of Pharmacy and Accreditation Council for Pharmacy Education's Confirmation of Appropriate Content for Continuing Education Provider Coursework

Mr. Weisser provided that the ACPE advisory to all state boards of pharmacy with independent approval authority for continuing education to ensure that pharmacists receive balanced and independent continuing education

Mr. Weisser provided that the Pharmacy Foundation of California, which is one of two approvers of pharmacist CE in California (the other is the ACPE) was provided with this information

No board or public comment was provided.

4. Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – Jefferson School of Pharmacy, Philadelphia, PA

Mr. Weisser provided that Title 16 CCR §1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE).

Mr. Weisser provided that Jefferson School of Pharmacy, Philadelphia, PA, was granted pre-candidate status by the ACPE during its January 2008 meeting and the first class of

students was admitted in the Fall of 2008. He indicated that Jefferson School of Pharmacy is undergoing review by the ACPE during 2008/09 Review Period for advancement to Candidate accreditation status.

Mr. Weisser provided that the Jefferson School of Pharmacy requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program, but who may spend some time and work in CA.

Mr. Weisser provided that the committee has recommended that the board recognize Jefferson School of Pharmacy for purposes of issuing a California pharmacist intern license

No board or public comment was provided.

MOTION: To recognize Jefferson School of Pharmacy for purposes of issuing a California pharmacist intern license.

Support: 6 Oppose: 0

5. Assembly Bill 418 (Emmerson): Pharmacy Technician Qualifications

Mr. Weisser provided that during the last legislative cycle, the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licensed in California as a pharmacy technician. This bill was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing consensus and new legislation again in 2009.

Mr. Weisser provided that CSHP sponsored stakeholder meetings with the California Pharmacists Association (CPhA) in 2008 as well as other stakeholders to elicit recommendations and comments to refine the proposal for 2009.

Mr. Weisser provided a summary of events since that time including that on December 4, 2008, CSHP sponsored another stakeholder meeting. He stated that discussion at this meeting revealed that there is still disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualifications requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. Mr. Weisser advised that CSHP has indicated that they may move forward with their legislative proposal, but scale back the requirements to apply to only pharmacy technicians working in the inpatient setting.

Mr. Weisser provided that AB 418 (Emmerson) will change the minimum qualifications for licensure as a pharmacy technician as well as require 20 hours of continuing education each renewal cycle. He stated that the bill was amended after the Licensing Committee Meeting. Mr. Weisser advised that this bill was discussed during the board's

Legislation and Regulation Committee Meeting on April 15. He provided that the committee is recommending a support position on the bill.

No board or public comment was provided.

6. ExCPT Examination For Pharmacy Technicians

Mr. Weisser provided that Business and Professions Code Section 4202 specifies the requirements for licensure as a pharmacist technician in California. He indicated that, specifically, an applicant must either be a high school graduate or possess a general education certificate equivalent as well as satisfy one of four qualification methods:

1. Possess an associate's degree in pharmacy technology.
2. Complete a course of training specified by the board in regulation.
3. Graduate from a school of pharmacy recognized by the board.
4. Be certified by the Pharmacy Technician Certification Board (PTCB).

Mr. Weisser stated that in September 2006, this committee discussed the Exam for the Certification of Pharmacy Technicians (ExCPT). He stated that the board directed a review of the exam to determine if it is job-related. Mr. Weisser explained that the ExCPT exam is a computer-based test used to assess the knowledge of pharmacist technicians and is accredited by the National Commission for Certifying Agencies. The examination is accepted by several states as a qualifying method for licensure. The exam is being offered in all 50 states and there are currently 42 test sites available in California. Mr. Weisser indicated that because of staffing changes with the Department's Office of Examination Resources as well as legislative proposals which would alter the licensing requirements for pharmacy technicians, this action was tabled in 2006.

Mr. Weisser provided that board staff met with the Chief Executive Officer fpr ExCPT her request to discuss the exam, and provided technical input on the process for California law to allow use of this exam as one of the qualification methods for licensure, which would require an assessment of the exam for job-relatedness as well as a statutory change to B&PC 4202(a)(4).

Mr. Wesisser provided that AB 418 (Emmerson) would alter the requirements for licensure. He advised that in its current form, the bill would make the necessary statutory changes to allow the use of the ExCPT in addition to any other exam that is accredited as specified. Mr. Weisser advised that if this bill is not enacted, and if the board so chooses, the board will need to sponsor legislation to allow for the use of this exam.

Mr. Weisser also discussed that the board will need an assessment of the examination for compliance with Section 139 of the Business and Professions Code and that board staff recommend that a similar assessment be conducted on the PTCB.

Board Discussion

President Schell discussed that the exams will need to be analyzed for the Sunset Review. He suggested that the board consider initiating a job analysis for both exams.

Ms. Herold agreed and reviewed the necessary assessments and impacts to staff workload required to ensure compliance with §139 of the Business and Professions Code.

There was no additional board discussion. No public comment was provided.

MOTION: To direct board staff to initiate job analysis for the ExCPT and PTCB exams.

M/S: SW/JB

Support: 6 Oppose: 0

7. Issue Statement on Pharmacy Workforce Shortage by the California Hospital Association Workforce Committee, December 1, 2008

Mr. Weisser provided in mid-2008, the California Hospital Association (CHA) established a coalition to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. He stated that this coalition was comprised of workforce committees, an advisory council and four workgroups. Mr. Weisser indicated that board executive staff was invited to participate on the pharmacy services workgroup.

Mr. Weisser referenced the issue statement provided and stated that the CHA report concludes that, although there has been an increase in the number of pharmacists educated within California over the prior few years, there continues to be a gap in the number of pharmacists that California will need.

Mr. Weisser provided that discussion indicated that it appears that the CHA used somewhat dated data regarding the number of pharmacists graduated. He stated that a footnote in CHA's report provided board statistics showing that in fiscal year 2007-08, 2,061 applicants took the board's examination. Mr. Weisser indicated that 890 were graduates of California schools of pharmacy. He added that in fiscal year 2007-08, a total of 1,385 pharmacists were licensed.

No board or public comment was provided.

8. US Department of Health and Human Services, Health Resources and Services Administration's Report: *The Adequacy of Pharmacist Supply: 2004-2030*

Mr. Weisser stated that the board was provided with a copy of a Health and Human Services Agency report entitled: *The Adequacy of Pharmacist Supply 2004-2030*. He indicated that this report presents a slightly less dire picture of the supply of future pharmacists than the California Hospital Association's Report; however both predict continued shortages of needed pharmacists.

Mr. Weisser highlighted the conclusions from the report, as follows:

- The supply of pharmacists is growing significantly faster than was previously projected.
- The demand for pharmacists continues to grow.
- There is currently a moderate shortfall of pharmacists.
- The future supply of pharmacists is projected to grow at a rate similar to the projected growth in demand from changing demographics.
- Supply and demand are projected with a level of uncertainty. Only under an optimistic supply projection combined with a conservative demand projection is future supply adequate to meet demand.

No board or public comment was provided.

9. Experiences of an Employer Recruiting Foreign-Trained Pharmacists for Work in the United States

Mr. Weisser provided that documentation of workforce shortages continues to emerge. He stated that with a limited number of pharmacy schools in the US and a rising demand for pharmacist services, one potential recruitment source are foreign-trained pharmacists. Mr. Weisser discussed that as recently as the November 2008 Pact Summit, the Department of Consumer Affairs encouraged all attendees to consider foreign-trained professionals to address shortages.

Mr. Weisser summarized the requirements for licensure, indicating such individuals must be certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) before applying for a license in California. The certification process through the FPGEC includes passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE); passing the Test of Spoken English (TSE) and Test of English as a Foreign Language (TOEFL) or iBT TOEFL; and evaluation by the FPGEC of educational curriculum and foreign licensure requirements of each applicant. In addition, the board is required by law to collect a social security number prior to the issuance of any license.

Mr. Weisser provided that while our law establishes the requirements for licensure of a pharmacist intern and pharmacist there are several other steps outside of the board's purview that must also be fulfilled. He stated that Alan Pope, representing Safeway,

presented during the committee meeting and discussed both the process and lessons learned when recruiting foreign-trained pharmacists.

Board Discussion

Dr. Kajioka sought clarification regarding the requirements for foreign pharmacist licensure and the NAPLEX examination.

Ms. Herold reviewed the requirements for licensure of a foreign-trained pharmacist for work in California. She advised that these individuals must pass an assessment to verify that they have the equivalent education of domestic graduates as well as the NAPLEX exam.

There was no additional board discussion. No public comment was provided.

10. Pharmacy Access Partnership's Request to Establish a Hormonal Contraception Pilot in Pharmacies

Mr. Weisser provided that the Pharmacy Access Partnership is seeking to provide patients with greater pharmacy access to hormonal contraception. He stated that to establish support for this practice, they propose a study under the aegis of the board.

Mr. Weisser provided that the Pharmacy Access Partnership proposed a pilot to establish practice protocols where physicians and pharmacists would collaborate in writing protocols to allow pharmacists in a community pharmacy to provide limited supplies (up to one year) of oral contraceptives, contraceptive patches and vaginal rings, to women who come into the pharmacy and meet the screening criteria. He advised that if the pilot is successful, they propose seeking statutory authority to allow such programs permanently.

Mr. Weisser provided that the request is based on 16 CCR §1706.5 which allows the board to waive specified provisions of regulations (Title 16) to an accredited school of pharmacy recognized by the board for purposes of an experimental plan or program. He advised that the board does not have the authority to waive statute (laws enacted by the Legislative). Mr. Weisser stated that based on discussion during the meeting and input from staff counsel, the committee advised Dr. Landau and Dr. Taylor-McGhee that the board does not have the statutory authority to approve their request. He added that these individuals will consider sponsoring future legislation.

No board or public comment was provided.

11. Competency Committee Report and Examination Statistics for the CPJE and NAPLEX Exams

Mr. Weisser provided that the Competency Committee workgroups met earlier this year and focused on examination development and item writing and additional workgroup meetings are scheduled throughout the year.

Mr. Weisser stated that the committee will also begin to develop a job survey to be used to complete an occupational analysis with the board's contracted psychometric firm. He advised 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 examination. Mr. Weisser provided that it is anticipated that distributing the survey to a random sample of pharmacists will begin before the end of year. He explained that the information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

No board or public comment was provided.

12. Meeting Summary of the Licensing Committee Meeting Held March 24, 2009

Mr. Weisser provided that the minutes of the Licensing Committee Meeting are contained within the board packet.

C. Third Quarterly Report on Licensing Committee Goals for 2008/09

Mr. Weisser referenced to the third quarterly report on the Licensing Committee's goals contained within the board packet.

D. Public Comment

Clarification was sought regarding the licensure of U.S. citizens who have trained abroad at a foreign pharmacy school.

Ms. Herold clarified that these individuals are considered foreign graduates and will have to meet the appropriate requirements.

Ms. Herold also provided some licensing updates. She acknowledged board staff for their efficient processing of 101 applications for UCSF students in two days time.
Ms. Herold provided that effective April 23, 2009, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). She advised that there will be a delay in the release of all CPJE examination scores until a certain number of individuals have taken the CPJE. Ms. Herold explained that this

process is done periodically to ensure the reliability of the examination. She stated that based on prior experience, the board believes this delay will last until the end of July 2009.

There was no additional public comment.

V. Organizational Development Committee Report and Action

A. Budget Update/Report

1. Governor's Executive Order to Furlough State Employees

President Schell provided that the worsening condition of the state's economy and the state's budget are at the forefront of legislative and executive branch activity. He stated that a number of reductions have been initiated or proposed by the Governor affecting state agencies, many of these will be placed on a special election ballot in May.

President Schell provided that the single greatest issue affecting the board (as a Special Fund Agency) is the furlough of staff two days per month, with a corresponding reduction in staff salaries. He advised that the parameters have changed slightly since late January and highlighted the following:

1. State employees will undergo a 9.2 percent monthly cut in salary for 18 months, beginning with February 2009.
2. Offsetting the salary reduction is a reduction in the time base of employees. Initially the Governor directed that all state agencies be closed two days per month. This occurred during February through March 6. However, since then all state agencies have been directed to resume normal operations (five days per week for the board). Now, employees are to select two days off per month as voluntary furlough days. If employees do not take these two days off each month, the days will need to be taken before 2012.

President Schell provided that board staff is very dedicated and work hard, but this 10 percent reduction will result in an increase in processing time to review applications, issue licenses, conduct routine inspections, and investigate and discipline licenses. He stated that, as in the past when faced with staff reductions implemented in response to budget reductions, the board's key business processes will be left intact and the focus of its activities will remain doing the most important activities first. President Schell stated that the board is nearly at full staff, and we hope that future budget restrictions will not result in layoffs of staff or longer furloughs.

No board or public comment was provided.

2. Budget for 2008/09

President Schell provided the following estimated budget figures from DCA's estimates done at the beginning of the fiscal year.

- Revenue: $8,396,000
- Expenditures: $9,800,000

President Schell provided that the new fiscal year started July 1, 2008, without a state budget being in place until mid September. He advised that the enacted budget contained a $1 million loan from the board's fund to the state's General Fund. President Schell explained that this loan will be repaid to the board in the future, in advance of any need for the board to increase fees because of a deficit in the board's fund.

President Schell provided that as of March 31, 2009, the board has collected $8,344,000 in revenue. He indicated that eighty-seven percent of the revenue comes from fees, with cite and fine and cost recovery generating 11 percent of the board's revenue.

No board or public comment was provided.

3. Fund Condition Report

President Schell 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:

2007/08	$10,833,000	13.3 months in reserve (actual)
2008/09	$8,999,000	10.1 months in reserve
2009/10	$7,566,000	8.3 months in reserve
2010/11	$4,786,000	5.2 months in reserve

No board or public comment was provided.

4. Reimbursement to Board Members

President Schell provided that expenses and per diem payments to board members are reported to the board and are provided in the board packet.

No board or public comment was provided.

5. I-Licensing Progress

President Schell provided that the I-Licensing project will offer online application and renewal of licenses.

President Schell provided that the board spent $50,000 in 2006/07 on programming specifications needed for its programs. He indicated that in the next three years, the board will spend $342,000 as its share of costs to implement this system department-wide.

President Schell provided that the department changed the name of the program from I-Licensing to BreEZe. He stated that a new logo has also been designed. President Schell advised that delays in securing vendors and hiring of new staff overseeing the project at the Department of Consumer Affairs have delayed the project. He indicated that new staff have been hired to lead the project and that the board is about 2 years away from implementing I-Licensing according to current estimates and timelines. President Schell provided that the department hopes to award the contract for the system this year.

President Schell provided that this priority project for the board potentially means additional delays before the board can achieve on-line renewals of licenses. He stated that the executive officer has been an executive sponsor of this project, and periodic meetings have just been resumed due to staff changes in the Office of Information Services.

No board or public comment was provided.

B. Discussion of the 2008 Audit Report Regarding the Independent Review of Board's Fee Structure by Sjoberg Evashenck Consulting, Inc.

President Schell provided that the board is solely self-funded from the fees it collects from its applicants and licensees. He stated that at every board meeting for at least the last four years, the board has discussed that it is nearing the time when it will need to seek a statutory increase in its fees that were last set in statute in the mid-1980s.

President Schell provided that monitoring the fund condition report prepared by the Department of Consumer Affairs has been integral to measuring the fiscal condition of the board and is done at every board meeting. He explained that, over the years, despite increasing workload and a substantial salary increase granted 18 months ago to the board's pharmacist inspectors (to enable recruitment of quality applicants), the board has waited to seek an increase in any of its fees until absolutely necessary.

President Schell provided that in January 2008, principally to help finance the salary increase to inspectors ($576,000), the board promulgated regulations to increase all fees to the statutory maximum.

President Schell provided that projections for the board's budget indicate a serious problem in 2010/11 and a deficit in 2012/13. He stated that recognizing that a fee increase was looming in the board's future, in 2008 the board commissioned an independent audit of the board's fees. President Schell indicated that this audit was undertaken as part of the background for any fee increase, to ensure that fees are set at the appropriate levels with respect to the expenses of providing services. He explained that this audit involved a cost allocation of all duties to ensure that fees are appropriately allocated to the time and cost required to provide the service. President Schell advised that the final audit report was submitted at the end of December, and the audit report was mailed to board members in early January 2009.

President Schell provided that at the January Board Meeting, Lynda McCallum of Sjoberg Evashenck Consulting presented the fee audit report to the board, and responded to questions.

President Schell provided that the board had questions about whether any licensing fee should subsidize the fee of another licensing group. He indicated that specifically, the board questioned whether the site licenses (pharmacies and wholesalers) should offset the licensing fees of pharmacist interns, pharmacy technicians and pharmacists.

President Schell provided that the board remained undecided about this question, and requested further discussion at this meeting.

President Schell provided that to keep with the Legislative deadlines for 2009, the board secured an author for its fee provisions, Assembly Member Emmerson, and proposed fee increases were introduced as AB 1071. He advised that the fees proposed in AB 1071 start stepping away from any subsidy from one licensing group to another, but do not totally end the subsidies.

President Schell provided that staff will continue to monitor the fund condition and provide a report to the board at each meeting. He advised that the Department of Consumer Affairs agreed that the board needed to sponsor legislation to increase fees either this or next year and recommended that we initiate the process this year.

President Schell provided that one component the board has instituted is that for purposes of cost recovery, the hourly reimbursement cost for Board of Pharmacy inspectors' investigation time, currently $65 per hour, will be increased to the auditor's recommended level of $102 per hour, effective July 2007 when the inspectors' salaries were increased by $2,000 per month.

No board or public comment was provided.

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

President Schell provided that the board will continue its program to recognize pharmacists who have been licensed for 50 years.

D. Personnel Update

Ms. Herold stated that board managers have been working very hard to fill all vacant positions. She indicated that a number of staff have been hired or promoted and most of the board's positions have been filled. Ms. Herold provided the following staff changes:

- Rob Buckner has been hired as the board's enforcement manager, replacing Karen Cates, who retired in February. Mr. Buckner formerly worked for the Department of Public Health, where he was a manager.
- Susan Sykes has become the new examination technician, processing examination applications. She is a new state employee.
- Todd Wallace has been hired to process change of PIC and DRC applications. He is a new state employee.
- Patrick Langdon has been hired to provide executive office support (Michelle Gallagher's prior position). He is a new state employee.

E. Professionals Achieving Consumer Trust Summit Scheduled for January 2010

President Schell provided that the department will host its second Professionals Achieving Consumer Trust Summit in late January 2010, although the date has not been finalized. He explained that this summit will follow the November 2008 Summit held in Los Angeles, where the boards and bureaus of the department host joint meetings and attend communal meetings on items of interest. President Schell stated that this may mean that the board has a three day meeting in January to accommodate both board business and the need to attend this summit.

No board or public comment was provided.

F. Board Meetings Scheduled for 2010

President Schell provided that the Board Meeting dates for 2010 are proposed as:

January 20-21: Sacramento *Note: this date may change to accommodate the scheduling of the PACT conference*

April 21-22: Loma Linda
July 28-29: San Francisco
October 20-21: San Diego

President Schell provided the remaining Board Meetings for 2009:
July 15-16: Los Angeles/LAX
October 21-22: San Francisco

G. Third Quarterly Report on the Committee's Goals for 2008/09

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

Public Comment

No public comment was provided.

VI. Election of Board Officers for 2009-10

President

MOTION: Reelect Ken Schell as president of the Board of Pharmacy

M/S: SW/JB

MOTION: To close further nominations.

M/S: AZ/GL

Approve: 6 Oppose: 0

Vice President

MOTION: Elect James Burgard as vice president of the Board of Pharmacy

M/S: AZ/GL

Approve: 4 Oppose: 3

MOTION: Elect Robert Swart as vice president of the Board of Pharmacy

M/S: SW/ RK

Approve: 3 Oppose: 4

Treasurer

MOTION: Reelect Stan Weisser as treasurer of the Board of Pharmacy

M/S: RS/AZ

MOTION: To close further nominations.

M/S: JB/RS

Approve: 6 Oppose: 0

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

Steve Gray, representing Kaiser Permanente, suggested that a discussion regarding the self-assessment forms be added to the agenda for the next board meeting. Dr. Gray indicated that this discussion is necessary to clarify concerns regarding the intent of a variety of items included on the forms.

There was no additional public comment.

Recess for Day

The board meeting was recessed at 3:40 p.m.

The board reconvened at 8:00 a.m. on May 1, 2009.

President Schell recognized the board's staff. Each staff member introduced themselves.

VIII. Overview: The Board's Role in the Disciplinary Process
Presentation and Discussion Led by Senior Staff Counsel Kristy Schieldge

Ms. Schieldge provided an overview of the board's disciplinary process. She also discussed the guidelines and factors to consider when deciding whether to adopt or nonadopt a proposed decision.

Board Discussion

The board discussed the disciplinary process. Discussion focused on board conduct with regards to the investigative process, the voting process, and a review and clarification of options available when adopting a decision.

There was no additional board discussion. No public comment was provided.

IX. Enforcement Committee Report and Action

Part 1: Workgroup on E-Pedigree

A. Review and Action on Items from the Meeting Held March 9, 2009

Dr. Swart provided that the Enforcement Committee convened a Workgroup on E-Pedigree Meeting. He indicated that future meetings of the workgroup will be convened as necessary; at present, the plan is to host such meetings once or twice a year for the next few years.

Dr. Swart provided that the 2008 Legislative Session ended September 30, which is the date when the Governor signed SB 1307(Ridley-Thomas). He stated that this law now staggers implementation of e-pedigree requirements in California away from 2011 to:

- 50 percent of a manufacturer's products by 2015
- The remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016, and
- Pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

Dr. Swart provided that there is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, they would take effect in CA. He stated that there are provisions that define drop shipments, 3PLs, repackagers and manufacturers. Dr. Swart advised that grandfathering provisions for drugs already in the supply chain are included.

Dr. Swart provided that the board will ultimately have to develop regulations for various components, including inference. Dr. Swart indicated that no action on these regulations is planned for several years.

No board or public comment was provided.

1. Review of the Board's Comments Submitted Regarding the FDA's Proposed Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification of Prescription Drug Packages

Dr. Swart provided that the committee discussed the FDA's request for comments on "Draft Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification for Prescription Drug Packages." He advised that these comments were due April 16, 2009.

Dr. Swart provided that under 2007 federal law (Federal Food and Drug Administration Amendments Act of 2007 (FDAAA)), the FDA was charged to develop a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing "sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug." Dr. Swart stated that this would be the serialized identifier referenced in California's e-pedigree law.

Dr. Swart provided that the Workgroup on E-Pedigree discussed the proposed identifier and whether an 8-digit random number, added to the NDC code, would be of sufficient size to track at the package level all drugs over the period of time a drug could remain in the supply chain coupled with record-keeping requirements. He indicated that several members suggested that an 8-digit alphanumeric identifier added to the NDC Code would substantially increase the number of items that could be tracked. Dr. Swart stated that the committee agreed to submit this as a recommendation, along with praise that the FDA is moving ahead nearly one year ahead of its deadline to specify this standard.

Dr. Swart provided that the board submitted comments to the FDA before the April 2009 deadline.

No board or public comment was provided.

2. FDA's Proposed Guidance for Industry on Unique Device Identification Systems

Dr. Swart provided that the committee was advised that on February 12, 2009, the FDA convened a hearing on "Unique Device Identification System." This hearing was convened to enable the FDA eventually to

> "promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary [of HHS] requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

Dr. Swart provided that while California's e-pedigree requirements exclude dangerous devices, the board still regulates the distribution of dangerous devices within, throughout and into California. He stated that a discussion of those present at the hearing indicated that serialization issues for dangerous devices are perhaps more complex than for dangerous drugs.

Dr. Swart provided that a proposed rule is expected to be released from the FDA by the end of the year.

No board or public comment was provided.

3. Review of Presentations Made to the Workgroup to Implement Electronic Pedigree Requirements

Dr. Swart provided that the committee heard presentations from several individuals willing to present information about the status of pedigree laws and regulations nationally.

Presentations were made by:

- FDA
- Congressman Buyer's Office
- GS1
- Oracle

Dr. Swart provided that Ilisa Bernstein of the FDA provided information about the FDA's request for guidance in identifying a unique identifier for drug packages at the unit level. He stated that she also advised that the FDA is considering a standard for tracking at the case and pallet level, and linking this to the serialization number of the unit packages.

Dr. Swart provided that the next speaker was Alison Hite of Congressman Buyer's Office, who in the past has co-authored federal legislation for drug supply security requirements via establishment of pedigree requirements.

Dr. Swart provided that Ms. Hite stated that while Congressman Buyer had hoped to use California's 2008 legislation as the model for federal pedigree requirements, the appointment of Mr. Waxman as Chair of the Energy and Commerce Committee has suspended efforts in this area until Mr. Waxman indicates the direction this committee will go. He added that Ms. Hite expects that food safety and drug safety will be separate issues, and that food safety may be first. Dr. Swart explained that Ms. Hite encouraged those with contacts with Mr. Waxman, who has been supportive of California's requirements in the past, to encourage him to move forward with federal legislation for drug safety.

Dr. Swart provided that Bob Celeste of GS1 provided an update on the status standards development for serialization in the US and worldwide. He stated that Mr. Celeste indicated that while California's implementation dates have been moved back, work by the supply chain is continuing as there is much interest in such work, particularly in Europe.

Dr. Swart provided that John Danese provided an update of how Oracle is working with pharmaceutical manufacturers on serialization efforts and producing electronic pedigrees at the unit level for their products. He added that Mr. Danese described in detail some of the products Oracle provides.

No board or public comment was provided.

Part 2: Enforcement Committee Matters

A. Internet Pharmacies Dispensing of Controlled Substances: DEA Implements Ryan Haight Online Pharmacy Consumer Protection Act of 2008 as an Interim Rule, Comments Sought on Implementation 21 CFR Part 1300, 1301, 1304 et al., Docket No. DEA-3221

Dr. Swart provided that on April 6, 2009, the FDA released its interim rule on requirements to implement the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. He indicated that these provisions took effect April 13, 2009 as interim rules. Dr. Swart stated that the DEA

is concurrently seeking comments on the temporary requirements and advised that these comments are due June 5, 2009.

Dr. Swart provided that the board may wish to provide comments on these requirements which establish requirements for registration with the DEA for online pharmacies under specified conditions.

Dr. Swart provided that on April 13, 2009, it became illegal under federal law to deliver, distribute or dispense a controlled substance by means of the Internet, except as authorized by the Controlled Substances Act. He stated that the law applies to all controlled substances, in any schedule. In 2010, as Part 2 of this act, the DEA will establish requirements for issuance of a special permit to practitioners who practice telemedicine.

Dr. Swart provided that as part of this rule, the DEA cites a number of statistics documenting the high abuse of controlled drugs, and the “false sense of security” that some associate with abusing prescription drugs as safer than using street drugs, and a belief that there is nothing wrong with using prescription drugs without a prescription “once in a while.”

Dr. Swart provided that the DEA cites as a growing problem rogue internet sites that sell or facilitate the sale of these drugs. He indicated that the DEA states that only 34 pharmacies in the US dispensed 98 million dosage units of hydrocodone in 2006, 2.9 million hydrocodone per pharmacy. Dr. Swart explained that the average pharmacy in the US dispenses 88,000 dosage units of hydrocodone per year.

Dr. Swart provided that the law requires any person who operates a Web site of an “online pharmacy” to obtain a DEA special online pharmacy permit. He stated that the definition of online pharmacy includes any entity, whether in the US or not, that knowingly or intentionally delivers, distributes or dispenses, or offers or attempts to deliver, distribute or dispense a controlled substance by means of the Internet. Dr. Swart added that this includes any Web site that sells, or offers to sell, any controlled substance or a prescription for controlled substances in the US. He indicated that this also includes any person who operates such a site, any person who pays a practitioner to write prescriptions for controlled substances for customers or any person who pays a pharmacy to fill prescriptions for controlled substances that are issued to customers of a Web site, any pharmacy that knowingly or intentionally fills prescriptions for controlled substances and any person who sends an email offering to sell controlled drugs, or directs buyers to a Web site.

Board Discussion

Ms. Herold provided that, for a number of years, California law has required a good faith examination of a human or animal before dispensing a drug over the Internet. She indicated that the board is able to cite and fine up to $25,000 per incidence (not investigation) for violations. Ms. Herold expressed that this issue is a serious and growing problem.

Mr. Room provided an overview of the law. He reiterated that the law is already in effect and discussed the two main focuses of the law including the requirement that

physicians perform in-person medical evaluations before issuing a controlled substance prescription and the requirement that any person who operates a Web site of an ”online pharmacy” to obtain a DEA special online pharmacy permit. Mr. Room reviewed two exemptions to this registration and indicated that e-prescribing is not subject to the act.

Mr. Brooks asked whether the Web sites are nationally or internationally based.

Mr. Room responded that it is difficult to determine where a Web site is hosted. He indicated that it is expected that most of these Web sites are foreign-based. Mr. Room advised that all Web sites, regardless of their origin, are subject to the act.

Mr. Room discussed two interesting parts of the act. He explained that the act provides a specific definition of a “refill” that only pertains to the authorization on the original prescription. Mr. Room also provided that the act contains an exemption for prescribers acting within the scope of their license. He cautioned that this may be a potential loophole for prescribers to own an online pharmacy and not be required to obtain the appropriate permit. Mr. Room explained that there is a safeguard in the regulations requiring that the Web sites identify any prescribers used to claim this exemption. Thus, the DEA believes that they will be able to identify legitimate Web sites who have listed the name and contact information of their practitioner.

Mr. Room noted that this law specifically indicates that states can enforce the law in federal court and that it will make it a violation of law to advertise for the elicit transit of drugs.

Dr. Kajioka sought clarification on the requirement that contact information for prescribers of online pharmacies be posted on valid Web sites.

Mr. Room clarified that prescribers have a broad exemption from the requirement of online pharmacy registration and noted that these practitioners will have to follow the other requirements of the law.

Public Comment

Steve Gray, representing Kaiser Permanente, discussed the complexity of the law and the difficulty involved when trying to distinguish the “bad guys” from legitimate practitioners. He provided that, in terms of pharmacist activity with controlled substances, California has the broadest scope of practice for pharmacists in the country. Mr. Gray explained the beneficial role of collaborative drug therapy management pharmacists. He explained conditions that would allow a pharmacist to provide a subscription to a patient without a good faith examination exam and the requirements for a pharmacist to fill a prescription by an out-of-state pharmacist.

Discussion continued regarding licensure requirements and the prescriptive authority of out-of-state pharmacists.

Mr. Room reviewed four new additions to the regulation including: (1) the nature and the scope of the exemptions that are created for electronic prescribing and automated dispensing systems, (2) the permanent definition of the practice of telemedicine, (3) the requirement that Web sites provide specific notifications and disclosures, and (4) the requirement of the prescriber exemption that contact information be disclosed. He suggested that the board may want to focus on these additions in their comments to the FDA.

The board discussed the option of submitting comments to the FDA.

Dr. Gray suggested that the board consider authorizing the executive staff to submit comments.

There was no additional board or public comment.

MOTION: To authorize board staff to draft comments to the FDA if considered necessary.

M/S: AZ/GL

Support: 7 Oppose: 0

B. Discussion of Policies Involving Home Generated Pharmaceutical Waste Take Back by Pharmacies

Dr. Swart provided that SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board to develop the parameters for “model” drug take-back programs in pharmacies. He stated that these model programs are intended to provide consumers with the ability to dispose of unwanted prescription and OTC drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Dr. Swart advised that under SB 966, these guidelines were to be in place by December 2008.

Dr. Swart provided that state and federal law regulates prescription medicine until it is dispensed to patients. He stated that it is not regulated again unless it is collected at consolidated points, at which point it becomes medical or pharmaceutical waste, and must be handled and destroyed in specific, mandated ways.

Dr. Swart provided that patients are often confounded about what to do with unwanted medicine. Californians increasingly want “green” options for disposing of unwanted medicine, which current law does not allow. He stated that there is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Dr. Swart advised that some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to be disposed of in this manner.

Dr. Swart provided that pharmacies have in some cases agreed to take back unwanted drugs from patients. Dr. Swart advised that this acquisition by pharmacies is not yet authorized in law.

Dr. Swart provided that some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Dr. Swart provided that some drug manufacturers (and the state of Maine, where there is a pilot program underway for seniors) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. He indicated that this is the process preferred by the DEA for controlled drugs.

Dr. Swart provided that the greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. He stated that there is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. Dr. Swart explained that, in some cases, drugs collected in collection bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Dr. Swart provided that pharmacies are areas where health care is provided – concern has been expressed that it is difficult for this purpose to be combined with a recycling center, where high sanitation is not necessarily a priority.

Dr. Swart provided that pharmacies also have expressed concern that they may be required to absorb the costs of paying for disposal of these returned drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safety and periodic emptying of collection bins.

Public Comment

Steve Gray, representing Kaiser Permanente, discussed the environmental issues involved with this policy and the responsibility of the pharmacy and the pharmaceutical industry.

There was no additional board or public comment.

1. Model Guidelines for Home Generated Pharmaceutical Waste Approved by the California Integrated Waste Management Board (February 2009)

Dr. Swart provided that at the January 2009 and October 2008 Board Meetings, the board discussed concern with the proposed model program guidelines as drafted by the California Integrated Waste Management Board (CIWMB). He indicated that the board did express its continued support for such programs on a voluntary basis with appropriate, specified safeguards.

Dr. Swart provided that the CIWMB approved its Model Guidelines initially in November 2008, but agreed to consider additional changes at its February 2009 meeting.

Dr. Swart provided that since the January 2009 Board of Pharmacy Meeting, Ms. Herold again provided written comments and testified before the CIWMB on February 18.

Dr. Swart provided that the board will feature the Model Guidelines for pharmaceutical take back programs in its July 2009 *The Script.*

Public Comment

Nils-Michael Langenborg, Program Director for Teleosis Institute, offered support for the written comments submitted by the board. He discussed concern regarding diversion, identification of take back drugs, and the management of the take back program. Mr. Langenborg promoted advanced disposal fees and producer responsibility funding. He stated that the Teleosis Institute has formed the SF Bay Area Pharmacy Coalition which aims to engage the health care community to safely dispose of unused medicines. He provided support to the board to advance these efforts.

Mr. Lippe sought clarification on whether a method to neutralize drugs is available.

Mr. Langenborg clarified that the DEA has offered recommendations for available methods.

Dr. Schell provided that the most valid method is to incinerate the drugs. He discussed the California emissions standards and indicated that California sends its drugs to other states.

Mr. Langenborg provided that there is a mailer program that allows consumers to mail their medicines to either Texas or Utah. He stated that consumers are embracing this program and change in behavior.

Ms. Herold highlighted the background of this issue and thanked Mr. Langenborg for his comments.

There was no additional board or public comment.

2. Senate Bill 26 (Simitian)

Dr. Swart provided that Senator Simitian has introduced SB 26 (discussed under the Legislation and Regulation Committee Report), which would direct the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable efficient policies to manage pharmaceutical wastes and the disposal of devices.

No board or public comment was provided.

3. Comments Submitted by the Board to the Federal Drug Enforcement Administration on Disposal of Controlled Substances by Persons Not Registered with the DEA – Docket No. DEA-316 A

Dr. Swart provided that the committee also discussed the disposal of controlled substances, which is a problem for drug-take back programs to handle, since only law enforcement agencies can take back these drugs.

Dr. Swart provided that the Drug Enforcement Administration recently sought comments for development of future requirements for the take back of controlled drugs in a public comment solicitation titled: “Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration.”

Dr. Swart provided that the committee discussed this opportunity and the board did submit comments for this item, which were due March 23, 2009.

No board or public comment was provided.

C. Update on Activities to Implement E-Prescribing in California

Dr. Swart provided that a number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing. He explained that a principal reason is that statistics indicate that medication errors cost the health care system $77 billion and cause 7,000 deaths annually. Dr. Swart indicated that a number of these errors could be prevented by full implementation of e-prescribing. He stated that other savings have been projected from redirected time currently spent by prescribers and pharmacies in verifying and switching prescription orders.

Dr. Swart provided that by the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. He stated that various provisions have been added or amended to keep law supportive of allowing electronic prescriptions. Dr. Swart explained that a current deterrent is that controlled substances cannot be e-prescribed.

Dr. Swart provided that on November 20, 2008, the Board of Pharmacy hosted an e-prescribing forum in conjunction with the Department of Consumer Affairs’ Professionals Achieving Consumer Trust Summit. He stated that other healing arts boards whose licensees prescribe drugs attended this forum as did our stakeholders and public interest groups. Dr. Swart added that the Dental Board and Medical Board joined us as partners.

Dr. Swart provided that the California HealthCare Foundation (CHCF) is strongly advocating adoption of e-prescribing. He advised that CHCF also hosted a forum on November 20, 2008, in San Francisco on e-prescribing.

Dr. Swart provided that CHCF has been working with the executive staff of the Medical Board

and the Board of Pharmacy to host in a series of statewide events where physicians and pharmacists at the local level could earn CE and simultaneously work through issues limiting adoption of e-prescribing. He indicated that the Medical Board also has agreed to co-sponsor these local events.

Dr. Swart provided that at the end of March 2009, the CHCF held its first “road show” on e-prescribing in Visalia. He stated that the California Pharmacists Association was very helpful in getting their members to this event. Dr. Swart indicated that the CHCF hopes to hold additional programs throughout California over the next few months.

Dr. Swart provided that Assembly Bill 718 has been introduced to require all prescribers and pharmacies to have the ability to transmit and receive prescriptions by electronic data transmission. He stated that the sponsor of this bill is a technology firm, Reed Elsevier, Inc.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that the DEA promised regulations on e-prescribing 9 years ago. He indicated that the new administration will likely have a new approach to this issue.

There was no additional board or public comment.

D. Review of the Presentation on California’s Controlled Substance Utilization Review and Evaluation System (CURES), a presentation and question and answer session led by Department of Justice, Bureau of Narcotics Enforcement

Dr. Swart provided that in mid December 2008, the board and California pharmacies were advised that effective January 1, 2009, the California Department of Justice (DOJ) would have a new data collection vendor for CURES, and that all California pharmacies were to submit data to this new vendor beginning January 1. He indicated that this was a short transition, and the board learned that some pharmacies are having transmission issues submitting data to the new vendor.

Dr. Swart provided that in hopes of resolving these issues, the California Department of Justice attended the March 9, 2009, Enforcement Committee Meeting to hear and resolve issues involving the transition to the new vendor. He stated that the Department of Justice indicated that most of the implementation problems have been resolved.

Dr. Swart provided that the DOJ also advised the committee that its plans are still on track to offer via the Internet (with secured access) online, real time reports involving controlled substances dispensed to patients. He advised that this service should be available online to practitioners and pharmacies by July 1, 2009.

Dr. Swart provided that the Enforcement Committee will hear an updated report on the CURES system upgrades at its June 2009 meeting.

Public Comment

Steve Gray, representing Kaiser Permanente and the California Pharmacists Association, provided that the Troy and Alana Pack Foundation has been established and is seeking to help put the CURES database online and in real-time. He explained that expediting this process will help to prevent the diversion of drugs and drug-seeking individuals who target busy emergency rooms for obtaining prescriptions. He encouraged donations to this foundation to fund the purchase of the servers required to establish this effort.

There was no additional board or public comment.

E. Department of Consumer Affairs' Policies Regarding Pursuit of Interim Suspension Orders

Dr. Swart provided that the Enforcement Committee reviewed a copy of a December 15, 2008, memorandum from the Deputy Director of Legal Affairs Doreathea Johnson. He stated that in this memorandum, the department issued the department's policy to encourage the practice of licensing agencies to use Interim Suspension Orders (ISO) and provisions in the Penal Code (PC 23s) when the conduct of a licensee is such that the board cannot afford to wait for the completion of the administrative process, before taking action to ensure the safety of the public. Dr. Swart indicated that this memo directs all DCA licensing agencies to institute procedures for ordering interim suspension orders as warranted as well as to make recommendations regarding specific conditions when the agency shall pursue a suspension via a PC 23. He added that the memo further provides suggested parameters.

Dr. Swart provided that the board uses all legal actions authorized, including both ISOs and PC 23s when a case is egregious and immediate public harm is eminent.

Dr. Swart provided that with the implementation of the Criminal Conviction Unit board staff anticipates an increase in the number of such actions as the board will have sufficient resources to more promptly address violations that warrant immediate suspension.

No board or public comment was provided.

F. Minutes of the Enforcement Committee Meeting of March 9, 2009

Dr. Swart provided that the minutes of the Enforcement Committee Meeting are contained within the board packet provided.

G. Enforcement Statistics 2008-2009

Dr. Swart provided the 2008-2009 Enforcement Statistics are contained within the board packet provided.

H. Third Quarterly Report on Enforcement Committee Goals for 2008/09

Dr. Swart referenced the third quarterly report on the Enforcement Committee's goals contained within the board packet.

Public Comment

President Schell recognized board member Andrea Zinder for her 10 years of service on the board and presented her with a clock.

Ms. Zinder thanked the board and commended the staff for their support.

No public comment was provided.

X. Closed Session

The board moved into closed session pursuant to Government Code section 1112(c)(3) to deliberate on disciplinary matters.

XI. Petition for Early Termination of Probation

Administrative law judge, Judith Kopek, conducted a hearing to consider petition for early termination of probation for:

- Anne Cabrera

XI. Closed Session

The board moved into closed session pursuant to Government Code § 11126(c)(3) to deliberate on the request for early termination of probation.

The board moved into closed session pursuant to Government Code § 11126(c)(3) to conclude deliberations on disciplinary matters.

The meeting was adjourned at 11:03 a.m.