California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES

DATE: April 16, 2009

LOCATION: Department of Consumer Affairs El Dorado Room
1625 North Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Andrea Zinder, Public Member, Chair
Kenneth Schell, PharmD
James Burgard, Public Member

BOARD MEMBERS NOT PRESENT:
Shirley Wheat, Public Member
Ryan Brooks, Public Member
Robert Swart, PharmD
Susan L. Ravnan, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Carolyn Klein, Legislation and Regulations Manager
Tessa Fraga, Staff Analyst

Call to Order

Chair Zinder called the meeting to order at 10:08 a.m.

A. REGULATIONS REPORT

1. Approved Regulations

Section 100 Changes

At the October 2008 Board Meeting, the board voted to pursue section 100 changes to update the forms. Board staff was recently advised that these forms were approved by

the Office of Administrative Law. The revised forms are on the board's Web site. Additionally, a notice was provided in the upcoming issue of *The Script* advising readers of the change.

a. 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

Assistant Executive Officer Anne Sodergren provided that section 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. The 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. Additionally, the forms make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their PICs. 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. Sodergren advised that the new self-assessment forms are now on the board's Web site.

b. 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. Sodergren provided that section 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. 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. Additionally, the form makes the inspection process more meaningful and provides relevant information to wholesalers and their DRC. 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. Sodergren advised that the self-assessment form is now available on the board's Web site.

2. Board Approved Regulations – Undergoing Administrative Review

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

At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. 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. As a result the matter was referred back to the board at the January 2009 Board Meeting.

During this 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. 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. 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 this rulemaking is currently undergoing review by the Office of Administrative Law.

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

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. Based on the work of this subcommittee, the subcommittee recommended to the full board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. 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. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

During the October 2008 Board Meeting, the board held a regulation hearing on the proposed changes. 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" as proposed in §1773.5(a)(5)(B). 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 amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

Ms. Sodergren provided that the 15-day comment period is over and no additional comments were received. She indicated that board staff compiled the rulemaking and it is currently undergoing review by the department.

3. Board Approved Regulations – Previously Noticed

a. Title 16 CCR Repeal §1716.1 and §1716.2, Amend and Adopt sections 1751 through 1751.8 and Adopt sections 1735 through 1735.8 – Pharmacies that Compound

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. 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. Based on the subcommittee's recommendation, at the January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the recordkeeping requirements sterile products that are compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Ms. Sodergren provided that 15- day notice period is over. She stated that the board has received several comments in response to this 15-day notice period. Ms. Sodergren added that these comments will be provided to the board for further consideration at the April 2009 Board Meeting.

Public Comment:

John Grupps, representing UC Davis Medical Center, sought clarification regarding the comments that were received.

Ms. Sodergren provided that many of the comments that were received were outside of the scope of the change. She added that the comments that are within the scope of the 15-day change will be provided at the April Board Meeting. Ms. Sodergren indicated that after consideration the board could vote to adopt the changes, pursue another 15-day comment period, or withdraw the changes.

Mr. Grupps sought confirmation on whether the 15-day comment period was specific to the exemption.

Ms. Sodergren confirmed and reviewed the rulemaking and proposal process.

Discussion continued regarding the comment period and the issue of compounding.

There was no additional committee or public comment.

4. Board Approved Regulations – Awaiting Notice

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

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

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Ms. Sodergren provided 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.

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

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.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. 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. Sodergren provided that language has been approved by the board. She added that staff anticipates release of notice of this proposed regulatory change sometime after the end of the legislative year.

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

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint

Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies. At the July 2007 Board Meeting, the board voted to move this proposal.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

Ms. Sodergren provided that language has been approved by the board. She added that staff anticipates release of notice of this proposed regulatory change sometime after the end of the legislative year.

5. Regulations Under Development

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

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

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. Sodergren provided that a subcommittee has been established and will be working with board staff and industry.

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

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.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need.

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.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. 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. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

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).

Additionally, the board will 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. Sodergren provided that language has not yet been developed.

B. LEGISLATIVE REPORT

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

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

Chair Zinder explained that, at the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. Many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

Changes based on recodification of B&PC §4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following B&PC sections and H&SC section reference 4052 and require technical updates.

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

Committee Discussion:

Ms. Sodergren provided that SB 819 is scheduled for hearing and will most likely be a consent item.

Discussion continued regarding the status of SB 819.

There was no additional committee or public comment.

General Omnibus Changes

The following proposals were also approved as omnibus provisions for 2008.

- §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.

- §4081 – Records of Dangerous Drugs and 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.”

- §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.

- §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.

- § 4362 – Entry Into Pharmacists Recovery Program

This section requires amendment to specify the administrative co-pay participants pay.

- 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.

<u>Omnibus Changes to Allow for the Use of Mobile Pharmacies</u>

- §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.

- §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.

<u>Omnibus Changes Specific to the PIC and DRC Requirements</u>

- §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.

- §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.

- §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.

- §4329 – Nonpharmacists; Prohibited Acts

This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

- §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.

b. SB 820 (Senate Business, Professions & Economic Development Committee) – New Omnibus Provisions

Ms. Sodergren 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. SB 820 (Senate Business, Professions & Economic Development Committee) make conforming changes throughout the Business and Professions Code to reflect this name change.

- §4200.3 – Exam Process; standards; development; reporting requirements

- §4200.4 – Retaking Examinations; Set Limits; Requirements

c. SB 821 (Senate Business, Professions & Economic Development Committee) – New Omnibus Provisions specific to PIC and DRC Requirements

Ms. Sodergren explained that, at the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions. These provisions are contained in SB 821 (Senate Business and Professions Committee).

- §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.

- §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.

- §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.

- §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.

- §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.

Committee Discussion:

Chair Zinder confirmed that the provisions are technical changes.

Ms. Herold provided that one provision will be added requiring all pharmacies in California to join the board's subscriber alert.

Public Comment:

Bryce Docherty, representing California Society of Health-System Pharmacists (CSHP), sought clarification regarding the subscriber alert provision.

Ms. Herold provided that the provision pertains to pharmacies and will place the burden on the pharmacist in charge (PIC) to register for the subscriber alert.

Cookie Quandt, representing Longs Drugs, confirmed that the provision pertains specifically to pharmacy sites.

Chair Zinder sought clarification regarding the number of pharmacies who currently subscribe to the subscriber alert.

Ms. Herold responded that there are methods to verify this number. She explained the importance of pharmacies receiving mail and notifications from the board.

Discussion continued regarding board notifications via mail and e-mail.

There was no additional committee or public comment.

d. SB 470 (Corbett) – "Purpose" bill. Proposal to amend B&P §4040 and §4076 re: prescription labeling.

Chair Zinder provided that, at the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a medicine is prescribed, with the "purpose" for which the medicine is prescribed.

Committee Discussion:

Ms. Sodergren provided that Senator Corbett is authoring this bill for the board. This bill will amend Business and Professions Code sections 4040 and 4076 to include the "condition or purpose" for which a medicine is prescribed. (Senator Corbett authored SB 472, Chapter 470, and Statutes of 2007, requiring the board to standardize the prescription label to make them patient-centered.)

Ms. Sodergren indicated that board staff has been working to establish a broad base of support for this proposal. 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. Senator Corbett's office has advised CMA that they will be accepting the amendments offered.

Ms. Herold provided that board staff will continue to advocate for this proposal and will engage with stakeholders who may have concerns.

There was no additional committee or public comment.

e. AB 977 (Skinner) – Pharmacists: Immunization Administration. Proposal to amend B&PC §4052 and §4052.8

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).

Assembly Member Skinner is authoring this bill for the board. The bill will amend Business and Professions Code section 4052 and add 4052.8 to allow a pharmacist to administer immunizations as specified. As introduced, the bill would have allowed 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. 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.

Board staff has been working with stakeholders to establish a broad base of support. Unfortunately, the California Medical Association (CMA) continues to oppose the bill, even with proposed amendments.

Committee Discussion:

Ms. Sodergren provided that, despite an amendment to only include influenza and pneumococcal vaccinations, the bill did not pass committee; however, was granted reconsideration.

Ms. Herold provided that if the bill is unsuccessful, the board is hoping that the profession will continue to work with the consumer advocates and the public health advocates to pursue this public health issue.

Discussion continued regarding access and administration of vaccinations.

There was no additional committee or public comment.

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

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

Committee Discussion:

Ms. Sodergren provided that Assembly Member Emmerson is authorizing 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. Sodergren indicated that this bill also builds in a cap to increase future fees by no more than 30 percent.

Chair Zinder expressed concern regarding the increase for pharmacy technicians.

Ms. Sodergren responded that pharmacy technician fee will be increased from $50 to $80. She explained that this fee will not be increased to the actual cost to deliver the service.

Discussion continued regarding subsidies and fee increases.

There was no additional committee or public comment.

2. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction – For Committee Consideration

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

Ms. Sodergren 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. She indicated that the bill has been amended to remove the CE requirements.

Public Comments:

Bryce Docherty, representing California Society of Health-System Pharmacists (CSHP), provided that the minimum intent for the bill is to raise the minimum standard for licensure of pharmacy technicians to better protect Californian consumers. He discussed the high volume of pharmacy technicians and the need for adequate training. Mr. Docherty stated that the bill did not receive the requisite number of votes to pass out of the committee; but it has been granted reconsideration. He requested that the committee provide support for the bill.

Mr. Docherty reviewed the amended requirements for a pharmacy technician license.

Discussion continued regarding various amendments and requirements of the bill and the role of a pharmacy technician.

Cookie Quandt, representing Longs Drugs, sought clarification on whether § 4410 has been removed.

Ms. Sodergren confirmed.

Greg Lippe discussed the potential cost factor in licensing technicians at a higher level; thus, resulting in higher salaries and increasing costs for pharmacies.

Discussion continued regarding potential costs and standards.

James Burgard expressed concern regarding stronger qualified technicians with greater responsibilities.

Mr. Docherty responded that technician responsibilities are outlined in law.

There was no additional committee or public comment.

MOTION: To support AB 418.

M/S: JB/ KS

Approve: 2 Oppose: 1

b. AB 484 (Eng) Franchise Tax board: professional or occupational licenses

Ms. Sodergren 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. The bill would 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.

Committee Discussion:

Mr. Lippe expressed concern for the bill and recommended that it be opposed.

Ms. Sodergren provided that the bill failed in committee; but, has been granted reconsideration.

Chair Zinder questioned if the department has taken a position on this bill.

Marc Mason, representing the Department of Consumer Affairs, provided that the department has no official position.

There was no additional committee or public comment.

COMMITTEE RECOMMENDATION: none

c. AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to electronically transmit data by 1/1/12

Ms. Sodergren 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.

MOTION: To support AB 718.

M/S: JB/KS

Approve: 3 Oppose: 0

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

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

Committee Discussion:

Discussion continued regarding the list of the compendium guides and the intent of this bill.

There was no additional board or public comment.

MOTION: To oppose AB 830.

M/S: KS/ JB

Approve: 3 Oppose: 0

e. AB 877 (Emmerson) (*Intent language*)Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice

Ms. Sodergren 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. Sodergren reviewed the intended committee composition. She indicated that bill has been amended to include that the cost will be born by the regulatory agency.

Ms. Herold suggested that the committee provide a neutral recommendation.

MOTION: To take no position on AB 877

M/S: JB/KS

Approve: 3 Oppose: 0

f. AB 931 (Fletcher) Emergency Supplies – Doses stored in an emergency supplies container

Chair 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. Chair Zinder stated that the bill is sponsored by the California Pharmacists Association (CPhA).

Ms. Herold provided that Department of Public Health is expected to oppose the bill.

COMMITTEE RECOMMENDATION: none

g. 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)

Chair 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.

Committee Discussion:

Ms. Sodergren provided that existing law defines the required information an applicant of licensure or renewal must provide. She stated that the board does not currently collect several of the required elements including worksite information, number of hours worked, as well as race and ethnicity. Ms. Sodergren indicated that the board will require funding for additional staff as well as funding to purchase a database. She added that the board would require three full-time Office Technicians to collect and input specified data for all new and renewal applicants.

Ms. Herold provided that the Governor’s Office is encouraging the department to select additional information regarding “manpower shortages.”

Dr. Schell sought clarification on whether it is intended that the bill will be revenue neutral.

Carolyn Klein, Legislation and Regulations Manager, provided that the staff consultant representing the author has indicated a fee increase for licensees and minimal changes to the computer system in order to gather the additional information.

Discussion continued regarding implementation costs.

There was no additional committee or public comment.

MOTION: To take no position on AB 1310.

M/S: JB/KS

Approve: 3 Oppose: 0

h. AB 1370 (Solorio) “Best Before” date on a prescription label

Chair 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 of device.

Committee Discussion:

Ms. Herold provided that this bill is expected to be dropped by the author. She indicated that the Enforcement Committee will further evaluate the date and its implications.

Discussion continued regarding conditions impacting the date on the bottle.

There was no additional committee or public comment.

The committee did not make a recommendation on this proposal given that it was being dropped by the author.

i. SB 26 (Simitian) Home-Generated Pharmaceutical Waste

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

Committee Discussion:

Ms. Herold reviewed comments provided to the California Integrated Waste Management Board (CIWMB). She indicated that Senator Simitain has agreed to take out provisions regarding the “common carrier.”

There was no additional committee or public comment.

MOTION: To take no position on SB 26.

M/S: JB/ KS

Approve: 3 Oppose: 0

j. SB 43 (Alquist) Cultural and Linguistic Competency

Chair 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.

Committee Discussion:

Ms. Sodergren provided that this bill does not create a mandate, rather it is permissive. She indicated that the bill would allow the Office of Statewide Health Planning and Development (OSHPD) to obtain data for inclusion in the health care workforce clearinghouse and require that personally identifiable information be kept confidential.

Dr. Schell expressed concern regarding the protection of confidential information and potential disclosure costs.

There was no additional committee or public comment.

MOTION: To support SB 43.

M/S: KS/JB

Approve: 3 Oppose: 0

k. SB 364 (Florez) Intent language (as introduced). Penalties on a pharmacy that fails to safeguard controlled substances, as specified.

Ms. Sodergren 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. She indicated that this bill has been amended and no longer pertains to pharmacy.

There was no position required.

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

Chair 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. 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.

MOTION: To support SB 389.

M/S: KS/JB

Approve: 3 Oppose: 0

m. SB 484 (Wright) Ephedrine Products / Schedule V

Ms. Sodergren provided that this bill would add ephedrine and pseudoephedrine to California's Controlled Substances in Schedule V. She indicated that a prescription would be required before a consumer could purchase these substances.

Presentation to the Board:

Kent Shaw, representing the Department of Justice (DOJ), 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 only have it available from a pharmacy. He discussed that Oregon has successfully implemented such a regulation and the results have been dramatic.

Mr. Shaw encouraged the board's support for SB 484.

Committee Discussion:

Dr. Schell discussed possible impacts the bill may have on pharmacies and the potential for pharmacy errors.

Mr. Shaw provided that Oregon has no experienced such issues as a result of their bill.

Dr. Schell questioned if other precursors and methods for manufacture have been addressed.

Mr. Shaw responded that other methods are not as frequent and effective. He added that California's methamphetamine labs are much larger than the other states and stated that these labs have a greater production capacity than all of the other states combined.

Chair Zinder questioned if alternative products are available for people who are uninsured.

Dr. Schell responded that alternative products are available but they may not be as effective.

Discussion continued regarding the dispersion and use of pseudoephedrine.

Public Comment:

Cookie Quandt, representing Longs Drugs, provided that pharmacists are concerned about the smurfing issue and indicated that pharmacies are requiring a significant amount of time to deal with this issue. She stated that Longs is a proponent of making pseudoephedrine a scheduled drug. Ms. Quandt questioned if this issue would be reported to CURES and sought clarification on what role the board would play with this issue.

Mr. Shaw responded that there are tentative plans for monitoring. He indicated that DOJ will bear the burden for this action.

Discussion continued regarding smurfing and its impact on pharmacists

Lynn Rolston, representing the California Pharmacists Association (CPhA), provided support to this initiative. She sought clarification on why the bill is seeking to add pseudoephedrine as a Schedule V drug as opposed to a Schedule IV drug that could be tracked by CURES.

Mr. Shaw responded that successfully requiring a prescription for this drug is the primary and most achievable challenge.

Ms. Herold discussed the purchase of pseudoephedrine via mail-order. She proposed the consideration for a sunset date on this provision for five years.
Discussion continued regarding the possible impacts for the implementation of SB 484.

There was no additional committee or public comment

COMMITTEE RECOMMENDATION: none

n. SB 599 (Negrete McLeod) Requirement for DCA Boards to post to board's Internet site within 10 days each accusation, statement of issues, or disciplinary action taken by the board

Chair Zinder provided this bill would require every board, as defined, to post each accusation, statement of issues, or disciplinary action taken by the board on that board's

Internet Web site within 10 days of the filing date of the accusation or statement of issues, or the effective date of the disciplinary action.

Ms. Sodergren provided that this bill has been amended and is now specific to workforce development.

There was no position required.

o. SB 638 (Negrete McLeod) DCA regulatory boards; sunset reviews; operations; report requirements

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

Ms. Sodergren provided that under existing law, all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence. She added that in the event the board becomes inoperative and is repealed, the board transforms into a bureau under the Department of Consumer Affairs. Ms. Sodergren indicated that this bill would redefine this process and would reconstitute any board that becomes inoperative or is repealed.

MOTION: To support AB 638.

M/S: KS/ JB

Approve: 3 Oppose: 0

p. SB 762 (Aanestad) Professions and Vocations; Healing Arts

Chair Zinder provided that this bill would also 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.

Committee Discussion:

The committee discussed the intent and focus of this bill in relation to pharmacy.

Mark Mason, representing the Department of Consumer Affairs, provided the department does not have a position on this bill.

There was no additional board or public comment.

COMMITTEE RECOMMENDATION: none

b. Other Legislation Introduced (Of Interest or for Information Only)

Chair Zinder acknowledged the following proposals that do not directly impact the board's jurisdiction but may be of interest.

a. AB 832 (Jones) Clinic Licensing

b. AB 1094 (Conway) Disposal of Personal Information

c. AB 1201 (Perez) – Immunizations (physician reimbursement)

d. SB 341 (DeSaulnier) California Department of Public Health. CDPH to contract with UC to study/evaluate the safety and effectiveness of prescription Drugs

C. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA

No public comments were provided

The meeting was adjourned at 12:40 p.m.