



California State Board of Pharmacy

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

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

DATE: July 14, 2010

LOCATION: Department of Consumer Affairs
El Dorado Room – Second Floor, N 220
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Kenneth Schell, PharmD, Chair
Greg Lippe, Public Member, Treasurer
Rosalyn Hackworth, Public Member
Shirley Wheat, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Tappan Zee, Public Member

STAFF

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

Call to Order

Chair Schell called the meeting to order at 1:00 p.m.

LEGISLATION REPORT

a. Board-Sponsored Legislation

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

Background

Last Amendment: June 17, 2010
Current Status: Assembly Appropriations

On January 20, 2010, the board voted to support the inclusion of several amendments in the Senate Business Professions and Economic Development Committee's Omnibus measure for 2010. SB 1489 was introduced on March 11, 2010 and included the board's requested proposals. This bill has been amended three times, most recently on June 17, 2010.

Included with the most recent amendments to the bill is a modification to Business and Professions Code section 4013. This amendment has been incorporated at the request of industry, which had concerns about the implementation of the e-mail notification requirement that took effect July 1, 2010. Board staff provided some technical input on the drafting of the language to ensure that the intent of the section was not altered as a result of the proposed change, which was accepted by staff of the Business Professions and Economic Development Committee and subsequently amended into the bill.

However, the board has not discussed this from a policy perspective and may wish to do so.

Chair Schell referenced to the following omnibus provisions, now contained in SB 1489.

General Omnibus Provisions

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

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

- §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4 time failure)

In October 2008, the board approved that the sunset provision within §4200.1 be eliminated. Though the Senate BP&ED committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. This language has been corrected to restore the provision to law without a sunset date.

- §4101 – Veterinary Food-Animal Drug Retailer

Provisions to Update References to the Department of Public Health (reflecting its new name):

- §4017 – Authorized Officers of the Law
- §4028 – Definition of Licensed Hospital
- §4037 – Definition of Pharmacy
- §4052.3(e) – Emergency Contraception Drug Therapy; Requirements and Limitations
- §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- §4072(b) – Oral or Electronic Transmission of Prescription – Health Care Facility
- §4119(a) – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
- §4127.1(d) – License to Compound Injectable Sterile Drug Products Required
- §4169 – Prohibited Acts (also, strike operative date of 2008)
- §4181(a) – License Requirements; Policies and Procedures; Who May Dispense
- §4191(a) – Compliance with California Department of Public Health Requirements; Who May Dispense Drugs

Provision to Correctly Reference the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)

- §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

Provisions to Correct References to the Department of Health Care Services (formerly known as the Department of Health Services)

- §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring
- §4426 – California Department of Health Care Services to Study Reimbursement Rates.

Public Comment

Steve Gray, representing Kaiser Permanente, asked if there have been any recent changes to SB 1489 that are not yet published.

Executive Officer Virginia Herold provided that there may be an amendment that would include the provision that was previously in SB1390.
There was no additional committee discussion or public comment.

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

1. Board of Pharmacy

AB 2104 (Hayashi) – California State Board of Pharmacy

Chair Schell provided that this bill has been recently amended to authorize the Board of Pharmacy, with the approval of the Department of Consumer Affairs, to appoint the Executive Officer of the Board.

Chair Schell provided that the previous version of the bill would have authorized the Governor to appoint the executive officer. He explained that this version would have required the board to receive approval from the DCA before sponsoring or taking positions on legislation and would define ex parte communications and establish reporting requirements for board members that engage in such communications.

Chair Schell provided that the board has taken an oppose position on this bill.

Chair Schell provided that the bill has passed out of the Senate Business, Professions and Economic Development Committee has been referred to the Senate Appropriations Committee.

Chair Schell provided that this bill specifically targets the Board of Pharmacy. He stated that the bill should be applicable to all healing arts boards.

Greg Lippe recommended that the board maintain its position of oppose.

Public Comment

Gil Deluna, representing the Department of Consumer Affairs Unlicensed Activity Program, provided that the department has no position on this version of the bill.

Assistant Executive Officer Anne Sodergren provided that the department initially took an opposed unless amended position on this bill and offered several amendments. None were added to the bill.

There was no additional committee discussion or public comment.

Committee Recommendation: To maintain position of oppose on AB 2104.

SB 1390 (Corbett) – Prescription Container Labels

Chair Schell provided that SB 1390, which was recently amended to establish statutory requirements for patient-centered prescription drug container labels, failed passage during a committee hearing before the Assembly Business, Professions and Consumer Protection Committee.

No public comment was provided.

2. Sunset Review and Legislative Oversight

AB 1659 (Huber) – State Government, Agency Repeals

Chair Schell provided that this bill creates a new Joint Sunset Review Committee with the responsibility to review and evaluate specified state agencies based on specific criteria and information provided by these agencies.

Chair Shell provided that the board has no position on this bill.

Chair Schell provided that the bill passed out of the Senate Committee on Business, Professions and Economic Development. He indicated that the matter has been referred to the Senate Committee on Rules.

No public comment was provided.

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

Chair Schell provided that this bill is a related bill to AB 1659 (Huber). He stated that it abolishes the Joint Committee of Boards, Commissions and Consumer Protection and refers the charge of that committee to the proposed Joint Sunset Review Committee established in AB 1659.

Chair Shell provided that the board has no position on this bill.

Chair Schell provided that the bill passed out of the Senate Committee on Business, Professions and Economic Development. He stated that the bill has been referred to the Senate Committee on Appropriations.

No public comment was provided.

MOTION: To recommend to the board to not establish a position on AB 1659 and AB 2130.

M/S: Lippe/Hackworth

Support: 3 Oppose: 0 Abstain: 1

3. Regulation of Dangerous Drugs and Devices

AB 1455 (Hill) – Pseudoephedrine

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

President Schell provided that the board has no position on this bill.

President Schell provided that the bill is being held in the Senate Judiciary Committee without recommendation.

Public Comment

Lynn Rolston, representing the California Pharmacists Association (CPhA), encouraged the board to consider this tracking system. She indicated that CPhA has taken a support position on the bill.

Steve Gray, representing Kaiser Permanente, stated that Kaiser now supports this bill.

There was no additional committee discussion or public comment.

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

Chair Schell provided that this bill establishes requirements for providers of blood clotting products for home use (providers) whose products are used to treat hemophilia and other bleeding disorders and designates the Board of Pharmacy to administer and enforce the provisions of the Standards of Service for Providers of Blood Clotting Products and Home Use Act.

Chair Schell provided that the board has no position on this bill.

Chair Schell provided that the board currently regulates pharmacies who provide such services.

Public Comment

Gil Deluna, representing the Department of Consumer Affairs Unlicensed Activity Program, provided that the department has taken an oppose position on SB 971. He stated that the department does not believe that this bill is necessary, as an existing problem has not been identified.

There was no additional committee discussion or public comment.

MOTION: To recommend to the board not to establish a position on SB 971.

M/S: Wheat/Lippe

Support: 3 Oppose: 0 Abstain: 1

SB 1071 (DeSaulnier) – CURES

Chair Schell provided that this bill creates a fund to support the Controlled Substance Utilization Review and Evaluation System (CURES) and imposes a tax on every manufacturer, importer, or other person that makes the sale in the state of a Schedule II, III or IV controlled substance, at the rate of \$0.0025 per pill.

Chair Schell provided that the board has no position on this bill.

Chair Schell provided that the hearing for this bill has been cancelled at the request of the author.

No public comment was provided.

SB 1106 (Yee) – Prescribers – Dispensing of Samples

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

Chair Schell provided that the board has taken a support position on this bill, if it is amended to clarify the drug information materials that would be provided to patients by a practitioner dispensing samples is the same that a pharmacy must currently provide to patients when dispensing drugs. He stated that discussions during hearings and with the author indicated that that is the intent of the bill.

Chair Schell provided that the bill passed out of the Assembly Committee on Business, Professions and Consumer Protection and has been referred to Committee on Appropriations.

Shirley Wheat sought clarification regarding the board's intentions for its support of this bill.

Chair Schell provided that the board will not be enforcing the provisions of this bill as it does not have jurisdiction over physicians. He indicated that the board's support ensures that prescribers will be required to provide the appropriate information when dispensing samples to patients, and would ensure patients are provided this information whether they receive a sample or are dispensed the drug by a pharmacy.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that the bill is ambiguous. He discussed that pharmacies are currently required to provide medication guides.

The committee discussed the intent of this bill with regards to the specific information required to be dispensed. Consideration was given to whether the board wants to support bills that are already current law.

Ms. Sodergren provided that the board's mission is consistent with the intent of this bill as it relates to consumers properly taking their medications.

Lynn Rolston, representing the California Pharmacists Association, provided that med guides only apply to those drugs for which med guides are available. She stated that physicians often dispense samples in an envelope with the name of the drug written on the envelope.

Dr. Gray clarified that this bill only applies to sample packages and starter kits. He suggested that a recommendation could be offered that the bill be amended to apply to all physician dispensing.

Ms. Herold recommended that the board not move from a position of support to an oppose position unless it has any strong objections.

There was no additional committee discussion or public comment.

Committee Recommendation: To recommend to the board to maintain its position of Support if Amended on SB 1106.

4. Pharmacy Licensing Issues

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

Chair Schell provided that this bill provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. He stated that the bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified in the bill. The bill requires bar coding and notification to the board of any hospital pharmacy doing such repackaging.

Chair Schell provided that the board has no position on this bill.

Chair Schell provided that the bill has passed out of the Senate Committee on Business, Professions and Economic Development and has been referred to the Committee on Appropriations.

Chair Schell provided that key provisions desired by the board in a prior Solorio bill have been incorporated.

Ms. Sodergren provided that there is currently no opposition to the bill.

No public comment was provided.

MOTION: To recommend to the board to establish a position of support on AB 2077.

M/S: Lippe/Hackworth

Support: 2 Oppose: 0 Abstain: 2

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

Chair Schell provided that this bill establishes the California Pharmacy Technician Scholarship and Loan Repayment Program (Program) for the repayment of pharmacy technician (PT) education loans.

Chair Schell provided that the board has no position on this bill.

Chair Schell provided that the bill passed out of the Senate Health Committee and was referred to the Committee on Appropriations.

Ms. Sodergren provided that this bill establishes independent funding sources instead of

requiring licensee contributions as required by other bills that have been before the board.

No public comment was provided.

Committee Recommendation: To maintain no position on AB 2551.

5. Distribution of Needles and Syringes

The committee discussed the following three bills. Consideration was given to the number of needles and syringes that can be provided at one time.

AB 1701 (Chesbro) – Hypodermic Needles and Syringes

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

Chair Schell provided that the board has a support position on AB 1701.

Recent Action: Passed out of Senate Committee on Health as amended. However, amendments are not yet in print. The bill would extend the sunset date for eight years, rather than repeal the date.

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

Chair Schell provided that this bill allows the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease through the sharing of unclean hypodermic needles and syringes.

Chair Schell stated that the board has no position on AB 1858.

Recent Action: Passed by the Senate Committee on Health as amended and referred to the Committee on Appropriations.

SB 1029 (Yee) – Hypodermic Needles and Syringes

Chair Schell provided that this bill allows a physician or pharmacist, beginning January 1, 2011 through December 31, 2018, to furnish 30 or fewer hypodermic needles and

syringes for human use to a person 30 years of age or older. He stated that the bill addresses the storage of products to ensure they are available only to authorized personnel, requires that disposal options are provided to consumers, and requires pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment.

Chair Schell provided that the board has no position on SB 1029.

Recent Action: Passed by the Assembly Committee on Business, Professions and Consumer Protection and referred to the Committee on Appropriations.

MOTION: Recommend to the board to maintain the positions established for AB 1701, AB 1858, and SB 1029.

M/S: Wheat/Hackworth

Support: 2 Oppose: 1 Abstain: 1

6. General / Other

AB 1310 (Hernandez) – Healing Arts Database

Ms. Sodergren provided that this bill would require specified healing arts boards (including the Board of Pharmacy), bureaus and committees to collect specified information from their licensees and would require these entities and the Department of Consumer Affairs to work with the Office of Statewide Health Planning and Development to transfer that data to the Health Care Workforce Clearinghouse. She stated that the clearinghouse would be required to report to the Legislature on an annual basis.

Ms. Sodergren provided that the board has no position on this bill and that there has been no activity on this bill since fall 2009.

Public Comment

Gil Deluna, representing the Department of Consumer Affairs Unlicensed Activity Program, provided that the department does not have a position on the bill.

Steve Gray, representing Kaiser Permanente, asked if the bill specifies where the data is to be collected from.

Ms. Sodergren provided that the data is provided to the board and is then provided to the Office of Statewide Health Planning and Development (OSHPD). She indicated that the board could obtain the information both at the time of application and at the time of renewal.

There was no additional committee discussion or public comment.

MOTION: To recommend to the board that no position be established on AB 1310.

M/S: Hackworth/Lippe

Support: 3 Oppose: 0 Abstain: 1
SB 1172 (Negrete McLeod) – Diversion Programs

Chair Schell provided that this bill requires specified healing arts boards (including the Board of Pharmacy) to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program. He indicated that this bill also allows a healing arts board to adopt regulations authorizing the board to order a licensee (on probation or in a diversion program) to cease practice for 1.) major violations or 2.) when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to uniform and specific standards, as specified.

Chair Schell provided that the board has no position on this bill.

Chair Schell provided that the bill was passed by the Assembly Committee on Business, Professions and Consumer Protection and was referred to the Committee on Appropriations.

Ms. Herold provided that participants in the Pharmacists Recovery Program (PRP) who test positive for any prohibited substance currently are removed from work pending the receipt of two negative tests.

Ms. Sodergren provided that cease practice for a positive test is typically called for in the terms and conditions of a licensee's probation. She provided an overview on the 16 standards established by the Substance Abuse Coordination Committee (SACC) as required by SB 1441. Ms. Sodergren stated that the board has not formally vetted these standards. She advised that the Board of Registered Nursing has been amended out of SB 1172, so its provisions will not affect nurses who test positive.

Public Comment

Gil Deluna, representing the Department of Consumer Affairs Unlicensed Activity Program, provided that the department does not have a position on the bill.

Ms. Herold provided that pharmacy technicians are not included in the PRP.

There was no additional committee discussion or public comment.

MOTION: To recommend to the board to maintain no position on SB 1172.

M/S: Wheat/Lippe

Support: 3 Oppose: 0 Abstain: 1

7. Other Legislation Impacting the Board's Jurisdiction

Lynn Rolston, recommended that the board review AB 2779 (Solorio) as it relates to the regulation of compounded prescriptions and worker's compensation.

No other legislation was offered.

c. Board Adopted Regulations – Undergoing Administration Review

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

Background

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

The formal rulemaking was noticed on October 30, 2009. The 45-day comment period concluded on December 14, 2009, and the board did not receive any comments to the proposed rulemaking.

The board adopted this regulation during the January 2010 Board Meeting. This rulemaking file was compiled and submitted to the department in March 2010.

Chair Schell indicated that earlier this month, the board was advised that this rulemaking was approved by the department and it is currently undergoing review by the Office of Administrative Law.

No public comment was provided.

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

Background

During the June 2010 Board Meeting, the board voted to approve the proposed addition of 16 CCR Section 1707.5 creating the patient centered prescription label requirements.

The formal rulemaking was noticed for the 45-Day Comment Period on November 20, 2009 and a regulation hearing was held on January 20, 2010. The first 15-day comment period started on February 22, 2010 and the second 15-day comment period began on April 28, 2010.

Chair Schell provided that at the direction of the board, staff prepared the Final Statement of Reasons and compiled the rulemaking file. He stated that the file was submitted to the department on Monday, July 12, 2010. Chair Schell indicated that before final approval of the regulation, the file will be reviewed by the department, the Department of Finance, State and Consumer Services Agency, and finally by the Office of Administrative Law.

No public comment was provided.

d. Board Adopted Regulations – Recently Approved

Adopt New Section at Title 16 California Code of Regulations Section 1702 -- Fingerprint Submissions for Pharmacists

Background

At the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file. The proposed rulemaking further specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The Initial Notice for the rulemaking was published on December 25, 2009, and the 45-day comment period concluded February 15, 2010.

The board adopted this regulation during the February 2010 Board Meeting. The rulemaking file was compiled and submitted to the department in February 2010. The board received final approval from the Office of Administrative Law on June 7, 2010. The effective date for this regulation change is December 7, 2010.

Board staff will be developing an implementation plan and hopes to advise all affected licensees by late summer of the fingerprint requirements. An article also will be included in the next version of The Script.

e. Board Approved – Awaiting Notice

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

Background

In 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. The regulation became operative on December 2, 2004.

Staff recommends that an error be corrected in the ‘chart’ of Dedicated Emergency Contraception that is specified in 16 CCR §1746(b)(11) to correct the heading of “Ethinyl Estradiol per Dose (mg).” The heading should designate micrograms – not milligrams. While the board deems this to be a typographical error, the regulation (as originally adopted) specified milligrams, not micrograms. As a result, a formal regulation proposal is required to correct this heading.

Chair Schell provided that during the January 2010 Board Meeting, the board voted to initiate the rulemaking process. He stated that board staff had anticipated releasing this regulation change for comment for adoption during the July 2010 Board Meeting, however because of competing priorities, has been unable to do so.

Ms. Herold suggested that board consider forming a committee to update the regulation as after six years, the medication may have changed.

No public comment was provided.

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

Background

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete review of examination questions if the committee member is not seeking reimbursement for his or her time. Additionally, the board previously voted to award CE for the following:

- 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).

This was included into the board's continuing education policy, but was never formally amended into regulation.

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

No public comment was provided.

f. Board Approved Regulations – Language Under Development

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

Ms. Sodergren 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.

Ms. Sodergren provided that this regulation has been tabled because the Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program.

No public comment was provided.

2. Title 16 CCR Section 1751.XX – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Ms. Sodergren provided that Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. She stated that since the inception of this statute, the board has approved two such agencies. Ms. Sodergren provided that the proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.

Ms. Herold provided that at least one of the accreditation agencies seeking board recognition will attend the July 2010 Board Meeting to seek accreditation from the board.

No public comment was provided.

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

Background

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.

Chair Schell provided that because of stated concerns about whether referencing the 2005 USP standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

Chair Schell indicated that a subcommittee had been established; but, as a result of recent vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

Public Comment

Steve Gray, representing Kaiser Permanente, suggested that the subcommittee seek some additional assistance in order to fully evaluate the standards.

There was no additional committee discussion or public comment.

g. Strategic Plan Update for the Legislation and Regulation Committee for 2010-11

Background

At the July Board Meeting, the board will update its 2010-11 Strategic Plan. The board truly manages its operations by its strategic plan. All activities undertaken by the board are reported in the plan -- in the component committee reports provided quarterly to the board (in the board packets).

Each fiscal year, the board updates its strategic plan. The current plan was developed in 2006-07 with the assistance of a consultant. Since then, each year the board has reviewed and as necessary revised its strategic plan. These are typically minor adjustments and additions.

The revision is done by each strategic committee by reviewing its portion of the strategic plan, making recommendations and then recommendations to the full board for review and approval at the board meeting.

The Legislation and Regulation Committee's strategic goals, objectives and tasks are being updated and will be provided at the meeting. The committee needs to review the plan to ensure its activities are current.

Chair Schell requested that committee members submit any changes or modifications prior to the July 2010 Board Meeting.

No public comment was provided.

h. Public Comment for Items Not On the Agenda

No public comment was provided.

The meeting was adjourned at 2:17 p.m.