MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: July 5, 2007
LOCATION: Department of Consumer Affairs
1625 N Market Blvd
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Ken Schell, PharmD, Acting Chair
Tim Dazé, Board Member
Robert Graul, Board Member

BOARD STAFF PRESENT:

Virginia Herold, Executive Officer
Robert Ratcliff, Supervising Inspector
Anne Sodergren, Staff Manager

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

Proposed Legislation – Board Sponsored

Omnibus Provisions

The committee reviewed omnibus provisions previously approved by the board to be introduced this legislative cycle. These provisions include amendments to the following:

B & PC 4084 – Adulterated or Counterfeit Drugs or Dangerous Devices
B & PC 4162 and 4162.5 – Wholesaler Bonding Requirements
B & PC 4314 and 4315 – Citation and Fine for Repository and Distribution Programs for Dangerous Drugs
B & PC 4160(f) and 4161(k) – Temporary License Fee for Wholesalers
B & PC 4208 – Intern Pharmacist License
B & PC 4101 – Pharmacist In Charge, Exemptee: Termination of Employment; Notification to Board
B & PC 4068 – Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements

No comments were made by the committee or public.

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

Dr. Schell provided a brief overview of each of the relevant bills, as well as the author's intent.

AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects

This proposal would allow for the use of General Fund money to purchase needles for NEP programs.

AB 249 (Eng) Licensees: Healing Arts: Settlement Agreements

This proposal would prevent all health care practitioners from including a "gag clause" in a civil action.

AB 501 (Swanson) Pharmaceutical Devices: Hypodermic Needle and Syringe Disposal

This proposal would require every pharmaceutical company whose product requires the use of prefilled syringe, prefilled pen needle or other prefilled injection device to provide a method for California patients to dispose of the device.

Board staff indicated that this proposal was recently amended, but is a two-year bill.

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

This proposal would standardize the licensing requirements for ambulatory surgical centers.

The committee was updated on the status of this proposal and was notified that with the approval of the board's president, staff offered amendments to this bill that would require the board to complete an initial inspection of all clinics issued a board license that are not also licensed by the DHS. In addition, the board would also be required to complete an annual inspection of such facilities.

Board staff has testified in support of this pending legislation.

AB 1025 (Bass) Professions and Vocations: Denial of Licensure

This proposal would prohibit the board from denying an application for licensure or pursuing administrative action against a licensee for a conviction that has been set aside or for an arrest where a final disposition has not occurred within one year.

The committee was updated on the status of this proposal as well as amendments. Board staff cautioned that even with the included amendments, this proposal would diminish the board's ability to consider all evidence of criminal backgrounds when evaluating applications and possible disciplinary actions, which could result in compromised consumer protection.

AB 1587 (De La Torre) Personal Information: Pharmacy

This proposal would make exemptions to the definition of marketing materials to allow a pharmacy to distribute drug information sponsored by drug manufacturers.

Jennifer Hendrick Snyder, representing the sponsor of this proposal, provided an overview to the committee about the intent of the proposal stating that the bill would authorize a pharmacy to provide written information.

Dr. Schell expressed concern that this bill would allow another form of direct to consumer marketing and questioned in a pharmacist can already provide this information.

Ms. Snyder indicated that this proposal would allow the information to be sponsored but that the information needs to be educational.

Dr. Schell stated that pharmacists already provide information and expressed concern about the requirement that allows for information on generic alternative therapies, but precludes brand alternatives.

Ms. Snyder provided clarification to several questions and reiterated that the contents of the flyer must be primarily educational and be approved by the FDA, the sponsor of the flyer as well as the pharmacy. Additionally, a pharmacy cannot accept remuneration for providing the supplemental information.

Committee Recommendation: Request that the board have a discussion about this proposal.

SB 472 (Corbett) Prescription Drugs: Labeling Requirements

This bill was amended to mandate that the board develop and adopt a standardized prescription label. These amendments were offered after consultation with the board president.

Fred Meyer representing PPSI, Gray Panthers and Consumer Advocate thanked the board for its support of SB 472 but questioned what is happening with AB 851, AB 1276 and AB 1399 all of which also deal with prescription labeling.

Ms. Herold clarified that SB 472 does not expand the informational requirements of the prescription label, but rather requires that the label become patient-centered and standardized.

Kathy Lynch, representing the California Pharmacists Association also thanked the board for engaging in SB 472 to help facilitate amendments and reiterated that CPhA is in support of the efforts of the panel responsible for the SCR 49 report.

SB 606 (Scott) Pharmaceutical Information: Clinical Trial Data

This bill would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available the results of every completed clinical trial, except a phase I trial or bioequivalence study, for that drug and an explanation of noncompletion for any clinical trial, except a phase I trial, that the company initiates or sponsors the initiation of, but does not complete.

Ms. Herold indicated that manufacturers that were originally opposed to this proposal are now neutral.

SB 615 (Oropeza) Pharmacy Technicians: Scholarship and Loan Repayment Program

This proposal would establish a scholarship and loan repayment program for pharmacy technicians and require all pharmacy technicians as well as pharmacies to contribute $10.00 at the time of renewal.

Board staff indicated that upon receipt of additional clarifying information, the board president changed the position of the board to one of support.

SB 963 (Ridley-Thomas) Regulatory Boards: Termination

This proposal would was recently amended to create an Office of Consumer Advocate with the DCA whose primary responsibility will be to ensure that the consumer protection mandate is met for boards within the DCA. This oversight would replace the sunset review process.

Ms. Herold stated that this proposal was going to interim study and would most likely be a two-year bill.

Mr. Dazé stated concern that this proposal imposes additional requirements on the board, but does not provide for funding.

The committee decided not to take a position on this bill.

SB 966 (Simitian) Pharmaceutical Drug Disposal

This proposal would require pharmacies to accept, then dispose of, returned unused medications.

Mr. Dazé stated agreement with the intent of the legislation, but expressed concern that the process offered in the bill is inadequate.

Dr. Schell also spoke in support of the intent of the proposal, but stated that the bill in its current form leaves a lot of issued unresolved and suggested that the board should continue to work with the author's office.

Heidi Barsugila, representing the California Retailers Association, stated that CRA is opposed to the bill but has tried to work with the author's office. Specifically, CRA is concerned with the 2010 effective date as well as possible issues with return of controlled substances. The CRA has suggested that the author work with the Department of Toxic Substances Control, the board, and law enforcement to define a workable solution.

Fred Meyer stated that the intent of the proposal is good, but that the board should focus efforts on education consumers on proper disposal of unused medicines. Mr. Meyer stated that he is opposed to the proposal because it imposes an unfunded mandate on pharmacies.

Ms. Herold highlighted that the proposal does not detail any parameters for a take back program and does not provide for any enforcement mechanism. Ms. Herold stated that board staff has tried to work with the author's office, but no amendments have been accepted. Ms. Herold believes that this bill will most likely make it to the governor's office.

Dr. Schell indicated that the agenda listed additional legislation that was provided for information only. These items were not discussed.

Approved Regulations

Dr. Schell stated that two regulations were recently approved by the Office of Administrative Law.

Addition of 16 CCR 1784 – Self-Assessment of a Wholesaler

The adoption of this section establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form will also aid wholesalers in complying with legal requirements of wholesaler operations and therefore increase public safety as a result of this compliance. This regulation went into effect the end of April 2007.

Amendment to 16 CCR 1706.2 - Abandonment of Applications

In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation. The effective date of this amended regulation was June 22, 2007.

Board Approved Regulations – Pending Administrative Review

Dr. Schell briefly discussed two rulemakings undergoing review by the Administration.

The Board of Pharmacy submitted the following Section 100 regulation package to the Office of Administrative Law. These changes are without regulatory effect because they merely conform to statutory changes already in effect as well as to remove an outdated regulation. The changes included:

> **Proposed Amendment to CCR §1707. Waiver Requirements for Off-Site Storage of Records -** In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.
> **16 CCR § 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge**. - In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee-in-charge" with "designated representative-in-charge" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Amendment to CCR § 1715 – Self Assessment Forms - The self-assessment forms, which is incorporated by reference in the regulation, is a compilation of laws. A Section 100 regulation change is necessary to update the self-assessment form to reflect changes in pharmacy law since the forms last revision date.

Proposed Amendment to CCR §1717. Pharmacy Practice – This section currently makes reference to section 1306.26 of the Code of Federal Regulations. This reference is incorrect and needs to be changed to the appropriate CFR section, 1306.25.

16 CCR §1780.1 and §1781 – Replace the term "Exemptee" with "Designated Representative"- In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

Proposed Repeal of 16 CCR §1786 – Return of Exemption Certificates - This section is outdated and needs to be repealed. The provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leave the employment of a wholesaler. This regulation is based on prior Pharmacy Law, which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

Proposed Amendment to CCR §1787. Authorization to Distribute Dialysis Drugs and Devices - In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure consistency with the Business and Professions Code.

Proposed Amendment to CCR §1790. Assembling and Packaging - In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure consistency with the Business and Professions Code.

Proposed Amendment to CCR § 1793.8. – Pharmacy Technicians in Hospitals - This section currently references Business and Professions Code section 4052, however because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006), this reference requires correction.

In addition to the Section 100 Changes, board staff also completed the rulemaking process in conformance with the California Building Standards Rulemaking Process.

Specifically, at the April 2006 Board Meeting, the board voted to amend language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. Thereafter, the Building Standards Commission advised the board of a new process to submit items into the California Building Code. Board staff anticipates adoption of these regulations by the end of July 2007.

Board Approved Regulations Currently Noticed

Dr. Schell advised the committee of two regulations that are currently noticed. Dr. Schell provided a brief overview of each of the two rulemakings and stated that the comment period for both ended July 3, 2007. No comments were received on either rulemaking.

Proposed Amendment to 16 CCR 1707.2 – Notice to Consumers

CCR 1707.2 currently requires every pharmacy to prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code section 4122. Assembly Bill 2583 (Chapter 487, Statutes of 2006) amended sections 733 and 4122 of the Business and Professions Code to require the board to amend the "Notice to Consumers" to include a statement that describes a patient's right to obtain medication from a pharmacy even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the medication is required.

This is the second rulemaking the board is pursuing to ensure compliance with AB 2583. The previous rulemaking was withdrawn from the Office of Administrative Law after the April 2007 Board Meeting.

Proposed Amendment to 16 CCR 1749 – Fee Schedule

CCR 1749 defines the application and renewal fees of licensees as set forth in Business and Professions Code. At the April 2007 Board Meeting, the board voted to approve a recommendation from the board's Organizational Development Committee to increase all board fees to their statutory maximum amounts.

This proposal will raise board fees to their statutory maximum as provided for in referenced Business and Professions Code sections. This proposal is necessary to ensure sufficient resources to maintain current board operations.

Specifically, for more than four years the board's expenses have exceeded board's revenues. Repayment of a 2001 $6 million loan to the General Fund has allowed the board to maintain its operating expenses. A review of the anticipated Fund Condition for the board reveals that a fee increase must be sought to continue board operations. It is estimated that absent a fee increase, the board's fund condition will be reduced to a little over a one-month reserve by the end of fiscal year 2008-09 and will be in a deficit by three and one half months by the end of fiscal year 2009-10.

Board Approved Regulations Awaiting Notice

Dr. Schell stated that in addition to the Section 100 changes undergoing administrative review by the Office of Administrative Law, the board approved one additional Section 100 change.

Proposed Amendment to 16 CCR 1780 – Update the USP Standards Reference Material

Section 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 standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

At the last committee meeting the committee was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather is seeking input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material.

Dr. Schell agreed to facilitate a meeting with stakeholders to discuss the revisions made in the 2005 version and make recommendations to the board.

Committee members were advised on the status of two additional regulations that were previously approved by the board that are awaiting notice.

2. Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines – FOR INFORMATION ONLY

Dr. Schell provided an updated on the status of the revisions to the Disciplinary Guidelines. Staff has suggested a number of amendments to the Disciplinary Guidelines that were last revised in 2001. Upon completion, this rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. Staff made recommendations for changes that were presented to the board at the June 2007 Enforcement Committee. Based on comments received during the Enforcement Committee Hearing, the Disciplinary Guidelines will remain with the Enforcement Committee for discussion at the September 2007 Meeting and will be forwarded to the board for consideration at the October 2007 Board Meeting.

3. Proposed Addition to 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.

Dr. Schell reported that staff is currently developing this form. It is anticipated that the draft form will be reviewed at the September 2007 Enforcement Committee meeting and could be forwarded to the board for consideration at the October 2007 Board Meeting.

Board Approved Regulations – Proposed Language

Process and Criteria to Approve Accreditation Agencies for Pharmacies

Dr. Schell provided a brief overview of this proposal.

Ms. Herold provided history on the board's current process to approve an accreditation agency for pharmacies that compound sterile injectable products and stated that the proposed regulation would formalize criteria the board uses to approve such agencies and would remove the administrative burden placed on the board for such approvals.

Committee Recommendation: Move the language to the full board for consideration.

Adjournment

The committee adjourned around 3:00 p.m.