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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: October 19, 2010

LOCATION: UC San Diego
Health Sciences Education Center Auditorium
9500 Gilman Drive
La Jolla, CA 92093

COMMITTEE MEMBERS PRESENT:
Rosalyn Hackworth, Public Member
Stan Weisser, Acting Chair
Randy Kajioka, Deputized Member

COMMITTEE MEMBERS NOT PRESENT:
Greg Lippe, Public Member, Treasurer
Kenneth Schell, PharmD, Chair
Shirley Wheat, Public Member
Tappan Zee, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Tessa Fraga, Staff Analyst

Board President Stan Weisser appointed himself and Board Member Randy Kajioka as members of the Legislation and Regulation Committee as a quorum of the committee was not present.

Call to Order

Acting Chair Weisser called the meeting to order at 1:58 p.m.

A. LEGISLATION REPORT

1. Board-Sponsored Legislation
SB 1489 Omnibus Provisions (Senate Committee on Business, Professions and Economic Development) – Chapter 653, Statutes of 2010

Background
At the January 2010 Board Meeting, the board voted to pursue several omnibus provisions, which were introduced in SB 1489. The measure was amended on June 17, 2010, to modify §4013 (subscriber alert provisions) and was again amended on August 12, 2010, to modify §4076.5 (patient-centered labels), as summarized below.

Chair Weisser highlighted the following general omnibus provisions.

- §4013. Subscriber Alert. Section 4013 was amended at the request of industry, which had concerns about the implementation of the e-mail notification requirement that went into effect July 1, 2010. Amendments allow an owner of two or more pharmacies the option of registering with the board one e-mail address, by which the owner will immediately transmit any board e-mail notification to its licensed facilities.
- §4076.5. Patient-Centered Prescription Labels. Section 4076.5 was amended to give the board the authority to exempt from prescription labeling requirements (16 CCR §1707.5.) prescriptions dispensed to a patient in a health facility as defined in Section 1250 of the Health and Safety Code, so long as the prescriptions are administered by a licensed health care professional. Prescriptions dispensed upon discharge, or those not administered by a health care professional are subject to the board's regulation. Additional amendments also authorize the board to exempt from prescription labeling regulations a prescription dispensed to a patient, so long as certain criteria is met (i.e., home infusion, specialty therapies, etc.).
- §4101. Veterinary Food-Animal Drug Retailer
- §4196(e). Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repackaged
- Add §4200.1. Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x failure)

Recodification of exact language previously in statute (which had sunset in 2009) Amendments to update references to the California Department of Public Health and the Physical Therapy Board of California

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

- §4191(a). Compliance with the California Department of Public Health; Who May Dispense Drugs

Amendments to update 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

Executive Officer Virginia Herold indicated that these legislative changes will be published in the next issue of *The Script*.

No public comment was provided.

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

The committee reviewed the following legislation.

a. Chaptered

Board of Pharmacy

- AB 2104 (Hayashi, Chapter 374, Statutes of 2010) – Board of Pharmacy: DCA Approval of Appointment of EO

Background
This bill requires that the Director of the DCA approve the board's appointment of the Executive Officer. The board had established an oppose position on this measure.

Chair Weisser provided a brief overview of the bill.

Licensing / General / Other

- SB 1172 (Negrete McLeod, Chapter 517, Statutes of 2010) – Diversion Programs

Background
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 licensees probation or diversion program. The bill authorizes the board to adopt regulations 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. Participants in the board's Pharmacists Recovery Program (PRP) who test positive for any prohibited substance currently are removed

from work pending the receipt of two negative tests. The board did not take a position on this bill.

Assistant Executive Officer Anne Sodergren provided an overview of the bill and discussed some of the possible implementation challenges. She stated that a legislative fix may be required with respect to cease practice orders for self referral participants in the PRP.

- AB 2699 (Bass, Chapter 270, Statutes of 2010) – Licensure exemption: State of Emergency.

Background

Existing law provides for an exemption from licensure and regulation requirements for a healing arts practitioner licensed in another state that offers or provides health care for which he or she is licensed, during a state of emergency. The provisions of AB 2699 provide other exemptions from licensure until January 2014, if the care is provided through a sponsored event and under specific circumstances. A practitioner would be exempt from state requirements for licensure, so long as the following criteria are met:

- Obtains authorization from the board by providing a valid license and photo identification;
- Has not committed any act or been convicted of a crime constituting grounds for denial of a license;
- Has the appropriate education;
- Agrees to comply with all practice requirements; and
- Pays a fee determined by the board by regulation which shall cover the cost of processing the request.

A sponsoring entity seeking to provide health care services must register with the board by completing a registration form and provide this information to the health department. Within 15 days of the health care services, the sponsoring entity would be required to file a report with the board that contains the description of care provided, and a list of practitioners providing the service. The board may revoke registration if the sponsoring entity fails to comply.

Ms. Herold provided an overview of the bill. She stated that although a pharmacist falls within the definition of a health care provider and, therefore, could be included in the provisions of his bill, the author's office indicated that pharmacists would most likely not be participating in events referenced in the measure.

Ms. Sodergren stated that the department will be taking the lead on developing a general regulation package to facilitate implementation of these new provisions for several boards.

- AB 1414 (Hill, Chapter 76, Statutes of 2010) – Controlled Substances: Apomorphine: Unscheduled.

Background
The California Uniform Controlled Substances Act currently lists Apomorphine as a Schedule II controlled substance. This bill moves Apomorphine from Schedule II to Schedule V. Schedule V drugs are generally defined by those drugs that have a currently accepted medical value, present a low potential for abuse, and may lead to limited psychological or physical dependence. Schedule V substances include cough suppressants and pain modulators, as well as many prescription drugs. There was no noted opposition to the measure, and the board did not take a position on this bill.

Chair Weisser highlighted the intent of the bill.

Carolyn Klein, Legislation and Regulation Manager, provided that Apomorphine is a drug used to treat people with advanced Parkinson's disease and despite the name, it has none of the pharmacological properties of morphine.

Sunset Review and Legislative Oversight Proposals

- AB 1659 (Huber) – State Government, Agency Repeals
- AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection

Background
AB 1659 creates a new Joint Sunset Review Committee with the responsibility to review and evaluate specified state agencies (including the Board of Pharmacy) based on specific criteria and information provided by these agencies. AB 2130 is a companion bill that abolishes the (current) Joint Committee on Boards, Commissions and Consumer Protection and refers the charge of that committee to the proposed Joint Sunset Review Committee.

Ms. Herold provided that the board currently has a sunset date of January 1, 2013. She stated that under the current sunset review process, if the board's sunset date is not extended beyond 2013, the Board of Pharmacy's duties and responsibilities would fall to the Department of Consumer Affairs, and the board – in effect – would operate as a bureau within DCA. Ms. Herold indicated that the provisions that created this process were repealed in this measure.

Ms. Sodergren provided that effective January 1, 2011, should any board currently under the Department of Consumer Affairs sunset, that profession will no longer be regulated as there is no provision to transfer the board's duties and responsibilities to DCA. She stated that that if the board's sunset date is not extended, the board would cease to exist and the practice of pharmacy would be unregulated. Ms. Sodergren indicated that the department is aware of this issue and is exploring options to remedy this.

Distribution of Needles and Syringes

- AB 1701 (Chesbro) – Hypodermic Needles and Syringes

Background
In 2004, the Disease Prevention Demonstration Project pilot was launched, with a sunset date of 2010, to allow 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. AB 1701 extends these provisions to 2018. The board did not take a position on this bill.

Chair Weisser provided an overview of the bill.

Other Legislation Impacting the Board's Jurisdiction

- SB 294 (Negrete McLeod) – Professions and Vocations: Regulation

Background
This bill resets the sunset dates of various boards within the Department of Consumer Affairs, but does not impact the Board of Pharmacy. The board did not take a position on this bill.

- SB 700 (Negrete McLeod, Chapter 505, Statutes of 2010) – Healing Arts: Peer Review

Background
Existing law provides for a peer review process of licentiate and that certain information regarding judgments and settlements is reported. This bill requires that in addition to current requirements, any additional exculpatory or explanatory statements submitted by the licentiate also be included; the bill also requires the agency to inform the licentiate that information submitted electronically will be publicly disclosed to those who request the information. The board did not take a position on this bill.

Ms. Herold provided that the following bills do not impact the board.

b. Vetoed

- AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

Background
Board position: Support

Ms. Herold provided background on this bill. She stated that this bill would have provided for centralized pharmacy packaging in a hospital, where the pharmacy could be located outside of a hospital on either the same premises or separate premises regulated under a hospital's license.

Ms. Herold indicated that she is unaware whether or not this proposal will be pursued again.

- AB 2747 (Lowenthal) – Prisoners: Pharmacy Services

Background
Board position: None

This bill would have authorized the California Department of Corrections and Rehabilitation (CDCR) to operate and maintain a centralized pharmacy distribution center for facilities under its jurisdiction.

Supervising Inspector Robert Ratcliff stated that the California Department of Public Health (CDPH) currently licenses a facility to provide these services and as such it was determined that the bill was not necessary.

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

Background
Board position: None

This bill would have established requirements for providers of blood clotting products for home use whose products are used to treat hemophilia and other bleeding disorders, and designated 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.

Ms. Herold provided that this bill may have been vetoed due to cost.

Other Vetoed Bills not discussed by the committee:

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

Background
Board position: None

This bill would have allowed the California Department of Public Health to authorize entities to provide hypodermic needles 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; and provided that a participant in a clean needle and syringe exchange program shall not be subject to criminal prosecution for possession of needles and syringes acquired under an approved program.

- SB 1029 (Yee) – Hypodermic Needles and Syringes

Background
Board position: None

This bill would have allowed 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. The bill addressed the storage of products to ensure they would be available only to authorized personnel, would have required that disposal options are provided to consumers, and would have required pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment.

c. Legislation That Failed Passage
   - SB 1390 (Corbett) – Patient-Centered Prescription Labels
   - AB 1455 (Hill) –Ephedrine; retail sale
   - SB 1071 (DeSaulnier) – CURES
   - SB 1106 (Yee) – Prescribers – Dispensing of Samples
   - AB 2551 (Hernandez) – Pharmacy Technician: Scholarship & Loan Repayment Program
   - AB 1310 (Hernandez) – Healing Arts Database

   The committee did not discuss these items.

No public comment was provided.

3. Legislation for Sponsorship During 2011-12 Session

a. Previously-Approved Board-Sponsored Legislation for 2011-2012

   - Section 4362 – Entry Into Pharmacists Recovery Program (Omnibus provision)

   Background
   In January 2010, the board voted to pursue an omnibus proposal to add Section 4362, to establish a co-pay for participants in the Pharmacists Recovery Program to offset a portion of the board's administrative fee for each participant. The proposal was not picked up for the 2009/2010 Legislative Session.

   Chair Weisser spoke in support of this provision.

   Ms. Herold indicated that this provision cannot be done as an omnibus bill because of the fee component.

- Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors

Background
Over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet. The board voted in January 2010 to pursue sponsorship of such legislation, to include the provisions below. These were not picked up in the 2009/2010 session.

a. Amend section 4040.5 – Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines "dispensed" for purposes of this section only. This provision was approved in concept only by the board in January 2009.

b. Amend section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines "licensed integrated waste hauler" for purposes of this section only. This provision was approved in concept only by the board in January 2009.

c. Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. (Language for the later provision will require development.) This provision has not previously been considered by the committee or the board.

Ms. Herold spoke in support of this proposal. She discussed that it would be to the benefit to the supply chain to better define this area.

Ms. Herold provided that currently there are not adequate requirements for reverse distributors.

- Sections 4104, 4105 and 4112 – Enforcement Enhancements

Background
The board voted at is meeting in January 2010 Board Meeting to pursue statutory changes as outlined in Sections 4104 and 4112. Proposed amendments to § 4105

mirror those contained in proposed changes to § 4081, related to the production of records, when requested by the board.

Ms. Herold reviewed the following provisions and indicated that an author is still needed. She stated that a potential author is currently reviewing these provisions.

a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure

Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of licensee's theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.

c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, to provide pharmacist related services to Californians.

b. Legislation for Consideration During 2011-2012 Legislative Session

The provisions below are offered for consideration for the 2011/2012 legislative session.

- Section 4200 – Pharmacist Examination (Omnibus provision)

Ms. Herold provided that this amendment would remove an obsolete reference in the pharmacist license requirements.

Ms. Sodergren provided that this change will strike the provision that referenced the previous written and practical exam that was given by the board prior to December 31, 2003. She indicated that the corrected provision will now only reference the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

- Section 4301.1 – To Allow the Board to Suspend the License of a Pharmacist or Pharmacist Intern for a Felony Conviction for a Crime of Unprofessional Conduct

Background
In October 2009, the Legislation and Regulation Committee considered a staff proposal to add Section 4301.1. to the Business and Professions Code to provide the board with the authority to suspend the license of a pharmacist or a pharmacist intern who is convicted of a felony for a crime of unprofessional conduct, as defined in §4301; that the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so; and that the issue of penalty shall be heard by an administrative law judge, or a committee of the board with an ALJ, or the board sitting with an ALJ, at the discretion of the board. The section would allow a pharmacist or pharmacist intern to request a hearing within a specified timeframe; and that if an accusation for permanent discipline is not filed within 90 days of the suspension that the suspension shall terminate.

Joshua Room, Deputy Attorney General, provided that this provision came from the department as other boards do not currently have this power. He advised that there are existing provisions that cover most of these issues.

Ms. Sodergren provided that there is duplication within section 4301.1 and 4311.

Ms. Herold recommended that this provision not be pursued.

No public comment was provided.

B. REGULATION REPORT

Note: All section references are to Title 16 of the California Code of Regulations unless otherwise stated

1. Discussion and Possible Action to Initiate a Rulemaking to Adopt §1707.6. – Notices to Consumers, and to Amend §1707.2. Notice to Consumers and Duty to Consult

Background
On June 10, 2010, the board adopted proposed regulation 16 CCR § 1707.5. to establish requirements for a patient-centered prescription drug container label. That regulation is currently undergoing administrative review.

The patient-centered prescription label regulation requires a pharmacy to provide a consumer with 12-point font for certain components of a prescription label, if requested; it also requires a pharmacy to provide oral interpretive services.

During the rulemaking process to adopt the prescription drug labeling requirements, it was suggested that the board establish requirement(s) that consumers be notified of the availability of oral language interpretive services and of 12-point font, as specified in the adopted regulation.

At the July 2010 Board Meeting, staff provided the board with draft language for consideration and possible action. The board discussed the draft text and directed staff to develop new draft language. At that time, the board voted to move the existing consumer notices from 16 CCR § 1702. to a new section that also includes any notice(s) regarding language interpretive services and larger font sizes.

Mr. Room reviewed the draft notice language for consideration (option 2 handout) that was developed in response to the board's feedback during the July 2010 Board Meeting on the previous draft (option 1 handout). He explained that the new draft is simpler, consolidates notice requirements, and allows for flexibility in the presentation of the notices.

Public Comment

Mary Staples, representing the National Association of Chain Drug Stores, expressed concern regarding the size and font requirements for the language assistance flyer/handout. She discussed that an 18-point font may be too large.

Mr. Room provided that the size requirements were established as a starting point and can be modified.

Dr. Kajioka discussed the use of language assistance providers and the associated cost to pharmacies. He expressed concern that this cost may be a burden for smaller pharmacies that only service certain language groups.

Ms. Staples provided that the cost may be more dependant on the length of the call.

Mr. Room indicated that oral language services are currently required under Title 7.

Dr. Kajioka provided that enforcement groups will recognize that cost is a valid concern with respect to these requirements.

Ms. Herold provided that the board will need to determine whether an inclusive or limited list of languages will be more beneficial for patients. She discussed that the progress of the regulation is dependant on this decision.

Chair Weisser expressed concerned regarding an all-inclusive list of languages. He spoke in support of the requirement for 14 languages on the notice.

Ms. Herold stated that it is common for the marketplace to take care of the language needs of its customers. She discussed the importance of communicating the notice information to the consumer, especially when their language is not on the notice.

Chair Weisser and Dr. Kajioka spoke in support of the consolidated language in sections a and b of the revised draft language (option 2).

Ms. Herold stated that adding additional notices may be less effective in communicating important information to consumers. She discussed that a pharmacy could post their label in the two different font sizes on the poster to allow the consumer to select the most appropriate label.

Mr. Room indicated that the board would have to design the new notice to consumers required in the draft and could include two designated spots for the pharmacy to attach their label.

Ms. Herold asked how Chair Weisser and Dr. Kajioka communicate with and identify the language of a non-English speaking patient as pharmacists.

Dr. Kajioka provided that he often used sign language to communicate how the patient should take their medication. He discussed that patients tend to bring a family member or friend to the doctor's office to translate. Dr. Kajioka added that this person is often responsible for picking up the medication for the patient.

Chair Weisser stated that his patients also brought a family member or friend to communicate. He discussed that pharmacies hired bilingual staff in order to service the specific language needs of their community.

Discussion continued. The committee evaluated additional means for communicating the notice information including the use of a video screen to attract more attention. Ms. Herold recommended that these alternatives be used in addition to the poster and cautioned the committee from permitting the replacement of the poster with a video screen. The committee requested samples of pamphlets currently being used in pharmacies to communicate language services.

Ms. Herold provided that the draft should be refined at the January 2011 Board Meeting as the regulation should be in place by January 1, 2011.

Dr. Kajioka provided that if the committee makes the recommendation to require the poster, there should be flexibility regarding the display of notice information on a video screen. He stated that there should be regulations regarding the use of a video screen if the committee makes the recommendation to allow for either a poster or use of a video screen.

Rosalyn Hackworth spoke in support of allowing either the poster or the video screen. She discussed that patients will be more attracted to the video screen and often do not pay attention to postings on the wall.

MOTION: Recommend to the full board to approve section (a) as written in option 2 of the draft language for consideration.

M/S: Hackworth/Kajioka

Support: 3 Oppose: 0 Abstain: 0

The committee continued its discussion with section (b) of the draft language.

Mr. Room provided that section (b) consolidates information from 4 or 5 potential notices. He stated that he believes this information will fit on one notice.

Ms. Herold expressed concern regarding the word “interpretive” as it may be confusing for some consumers.

Mr. Room provided that this word can be evaluated and modified during the regulation hearing.

MOTION: Recommend to the full board to approve section (b) as written in option 2 of the draft language for consideration.

M/S: Kajioka/Hackworth

Support: 3 Oppose: 0 Abstain: 0

The committee continued its discussion with section (c) of the draft language.

Public Comment

Mary Staples, representing the National Association of Chain Drug Stores, asked whether the board would consider producing the document in the 14 languages as required by section (c) of the draft language.

Mr. Room suggested that the board could create a pdf document for pharmacies to print from the board’s Web site.

Ms. Herold provided that the board will need to determine how many languages will be included on this document.

Chair Weisser provided that 14 languages is a good start.

Dr. Ratcliff discussed possible enforcement challenges with this document. He indicated that it will be easier to ensure compliance with a document supplied by the board.

Ms. Sodergren discussed that a 14 language requirement would be consistent with current state requirements for Medi-Cal prescriptions.

Dr. Kajioka discussed that this document may be provided by the interpreter contractor to the pharmacy.

Ms. Staples stated that a poster may not be necessary if this information is communicated to the patient at the point of service.

Mr. Room clarified that this section does not require a poster. He stated that it allows for the video screen option as well as the use of a flyer or handout.

Ms. Herold indicated that the board will have time to further discuss and evaluate this section.

There was no additional committee discussion or public comment.

2. Proposal to Initiate a Rulemaking to Update 16 CCR Section 1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge and 16 CCR 1784 Self-Assessment by a Wholesaler by the Designated Representative-in-Charge

Background

Pharmacy law requires pharmacies and wholesalers to conduct self-assessments to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms provide references to relevant laws and regulations, and also serve as an easy reference guide for the Pharmacist-in-Charge (PIC) or Designated Representative-in-Charge (DRIC).

Section 1715 of Title 16 Cal. Code of Regulations applies to the self-assessment of a pharmacy by the Pharmacist-in-Charge. The regulation was established in 1997 and was last amended in 2009. The following self-assessment forms are incorporated by reference in § 1715:

- 17M-13 (Rev 10/08) “Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment”
- 7M-14 (Rev 10/08) “Hospital Pharmacy and Self-Assessment”

Section 1784 of Title 16 Cal. Code of Regulations applies to wholesalers. This regulation was established in 2007 and was also updated in 2009. It incorporates by reference the following self-assessment form:

- 17M-26 (Rev 10/08) “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment”

Ms. Herold provided that after the conclusion of the 2009/2010 Legislative Session, board staff will draft changes to the self-assessment forms to reflect statutory changes for the board’s consideration at a future meeting in preparation for deployment on July

1, 2011. She stated that any substantive changes would be required to go through the regular rulemaking process.

Ms. Klein provided that the last amendment was done via a section 100 change. She indicated that this process is faster and less formal.

No public comment was provided.

3. Board Adopted Regulations – Approved by OAL
New 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 (effective 9/17/2010)

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

The board adopted the regulation at its January 2010 Board Meeting, and the rulemaking was submitted to the department for review in March 2010. Following department approval, the rulemaking was submitted to the Office of Administrative Law for review in July 2010; that office approved the file and filed the regulation with the Secretary of State.

Ms. Herold provided that the regulation became effective on September 17, 2010.

No public comment was provided.

4. Board Adopted Regulations – Undergoing Administrative Review
Proposed Adoption of New Section 1707.5. in Title 16 of the California Code of Regulations – Requirements For Patient-Centered Prescription Drug Container Labels

Background
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. The board received about 1,200 comments.

The board adopted the regulation text at its June 2010 Board Meeting. The rulemaking file was compiled and submitted to the Department for review in July 2010. The rulemaking file was transmitted to the Office of Administrative Law (OAL) for review on October 5, 2010. The board is utilizing "Subscriber Alert" notifications to advise subscribers of the status of the regulation. "Subscriber Alerts" were issued on August 11, August 31 and October 6, 2010. The Final Statement of Reasons and Adopted Text have been added to the board's Web site.

Ms. Herold provided that board staff expects to hear back from OAL by the end of November 2010.

No public comment was provided.

5. Board Approved Regulations – Recently Noticed (Not for Discussion at this Committee Meeting) Proposed Amendments to § 1732.2. – Board Accredited Continuing Education

Background

At the February 2010 Board Meeting, the board voted to initiate the rulemaking process to amend 16 CCR § 1732.2 related to board-accredited continuing education. The proposed text was formally noticed for comment on October 8, 2010, and the 45-day comment period concludes on November 22, 2010.

The proposed regulation would modify the term "continuing education credit" to "continuing education hours" and would add board-approved continued education for the following:

- A pharmacist serving on a designated subcommittee for conducting a review of exam test questions (up to 6 hours of CE)
- Attending a full-day board meeting (up to 6 hours annually)
- Attending a full committee meeting (up to 2 hours for each meeting, maximum of four hours annually)
- A pharmacist who completes the PSAM administered by the National Association of Boards of Pharmacy (up 6 hours of CE)
- Successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy (3 hours of CE)

The committee did not discuss this item.

6. Board Approved Regulations – Awaiting Notice
Proposed Amendments to §1728, §1728.2, and §1793.5, and Application Forms To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB/HIPDB)

Background

The Licensing Committee considered at its October 5, 2010 meeting a proposal to amend Sections 1728 and 1793.5, and a proposal to add Section 1727.2 to Title 16 of

the California Code of Regulations. The Licensing Committee has provided a recommendation to the board to initiate the rulemaking process to require that applicants, as specified in the proposal, submit to the board a Self Query Report from the National Practitioner Data Bank / Healthcare Integrity and Protection Data Bank (NPDB/HIPDB).

The committee did not discuss this item.

7. Regulations Under Development

a. Proposed Amendments to § 1746 – Emergency Contraception Protocol

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

Ms. Sodergren provided that this regulation needs to be updated to include additional manufacturers as well as to correct a typo. She indicated that updates to the Dedicated Emergency Contraception regulation will be addressed by a subcommittee or ad hoc committee to address changes to existing drugs or the inclusion of additional drugs approved since the regulation was established six years ago. Ms. Sodergren advised that any updates to the protocol are required to first be approved by the Medical Board prior to the board's initiation of a rulemaking.

Mr. Weisser suggested that the Subcommittee to Evaluate Drug Distribution Within Hospitals be redirected to address this issue.

No public comment was provided.

b. Proposed Amendments to § 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

<u>Background</u>
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.

Ms. Sodergren provided that the proposed regulation would specify the criteria the board will utilize to consider approval of accreditation agency requests. Staff is working with counsel to develop language for consideration at a future meeting.

No public comment was provided.

c. Proposed Amendments to § 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers)

Background

Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

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.

Ms. Sodergren provided an overview on the proposed amendments. She indicated that the board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

No public comment was provided.

d. Proposed Amendments to § 1785 – Self-Assessment of a Veterinary Food Animal Drug Retailer [referred to Licensing Committee]

Background

The requirements of § 1785 establish a self-assessment form for veterinary food-animal drug retailers and requires a designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Self-assessment forms also aid licensees in complying with legal requirements of their operations and, therefore, increase public safety as a result of this compliance.

In 2007, the Enforcement Committee and the board approved draft amendments to the regulation and related self-assessment form; subsequently, however, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

Chair Weisser provided that this item has been referred to the Licensing Committee. The committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. Staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

No public comment was provided.

8. Notification of Temporary Delay in Implementing New Section at Title 16 California Code of Regulation Section 1702 – Fingerprint Submissions for Pharmacists

   Chair Weisser provided that there is a temporary delay in implementing this regulation.

   Ms. Sodergren provided that some of the fingerprinting processes are being challenged. She indicated that the board may not be in a position to fully implement this requirement as a result of current workload and staffing demands. Ms. Sodergren advised that the board has moved forward with the new requirement that pharmacist applicants disclose on the renewal form whether he or she has been convicted of a crime as a condition of renewal.

   No public comment was provided.

C. First Quarterly Report on Legislation / Regulations Committee Goals for 2010/2011

Background

Each fiscal year, the board updates its strategic plan. The current plan was developed in 2007-08 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.

Ms. Sodergren provided that the updated plan was provided in the meeting materials.

No public comment was provided.

D. Request for Legislative and Regulation Changes Submitted by the Public or Staff

No proposals were submitted.

E. Public Comment for Items Not On the Agenda

No public comment was provided.

The meeting was adjourned at 3:40 p.m.

Potential Regulatory Proposal(s) re: Notices to Consumers

OPTION 1: DISCUSSED AT JULY 29, 2010 BOARD MEETING

Delete 16 CCR § 1707.2, subds. (f) and (g)

Add 16 CCR § 1707.6. Notices Required in Pharmacies.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, notices containing the text in subdivisions (b), (c), (d) and (e). The board has previously developed and distributed standardized posters for the notices that are required by subdivisions (b) and (c). The board shall similarly develop a standardized poster for the notice required by subdivision (d). For the notices required by subdivisions (b), (c), and (d), the pharmacy shall display the poster developed by the board, or a full-color duplicate thereof.

As an alternative to printed notices, the pharmacy may display one or more required notices on a video screen located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, where the video screen display meets the following requirements:

(1) The video screen is at least 30 inches, measured diagonally;

(2) The text and format of the notice(s) is the same as it would be in printed form, including the size of the notice(s), the size of the text, and the colors utilized;

(3) The text of the notice(s) remains on the screen for a minimum of 30 seconds;

(4) Where the entire text of a notice does not fit onto a single screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least 30 seconds; and

(5) No more than four minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

Staff Note: Subdivision (b) is the Notice to Consumers currently at § 1707.2, subd. (f)

(b) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

What is the name of the medicine and what does it do?

How and when do I take it - and for how long? What if I miss a dose?

What are the possible side effects and what should I do if they occur?

Will the new medicine work safely with other medicines and herbal supplements I am taking?

What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

Staff Note: Subdivision (c) is the Notice to Consumers currently at § 1707.2, subd. (g)

(c) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:

1. The medicine or device is not in stock in the pharmacy,

2. The pharmacist, based upon his or her professional judgment determines providing the item:

- is against the law,
- could cause harmful drug interaction, or
- could have a harmful effect on your health.

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

(d) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

The container label for your prescription medication contains vital information. Please take a moment to check the container label before you leave the pharmacy to be sure that:

The container label has the correct patient name;

The container label has the correct medication name and strength;

The container label has the correct directions for use; and

The container label includes the purpose or condition for which the medication was prescribed, if that information was included in the prescription.

All of these four categories of information must be clustered into one area of the label, and must appear on the label, in the order given above, in at least a 10 point font.

If you would like the text on your container label to be larger, please ask. Upon request, the pharmacy will print a label with the text for these four categories of information in at least a 12-point font. This may result in use of a larger label and/or a larger container.

If you have questions about any of the information on the label, ask the pharmacist.

(e) There shall be a notice containing the following text, repeated in English and in each of the languages for which interpretive services are available, printed in at least an 18-point boldface type in a color that sharply contrasts with the background color of the notice:

NOTICE TO CONSUMERS

It is very important that you understand the information on the container label for your prescription medication. If you have trouble reading or understanding English, this pharmacy will make interpretive services available to you in your own language.

(f) The pharmacy shall also post or provide the following statement, repeated in English and in each of the languages for which interpretive services are available, written in at least an 18-point boldface type in a color that sharply contrasts with the background color of the statement, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This statement, repeated in all available languages, may be made available by posted notice or by video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she is requesting assistance.

If the posted notice or video screen is not positioned so that a consumer can easily point to and touch the notice or video screen, the statement, repeated in all available languages, shall be made available on a cardstock flyer or handout kept within reach of consumers at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished. Such flyer/handout shall be at least 8 inches by 11 inches, on at least 8 point cardstock, which may be laminated. At least one copy of the flyer/handout shall be available at all hours that the pharmacy is open.

OPTION 2: NEW STAFF PROPOSAL BASED ON JULY 29, 2010 BOARD DISCUSSION

Delete 16 CCR § 1707.2, subds. (f) and (g)

Add 16 CCR § 1707.6. Notices Required in Pharmacies.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to give such approval to a committee or the Executive Officer. The pharmacy may also or instead display the notice on video screen(s) located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, so long as: (1) the video screen is at least 30 inches, measured diagonally; (2) The text, format, size, and colors utilized are the same as the poster-sized notice; (3) The notice remains on-screen for a minimum of sixty (60) seconds; and (4) Where the text of the notice does not fit on one screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least sixty (60) seconds.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

You may ask this pharmacy to use larger print on your prescription drug labels.

Interpretive language services will be made available to you in this pharmacy at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost or a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not in stock, or cannot be immediately provided, the pharmacy will work with you to ensure that you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text repeated in English and in each of the languages for which interpretive services are available, printed in an least an 18-point boldface type in a color that sharply contrasts with the background color of the notice, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This text shall be repeated in at least fourteen (14) languages, to include all of the non-English languages now or hereafter identified by the Medi-Cal Managed Care Division, Department of Health Care Services, for translation of vital documents, as well as any other primary languages for groups of ten thousand (10,000) or more limited-English-proficient persons in California.

The pharmacy may post this notice in paper form or on a video screen meeting the requirements of subdivision (a) if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a cardstock flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer/handout shall be at least 8 1/2 inches by 11 inches, shall be printed on durable cardstock, and may be laminated.