



Legislation and Regulation Committee

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PART 3: LEGISLATION AND REGULATION COMMITTEE

Including a report of the meeting held July 14, 2010

a. FOR INFORMATION: Update of the Legislation and Regulation Committee's Strategic Plan for 2010-11

Attachment 1

Background

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.

As part of the Organizational Development Committee Report scheduled for tomorrow, the board will be voting on the strategic plan in its entirety.

Committee Discussion/Action

The committee was provided with suggested additions to the strategic plan for consideration and discussion. Chair Schell requested that the committee members submit any changes or modifications prior to the July 2010 Board Meeting.

b. FOR INFORMATION: Fourth Quarterly Update Report on the Legislation and Regulation Committee for 2009-10

Attachment 2

ATTACHMENT 1

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<ol style="list-style-type: none">1. Secure extension of board's sunset date.2. Sponsor legislation to update pharmacy law.3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices.4. Secure statutory standards for pharmacies that compound medications.5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.10. Advocate legislation to enhance the board's enforcement activities.

<p>Objective 3.2</p>	<p>Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.</p>
<p>Measure:</p>	<p>Percentage successful enactment of promoted regulatory changes</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). 3. Make technical changes in pharmacy regulations to keep the code updated. <ul style="list-style-type: none"> Section 1706.2 criteria for abandonment of files Section 1775.4 contested citations Section 1709.1 designation of pharmacist-in-charge Section 1780 standards for wholesalers Section 1780.1 standards for veterinary food animal drug retailers Section 1781 Designated Representative certificate Section 1786 Designated Representative 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). 5. Revise and update Disciplinary Guidelines revision and update (section 1760). 6. Self-assessment of a wholesaler by the designated representative (section 1784). 7. Exempt the address of records of interns from display on the board's Web site (section 1727.1). 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. 9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2). 10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current. 11. Increase fees to keep the board's contingency fund solvent and maintain operations. 12. Secure regulatory standards for pharmacies that compound. 13. Establish an ethics course. 14. Pharmacist renewal requirements. 15. Dishonest conduct during pharmacist examination; confidentiality of exam questions. 16. Standardized, patient-centered prescription labels. 17. Update protocol for pharmacists furnishing emergency contraception (EC). 18. Board issued continuing education (CE) credit. 19. Notice to Consumers re: Patient-Centered Prescription Labels.
<p>Objective 3.3</p>	<p>Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.</p>
<p>Measure:</p>	<p>Number of areas of pharmacy law reviewed</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Initiate review of the pharmacist-in-charge requirement.

ATTACHMENT 2

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<p>1. Secure extension of board's sunset date.</p> <p><i>1st Qtr 06/07: Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</i></p> <p><i>4th Qtr 06/07: SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</i></p> <p><i>1st Qtr 08/09: SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.</i></p> <p><i>Governor signs SB 963 (Chapter 385, Statutes of 2008)</i></p> <p><i>1st Qtr 09/10: Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.</i></p> <p><i>2nd Qtr 09/10: Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.</i></p> <p><i>3rd Qtr 09/10: Sunset bills introduced</i></p> <p><i>AB 1659 (Huber) – State Government, Agency Repeals</i></p> <p><i>AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection</i></p> <p><i>SB 954 (Harmon) – Legislative Procedure, Committee Referrals</i></p> <p><i>SB 1171 (Negrete McLeod) – Regulatory Boards, Operations</i></p> <p><i>4th Qtr 09/10: SB 954 (Harmon) – Bill is dead (Failed deadline)</i></p> <p><i>SB 1171 (Negrete McLeod) – Bill is dead (Failed deadline)</i></p>

2. Sponsor legislation to update pharmacy law.

Enacted - 1st Qtr. 08/09: SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions

Oct. 2007: Board sponsors omnibus provisions for 2008. Four types of changes are discussed.

(1) Changes specific to the PIC and DRC requirements

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
- Section 4036.5 – Pharmacist-in-Charge
- Section 4161 – Nonresident wholesaler
- Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
- Section 4329 – Nonpharmacists; Prohibited Acts
- Section 4330 – Proprietors; Prohibited Acts

(2) Changes to allow for the use of mobile pharmacies

- Section 4062 – Furnishing Dangerous Drugs During an Emergency.
- Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.

(3) General changes

- Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.
- Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.
- Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.
- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) Changes based on recodification of Business and Professions Code section 4052

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

Jan. 2008:	<i>Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779.</i>
	<i>Board approved language for omnibus bill.</i>
April 2008:	<i>Some provisions of omnibus bill removed:</i>
	<ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i>
Oct. 2008:	<i>Governor vetoes SB 1779</i>
1st Qtr 08/09:	<i>Board seeks to pursue omnibus provisions (formerly contained in SB 1779).</i>
	<i>Four areas of change:</i>
	<i>(1) Changes specific to the PIC and DRC requirements</i>
	<ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i>
	<i>(2) Changes to allow for the use of mobile pharmacies</i>
	<ul style="list-style-type: none"> • <i>Section 4062 – Furnishing Dangerous Drugs During an Emergency.</i> • <i>Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.</i>
	<i>(3) General changes</i>
	<ul style="list-style-type: none"> • <i>Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.</i> • <i>Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory</i> • <i>Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.</i> • <i>Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.</i> <p><i>H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.</i></p>

(4) *Changes based on recodification of Business and Professions Code section 4052*

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

1st Qtr 08/09: *Board seeks to introduce additional changes:*

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

New Provisions

- *4200.1 – Pharmacist Examination; Remedial Education*
- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

2nd Qtr 08/09: *Provisions contained in SB 821:*

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*

New Provisions

- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

3rd Qtr 08/09: Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.

Jan. 2010: Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.

Omnibus Proposal #1:

- (1) Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)
 - §4017 – Authorized Officers of the Law
 - §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
 - §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, strike operative date of 2008)
 - §4181 – License Requirements; Policies and Procedures; Who May Dispense
 - §4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs
- (2) Amendment to update a reference to 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
- (3) Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)
 - §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
 - §4426 – Department of Health Care Services to Study Reimbursement Rates

Omnibus Proposal #2

- (1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative in Charge
- (2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)
- (3) Add §4362 – Pharmacists Recovery Program

3rd Qtr 09/10: SB 1489 introduced (Senate Business, Professions, and Economic Development Committee). Includes proposals #1 and #2, with the exception of §4362.

4th Qtr 09/10: Board establishes support position of SB 1489. SB 1489 is amended to modify §4013 – Subscriber Alert provisions for an owner of two or more pharmacies.

	<p>3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408). <i>Sep. 30, 2006:</i> Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.</p> <p>4. Secure statutory standards for pharmacies that compound medications (AB 595). <i>Aug. 2006:</i> Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future. <i>Aug. 2008:</i> Regulatory effort initiated. (See Objective 3.2, Task 12) <i>Oct. 2009:</i> Board approves regulatory language for Initial Notice. <i>Jan. 2010:</i> Office of Administrative Law approves regulation. <i>July 2010:</i> Regulation effective.</p> <p>5. Secure implementation of e-pedigrees on prescription drugs dispensed in California. <i>Sep. 2006:</i> Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations. <i>Sep. 2008:</i> Governor signs SB 1307 which delays implementation of e-pedigree.</p>
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	<p>6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.</p> <p>Oct. 2007: <i>Governor signs the following:</i> <i>AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.</i> <i>SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.</i> <i>SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.</i></p> <p><i>Governor vetoes the following:</i> <i>AB 249 (Eng) Healing Arts: Settlement Agreements.</i> <i>AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.</i> <i>AB 1025 (Bass) Professions and Vocations: Denial of Licensure.</i> <i>SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.</i></p> <p>Oct. 2008: <i>Governor signs the following:</i> <i>AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks</i> <i>SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review</i></p> <p><i>Governor vetoes the following:</i> <i>AB 501 (Swanson) Pharmaceutical Devices</i> <i>AB 865 (Davis) State Agencies</i> <i>AB1574 (Plescia) Surgical Clinics: Licensure</i></p> <p>Jan. 2009: <i>Legislation introduced affecting Pharmacy law:</i> (New Session) <i>AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.</i> <i>SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.</i></p>
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4th Qtr 08/09: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements
 AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License
 AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012
 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
 AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
 AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
 AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)
 AB 1370 (Solorio) “Best Before” Date on a Prescription Label
 AB 1458 (Davis) Drugs: Adverse Effects Reporting
 SB 26 (Simitian) Home-Generated Pharmaceutical Waste
 SB 43 (Alquist) Cultural and Linguistic Competency
 SB 238 (Calderon) Medical Information
 SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs
 SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
 SB 484 (Wright) Ephedrine Products to Schedule V
 SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews
 SB 762 (Aanestad) Professions and Vocations; Healing Arts
 AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012
 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
 AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
 AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)
 SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
 SB 484 (Wright) Ephedrine Products to Schedule V
 SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews
 SB 762 (Aanestad) Professions and Vocations; Healing Arts

1st Qtr 09/10: Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts

2nd Qtr 09/10: Governor signs SB 819 (Omnibus)
 Governor vetoes SB 820 (Omnibus)
 Governor signs SB 821 (Omnibus)
 Governor signs SB 470 (Corbett) - “Purpose”
 Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset
 Governor signs AB 931 (Fletcher) - Emergency Supplies Container
 Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia

3rd Qtr 09/10: Board considers new legislation

1. *Board of Pharmacy*
 - *AB 2104 (Hayashi) – California State Board of Pharmacy*
 - *SB 1390 (Corbett) – Prescription Container Labels*
2. *Pharmacy Practice*
 - *AB 1869 (Anderson) – Pharmacy (spot bill)*
 - *AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors*
3. *Sunset Review and Legislative Oversight Proposals*
 - *AB 1659 (Huber) – State Government, Agency Repeals*
 - *AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection*
 - *SB 954 (Harmon) – Legislative Procedure, Committee Referrals*
 - *SB 1171 (Negrete McLeod) – Regulatory Boards, Operations*
 - *SB 1172 (Negrete McLeod) – Sunset of Diversion Program*
4. *Regulation of Dangerous Drugs and Devices*
 - *AB 1455 (Hill) -- Pseudoephedrine*
 - *AB 2548 (Block) – CURES – Prescription Drug Monitoring Program*
 - *SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products*
 - *SB 1071 (DeSaulnier) – CURES*
 - *SB 1106 (Yee) – Prescribers – Dispensing of Samples*
5. *Pharmacy Licensing Issues*
 - *AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies*
 - *AB 2292 (Lowenthal) – Pharmacy: Clinics*
 - *AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program*
6. *Distribution of Needles and Syringes*
 - *AB 1701 (Chesbro) – Hypodermic Needles and Syringes*
 - *AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services*
 - *AB 2139 (Chesbro) – Solid Waste: Product Stewardship*
 - *SB 1029 (Yee) -- Hypodermic Needles and Syringes*
7. *General / Other*
 - *AB 2112 (Monning) – Prescription Record Privacy Act*

	<p>4th Qtr 09/10: Board considers additional legislation AB 1939 (Fletcher) Sharps Waste SB1111 (Negrete McLeod) DCA Enforcement Model</p> <p>Apr. 2010: Board takes positions on legislative measures: AB 1701 (Chesbro) Support AB 2104 (Hayashi) Oppose AB 2292 (Lowenthal) Support SB 1106 (Yee) Support if Amended AB 1916 (Davis) Bill is dead (failed deadline) AB 2112 (Monning) Bill is dead (failed deadline) SB 1111 (Negrete McLeod) Bill is dead (failed deadline)</p> <p>May 2010: AB 1869 (Anderson) Bill is dead (failed deadline) AB 1939 (Fletcher) Bill is dead (failed deadline)</p> <p>June 2010: SB 1390 (Corbett) Fails passage in policy committee SB 954 (Harman) Bill is dead (failed deadline) SB 1171 (Negrete McLeod) Bill is dead (failed deadline) AB 2139 (Chesbro) Bill is dead (failed deadline) AB 2292 (Lowenthal) Bill is dead (failed deadline) AB 2548 (Block) Bill is dead (Failed deadline)</p> <p>Apr./May 2010: AB 2104 (Hayashi) Amended twice</p> <p>June 2010: AB 2104 (Hayashi) Amended to authorize Board appointment of Executive Officer with approval of DCA Director.</p>
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7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.
- March 2007: Licensing Committee considers and approves concept. More work is required.*
- June 2007: Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.*
- Sept. 2007: Licensing Committee forwards to full board legislative proposal.*
- Oct. 2007: Board approved draft legislation.*
- Nov. 2007: Staff meeting with stakeholders to elicit support for the proposal.*
- Dec. 2007: Staff develop fact sheets and work with experts in immunizations.*
- Feb. 2009: Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.*
- April 2009: Bill amended to allow pharmacists to initiate and administer pneumococcal and influenza vaccines.*
- May 2009: Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)*
- Jan. 2010: Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.*
- Jan. 2010: AB 977 passes out of Assembly Health Committee
Board reaffirms "support" position.*
- April 2010: Board changes position from "sponsor" to "support".*
- June 2010: AB 977 amended to apply only to a pharmacist associated with an independent community pharmacy.*

- 8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.**
- Oct. 2007: Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.*
- Apr. 2008: First public forum held in Fremont.*
- May 2008: Staff develop survey form to distribute to consumers to solicit input
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.*
- June 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.*
- July 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.*
- Oct. 2008: Staff continues to attend community events, interview attendees about prescription label and distribute surveys.
Public Education Committee updated on the status of survey results.*
- Feb. 2009: Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.*
- May 2009: Bill passes out of the Senate*
- Oct. 2009: Governor signs SB 470 (Chapter 590, Statutes of 2009).*
- Oct. 2009: Board approves regulatory language for notice.*
- Nov. 2009: Regulatory effort initiated*
- June 2010: Board adopts final text (See Objective 3.2, Task 16)*
- 9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.**
- Dec. 2008: Board receives findings of independent fee audit.*
- Jan. 2009: Board votes to pursue fee increase.*
- Feb. 2009: Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.*
- June 2009: Bill passes out of the Assembly.*
- Sept. 2009: Bill is enrolled and sent to the Governor.*
- Sept. 2009: Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.*
- Oct. 2009: Governor signs AB 1071 (Chapter 270, Statutes of 2009)*
- Jan. 2010: Statutory fee schedule implemented (supersedes 16 CCR 1749)*
- 10. Advocate legislation to enhance the board's enforcement activities.**
- Jan. 2010: Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):
Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory.
Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.
Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation*

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 258 1471 359">1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 369 1471 506">2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i> <li data-bbox="370 516 1471 726">3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i> <li data-bbox="370 737 1471 800">4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 810 1471 911">5. Revise and update Disciplinary Guidelines revision and update (section 1760). <i>Oct. 2007: Board approves regulation for 45-day comment period.</i> <i>May 2009: Regulation and revised Disciplinary Guidelines approved and takes effect.</i> <li data-bbox="370 921 1471 984">6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 995 1471 1134">7. Exempt the address of records of interns from display on the board's Website (section 1727.1). <i>Sept. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i> <li data-bbox="370 1144 1471 1354">8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i> <li data-bbox="370 1365 1471 1547">9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2). <i>Feb. 2007: Board notices regulation for 45 days comment period.</i> <i>Nov. 2007: Regulation changes takes effect.</i> <i>Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.</i>

- 10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.**
Dec. 2007: Office of Administrative Law approves Section 100 Changes. Amend the following:
1707 – Waiver of requirements for off-site storage of records
1709.1 – Designation of pharmacist-in-charge
1715 – Self-assessment of a pharmacy by the pharmacist-in-charge
1717 – Pharmacy practice
1746 – Emergency contraception
1780.1 – Minimum standards for veterinary food-animal drug retailers
1781 – Exemption certificate
1787 – Authorization to distribute dialysis drugs and devices
1790 – Assembling and packaging
1793.8 – Technician check technician
Repeal section 1786 – Exemptions
March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.
- 11. Increase fees to keep the board's contingency fund solvent and maintain operations.**
Nov. 2007: Office of Administrative Law approves rulemaking.
Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.
Jan. 1, 2008: New fees take effect.
Oct. 2009: Governor signs AB 1071, new fee schedule.
Jan. 2010: Statutory fee schedule becomes effective (supersedes 16 CCR §1749)
- 12. Secure regulatory standards for pharmacies that compound. (§1735 et al)**
Nov. 2007: Board releases language for the 45-day comment period.
Sep. 2008: Board releases (withdrawn) language for 45-day comment period.
Oct. 2008: Regulation hearing
Jan. 2010: Office of Administrative Law approves regulation.
July 2010: Regulation and Self-Assessment Form 17M-39 is effective. Board staff developing fact sheet for pharmacies.
- 13. Establish an ethics course (§1773 and §1773.5).**
Sep. 2008: Board notices regulation for 45-day comment period.
Sep. 2009: Regulation takes effect.
- 14. Pharmacist Renewal Requirements (§1702).**
Dec. 2009: Board notices regulation for 45-day comment period.
Feb. 2010: Board adopts regulation.
June 2010: Office of Administrative Law approves regulation (to be effective Dec. 2010)
- 15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions (§1721 and §1723.1).**
Oct. 2009: Board notices regulation for 45-day comment period.
Jan. 2010: Board adoption of regulation as noticed.
July 2010: Rulemaking submitted to the Office of Administrative Law for review.

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| | <p>16. Standardized, Patient-Centered Prescription Labels
 <i>Oct. 2009: Board approves language to initiate rulemaking.</i>
 <i>Nov. 2009: Board notices regulation for 45-day comment period.</i>
 <i>Jan. 2010: Regulation hearing.</i>
 <i>Feb. 2010: Board modifies text of regulation.</i>
 <i>Board notices modified text for 1st 15-day comment period.</i>
 <i>Apr. 2010: Board modifies text of regulation.</i>
 <i>Board notices modified text for 2nd 15-day comment period.</i>
 <i>June 2010: Board adopts regulation language noticed on April 28.</i>
 <i>July 2010: Rulemaking submitted to Department for review.</i></p> <p>17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (\$1746)
 <i>Jan. 2010: Board approves language to initiate rulemaking to correct a typographical error in the Emergency Contraception Protocol regulation.</i></p> <p>18. Board Issued Continuing Education (CE) Credit (\$1732.2)
 <i>Feb. 2010: Board votes to amend section 1732.2 defining board-issued CE and notice regulation for 45-day comment period.</i></p> <p>19. Notice to Consumers re: Patient-Centered Prescription Labels
 <i>Apr. 2010: Board directs staff to bring regulatory language to the July 2010 meeting re: increased font size, and language services.</i></p> <p>20. Update references to USP Standards (\$1780)
 <i>1st Qtr 07/08: Board considers review of USP references.</i>
 <i>2nd Qtr 07/08: Subcommittee established to conduct full review of USP updates needed.</i></p> <p>21. Veterinarian Food-Animal Drug Retailer Self-Assessment (\$1785)
 <i>1st Qtr 07/08: Board approves regulation for notice.</i>
 <i>2nd Qtr 07/08: Work on rulemaking stopped to allow for comprehensive review of Veterinary Food-Animal Drug Retailer Program.</i></p> <p>22. Accreditation Agencies for Pharmacies that Compound (\$1751.x)
 <i>1st Qtr 07/08: Board approves regulation text for notice (upon additional review by counsel, modification of language is necessary prior to notice of proposed text)</i></p> |
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Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007:</i> Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</p> <p><i>Oct. 2007:</i> Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</p> <p><i>Jan. 2008:</i> Board approves omnibus language recommended by Legislation and Regulation Committee.</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p><i>April 2008:</i> The following provisions are not incorporated into omnibus bill.</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked <p><i>Sept. 2008:</i> Governor vetoes SB 1779.</p> <p><i>Jan. 2009:</i> Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821. Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.</p> <p><i>Sept. 2009:</i> SB 819 and SB 821 enrolled and sent to the Governor.</p> <p><i>Oct. 2009:</i> Governor signs SB 819 and SB 821. Provisions go into effect January 2010.</p>

ATTACHMENT 3



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
Rosaly n 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/Hack worth

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/Hack worth

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.