

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.

<p>Objective 3.1</p>	<p>Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.</p>
<p>Measure:</p>	<p>100 percent successful enactment of promoted legislative changes</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Secure extension of board's sunset date (SB 1476). <i>Sept. 30, 2006: 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> 2. Sponsor legislation to update pharmacy law (SB 1475). <i>Sept. 30, 2006: Governor signs SB 1475 containing provisions that:</i> <ol style="list-style-type: none"> (a) <i>Allow a check-off box on electronic prescriptions that if marked by a prescriber, would prevent generic substitution at a pharmacist's discretion (B&P 4073).</i> (b) <i>Clarify requirements for reporting to the board when a licensee is impaired to the extent it affects the licensee's safe practice or who has stolen or diverted drugs (B&P 4104).</i> (c) <i>Establish the authority to issue a temporary sterile injectable compounding license following a change in ownership (B&P 4127.8)</i> (d) <i>Exempt government-owned wholesalers from having to post a \$100,000 bond (B&P 4162).</i> (e) <i>Exempt drug manufacturers who hold a biologics license application from the FDA from having to post a \$100,000 bond otherwise required for nonresident wholesalers (B&P 4162.5).</i> (f) <i>Make technical changes in the licensure requirements for clinics (B&P 4180 - 4182, 4190 - 4192).</i> 3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408). <i>Sept. 30, 2006: 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.</i> 4. Secure statutory standards for pharmacies that compound medications (AB 595). <i>Aug. 2006: 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> <i>Dec. 2006: Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.</i>

	<p>5. Secure implementation of e-pedigrees on prescription drugs dispensed in California (SB 1476). <i>Sept. 30, 2006: 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></p>
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"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). <i>Aug. 2006: Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.</i> <i>Nov. 2006: Rulemaking file submitted to the office of Administrative Law</i> 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). <i>Aug. 2006: Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.</i> <i>Jan. 2007: Regulation takes effect following approval by the office of Administrative Law.</i> <i>Jan. 4, 2007: Regulation takes effect approved by the office of Administrative Law.</i> 3. Make technical changes in pharmacy regulations to keep the code updated. Section 1706.2 criteria for abandonment of files <i>Dec. 2006: Board notices regulation for 45 days of public comment.</i> Section 1775.4 contested citations <i>Dec. 2006: Board notices regulation for 45 days of public comment.</i> 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-exemption certificate Section 1786 exemptions 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). <i>July 2006: Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting.</i> <i>Oct. 2006: Board approves regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration review.</i> 5. Revise and update Disciplinary Guidelines revision and update (section 1760). <i>Aug. 2006: Final changes to Disciplinary Guidelines being compiled by staff.</i> <i>Dec. 2006: Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.</i> 6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>July 2006: Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting.</i> <i>Oct. 2006: Board approves regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration review.</i>

	<p>7. Exempt the address of records of interns from display on the board's Web site (section 1727.1). <i>Sept. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i></p> <p>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></p>
Objective 3.3	Review 5 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:	