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LEGISLATION AND REGULATION COMMITTEE REPORT

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LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee did not meet this quarter.

Part 1: LEGISLATION REPORT

a. Board Sponsored Legislation

A copy of each sponsored bill is provided in **Attachment 1**.

1. AB 1073 (Ting) Pharmacy: Prescription Drug Labels
   Version: Amended July 8, 2015
   Location: Senate Appropriations
   Status: Hearing scheduled for August 17
   Summary: Assembly Bill 1073 would require dispensers to use a standardized direction for use on a label of a prescription container when applicable and would permit a dispenser, upon request, to select the appropriate translated directions for use from the board's web site to include on the prescription label or on supplemental information. The bill also allows for a dispenser to provide his or her own translated directions. Drugs dispensed by a veterinarian are exempt from providing translated directions for use, and the bill makes conforming changes to section 4199 BPC for this purpose.
   The board's Executive Officer testified in support of the bill in Senate Judiciary Committee on July 6. The bill passed out of committee and was referred to Senate Appropriations Committee where it is scheduled to be heard on August 17.

2. SB 590 (Stone) Pharmacy: Intern Licenses
   Version: Amended April 22, 2015
   Location: Assembly Floor (consent as of July 9)
   Summary: This measure would amend Business and Professions Code section 4209 to streamline the application process for graduates from an ACPE accredited school or

school of pharmacy recognized by the board for purposes of confirming completion of the required pharmacy practice experience requirements. This bill was amended April 22, 2015 to address some concerns from the California Pharmacy Council and successfully passed out of the Senate.

Recent Update: The measure passed out of the Assembly Committee on Business, Professions and Consumer Protection on June 23 and thereafter was heard and passed out of Assembly Appropriations on consent (July 8). As of July 9, the bill was on the Assembly Floor consent calendar.

3. SB 619 (Morrell) Pharmacy: Outsourcing Facilities: Licensure
Version: Amended April 6, 2015
Location: Senate Appropriations (held on suspense)

Summary: Senate Bill 619 would have established the regulatory framework for licensure of outsourcing facilities that would compound non-patient specific medications for administration to California patients.

Recent Update: As reported to the board in June, the bill was held on suspense in Senate appropriations. Thus, the bill will need to be reintroduced next year.

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

Unless otherwise noted, a copy of each bill in its current form and related analysis, if applicable, are provided in **Attachment 2.**

1. AB 45 (Mullin) Household Hazardous Waste *(2-Year Bill)*
Version: Amended April 30, 2015
Location: Asm Appropriations
Status: On suspense file (2-Year Bill)
Board Position: Oppose Unless Amended

Summary: AB 45 is now a 2-year bill. AB 45 states that it is the intent of the Legislature to enact legislation that would establish various household hazardous waste collection programs, including curbside, door-to-door and residential pickup services as a principal means of collection such waste and diverting it from California's landfills and waterways. This measure would require each jurisdiction that provides for residential collection and disposal of solid waste, including household pharmaceutical waste, to increase its collection and diversion of such waste by 15% by July 1, 2020 unless otherwise specified. Board staff offered amendments to require the use of mail-back programs unless the jurisdiction complies with the provisions of federal law relating to the safe collection and disposal of such waste, but our amendment was not accepted. Board staff has continued to try to find a workable solution, and the board's Enforcement Committee has begun discussions on the matter.

2. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels
   Status: On Third Reading File – Senate Floor
   Board Position: Support

   Summary: AB 486 would provide an alternative method to maintain certain medication information that shall be readable at the patient's bedside, either via a barcode scan or human-readable, for unit dose medications prepared in a centralized hospital packaging facility. AB 486 contains an urgency clause, which would enact the provisions upon signature by the Governor and the filing with the Secretary of State.

   Recent Update: The bill is currently on the Senate Third Reading File.

3. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
   Version: Amended July 1, 2015
   Location: Senate Appropriations
   Status: Hearing – August 17
   Board Position: Oppose Unless Amended

   Summary: AB 1069 would expand the provisions under which a county established repository and distribution program allow the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

   Recent Update: Board staff, working with the author's office, has secured some amendments to address many of the legal conflicts the measure initially contained. There are still some concerns with the bill in its current form. Currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a "participating entity" to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources … all to the detriment of patient safety. Staff continues to work with the author's office.

4. SB 671 (Hill) Biosimilar Drug Substitution
   Version: As Amended June 23, 2015
   Location: Assembly Floor – Second Reading *(7/16)*
   Board Position: Oppose Unless Amended *(4/14/15)*

   Summary: SB 671 would authorize a pharmacist, in his or her discretion (except when the prescriber has specified "Do not substitute" or words to that effect), where there is an identically priced or cheaper alternative interchangeable biosimilar, to select the alternative biological product when filling a prescription order for a prescribed biological product. The measure requires the pharmacist, within a specified period of time after

dispensing, to notify the prescriber of exactly what was dispensed. The most recent version of the bill allows for such communication to be entered into an electronic system, as specified.

Given the most recent amendments, staff requests the board's direction as to whether or not the board's position should be modified.

c. Legislation Impacting Board Operations **Attachment 3**

1. AB 12 (Cooley) State Government: Administrative Regulations Review
   Version: Amended April 30, 2015
   Location: Senate Appropriations
   Status: Hearing set for August 17
   Board Position: Oppose

   Summary: Assembly Bill 12 would require state agencies and departments to review, adopt, amend, or repeal any application regulations that are duplicative, overlapping, inconsistent, or out of date by January 1, 2018. The measure also would establish notice and reporting requirements.

   The board has determined that AB 12 would have a significant impact to its current operations. Given the complexity of the board's regulatory structure, board staff has concerns that the board would not be able to achieve compliance within the time allotted for completion of the review (2 years), without having a significant impact on other areas of the board's operations.

2. AB 85 (Wilk) Open Meetings
   Version: As Amended April 15, 2015
   Location: Asm Appropriations
   Status: Appropriations Suspense File
   Board Position: Oppose

   Summary: According to the author, this measure is intended to clarify language within the Bagey-Keene Open Meeting Act by stating that when an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body is acting in an official capacity of a state body, the entity (regardless of the committee size) is subject to the Open Meeting Act.

   Board staff advised the author's office of our position as well as the reason for the opposition. At the request of the author, board staff offered technical changes that would have addressed some of the concerns with the measure, but they were not accepted. The author's office has indicated a willingness to address the board's concern, but a solution has not yet been identified.

3. AB 1060 (Bonilla) (No longer impacts Professions and Vocations / Licensure)
   Version: As Amended June 17, 2015

   For Information Only: The prior version of AB 1060 would have required the board to advise an ex-licensee with certain information via first-class mail and by email if the board had an email address on file for the ex-licensee. The board had an oppose position on the measure.

   Recent Update: The bill was gutted and no long impacts the board or its jurisdiction. No analysis is provided.

5. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
   Version: As Introduced February 23, 2015
   Location: Senate Appropriations *(7/15)*
   Board Position: Oppose (as Introduced 2/27/15)

   Summary: This measure would change the existing deferred entry of judgment program into a pretrial diversion program. Under the pretrial diversion program created by this bill, a defendant qualifies if they have no prior conviction for any offense involving controlled substances (other than the offense that qualifies for the program), the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies for the program) and the defendant has no prior conviction for a serious or violent felony in the five years prior to the alleged commission of the charged offense.

   The bill has the potential to significantly increase the board's costs of prosecution or lead to the dismissal of certain disciplinary charges, to the detriment of public safety. This is because the changes proposed will allow defendants to not plead guilty. This means the Board won't be able to use a guilty plea as an admission of guilt, and when a defendant participates in a pretrial diversion program, the board can't consider that an admission of guilt.

   Recent Update: Staff continues to try and work with the author's office to identify language that could resolve the board's concerns. Earlier amendments offered were rejected.

   Staff recommends that the board change its position to "Oppose Unless Amended" and that staff be directed to continue to engage with the author's office.

6. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea
   Version: As Amended May 19, 2015
   Location: Senate Appropriations
   Status: Hearing – August 17
   Board Position: Oppose *(2/27/15)*

Summary: This measure would require a court to allow a defendant who was granted deferred entry of judgment on or after January 1, 1997, after pleading guilty or nolo contendere to the charged offense, to withdraw his or her plea and enter a plea of not guilty if the charges were dismissed after the defendant performed satisfactorily during the deferred entry of judgment period and the defendant shows that the plea may result in the denial or loss to the defendant of any employment, benefit, license, or certificate, including, but not limited to, causing a noncitizen defendant to potentially be found inadmissible, deportable, or subject to any other kind of adverse immigration consequence.

This bill adds to the Penal code in such a way as to strongly impact the Board's ability to prove in disciplinary proceedings that a licensee or applicant is engaged, or has been engaged, in illicit drug activities. The bill is likely to increase the board's costs of prosecution or could lead to the dismissal of certain disciplinary charges, to the detriment of public safety. The changes proposed will allow a defendant to change a prior guilty plea, and since no guilty plea will be made going forward to get into the pretrial diversion program, the Board can't view participation in the pretrial diversion program as an admission of guilt.

Staff does not recommend any change to the board's position.

d. Other Pieces of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

During the meeting the board may hear comments on measures involving the regulation of prescription drugs and/or controlled substances; application, licensing and renewal requirements for board licensees; authorities granted to board licensees; measures adding, modifying or removing requirements that impact the board and its operations or that of the Department of Consumer Affairs.

Part 2: REGULATION REPORT

a. Board Approved – Awaiting Administrative Review

1. Proposal to Amend Title 16 California Code of Regulations (CCR) Section 1793.5 Pharmacy Technician Application

   At the July 2014 Board meeting, the board approved a proposal to amend Title 16 CCR section 1793.5 to change the wording of the criminal conviction question on the Pharmacy Technician Application to be consistent with the wording on the Pharmacist application. The Pharmacy Technician Application is incorporated by reference in the

regulation. The rulemaking was initiated in February, and a 15-day comment period ran from May 26, through June 15, 2015. No comments were received in response to the 15-day comment period; thus, in accordance with the board's motion, the regulation was adopted and the final rulemaking file is being prepared for submission to the Department of Consumer Affairs to start the review process.

A copy of the adopted text text is provided in **Attachment 4**.

b. Board Approved – Recently Noticed

The text of each proposed regulation is provided in **Attachment 5**.

1. Proposal to Amend Title 16 CCR Sections 1784 and 1751 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

   At the October 2014 Board Meeting, the board directed staff to initiate the formal rulemaking to amend the text of 16 CCR sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by reference in those sections. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s). The 45-day comment period began on March 20, 2015 and ended on May 6, 2015. Due to issues with the Notice, a second 45-day comment period began May 29, 2015 and ended July 13, 2015. No negative comments were received and, in accordance with the board's motion, board staff is compiling the final rulemaking file for submission to the Department of Consumer Affairs to begin the administrative review process.

2. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text to Add Title 16 CCR Section 1746.2 Nicotine Replacement Products

   At the January 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 CCR section 1746.5 for Nicotine Replacement Products. The 45-day comment period began on May 8 and ended on June 22, 2015, during which time the board received four comments.

   A copy of the noticed text and the comments received is provided in Attachment 5. If the board does not believe any changes are necessary to the regulation text in response to the comments, staff would recommend that the board direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.2, as noticed.

3. Discussion and Possible Action to Make Changes in Response to Comment or to Adopt or Amend Proposed Text to Add Title 16 CCR Section 1746.3 Naloxone Hydrochloride

   At the January 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 CCR section 1746.3. The 45 day comment period began on May 22, 2015 and ended on July 13, 2015, and the board received one comment in response to the noticed text.

   A copy of the noticed text and the comment received is provided in Attachment 5. If the board does not believe any changes are necessary to the regulation text in response to comment, staff would recommend that the board direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.3, as noticed.

4. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 CCR Section 1746.1 Self-Administered Hormonal Contraception

   At the March 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 CCR section 1746.1 for Self-Administered Hormonal Contraception. The 45-day comment period began on May 8 and ended on June 22, 2015.

   A copy of the noticed text, comments received, and a staff summary and possible board responses to the comments are provided in Attachment 5 for the board's review and discussion.

   If the board does not believe any changes are necessary to the regulation text in response to comments, staff would recommend that the board direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.1, as noticed.

c. Board Approved – Awaiting Notice

A copy of each proposal, as approved by the board for public notice, is provided in **Attachment 6**.

1. Combined Rulemaking – Proposal to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

   At the July 2013 Board Meeting, the board approved proposed text to amend sections 1702 and 1702.5 and to add Sections 1702.1 and 1702.2 to Title 16 CCR. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

2. Combined Rulemaking – Proposal to Amend Title 16 CCR Sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education

   In 2013, the board approved a proposal to initial a formal rulemaking to amend the text of Title 16 CCR sections 1732.05, 1732.2, and 1732.5 relative to continuing education. At the October 2014 board meeting, the board discussed and thereafter voted to add "compounding education" as a sixth area of subject-specific continuing education in Section 1732.5. At the April 2015 board meeting, the board discussed and thereafter voted to add "Including Indicated of Red Flags and a Pharmacist's Corresponding Responsibility" to area five "Substance Abuse." Staff is preparing the required notice documents and will be noticing these proposals as a combined rulemaking.

3. Proposal to Amend Title 16 CCR Section 1703 Related to "Section 100" Regulatory Actions

   At the October 2013 Board Meeting, the board approved a proposal to amend Title 16 CCR section 1703 to delegate to the Executive Officer the authority to initiate a rulemaking to adopt "changes without regulatory effect." Staff is preparing the required notice documents.

4. Proposal to Amend Title 16 CCR Section 1707.5 Related to Written Language Translations

   At the January 2015 Board Meeting, the board approved proposed text to amend section 1707.5(d) of Title 16 CCR. Staff is preparing the required notice documents.

5. Proposal to Add Title 16 CCR Section 1730 Related to Advanced Practice Pharmacist

   At the June 2015 Board Meeting, the board approved proposed text to add section 1730 to Title 16 CCR related to Advanced Practice Pharmacist. This proposal is part of the SB 493 implementation. Staff is preparing the required notice documents.

6. Proposal to Add Title 16 CCR Section 1746.4 Related to Immunizations

   At the June 2015 Board Meeting, the board approved a proposal to add section 1746.4 to Title 16 CCR related to Immunizations. This proposal is part of the SB 493 implementation. On July 24, 2015, this regulation will be noticed and is scheduled to be

published in the California Notice Registry. The 45-day comment period will run from July 24 through September 7, 2015.

7. Proposal to Add Title 16 California Code of Regulations Section 1746.5 Related to Travel Medications

   At the June 2015 Board Meeting, the board approved proposed text to add section 1746.5 to Title 16 CCR related to Travel Medications. This proposal is part of the SB 493 implementation. Staff is preparing the required notice documents.

8. Proposal to Amend Title 16 California Code of Regulations Section 1744 Related to Drug Warnings

   At the April 2015 Board Meeting, the board approved proposed text to amend Section 1744 of Title 16 CCR. This proposal is part of the SB 493 implementation. Staff is preparing the required notice documents.

Attachment 1

AMENDED IN SENATE APRIL 22, 2015

SENATE BILL No. 590

Introduced by Senator Stone

February 26, 2015

An act to amend Section 4209 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 590, as amended, Stone. Pharmacy: intern pharmacists.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy within the Department of Consumer Affairs and sets forth its powers and duties over the licensing and regulation of the practice of pharmacies, pharmacists, intern pharmacists, and pharmacy technicians. A knowing violation of these provisions is a crime.

Existing law requires an intern pharmacist to complete 1,500 hours of pharmacy practice or intern experience before applying for the pharmacist licensure examination. Existing law authorizes an applicant for examination who has been licensed as a pharmacist in any state for at least one year to submit certification to satisfy the required 1,500 hours ~~or~~ *of* intern experience if that applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist.

This bill would instead require, for all applicants, that 900 hours of the 1,500 required pharmacy practice experience include experience in a pharmacy, including experience in both a community and institutional pharmacy practice setting.

Existing law requires the pharmacy practice to comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education (ACPE) or with regulations adopted by the board.

Existing law requires an intern pharmacist to submit proof of his or her experience under penalty of perjury.

This bill would require that an applicant for the licensure examination who has graduated after January 1, 2016, from an ~~ACPE-approved~~ *ACPE accredited* college of pharmacy or ~~department~~ *school* of pharmacy ~~of a university~~ recognized by the board, be deemed by the board to have satisfied the ~~1,500~~ *required* hours of pharmacy practice ~~experience.~~ *experience, as specified.*

By expanding the scope of an existing crime, this bill would create a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4209 of the Business and Professions Code is amended to read:

4209. (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice experience before applying for the pharmacist licensure examination.

(2) This pharmacy practice experience shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education (ACPE) or with regulations adopted by the board.

(3) This pharmacy practice experience shall include 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and shall include pharmacy practice experience in both a community and institutional pharmacy practice setting.

(b) An intern pharmacist shall submit proof of his or her pharmacy practice experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision the experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Pharmacy practice experience earned in another state may be

certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of pharmacy practice experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and has pharmacy practice experience in both a community and institutional pharmacy practice setting. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

(d) An applicant for the examination who has graduated after January 1, 2016, from an ~~ACPE-approved~~ *ACPE accredited* college of pharmacy or ~~department~~ *school* of pharmacy ~~of a university~~ recognized by the board shall be deemed to have satisfied the ~~1,500 hours of~~ pharmacy practice ~~experience.~~ *experience requirements specified in subdivisions (a) and (b).*

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AMENDED IN SENATE APRIL 6, 2015

SENATE BILL No. 619

Introduced by Senator Morrell
(Coauthor: Senator Stone)

February 27, 2015

~~An act to amend Section 14105.455 of the Welfare and Institutions Code, relating to Medi-Cal.~~ *An act to amend Section 4400 of, to add Section 4034 to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 619, as amended, Morrell. ~~Medi-Cal.~~ *Pharmacy: outsourcing facilities: licensure.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. The law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board, and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding. Existing law provides that fees collected on behalf of the board are credited to the Pharmacy Board Contingent Fund, a continuously appropriated fund.

This bill would require the board to license an outsourcing facility, as defined, and would prohibit an outsourcing facility to be concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill would require an outsourcing facility to be licensed with the board before doing business within or into the state, and would

require an outsourcing facility to, among other things, notify the board of any disciplinary or other action taken by another state or the federal Food and Drug Administration within 10 days of the action. The bill would require the board to, among other things, inspect the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations before issuing or renewing an outsourcing facility's license. The bill would make a violation of any of these provisions or regulations adopted thereto punishable by a fine of up to $5,000 per occurrence. The bill would, on or after January 1, 2018, require the board to provide a report, as specified, to the Legislature regarding the regulation of nonresident outsourcing facilities. The bill would also authorize the board to collect a fee of $780 for the issuance and renewal of an outsourcing license and a fee of $715 for a temporary license, as specified. By increasing the amount of money deposited into a continuously appropriated fund, the bill would make an appropriation.

~~Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services, including pharmacy services and drugs. Existing law requires pharmacy providers to submit their usual and customary charge when billing the Medi-Cal program for prescribed drugs.~~

~~This bill would make a technical, nonsubstantive change to that provision.~~

Vote: majority. Appropriation: ~~no~~ *yes*. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4034 is added to the Business and Professions Code, to read:

4034. "Outsourcing facility" means a facility that meets all of the following:

(a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.

(b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

(c) Is doing business within or into California.

(d) Is licensed with the board as an outsourcing facility.

SEC. 2. Article 7.7 (commencing with Section 4129) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.7. Outsourcing Facilities

4129. (a) An entity licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for patients or practitioners within or into California. A product compounded by an outsourcing facility shall be distributed without a patient-specific prescription.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location. A sterile compounding pharmacy compounds and dispenses pursuant to a prescription.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after the release in order to determine whether revisions are necessary for any regulations.

(e) An outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients, within the outsourcing facility. Patient-specific compounding shall be performed only by a licensed pharmacy. An outsourcing facility shall not be located in the same licensed premises as a pharmacy.

4129.1. (a) An outsourcing facility that is licensed with the FDA and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within or into this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with current federal good manufacturing practices.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all inspection reports of the outsourcing facility's premises conducted in the prior 12 months.

(3) Receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) Notice within 24 hours after learning of adverse effects reported or potentially attributable to an outsourcing facility's products.

4129.2. (a) An outsourcing facility that is licensed with the FDA as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for shipment into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products in compliance with current federal good manufacturing practices.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse

the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:

(1) Reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all inspection reports of the nonresident outsourcing facility's premises conducted in the prior 12 months.

(3) Receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.

(e) A nonresident outsourcing facility licensed pursuant to this section shall do all of the following:

(1) Provide the board with a copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Provide the board notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.

(3) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(f) A nonresident outsourcing facility shall provide to the board notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility's products.

4129.3. (a) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident outsourcing facilities. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident outsourcing facilities.

(2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules, regulations, or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident outsourcing facilities as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(b) The requirement for submitting a report imposed under subdivision (a) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

4129.4. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section is unprofessional conduct.

4129.5. Notwithstanding any other law, a violation of this article, or regulation adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to five thousand dollars ($5,000) per occurrence pursuant to a citation issued by the board.

4129.6. For purposes of this article, "sterile compounded products" means compounded preparations for injection administration into the eye, or inhalation.

4129.8. The board, at its discretion, may issue a temporary license to an outsourcing facility when the ownership of the outsourcing facility is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licenseholder or service by certified mail with return receipt requested at the licenseholder's address of record with the board. The temporary licenseholder shall not be deemed to have a vested property right or interest in the license for purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.

4129.9. (a) An outsourcing facility licensed pursuant to Section 4129.1 or 4129.2 that issues a recall notice for a sterile drug or nonsterile drug compounded by the outsourcing facility, in addition to any other duties, shall contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 24 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber and the prescriber shall ensure the patient is notified.

(2) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy and that pharmacy shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

SEC. 3. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars ($200) and may be increased to two hundred sixty dollars ($260).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than

two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars ($125) and may be increased to one hundred sixty-five dollars ($165).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section

4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars ($80) and may be increased to one hundred five dollars ($105). The fee for renewal of a pharmacy technician license shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars ($405) and may be increased to four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two

hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars ($780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

~~(w) This section shall become operative on July 1, 2014.~~

(w) The fee for issuance or renewal of a nongovernmental outsourcing facility license shall be seven hundred eighty dollars ($780). The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance or renewal of a nonresident outsourcing facility license shall be seven hundred eighty dollars ($780). In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice

for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

~~SECTION 1. Section 14105.455 of the Welfare and Institutions Code is amended to read:~~

~~14105.455. (a) Pharmacy providers shall submit their usual and customary charge when billing the Medi-Cal program for prescribed drugs.~~

~~(b) "Usual and customary charge" means the lower of either of the following:~~

~~(1) The lowest price reimbursed to the pharmacy by other third-party payers in California, excluding Medi-Cal managed care plans and Medicare Part D prescription drug plans.~~

~~(2) The lowest price routinely offered to any segment of the general public.~~

~~(c) Donations or discounts provided to a charitable organization are not considered usual and customary charges.~~

~~(d) Pharmacy providers shall keep and maintain records of their usual and customary charges for a period of three years from the date the service was rendered.~~

~~(e) Payment to pharmacy providers shall be the lower of the pharmacy's usual and customary charge or the reimbursement rate pursuant to subdivision (b) of Section 14105.45.~~

~~(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.~~

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AMENDED IN SENATE JULY 8, 2015

AMENDED IN SENATE JUNE 9, 2015

AMENDED IN ASSEMBLY APRIL 28, 2015

AMENDED IN ASSEMBLY APRIL 6, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1073

Introduced by Assembly Member Ting

February 27, 2015

An act to *amend Section 4199 of, and to* add Section 4076.6 ~~to~~ *to,* the Business and Professions Code, ~~and to add Section 1714.20 to the Civil Code,~~ relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1073, as amended, Ting. Pharmacy: prescription drug labels.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Existing regulations of the board implement that ~~requirement.~~ *requirement, establishing standardized directions for use to be used when applicable, and requiring that the board publish on its Internet Web site translation of those directions for use into at least 5 languages other than English.* A violation of that law is a crime.

This bill would require a dispenser, ~~in his or her professional judgment, to use a standardized direction for use on the label of the prescription container from a list in existing regulations. The bill would~~

~~require the board to make available translations, in a minimum of 5 languages other than English, of those standardized directions for use and post the translated standardized directions for use on its Internet Web site. This bill would require the board to allow a dispenser 180 days to implement changes to translated standardized directions as may be adopted by the board. The bill would require a dispenser, upon request of a patient for a translated direction for use, to select the appropriate translated standardized direction for use, if available, and append it to the label on the patient's prescription container or provide it on a supplemental document. The bill would authorize a dispenser to provide his or her own translated directions, in any language other than English, as an alternative to the translations made available by the board and the above-described procedure.~~ *excluding a veterinarian, upon the request of a patient or patient's representative, to provide translated directions for use as prescribed. The bill would authorize a dispenser to use translations made available by the board pursuant to those existing regulations. The bill would make a dispenser responsible for the accuracy of English-language directions for use provided to the patient.* By imposing new requirements on dispensers, the violation of which would be a crime, this bill would impose a state-mandated local program.

~~The bill would exempt from civil liability a dispenser who complies with the requirement to select the appropriate translated standardized direction for use, if available, and append it to the label, for any error that results from the inability of the dispenser to understand a translated direction for use in a language other than English.~~

The Pharmacy Law also provides for the licensure and regulation of veterinary food-animal drug retailers by the board. That law subjects to specific prescription drug labeling requirements any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food-producing animals from a veterinary food-animal drug retailer pursuant to that law.

This bill would also subject any veterinary food-animal drug so dispensed to the above drug labeling requirements relating to standardized directions for use.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

~~SECTION 1. Section 4076.6 is added to the Business and Professions Code, to read:~~

~~4076.6. (a) For all dangerous drugs dispensed to patients in this state, when applicable and in the professional judgment of the dispenser, a dispenser shall use a standardized direction for use on the label of the prescription container from the list in subdivision (a) of Section 1707.5 of Title 16 of the California Code of Regulations.~~

~~(b) The board shall make available translations, in a minimum of five languages other than English, of the standardized directions for use that are listed in subdivision (a) of Section 1707.5 of Title 16 of the California Code of Regulations. These translations shall be approved by qualified translators, as determined by the board. The board shall post these translated standardized directions for use on its Internet Web site. The board shall allow a dispenser a period of 180 days from the date of adoption by the board of any change to the translated standardized directions for use to implement that change.~~

~~(c) Upon the request of a patient for a translated direction for use, a dispenser shall select the appropriate translated standardized direction for use from those established in accordance with subdivision (b), if available, and append it to the label on the patient's prescription container or provide it on a supplemental document. If a translated direction for use appears on a prescription container label, the English version of the direction shall also appear on the container. The translated direction for use shall appear in the patient-centered area of the label in accordance with subdivision (a) of Section 1707.5 of Title 16 of the California Code of Regulations. The English version may appear in an area of the label outside the patient-centered area.~~

~~(d) A dispenser may provide his or her own translated directions, in any language other than English, as an alternative to the translations made available by the board and the procedure established in subdivisions (a) to (c), inclusive. The translated directions for use shall appear in the patient-centered area of the~~

~~label in accordance with subdivision (a) of Section 1707.5 of Title 16 of the California Code of Regulations or a supplemental document. If a translated direction for use appears on a prescription container label, the English version of the direction shall also appear on the container. The English version may appear in other areas of the label outside the patient-centered area.~~

~~SEC. 2. Section 1714.20 is added to the Civil Code, immediately following Section 1714.2, to read:~~

~~1714.20. (a) A dispenser who complies with subdivision (c) of Section 4076.6 of the Business and Professions Code shall not be liable for civil damages for any error that results from the inability of the dispenser to understand a translated direction for use in a language other than English.~~

~~(b) This section does not affect existing liability under this division for translated directions not approved by the California State Board of Pharmacy.~~

SECTION 1. Section 4076.6 is added to the Business and Professions Code, to read:

4076.6. (a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document.

(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.

(c) A dispenser shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.

(d) Nothing in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient.

(f) For purposes of this section, a dispenser does not include a veterinarian.

SEC. 2. Section 4199 of the Business and Professions Code is amended to read:

4199. (a) Any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food producing animals from a veterinary food-animal drug retailer pursuant to this chapter is subject to the labeling requirements of Sections ~~4076~~ *4076, 4076.6,* and 4077.

(b) All prescriptions filled by a veterinary food-animal drug retailer shall be kept on file and maintained for at least three years in accordance with Section 4333.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment 2

AMENDED IN ASSEMBLY APRIL 30, 2015

AMENDED IN ASSEMBLY APRIL 23, 2015

AMENDED IN ASSEMBLY APRIL 13, 2015

AMENDED IN ASSEMBLY MARCH 19, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 45

Introduced by Assembly Member Mullin

December 1, 2014

An act to add Article 3.4 (commencing with Section 47120) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to hazardous waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 45, as amended, Mullin. Household hazardous waste.

The California Integrated Waste Management Act of 1989, which is administered by the Department of Resources Recycling and Recovery, requires, among other things, each city and each county to prepare a household hazardous waste element containing specified components, and to submit that element to the department for approval. Existing law requires the department to approve the element if the local agency demonstrates that it will comply with specified requirements. A city or county is required to submit an annual report to the department summarizing its progress in reducing solid waste, including an update of the jurisdiction's household hazardous waste element.

This bill would require each jurisdiction that provides for the residential collection and disposal of solid waste to increase the collection and diversion of household hazardous waste in its service

area, on or before July 1, 2020, by 15% over a baseline amount, to be determined in accordance with department regulations. The bill would authorize the department to adopt a model ordinance for a comprehensive program for the collection of household hazardous waste to facilitate compliance with those provisions, and would require each jurisdiction to annually report to the department on progress achieved in complying with those provisions. By imposing new duties on local agencies, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares all of the following:

(1) Household hazardous waste is creating environmental, health, and workplace safety issues. Whether due to unused pharmaceuticals, batteries, medical devices, or other disposable consumer items, effective and efficient disposal remains an extraordinary challenge.

(2) State and local efforts to address disposal of these items have been well intended and, in some cases, effective. However, even the most effective programs have very low consumer participation. Other approaches being promoted throughout the state would fragment the collection of household hazardous waste and move collection away from consumer convenience.

(3) In addition to other programs for the collection of household hazardous waste, a number of cities in California are already using curbside household hazardous waste collection programs, door-to-door household hazardous waste collection programs, and household hazardous waste residential pickup services as mechanisms for collecting and disposing of many commonly used household items for which disposal has been the subject of state legislation or local ordinances. The waste disposal companies and local governments that have implemented these programs have

found them to be valuable components of a comprehensive approach to the management of household hazardous waste.

(4) There is also an appropriate role for manufacturers and distributors of these products in comprehensive efforts to more effectively manage household hazardous waste. That role should be based on the ability of manufacturers and distributors to communicate with consumers.

(b) It is the intent of the Legislature to enact legislation that would establish curbside household hazardous waste collection programs, door-to-door household hazardous waste collection programs, and household hazardous waste residential pickup services as the principal means of collecting household hazardous waste and diverting it from California's landfills and waterways.

SEC. 2. Article 3.4 (commencing with Section 47120) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:

Article 3.4. Household Hazardous Waste Collection and Reduction

47120. For purposes of this article, the following terms have the following meanings:

(a) "Comprehensive program for the collection of household hazardous waste" means a local program that ~~includes~~ *may include, but is not limited to,* the following components:

(1) Utilization of locally sponsored collection sites.

(2) Scheduled and publicly advertised drop off days.

(3) Door-to-door collection programs.

(4) Mobile collection programs.

(5) Dissemination of information about how consumers should dispose of the various types of household hazardous waste.

(6) Education programs to promote consumer understanding and use of the local components of a comprehensive program.

(b) "Household hazardous waste" includes, but is not limited to, the following:

(1) Automotive products, including, but not limited to, antifreeze, batteries, brake fluid, motor oil, oil filters, fuels, wax, and polish.

(2) Garden chemicals, including, but not limited to, fertilizers, herbicides, insect sprays, pesticides, and weed killers.

(3) Household chemicals, including, but not limited to, ammonia, cleaners, strippers, and rust removers.

(4) Paint products, including, but not limited to, paint, caulk, glue, stripper, thinner, and wood preservatives and stain.

(5) Consumer electronics, including, but not limited to, televisions, computers, laptops, monitors, keyboards, DVD and CD players, VCRs, MP3 players, cell phones, desktop printers, scanners, fax machines, mouses, microwaves, and related cords.

(6) Swimming pool chemicals, including, but not limited to, chlorine tablets and liquids, pool acids, and stabilizers.

(7) Household batteries. For purposes of this section, "household batteries" means batteries that individually weigh two kilograms or less of mercury, alkaline, carbon-zinc, or nickel-cadmium, and any other batteries typically generated as household waste, including, but not limited to, batteries used to provide power for consumer electronic and personal goods often found in a household.

(8) Fluorescent tubes and compact florescent lamps.

(9) Mercury-containing items, including, but not limited to, thermometers, thermostats, and switches.

(10) Home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code.

(11) Home-generated pharmaceutical waste. For purposes of this section, "home-generated pharmaceutical waste" means a prescription or nonprescription drug, as specified in Section 4022 or 4025.1 of the Business and Professions Code, that is a waste generated by a household or households. "Home-generated pharmaceutical waste" shall not include drugs for which producers provide a take-back program as a part of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, or waste generated by a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and a retailer.

47121. (a) (1) On or before July 1, 2020, each jurisdiction shall increase its collection and diversion of household hazardous waste in its service area by 15 percent over its baseline amount, as established pursuant to subdivision (b).

(2) Notwithstanding paragraph (1), a jurisdiction that has in place or adopts an ordinance implementing a comprehensive program for the collection of household hazardous waste shall

have an additional two years to meet the collection and diversion objective in paragraph (1).

(b) No later than July 1, 2016, each jurisdiction shall inform the department of its baseline amount of collection and diversion of hazardous waste in accordance with regulations adopted by the department. The baseline amount may be expressed in tonnage or by the number of households participating, and may focus on particular types of household hazardous waste.

47122. (a) The department shall adopt regulations to implement this article.

(b) The department may adopt a model ordinance for a comprehensive program for the collection of household hazardous waste to facilitate compliance with this article.

47123. Commencing July 1, 2020, and annually thereafter, each jurisdiction shall report to the department on progress achieved in complying with this section. A jurisdiction shall make a good faith effort to comply with this section, and the department may determine whether a jurisdiction has made a good faith effort for purposes of this program. To the maximum extent practicable, it is the intent of the Legislature that reporting requirements under this section be satisfied by submission of similar reports currently required by law.

47124. This article does not apply to a jurisdiction that does not provide for the residential collection and disposal of solid waste.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because a local agency or school district has the authority to levy service charges, fees, or assessments sufficient to pay for the program or level of service mandated by this act, within the meaning of Section 17556 of the Government Code.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 45**
Current Version:	**As Amended April 30, 2015**
Author:	**Mullin**
Topic:	**Household Hazardous Waste**
Board Position:	**Oppose Unless Amended**

Affected Sections: Public Resources Code

Status: 2-Year Bill

SUMMARY:
This measure makes several legislative findings related to household hazardous waste and its impact on environmental, health, and workplace safety issues. This measure further sets forth several definitions including home-generated pharmaceutical waste which would include prescription and nonprescription drugs and would establish increased collection rates for household hazardous waste.

EXISTING LAW:
According to the author's office, existing law does not create a "diversion" goal for household hazardous waste to be "diverted" from landfills.

THIS BILL WOULD:
Add several sections to the Public Resources Code including:

Section 47120: Establishes definitions including:

(a) "Comprehensive program for the collection of household hazardous waste" means a local program that includes several components:
    a. Utilization of locally sponsored collection sites
    b. Scheduled and publicly advertised drop off days
    c. Door-to-door collection programs
    d. Mobile collection programs
    e. Dissemination of information about how consumers should dispose of the various types of household hazardous waste
    f. Education programs to promote consumer understanding and use of the location components of a comprehensive program.

(b) (11) Home-generated pharmaceutical waste. For purposes of this section," home-generated pharmaceutical waste" means a prescription or nonprescription drug, as specified in Section 4022 or 4025.1 of the Business and Professions Code, that is a waste generated by a household or households. "Home-generated pharmaceutical

waste" shall not include drugs for which producers provide a take-back program as specified or waste generated by a business, corporate, limited partnership, or an entity involved in a wholesale transaction between distributor and a retailer.

Section 47121 would:

(a)(1) Establish a 15 percent increase by which each jurisdiction shall increase its collection and diversion of household hazardous waste in its services by a yet to be determined date.
(a)(2) Provide that this must be increase must be met by July 1, 2016.
(b) Establish a requirement to report on compliance with this section.

Section 47122 would allow the department (Department of Resources Recycling and Recovery) to adopt regulations as well as a model ordinance for a comprehensive program for collection.

Section 47123 would establish a reporting requirement to the legislature.

Section 47124 would exempt jurisdiction that do not provide for the residential collection and disposal of solid waste.

STAFF COMMENTS:

Prior versions of this bill allowed for curbside pickup of household hazardous waste (including prescription drugs). Although such an approach is convenient for residents, such an allowance is contrary to the board's position on the issue and could significantly undermine the efforts of not only our board, but several other entities working diligently to reduce prescription drug abuse. Board staff provided preliminary comments to the sponsors based on the prior versions of this bill.

In its current form it is unclear to staff what safety measures would be in place to ensure the security of the home-generated pharmaceutical waste as part of the comprehensive program, given the various components allowed in the measure.

Board staff has conveyed concerns to the sponsors of this measure as well as amendments. These amendments were not accepted. Board staff continues to reach an agreeable amendment. If staff are unable to find a solution that is agreeable to the sponsors, staff may recommend the board consider changing its position to an oppose position.

FISCAL IMPACT ON THE BOARD:

Board staff does not anticipate any major fiscal impact as a result of this measure. Any minor impact could be absorbed within existing resources.

Date	Action
05/28/15	In committee: Hearing postponed by committee.
05/20/2015	May 20 In committee: Set, first hearing. Referred to suspense file.
05/04/2015	May 4 Re-referred to Com. on APPR.
04/30/2015	Apr. 30 Read second time and amended.
04/29/2015	Apr. 29 From committee: Amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 4. Noes 2.) (April 28).
04/27/2015	Apr. 27 Re-referred to Com. on E.S. & T.M.
04/23/2015	Apr. 23 From committee: Do pass and re-refer to Com. on E.S. & T.M. (Ayes 6. Noes 3.) (April 22). Re-referred to Com. on E.S. & T.M. From committee chair, with author's amendments: Amend, and re-refer to Com. on E.S. & T.M. Read second time and amended.
04/14/2015	Apr. 14 Re-referred to Com. on L. GOV.
04/13/2015	Apr. 13 From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.
03/23/2015	Mar. 23 Re-referred to Com. on L. GOV.
03/19/2015	Mar. 19 Referred to Coms. on L. GOV. and E.S. & T.M. From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.
12/02/2014	Dec. 2 From printer. May be heard in committee January 1.
12/01/2014	Dec. 1 Read first time. To print.

ASSEMBLY BILL No. 486

Introduced by Assembly Member Bonilla

February 23, 2015

An act to amend Sections 4128, 4128.4, and 4128.5 of the Business and Professions Code, relating to pharmacy, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 486, as introduced, Bonilla. Centralized hospital packaging pharmacies: medication labels.

The Pharmacy Law provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law authorizes a centralized hospital packaging pharmacy to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals.

Existing law requires that these medications be barcoded to be readable at the inpatient's bedside in order to retrieve certain information, including, but not limited to, the date that the medication was prepared and the components used in the drug product.

This bill would require that this information be displayed on a human-readable unit-dose label, and that the information be retrievable by the pharmacist using the medication lot number or control number.

This bill would require that the medication's barcode be machine readable, using medication administration software, and that the software compare the information contained in the barcode to the electronic medical record of the inpatient in order to verify that the medication to

be given is the correct medication, dosage, and route of administration for that patient.

Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4128 of the Business and Professions Code is amended to read:

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded *pursuant* to ~~contain at least the information required by~~ Section 4128.4.

(2) Preparing *sterile* compounded unit dose drugs for ~~parenteral therapy for~~ administration to inpatients, if each compounded unit dose drug is barcoded *pursuant* to ~~contain at least the information required by~~ Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded *pursuant* to ~~contain at least the information required by~~ Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed

pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

SEC. 2. Section 4128.4 of the Business and Professions Code is amended to read:

4128.4. *(a)* Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be *machine* readable at the inpatient's ~~bedside. Upon reading the barcode, the following information shall be retrievable:~~ *bedside using barcode medication administration software.*

~~(a) The date the medication was prepared.~~

(b) The ~~components used~~ *barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient,* in the ~~drug product.~~ *right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.*

(c) ~~The lot number or control number.~~ *For purposes of this section, "barcode medication administration software" means a computerized system designed to prevent medication errors in health care settings.*

~~(d) The expiration date.~~

~~(e) The National Drug Code Directory number.~~

~~(f) The name of the centralized hospital packaging pharmacy.~~

SEC. 3. Section 4128.5 of the Business and Professions Code is amended to read:

4128.5. ~~The~~ *(a) Any* label for each unit dose medication produced by a centralized hospital packaging pharmacy shall ~~contain~~ *display a human-readable label that contains* all of the following:

~~(a)~~

(1) The ~~expiration date.~~ *date that the medication was prepared.*

(2) The beyond-use date.

~~(b)~~

(3) The established name of the drug.

~~(c)~~

(4) The quantity of ~~the~~ *each* active ingredient.

~~(d)~~

(5) Special storage or handling requirements.

(6) The lot number or control number assigned by the centralized hospital packaging pharmacy.

(7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

(1) The components used in the drug product.

(2) The expiration date of each of the drug's components.

(3) The National Drug Code Directory number.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 5. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

To eliminate, at the earliest possible time, requirements that exceed the current technological capabilities of hospitals and that create overly burdensome administrative costs for the California State Board of Pharmacy, it is necessary this act take effect immediately.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 486**
Current Version:	**As Introduced February 23, 2015**
Board Position:	**Support**
Author:	**Bonilla**
Topic:	**Centralized Hospital Packaging Pharmacies: medication labels**

Affected Section(s): Sections 4128, 4128.4, and 4128.5 of the Business & Professions Code,

Status: On Senate Third Reading File *(6/23/15)*

SUMMARY:
AB 486 would modify current law which allows a centralized hospital packaging pharmacy to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals. The measure would change the current requirement that medication labels provide certain information via barcode which is readable at the inpatient's bedside to require instead a human-readable unit-dose label which sets out certain information, and that other information must be retrievable by the pharmacist by accessing the medication lot number or control number.

EXISTING LAW:
Existing law authorizes a centralized hospital packaging pharmacy (CHP) to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals within a 100 mile radius. CHPs are required to label drugs with a barcode containing specified information that is readable at the inpatient's bedside.

THIS BILL WOULD:

1. Specify that any unit dose medication produced by a CHP be barcoded to be machine readable at the patient's bedside using barcode medication administration software. Further the software shall allow a health care practitioner to ensure that it is the right medication, for the right inpatient, in the right does and via the right route of administration. This shall be achieved by the reading the barcode on the medication and comparing the information retrieved to the electronic medical records of the inpatient.
2. Define "barcode medication administration software" as a computerized system designed to prevent medication errors in health care settings.
3. Require any label for each unit dose medication produced by the CHP to display a human-readable label that contains the following:
    a. Date the medication was prepared

   b. Beyond use date
   c. Quantity of each active ingredient
   d. Special storage or handling requirements
   e. Lot number of control number assigned by the CHP
   f. Name of the CPH
4. Specify that a pharmacist shall be able to retrieve the following information using the lot number or control number
   a. Components used in the drug product
   b. Expiration date of each of the drug components
   c. National Drug Code Directory number
5. Contains an urgency clause to allow for the provisions to go into effect immediately.

STAFF COMMENTS:
The board supported the initial legislation that allowed for the licensure of CHPs as a way to reduce medication errors through the use of barcode technology (Solorio, SB 377, Chapter 687, Statutes 2012). After this legislation was enacted, the board was advised that the technology available to facilitate implementation could not accommodate all of the requirements of the law. Given that, and to facilitate implementation, the board has approved waivers of some of the provisions to allow for licensure. It appears that this measure will allow for CHPs to continue providing unit dose medications that will reduce medication errors by ensuring that the right patient gets the right medication.

FISCAL IMPACT ON THE BOARD:
Board staff does not anticipate any major fiscal impact on measure. Any minor impact could be absorbed within existing resources.

SUPPPORT/OPPOSITION:

Support
California Society of Health-System Pharmacists (Sponsor)
California Association of Joint Powers Authorities
California Association of Physician Groups
California Council for the Advancement of Pharmacy
California Hospital Association
California Pharmacists Association
Providence Health & Services Southern California

Opposition
None

PREVIOUS/RELATED LEGISLATION:
AB 377 (Solario) 2011- 2012 Legislative Session, Chapter 687, Statutes of 2012. This bill established the licensing category of a "centralized hospital pharmacy" (a pharmacy which prepares medications for hospitals under common ownership or control within a 100-mile geographic radius). One of the reasons cited to establish the need for AB 377 in the Fact Sheet was that requiring all medications be prepared by an on-site hospital pharmacy "limits the opportunity to invest in expensive technology that would

improve efficiency and enhance patient safety." Underpinning AB 486 is the presumption, which may be accurate, that the present cost of developing the technology needed for bedside reading of barcoded medicines is too high for even commonly owned groups of hospitals to bear.

HISTORY:

Date	Action
06/23/15	Read second time. Ordered to third reading.
06/22/15	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
06/08/15	From committee: Do pass and re-refer to Com. On APPR. (Ayes 9. Notes 0.) (June 8). Re-referred to Com. On APPR.
05/28/15	Referred to Com. On B., P. & E.D.
05/14/15	In Senate. Read first time. To Com. on RLS. for assignment.
05/14/15	Read third time. Urgency clause adopted. Passed. Ordered to the Senate. (Ayes 78. Noes 0.).
05/07/15	Read second time. Ordered to Consent Calendar.
05/06/15	From committee: Do pass. To Consent Calendar. (Ayes 17. Noes 0.) (May 6).
04/29/15	From committee: Do pass and re-refer to Com. on APPR. with recommendation: To Consent Calendar. (Ayes 14. Noes 0.) (April 28). Re-referred to Com. on APPR.
04/22/15	From committee: Do pass and re-refer to Com. on B. & P. (Ayes 19. Noes 0.) (April 21). Re-referred to Com. on B. & P.
04/14/15	In committee: Set, first hearing. Hearing canceled at the request of author.
03/05/15	Referred to Coms. on HEALTH and B. & P.
02/24/15	From printer. May be heard in committee March 26.
02/23/15	Read first time. To print.

AMENDED IN ASSEMBLY JUNE 23, 2015

AMENDED IN SENATE MAY 5, 2015

AMENDED IN SENATE APRIL 14, 2015

SENATE BILL No. 671

Introduced by Senator Hill

February 27, 2015

An act to add Section 4073.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 671, as amended, Hill. Pharmacy: biological product.

The Pharmacy Law governs the practice of pharmacy in this state, including the permissible duties of licensed pharmacists. ~~Among other permitted acts,~~ *The Pharmacy Law authorizes* a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name ~~is authorized~~ to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined, as specified, of those drug products having the same active chemical ingredients. A ~~person who knowingly violates~~ *knowing violation of* the Pharmacy Law is ~~guilty of a misdemeanor, as specified.~~ *a misdemeanor.*

This ~~bill~~ *bill, except as specified,* would authorize a ~~pharmacist, in his or her discretion, except as specified,~~ *pharmacist* to select an alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable, as defined, and the prescriber does not personally indicate ~~"Do not substitute," as specified.~~ *in a prescribed manner that a substitution is not to be made.* The bill would ~~also~~ require a pharmacist

~~or his or her designee when dispensing a biological product to communicate to the prescriber~~ *or a designee, within a specified period following the dispensing of a biological product, to make an electronically accessible entry in a described entry system of* the specific biological product provided to the ~~patient, including the name of the product and the manufacturer, except as specified.~~ *patient. The bill would provide an alternate means of communicating the name of the biological product dispensed to the prescriber if the pharmacy does not have access to one or more of the described entry systems. The bill would also require that the substitution of a biological product be communicated to the patient.* The bill would prohibit a pharmacist from selecting an alternative biological product that meets the requirements of these provisions unless the cost to the patient of the alternative biological product selected is the same or less than the cost of the prescribed biological product. ~~The bill would also require that the substitution of a biological product be communicated to the patient.~~ Because a knowing violation of these requirements would be a misdemeanor, the bill would create new crimes, thereby imposing a state-mandated local program.

The bill would also require the California State Board of Pharmacy to maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4073.5 is added to the Business and Professions Code, to read:

4073.5. (a) A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:

(1) The alternative biological product is interchangeable.

(2) The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision ~~(c).~~ *(d).*

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall ~~communicate to the prescriber~~ *make an entry of* the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry ~~into an interoperable electronic medical records system, through electronic prescribing technology, or a pharmacy record that is electronically accessible by the prescriber. Otherwise,~~ *that can be electronically accessed by the prescriber through:*

(1) An interoperable electronic medical records system,

(2) An electronic prescribing technology,

(3) A pharmacy benefit management system, or

(4) A pharmacy record.

(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber. If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:

(1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

~~(c)~~

(d) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning.

(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark.

(2) To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription, as

defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

~~(d)~~

(e) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision ~~(c)~~. *(d)*. A pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, as used in this subdivision, includes any professional fee that may be charged by the pharmacist.

~~(e)~~

(f) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

~~(f)~~

(g) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

~~(g)~~

(h) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.

~~(h)~~

(i) For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product" has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).

(2) "Interchangeable" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in 42 U.S.C. Section 262(k)(4), or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

(3) "Prescription," with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

~~(i)~~

(j) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.

~~(j)~~

(k) This section shall not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 671**
Current Version:	**As Amended June 23, 2015**
Board Position:	**Oppose Unless Amended (4/14/15)**
Author:	**Hill**
Topic:	**Biosimilar Drug Substitution**

Affected Section(s): Add Section 4073.5 of the Business & Professions Code

Status: On the Assembly Floor – Second Reading *(7/16)*

SUMMARY:
This measure would authorize a pharmacist, in his or her discretion (except when the prescriber has specified "Do not substitute" or words to that effect), where there is an identically priced or cheaper alternative interchangeable biosimilar, to select the alternative biological product when filling a prescription order for a prescribed biological product. The measure requires the pharmacist, within a specified period of time after dispensing, to notify the prescriber of exactly what was dispensed. The most recent version of the bill allows for such communication to be entered into an electronic system, as specified.

EXISTING LAW:
Pharmacy law permits a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name to select a generic version of the drug. Biosimilars are relatively new drugs, not in widespread use, and are presently not addressed in CA pharmacy law.

THIS BILL WOULD:

1. This bill would authorize a pharmacist (except where a prescriber has indicated "Do not substitute" or words to that effect) to select an identically priced or cheaper alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable, as defined.
2. The bill would require a pharmacist when dispensing a biological product to communicate to the prescriber the specific biological product provided to the patient, including the name of the product and the manufacturer, except as specified, and communicate to the patient that a biological product was substituted.

STAFF COMMENTS:
Background information: Biologic medicines can't be exactly duplicated, due to their having one or more chains of amino acids with complex multi-dimensional structures. On 3/6/15, the FDA approved the first "biosimilar" product – Zarxio. Quoting from the FDA announcement: "A biosimilar product is a biological product that is approved based on a showing that it is highly

similar to an already-approved biological product, known as a reference product. The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products." There are 4 other biosimilars in the FDA pipeline.

Biosimilars are injectable, higher risk drugs. While Zarxio has been approved by the FDA, negative results with biosimilars can take 6-9 months from initial use, results that build slowly as the body reacts. Being "in the lead" in this area may be a disservice to the public. As written, the notification portion of the bill is not workable for some pharmacies, which may lack access to certain electronic records systems.

In April, the bill was amended to change the pharmacist notification language from "within a reasonable time following the dispensing" to "within five days following the dispensing" and other non-substantive corrections. The amendments did not address the concerns expressed by the CA Pharmacists Association about the electronic notification requirements and the need for pharmacists to know they have complied with the bill's mandates. The most recent amendment specifies that the pharmacist notification may be made through an electronic entry, as specified.

Staff has communicated the board's opposition to the prescriber notification. The author's office has stated that the pharmacist notification requirement is a core component of the measure and that it will not be eliminated.

FISCAL IMPACT ON THE BOARD:
SB 671 would have an unknown fiscal impact on the board to:

- Update on its website information concerning FDA approved biosimilars.
- Update its self-assessment forms to pharmacies.

SUPPPORT/OPPOSITION (According to the July 10th Assembly Health Analysis):
Support
AIM at Melanona
American Cancer Society – Cancer Action Network
Amgen
Arthritis Foundation
Association of Northern California Oncologists
Biocom
Biotechnology Industry Organization
Boehringer-Ingelheim Pharmaceutical Company
California Life Sciences Association
Crohn's & Colitis Foundation of America
Express Scripts
Genentech
Hospira
Johnson & Johnson
Lilly USA, LLC
Lupus Foundation
Medical Oncology Association of Southern California, Inc

Merck
National Black Nurses Association
National Kidney Foundation
Novartis Pharmaceuticals
Novo Nordisk, Inc
Pharmaceutical research and Manufacturers of America
Sandoz
State Building and Construction Trades Council, AFL-CIO
UCB, Inc

Opposition
America's Health Insurance Plans
Association of California Life and Health Insurance Companies
California Association of Health Plans
Kaiser Permanente

PREVIOUS/RELATED LEGISLATION:
SB 598 (Hill), 2013-14 Legislative Session. This measure would have authorized pharmacists, in their discretion, except as specified, to select an identically priced or cheaper biosimilar if the prescriber has not indicated "Do Not Substitute." The bill also required until January 1, 2017, that within 5 business days a pharmacist must notify the prescriber or enter into the patient record whether the prescription dispensed was a biological product or a biosimilar. The patient had to be told of the provision of a biosimilar, and the Board was instructed to post FDA approved biosimilars on the Board website. This measure was vetoed by the Governor on October 12, 2013.

AB 1139 (Lowenthal) 2013-2014 Legislative Session. This measure was similar to SB 598 and died in the B&P committee.

HISTORY:

Date	Action
07/16/15	Read second time and amended. Re-referred to Com. on APPR.
07/15/15	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 18. Noes 0.) (July 14).
07/07/15	From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 14. Noes 0.) (July 7). Re-referred to Com. on HEALTH.
06/30/15	June 30 hearing postponed by committee.
06/23/15	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B. & P.

AMENDED IN SENATE JULY 1, 2015

AMENDED IN ASSEMBLY MAY 6, 2015

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1069

Introduced by Assembly Member Gordon
(Coauthors: Assembly Members Chu, Low, and Mark Stone)
(Coauthors: Senators Beall and Wieckowski)

February 26, 2015

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, as amended, Gordon. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy, including a pharmacy that is owned by, or contracts with, the county, may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that establishes a depository and redistribution program to develop written procedures for, among other things, establishing eligibility for medically indigent patients who may participate in the program, and ensuring that patients eligible for the program are not charged for any medications provided under the program. Existing law also prohibits the donation of controlled substances to the repository and distribution program. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose

containers that meet the United States Pharmacopoeia standards, and that includes lot numbers and expiration dates, is eligible for donation to the program. Existing law authorizes a county-owned pharmacy participating in the program to transfer eligible donated medication to a county-owned pharmacy participating in the program within another adjacent county, as specified. Existing law prohibits medication that does not meet the requirements for donation and distribution from being sold, dispensed, or otherwise transferred to any other entity. Existing law requires medication donated to the repository and distribution program to be maintained in the donated packaging units.

This bill would authorize ~~a county-owned pharmacy~~ *an entity* participating in the medication repository and distribution program to transfer eligible donated medication to a participating ~~county-owned pharmacy~~ *entity* in any other county, as specified. *The bill would generally prohibit an entity from transferring more than 15% of its donated medications annually.* The bill would authorize medication donated to a medication repository and distribution program to be maintained in new, properly labeled ~~containers.~~ *containers, as specified.* The bill would prohibit donated medication from being repackaged more than 2 times. This bill would also make a technical, nonsubstantive change to these provisions.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State

Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in Section 150201, shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to

subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating ~~county-owned pharmacy~~ *entity* may transfer eligible donated medication to a participating ~~county-owned pharmacy~~ *entity* within another county that has adopted a program pursuant to this division, if the ~~pharmacies~~ *participating entities* transferring the medication have a written agreement ~~between the entities~~ that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division. *A participating entity shall not transfer more than 15 percent of its donated medications annually unless the transfer is performed pursuant to Section 4126.5 of the Business and Professions Code.*

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled

pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. Donated medication that does not meet the requirements of this division shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) *(1)* Medication donated to the repository and distribution program shall be maintained in the donated packaging units or new, properly labeled containers until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed. Donated medication shall not be repackaged more than two times. Nothing in this section requires donated medication to be repackaged two times.

(2) All of the following requirements shall be satisfied when repackaging donated medication:

(A) Medication shall be repackaged into a container that holds an individual prescription for a supply of no more than 90 days.

(B) Repackaged medication shall be identifiable as donated medication.

(C) Repackaged medication shall be labeled with all of the following:

(i) All applicable lot numbers.

(ii) The earliest expiration date.

(iii) The number of times that the medication has been repackaged.

(j) Medication donated to the repository and distribution program shall be segregated from the participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and

distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 1069**
Current Version:	**As amended July 1, 2015**
Author:	**Gordon**
Topic:	**Prescription Drugs: Collection and Distribution Program**
Board Position:	**Oppose Unless Amended**

Affected Sections: Amend Sections 150201 and 150204 of the Health and Safety Code (H&SC)

Status: Referred to Senate Appropriations Committee

SUMMARY: Would expand the provisions under which a county established repository and distribution program allow the transfer of drugs to between counties that are not adjacent, and would allow for the repackaging of donated medications in advance of a prescription.

EXISTING LAW: Authorizes a county to establish a repository and distribution program to allow for the distribution of surplus unused medications to persons in need of financial assistance.

H&SC Section 150201 provides definitions for purposes of the division including

- Donor organization as a health and care facilities that donates centrally stored unused medications including: general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, correctional treatment center, psychiatric health facility, chemical dependency recovery hospital, residential care home, and approved mental health rehabilitation center.
- Eligible Entity which includes a licensed pharmacy as specified
- Medication as a dangerous drug as defined in B&PC 4022
- Participating Entity as an entity eligible that operates a repository and distribution program

H&SC 150202.5 allows for donor organizations to donate unused, unexpired medication if the medication was received directly from a manufacturer or wholesaler or the medication was returned from a health facility to the issuing pharmacy.

H&SC 150203 allows for a wholesaler and drug manufacturer to donate unused medication.

H&SC 150204 sets forth the means by which a county may establish a program, the reporting requirements as well as the written procedures that address the following:

- Establishing eligibility for medically indigent patients who may participate
- Ensuring that eligible patients are not charged for medications received under the program
- Develop a formulary of medications appropriate for the program
- Ensure proper safety and management of any medication collected and maintained
- Ensure the privacy of individuals for whom the medication was originally prescribed

In addition, the section specifies that only medication that is donated in unopened, tamper-evident packaging or modified unit does containers that meet USP standards for donation, provided lot numbers and expiration dates are affixed.

Further this section also provides that the medication donated to the program shall be maintained in the donated packaging units until dispensed to the eligible patient who presents a valid prescription and allows for donated medication to be transferred to an adjacent county.

Federal law provides a definition of tamper evident packaging as well as the labeling requirements of unit dose medications, including the lot or control number
[Ref. 21 CFR 201.100(b), 211.130]

THIS BILL WOULD:
Amend H&SC Section 150204

a. To allow for the transfer of donated medications from one county entity to entity in another county. It would also allow for a transfer of up to 15% of the donated mediations received annually unless a transfer is done that is patient and prescription specific.
b. To allow for medications to be repackaged into new, properly labeled containers until dispensed and specify that such a medication cannot be repackaged more than two times. The repackaging could be of a supply of no more than 90 days and would allow for the mixing of lot numbers and expiration dates. Such information would be required to be included on the label.

STAFF COMMENTS:
During the previous committee meeting and board meeting, Board staff discussed several concerns with the proposed expansion of this program and the conflicts it created with federal and state law. Board staff has spent considerable staff time working with the author's office and sponsors to highlight these conflicts and secure amendments to remove such conflicts. The recent amendments to this law create new conflicts with federal and state law, including repackaging in entitles that are neither pharmacies nor licensed by the State Food and Drug Branch or the FDA. Such repackaging could also be performed without a pharmacist oversight. This repackaging appears to create conflict with Good Manufacturing Practices and is in conflict with USP standards.

Further, board staff continues to question the need to expand the transfer provisions of the current law given that only one county in California is currently operating a program and staff is unaware of any eminent adoption by other counties.

FISCAL IMPACT ON THE BOARD:

The measure in its current form creates significant challenges in monitoring for compliance as well as from an enforcement perspective. Board staff anticipates that an additional inspector will be required to confirm compliance and enforce these provisions. Routine investigations will become far more difficult and there could be significant travel involved depending on the locations of the donating entities as well as the original dispensing pharmacies. For example, confirming the transaction information and pedigree of a repackaged medication would become extremely complicated and resource intensive.

HISTORY:

Date	Action
07/07/2015	July 7 From committee: Do pass and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (July 6). Re-referred to Com. on APPR.
07/01/2015	July 1 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/15/2015	June 15 In committee: Set, first hearing. Hearing canceled at the request of author.
06/11/2015	June 11 Referred to Com. on B., P. & E.D.
06/01/2015	June 1 In Senate. Read first time. To Com. on RLS. for assignment.
06/01/2015	June 1 Read third time. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1685.)
05/07/2015	May 7 Read second time. Ordered to third reading.
05/06/2015	May 6 Read second time and amended. Ordered returned to second reading.
05/05/2015	May 5 From committee: Amend, and do pass as amended. (Ayes 17. Noes 0.) (May 5).
04/21/2015	Apr. 21 In committee: Hearing postponed by committee.
04/06/2015	Apr. 6 Re-referred to Com. on HEALTH.
03/26/2015	Mar. 26 Referred to Com. on HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
02/27/2015	Feb. 27 From printer. May be heard in committee March 29.
02/26/2015	Feb. 26 Read first time. To print.

Attachment 3

AMENDED IN ASSEMBLY APRIL 22, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 12

Introduced by Assembly Member Cooley
(Coauthors: Assembly Members Chang, Daly, and Wilk)

December 1, 2014

An act ~~to amend Section 11349.1.5 of, and~~ to add and repeal Chapter 3.6 (commencing with Section 11366) of Part 1 of Division 3 of Title 2 ~~of,~~ *of* the Government Code, relating to state agency regulations.

LEGISLATIVE COUNSEL'S DIGEST

AB 12, as amended, Cooley. State government: administrative regulations: review.

~~(1) Existing~~

Existing law authorizes various state entities to adopt, amend, or repeal regulations for various specified purposes. The Administrative Procedure Act requires the Office of Administrative Law and a state agency proposing to adopt, amend, or repeal a regulation to review the proposed changes for, among other things, consistency with existing state regulations.

This bill would, until January 1, 2019, require each state agency to, on or before January 1, 2018, ~~and after a noticed public hearing, review and revise that agency's regulations to eliminate any inconsistencies, overlaps, or outdated provisions in the regulations, adopt the revisions as emergency regulations,~~ *review that agency's regulations, identify any regulations that are duplicative, overlapping, inconsistent, or out of date, to revise those identified regulations, as provided,* and report to the Legislature and Governor, as specified. ~~The bill would further~~

require each agency to, on or before January 1, 2017, compile an overview of the statutory law that agency administers.

(2) The act requires a state agency proposing to adopt, amend, or repeal a major regulation, as defined, to prepare a standardized regulatory impact analysis of the proposed change. The act requires the office and the Department of Finance to, from time to time, review the analyses for compliance with specific department regulations. The act further requires the office to, on or before November 1, 2015, submit a report on the analyses to the Senate and Assembly Committees on Governmental Organization, as specified.

This bill would instead require the office and department to annually review the analyses. The bill would also require the office to annually submit a report on the analyses to the Senate Committee on Governmental Organization and the Assembly Committee on Accountability and Administrative Review.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 11349.1.5 of the Government Code is amended to read:

11349.1.5. (a) The Department of Finance and the office shall annually review the standardized regulatory impact analyses required by subdivision (c) of Section 11346.3 and submitted to the office pursuant to Section 11347.3, for adherence to the regulations adopted by the department pursuant to Section 11346.36.

(b) (1) On or before November 1, 2015, and annually thereafter, the office shall submit to the Senate Committee on Governmental Organization and the Assembly Committee on Accountability and Administrative Review a report describing the extent to which submitted standardized regulatory impact analyses for proposed major regulations for the fiscal year ending in June 30, of that year adhere to the regulations adopted pursuant to Section 11346.36. The report shall include a discussion of agency adherence to the regulations as well as a comparison between various state agencies on the question of adherence. The report shall also include any recommendations from the office for actions the Legislature might consider for improving state agency performance and compliance

~~in the creation of the standardized regulatory impact analyses as described in Section 11346.3.~~

~~(2) The report shall be submitted in compliance with Section 9795 of the Government Code.~~

~~(c) In addition to the annual report required by subdivision (b), the office shall notify the Legislature of noncompliance by a state agency with the regulations adopted pursuant to Section 11346.36, in any manner or form determined by the office and shall post the report and notice of noncompliance on the office's Internet Web site.~~

~~SEC. 2.~~

SECTION 1. Chapter 3.6 (commencing with Section 11366) is added to Part 1 of Division 3 of Title 2 of the Government Code, to read:

CHAPTER 3.6. REGULATORY REFORM

Article 1. Findings and Declarations

11366. The Legislature finds and declares all of the following:

(a) The Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500)) requires agencies and the Office of Administrative Law to review regulations to ensure their consistency with law and to consider impacts on the state's economy and businesses, including small businesses.

(b) However, the act does not require agencies to individually review their regulations to identify overlapping, inconsistent, duplicative, or out-of-date regulations that may exist.

(c) At a time when the state's economy is slowly recovering, unemployment and underemployment continue to affect all Californians, especially older workers and younger workers who received college degrees in the last seven years but are still awaiting their first great job, and with state government improving but in need of continued fiscal discipline, it is important that state agencies systematically undertake to identify, publicly review, and eliminate overlapping, inconsistent, duplicative, or out-of-date regulations, both to ensure they more efficiently implement and

enforce laws and to reduce unnecessary and outdated rules and regulations.

~~(d) The purpose of this chapter is to require each agency to compile an overview of the statutory law that agency oversees or administers in its regulatory activity that includes a synopsis of key programs, when each key program was authorized or instituted, and any emerging challenges the agency is encountering with respect to those programs.~~

Article 2. Definitions

11366.1. For the ~~purpose~~ *purposes* of this chapter, the following definitions shall apply:

(a) "State agency" means a state agency, as defined in Section 11000, except those state agencies or activities described in Section 11340.9.

(b) "Regulation" has the same meaning as provided in Section 11342.600.

Article 3. State Agency Duties

11366.2. On or before January 1, 2018, each state agency shall do all of the following:

(a) Review all provisions of the California Code of Regulations applicable to, or adopted by, that state agency.

(b) Identify any regulations that are duplicative, overlapping, inconsistent, or out of date.

(c) Adopt, amend, or repeal regulations to reconcile or eliminate any duplication, overlap, inconsistencies, or out-of-date ~~provisions.~~ *provisions, and shall comply with the process specified in Article 5 (commencing with Section 11346) of Chapter 3.5, unless the addition, revision, or deletion is without regulatory effect and may be done pursuant to Section 100 of Title 1 of the California Code of Regulations.*

(d) Hold at least one noticed public hearing, that shall be noticed on the Internet Web site of the state agency, for the purposes of accepting public comment on proposed revisions to its regulations.

(e) Notify the appropriate policy and fiscal committees of each house of the Legislature of the revisions to regulations that the state agency proposes to make at ~~least 90 days prior to a noticed~~

~~public hearing pursuant to subdivision (d) and at least 90 days prior to the proposed adoption, amendment, or repeal of the regulations pursuant to subdivision (f), for the purpose of allowing those committees to review, and hold hearings on, the proposed revisions to the regulations.~~

~~(f) Adopt as emergency regulations, consistent with Section 11346.1, those changes, as provided for in subdivision (c), to a regulation identified by the state agency as duplicative, overlapping, inconsistent, or out of date.~~ *least 30 days prior to initiating the process under Article 5 (commencing with Section 11346) of Chapter 3.5 or Section 100 of Title 1 of the California Code of Regulations.*

(g) (1) Report to the Governor and the Legislature on the state agency's compliance with this chapter, including the number and content of regulations the state agency identifies as duplicative, overlapping, inconsistent, or out of date, and the state agency's actions to address those regulations.

(2) The report shall be submitted in compliance with Section 9795 of the Government Code.

11366.3. (a) On or before January 1, 2018, each agency listed in Section 12800 shall notify a department, board, or other unit within that agency of any existing regulations adopted by that department, board, or other unit that the agency has determined may be duplicative, overlapping, or inconsistent with a regulation adopted by another department, board, or other unit within that agency.

(b) A department, board, or other unit within an agency shall notify that agency of revisions to regulations that it proposes to make at least 90 days prior to a noticed public hearing pursuant to subdivision (d) of Section 11366.2 and at least 90 days prior to adoption, amendment, or repeal of the regulations pursuant to ~~subdivision (f) of~~ *subdivision (c) of* Section 11366.2. The agency shall review the proposed regulations and make recommendations to the department, board, or other unit within 30 days of receiving the notification regarding any duplicative, overlapping, or inconsistent regulation of another department, board, or other unit within the agency.

11366.4. An agency listed in Section 12800 shall notify a state agency of any existing regulations adopted by that agency that

may duplicate, overlap, or be inconsistent with the state agency's regulations.

~~11366.43. On or before January 1, 2017, each state agency shall compile an overview of the statutory law that state agency oversees or administers. The overview shall include a synopsis of the state agency's key programs, when each program was authorized or instituted, when any statute authorizing a program was significantly revised to alter, redirect, or extend the original program and the reason for the revision, if known, and an identification of any emerging challenges the state agency is encountering with respect to the programs.~~

11366.45. This chapter shall not be construed to weaken or undermine in any manner any human health, public or worker rights, public welfare, environmental, or other protection established under statute. This chapter shall not be construed to affect the authority or requirement for an agency to adopt regulations as provided by statute. Rather, it is the intent of the Legislature to ensure that state agencies focus more efficiently and directly on their duties as prescribed by law so as to use scarce public dollars more efficiently to implement the law, while achieving equal or improved economic and public benefits.

Article 4. Chapter Repeal

11366.5. This chapter shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 12**
Current Version:	**As amended April 22, 2015**
Author:	**Cooley**
Topic:	**State Government, Administration Regulations: Review**
Board Position:	**Oppose** *(6/4/15)*

Affected Sections: Adds Chapter 3.6 to Part 1 of Division 3 of Title 2 of the Government Code.

Status: Hearing: Senate Appropriations – August 17

SUMMARY: Would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018.

EXISTING LAW:
The Administrative Procedure Act establishes requirements for the adoption, amendment or repeal of regulations.

THIS BILL WOULD:
Require the board to identify all regulations that are duplicative, overlapping, inconsistent or out of date and ensure that necessary changes are made via the rulemaking process to correct any such identified changes. Further, this measure would require that all actions be completed on or before January 1, 2018.

STAFF COMMENTS:
Board staff notes that this measure could have a significant impact to its current operations. Completing the necessary review of its regulations as well as securing the changes within the time allotted (two years) seems extremely challenging. Given the complexity of the board's regulatory structure, board staff has concerns that the board could achieve compliance with this measure in the timeframe allowed without significantly impacting other areas of board operations.

FISCAL IMPACT ON THE BOARD:

Board staff have identified a significant fiscal impact to this measure to ensure the necessary review of its regulations are conducted and necessary changes secured in conformance with this measure.

SUPPORT / OPPOSITION: (According to the Senate Governmental Organization analysis)

SUPPORT
American Federation of State, County and Municipal Employees
Associated Builders and Contractors of California Building Owners and Managers Association of California
California Asian Pacific Chamber of Commerce
California Association of Bed & Breakfast Inns
California Building Industry Association
California Business Properties Association
California Business Roundtable
California Chamber of Commerce
California Construction and Industrial Materials Association
California Grocers Association
California Hotel & Lodging Association
California League of Food Processors
California Manufacturers & Technology Association
California Retailers Association
California Taxpayers Association
Commercial Real Estate Development Association
Consumer Specialty Products Association
Family Business Association
Industrial Environmental Association
International Council of Shopping Centers
National Federation of Independent Business/California
Small Business California
USANA Health Services, Inc.
Western States Petroleum Association

OPPOSITION:
None

HISTORY:

Date	Action
07/14/15	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (July 14). Re-referred to Com. on APPR.
06/11/15	Referred to Com. on G.O.
06/01/15	In Senate. Read first time. To Com. on RLS. for assignment.
06/01/15	Read third time. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1693.)
05/28/15	Read second time. Ordered to third reading.
05/28/15	From committee: Do pass. (Ayes 17. Noes 0.) (May 28).
05/13/15	In committee: Set, first hearing. Referred to APPR. suspense file.
04/29/15	From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (April 29). Re-referred to Com. on

Date	Action
	APPR.
04/23/15	Re-referred to Com. on A. & A.R.
04/22/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on A. & A.R. Read second time and amended.
03/23/15	In committee: Set, first hearing. Hearing canceled at the request of author.
01/16/15	Referred to Com. on A. & A.R.
12/02/14	From printer. May be heard in committee January 1.
12/01/14	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 15, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 85

Introduced by Assembly Member Wilk

January 6, 2015

An act to amend Section 11121 of the Government Code, relating to state government, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 85, as amended, Wilk. Open meetings.

The Bagley-Keene Open Meeting Act requires that all meetings of a state body, as defined, be open and public and that all persons be permitted to attend and participate in a meeting of a state body, subject to certain conditions and exceptions.

This bill would specify that the definition of "state body" includes an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body that consists of 3 or more individuals, as prescribed, except a board, commission, committee, or similar multimember body on which a member of a body serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

~~This bill would make legislative findings and declarations, including, but not limited to, a statement of the Legislature's intent that this bill is declaratory of existing law.~~

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. The Legislature finds and declares all of the following:~~

~~(a) The unpublished decision of the Third District Court of Appeals in Funeral Security Plans v. State Board of Funeral Directors (1994) 28 Cal. App.4th 1470 is an accurate reflection of legislative intent with respect to the applicability of the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code) to a two-member standing advisory committee of a state body.~~

~~(b) A two-member committee of a state body, even if operating solely in an advisory capacity, already is a "state body," as defined in subdivision (d) of Section 11121 of the Government Code, if a member of the state body sits on the committee and the committee receives funds from the state body.~~

~~(c) It is the intent of the Legislature that this bill is declaratory of existing law.~~

~~SEC. 2.~~

SECTION 1. Section 11121 of the Government Code is amended to read:

11121. As used in this article, "state body" means each of the following:

(a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order.

(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory

body so created consists of three or more persons, except as in subdivision (d).

(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

~~SEC. 3.~~

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to avoid unnecessary litigation and ensure the people's right to access the meetings of public bodies pursuant to Section 3 of Article 1 of the California Constitution, it is necessary that *this* act take effect ~~immediately~~ *immediately.*

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 85**
Current Version:	**As Amended April 15, 2015 - Oppose**
Author:	**Wilk**
Topic:	**Open Meetings**

Affected Section(s): Section 11121 of the Government Code

Status: Hearing: Senate Appropriations – August 17 *(as of 7/16)*

SUMMARY:
According to the author, this measure is intended to clarify language within the Bagley-Keene Open Meeting Act by stating that when an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body is acting in an official capacity of a state body, the entity (regardless of the committee size) is subject to the Open Meeting Act.

EXISTING LAW:
Established the Bagley-Keene Open Meeting Act that all state boards and commissions must operate under including the requirement to publicly notice meetings, prepare agendas, accept public testimony and conduct business in public unless expressly authorized to meet in closed session.

THIS BILL WOULD:

1. Amend Section 11121 of the Government Code to change the definition of "state body" to specify that a state board includes an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body that consists of 3 or more individuals, EXCEPT a board, commission, committee, or similar multimember body on which a member of a body serves in his or her official capacity as a representative of that state body as specified.

STAFF COMMENTS:

The board conducts all business consistent with the Bagley-Keene Open Meeting Act. The board has an Organization Development Committee that is comprised of two members who serve in an advisory role to board staff on such items as decisions relating to Budget Change Proposals (BCP), which the Department of Finance has determined is not public information until a BCP is approved and included in the governor's budget. In addition, the board has used a two-member committee to vet emerging issues that arise or that require significant expertise such as on complex rulemakings. Under this proposal, the board would lose the ability to utilize two-member committees for the purposes so stated.

These two-member committees are not authorized to act independently on behalf of the board; rather the information discussed that requires board action is discussed publicly during open meetings where the full board considers not only the comments but also comments from the public. The author's office has indicated a willingness to work with the board and others to reach consensus.

Board staff has conveyed the board's Oppose position as well as the reasons behind the position. The author's office has conveyed its desire to work with the board and others to reach consensus.

FISCAL IMPACT ON THE BOARD:
Board staff does not anticipate any major fiscal impact based on this measure. Any minor impact could be absorbed within existing resources.

SUPPPORT/OPPOSITION:
Support
California Association of Licensed Investigators

Opposition
California Board of Accountancy
Board of Pharmacy

PREVIOUS/RELATED LEGISLATION:
AB 2058 (Wilk), 2013-14 Legislative Session. This measure would have required all standing committees of a state board, irrespective of composition, that has continuing subject matter jurisdictions or fixed meeting schedule to comply with the provision of the Act. The board had an oppose position on this bill which was vetoed by the governor. In his veto message the governor noted that an advisory committee does not have the authority to act on its own and must present any findings and recommendations to a larger body in a public setting for formal action.
AB 2720 (Ting), Chapter 510, Statutes of 2014. This measure requires the board to publicly report any action taken during an open meeting and include the vote of abstention on that action of each member present.

HISTORY:

Date	Action
07/14/15	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (July 14). Re-referred to Com. on APPR.
06/11/15	Referred to Com. on G.O.
06/01/15	In Senate. Read first time. To Com. on RLS. for assignment.
06/01/15	Read third time. Urgency clause adopted. Passed. Ordered to the Senate. (Ayes 80. Noes 0. Page 1698.).
05/28/15	Read second time. Ordered to third reading.
05/28/15	From committee: Do pass. (Ayes 17. Noes 0.) (May 28).
04/22/15	In committee: Set, first hearing. Referred to APPR. suspense file.
04/16/15	Re-referred to Com. on APPR.
04/15/15	Read second time and amended.
04/14/15	From committee: Amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 21. Noes 0.) (April 8).
01/26/15	Referred to Com. on G.O.
01/07/15	From printer. May be heard in committee February 6.
01/06/15	Read first time. To print.

AMENDED IN ASSEMBLY JUNE 1, 2015

AMENDED IN ASSEMBLY APRIL 16, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1351

Introduced by Assembly Member Eggman
(Coauthor: Senator Hall)

February 27, 2015

An act to amend Sections 1000, 1000.1, 1000.2, 1000.3, 1000.4, 1000.5, and 1000.6 of the Penal Code, relating to deferred entry of judgment.

LEGISLATIVE COUNSEL'S DIGEST

AB 1351, as amended, Eggman. Deferred entry of judgment: pretrial diversion.

Existing law allows individuals charged with specified crimes to qualify for deferred entry of judgment. A defendant qualifies if he or she has no conviction for any offense involving controlled substances, the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs other than a violation that qualifies for the program, the defendant's record does not indicate that probation or parole has ever been revoked without being completed, and the defendant's record does not indicate that he or she has been granted diversion, deferred entry of judgment, or was convicted of a felony within 5 years prior to the alleged commission of the charged offense.

Under the existing deferred entry of judgment program, an eligible defendant may have entry of judgment deferred, upon pleading guilty to the offenses charged and entering a drug treatment program for 18

months to 3 years. If the defendant does not perform satisfactorily in the program, does not benefit from the program, is convicted of specified crimes, or engages in criminal activity rendering him or her unsuitable for deferred entry of judgment, the defendant's guilty plea is entered and the court enters judgment and proceeds to schedule a sentencing hearing. If the defendant completes the program, the criminal charges are dismissed. Existing law allows the presiding judge of the superior court, with the district attorney and public defender, to establish a pretrial diversion drug program.

This bill would change the deferred entry of judgment program into a pretrial diversion program. Under the pretrial diversion program created by this bill, a defendant would qualify if he or she has no prior conviction for any offense involving controlled substances other than the offenses that qualify for diversion, the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs other than a violation that qualifies for the program and the defendant has no prior conviction for a serious or violent felony within 5 years prior to the alleged commission of the charged offense.

Under the pretrial diversion program created by this bill, a qualifying defendant would ~~not enter a guilty plea, but instead~~ *enter a not guilty plea, and* would suspend the proceedings in order to enter a drug treatment program for 6 months to one ~~year.~~ *year, or longer if requested by the defendant with good cause.* If the defendant does not perform satisfactorily in the program or is convicted of specified crimes, the court would terminate the program and the criminal proceedings would be reinstated. If the defendant completes the program, the criminal charges would be dismissed.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1000 of the Penal Code is amended to read:

1000. (a) This chapter shall apply whenever a case is before any court upon an accusatory pleading for a violation of Section 11350, 11357, 11364, or 11365, paragraph (2) of subdivision (b) of Section 11375, Section 11377, or Section 11550 of the Health and Safety Code, or subdivision (b) of Section 23222 of the Vehicle

Code, or Section 11358 of the Health and Safety Code if the marijuana planted, cultivated, harvested, dried, or processed is for personal use, or Section 11368 of the Health and Safety Code if the narcotic drug was secured by a fictitious prescription and is for the personal use of the defendant and was not sold or furnished to another, or subdivision (d) of Section 653f if the solicitation was for acts directed to personal use only, or Section 381 or subdivision (f) of Section 647 of the Penal Code, if for being under the influence of a controlled substance, or Section 4060 of the Business and Professions Code, and it appears to the prosecuting attorney that, except as provided in subdivision (b) of Section 11357 of the Health and Safety Code, all of the following apply to the defendant:

(1) The defendant has no prior conviction for any offense involving controlled substances other than the offenses listed in this subdivision.

(2) The offense charged did not involve a crime of violence or threatened violence.

(3) There is no evidence of a violation relating to narcotics or restricted dangerous drugs other than a violation of the sections listed in this subdivision.

(4) The defendant has no prior conviction within five years prior to the alleged commission of the charged offense for a serious felony, as defined in subdivision (c) of Section 1192.7, or a violent felony, as defined in subdivision (c) of Section 667.5.

(b) The prosecuting attorney shall review his or her file to determine whether or not paragraphs (1) to (4), inclusive, of subdivision (a) apply to the defendant. If the defendant is found eligible, the prosecuting attorney shall file with the court a declaration in writing or state for the record the grounds upon which the determination is based, and shall make this information available to the defendant and his or her attorney. This procedure is intended to allow the court to set the hearing for pretrial diversion of judgment at the arraignment. If the defendant is found ineligible for pretrial diversion, the prosecuting attorney shall file with the court a declaration in writing or state for the record the grounds upon which the determination is based, and shall make this information available to the defendant and his or her attorney. The sole remedy of a defendant who is found ineligible for pretrial diversion is a postconviction appeal.

(c) All referrals for pretrial diversion granted by the court pursuant to this chapter shall be made only to programs that have been certified by the county drug program administrator pursuant to Chapter 1.5 (commencing with Section 1211) of Title 8, or to programs that provide services at no cost to the participant and have been deemed by the court and the county drug program administrator to be credible and effective. The defendant may request to be referred to a program in any county, as long as that program meets the criteria set forth in this subdivision.

(d) Pretrial diversion for an alleged violation of Section 11368 of the Health and Safety Code shall not prohibit any administrative agency from taking disciplinary action against a licensee or from denying a license. Nothing in this subdivision shall be construed to expand or restrict the provisions of Section 1000.4.

(e) Any defendant who is participating in a program referred to in this section may be required to undergo analysis of his or her urine for the purpose of testing for the presence of any drug as part of the program. However, ~~urine analysis~~ *urinalysis* results shall not be admissible as a basis for any new criminal prosecution or proceeding.

SEC. 2. Section 1000.1 of the Penal Code is amended to read:

1000.1. (a) If the prosecuting attorney determines that this chapter may be applicable to the defendant, he or she shall advise the defendant and his or her attorney in writing of that determination. This notification shall include all of the following:

(1) A full description of the procedures for pretrial diversion.

(2) A general explanation of the roles and authorities of the probation department, the prosecuting attorney, the program, and the court in the process.

(3) A clear statement that the court may grant pretrial diversion with respect to any crime specified in subdivision (a) of Section 1000 that is charged, provided that the defendant *pleads not guilty to the charge or charges*, waives the right to a speedy preliminary hearing, if applicable, and that upon the defendant's successful completion of a program, as specified in subdivision (c) of Section 1000, the positive recommendation of the program authority and the motion of the defendant, prosecuting attorney, the court, or the probation department, but no sooner than six months and no later than one year from the date of the defendant's referral to the

program, the court shall dismiss the charge or charges against the defendant.

(4) A clear statement that upon any failure of treatment or condition under the program, or any circumstance specified in Section 1000.3, the prosecuting attorney or the probation department or the court on its own may make a motion to the court to terminate pretrial diversion and schedule further proceedings as otherwise provided in this code.

(5) An explanation of criminal record retention and disposition resulting from participation in the pretrial diversion program and the defendant's rights relative to answering questions about his or her arrest and pretrial diversion following successful completion of the program.

(b) If the defendant consents and waives his or her right to a speedy trial and a speedy preliminary hearing, if applicable, the court may refer the case to the probation department or the court may summarily grant pretrial diversion. When directed by the court, the probation department shall make an investigation and take into consideration the defendant's age, employment and service records, educational background, community and family ties, prior controlled substance use, treatment history, if any, demonstrable motivation, and other mitigating factors in determining whether the defendant is a person who would be benefited by education, treatment, or rehabilitation. The probation department shall also determine which programs the defendant would benefit from and which programs would accept the defendant. The probation department shall report its findings and recommendations to the court. The court shall make the final determination regarding education, treatment, or rehabilitation for the defendant. If the court determines that it is appropriate, the court shall grant pretrial diversion if the defendant *pleads not guilty to the charge or charges and* waives the right to a speedy trial and to a speedy preliminary hearing, if applicable.

(c) (1) No statement, or any information procured therefrom, made by the defendant to any probation officer or drug treatment worker, that is made during the course of any investigation conducted by the probation department or treatment program pursuant to subdivision (b), and prior to the reporting of the probation department's findings and recommendations to the court,

shall be admissible in any action or proceeding brought subsequent to the investigation.

(2) No statement, or any information procured therefrom, with respect to the specific offense with which the defendant is charged, that is made to any probation officer or drug program worker subsequent to the granting of pretrial diversion shall be admissible in any action or proceeding.

(d) A defendant's participation in pretrial diversion pursuant to this chapter shall not constitute a conviction or an admission of guilt for any purpose.

SEC. 3. Section 1000.2 of the Penal Code is amended to read:

1000.2. (a) The court shall hold a hearing and, after consideration of any information relevant to its decision, shall determine if the defendant consents to further proceedings under this chapter and if the defendant should be granted pretrial diversion. If the defendant does not consent to participate in pretrial diversion the proceedings shall continue as in any other case.

(b) At the time that pretrial diversion is granted, any bail bond or undertaking, or deposit in lieu thereof, on file by or on behalf of the defendant shall be exonerated, and the court shall enter an order so directing.

(c) The period during which pretrial diversion is granted shall be for no less than six months nor longer than one year. *However, the defendant may request and the court shall grant, for good cause shown, an extension of time to complete a program specified in subdivision (c) of Section 1000.* Progress reports shall be filed by the probation department with the court as directed by the court.

SEC. 4. Section 1000.3 of the Penal Code is amended to read:

1000.3. (a) If it appears to the prosecuting attorney, the court, or the probation department that the defendant is performing unsatisfactorily in the assigned program, or that the defendant is convicted of an offense that reflects the defendant's propensity for violence, or the defendant is convicted of a felony, the prosecuting attorney, the court on its own, or the probation department may make a motion for termination from pretrial diversion.

(b) After notice to the defendant, the court shall hold a hearing to determine whether pretrial diversion shall be terminated.

(c) If the court finds that the defendant is not performing satisfactorily in the assigned program, or the court finds that the defendant has been convicted of a crime as indicated in subdivision

(a) the court shall ~~reinstate the criminal charge or charges and~~ schedule the matter for further proceedings as otherwise provided in this code.

(d) If the defendant has completed pretrial diversion, at the end of that period, the criminal charge or charges shall be dismissed.

(e) Prior to dismissing the charge or charges or terminating pretrial diversion, the court shall consider the defendant's ability to pay and whether the defendant has paid a diversion restitution fee pursuant to Section 1001.90, if ordered, and has met his or her financial obligation to the program, if any. As provided in Section 1203.1b, the defendant shall reimburse the probation department for the reasonable cost of any program investigation or progress report filed with the court as directed pursuant to Sections 1000.1 and 1000.2.

SEC. 5. Section 1000.4 of the Penal Code is amended to read:

1000.4. (a) Any record filed with the Department of Justice shall indicate the disposition in those cases referred to pretrial diversion pursuant to this chapter. Upon successful completion of a pretrial diversion program, the arrest upon which the defendant was diverted shall be deemed to have never occurred. The defendant may indicate in response to any question concerning his or her prior criminal record that he or she was not arrested or granted pretrial diversion for the offense, except as specified in subdivision (b). A record pertaining to an arrest resulting in successful completion of a pretrial diversion program shall not, without the defendant's consent, be used in any way that could result in the denial of any employment, benefit, license, or certificate.

(b) The defendant shall be advised that, regardless of his or her successful completion of the pretrial diversion program, the arrest upon which pretrial diversion was based may be disclosed by the Department of Justice in response to any peace officer application request and that, notwithstanding subdivision (a), this section does not relieve him or her of the obligation to disclose the arrest in response to any direct question contained in any questionnaire or application for a position as a peace officer, as defined in Section 830.

SEC. 6. Section 1000.5 of the Penal Code is amended to read:

1000.5. (a) The presiding judge of the superior court, or a judge designated by the presiding judge, together with the district

attorney and the public defender, may agree in writing to establish and conduct a preguilty plea drug court program pursuant to the provisions of this chapter, wherein criminal proceedings are suspended without a plea of guilty for designated defendants. The drug court program shall include a regimen of graduated sanctions and rewards, individual and group therapy, ~~urine analysis~~ *urinalysis* testing commensurate with treatment needs, close court monitoring and supervision of progress, educational or vocational counseling as appropriate, and other requirements as agreed to by the presiding judge or his or her designee, the district attorney, and the public defender. If there is no agreement in writing for a preguilty plea program by the presiding judge or his or her designee, the district attorney, and the public defender, the program shall be operated as a pretrial diversion program as provided in this chapter.

(b) The provisions of Section 1000.3 and Section 1000.4 regarding satisfactory and unsatisfactory performance in a program shall apply to preguilty plea programs. If the court finds that (1) the defendant is not performing satisfactorily in the assigned program, (2) the defendant is not benefiting from education, treatment, or rehabilitation, (3) the defendant has been convicted of a crime specified in Section 1000.3, or (4) the defendant has engaged in criminal conduct rendering him or her unsuitable for the preguilty plea program, the court shall reinstate the criminal charge or charges. If the defendant has performed satisfactorily during the period of the preguilty plea program, at the end of that period, the criminal charge or charges shall be dismissed and the provisions of Section 1000.4 shall apply.

SEC. 7. Section 1000.6 of the Penal Code is amended to read:

1000.6. (a) Where a person is participating in a pretrial diversion program or a preguilty plea program pursuant to this chapter, the person shall be allowed, under the direction of a licensed health care practitioner, to use medications including, but not limited to, methadone, buprenorphine, or levoalphacetylmethadol (LAAM) to treat substance use disorders if the participant allows release of his or her medical records to the court presiding over the participant's preguilty plea or pretrial diversion program for the limited purpose of determining whether or not the participant is using such medications under the direction of a licensed health care practitioner and is in compliance with the pretrial diversion or preguilty plea program rules.

(b) If the conditions specified in subdivision (a) are met, using medications to treat substance use disorders shall not be the sole reason for exclusion from a pretrial diversion or preguilty plea program. A patient who uses medications to treat substance use disorders and participates in a preguilty plea or pretrial diversion program shall comply with all court program rules.

(c) A person who is participating in a pretrial diversion program or preguilty plea program pursuant to this chapter who uses medications to treat substance use disorders shall present to the court a declaration from their health care practitioner, or their health care practitioner's authorized representative, that the person is currently under their care.

(d) Urinalysis results that only establish that a person described in this section has ingested medication duly prescribed to that person by his or her physician or psychiatrist, or medications used to treat substance use disorders, shall not be considered a violation of the terms of the pretrial diversion or preguilty plea program under this chapter.

(e) Except as provided in subdivisions (a) to (d), inclusive, this section shall not be interpreted to amend any provisions governing diversion programs.

O

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 1351**
Current Version:	**As Amended June 1, 2015**
Board Position:	**Oppose (as introduced 2/27/15)**
Author:	**Eggman**
Topic:	**Deferred Entry of Judgment: pretrial diversion**

Affected Section(s): Sections 1000, 1000.1, 1000.2, 10000.3, 1000.4, 1000.5, and 1000.6 of the Penal Code

Status: The bill passed out of Senate Public Safety on July 13.

SUMMARY:
This measure would change the existing deferred entry of judgment program into a pretrial diversion program. Under the pretrial diversion program created by this bill, a defendant qualifies if they have no prior conviction for any offense involving controlled substances (other than the offenses that qualify for the diversion program), the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies for the program) and the defendant has no prior conviction for a serious or violent felony in the five years prior to the alleged commission of the charged offense.

EXISTING LAW:
Existing law allows individuals convicted of specified crimes to qualify for deferred entry of judgment if they had no conviction for any offense involving controlled substances, the charged offense did not involve violence, there was no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualified the individual for the program), the defendant's record did not indicate that probation or parole has ever been revoked without being completed, and the defendant's record did not indicate that he or she has been granted diversion, deferred entry of judgment, or was convicted of a felony.

Further, under the existing "deferred entry of judgment program," defendants plead guilty and have entry of judgment deferred, in return for entering a drug treatment program for 18 months to 3 years. If the defendant doesn't perform satisfactorily in the program, doesn't benefit from the program, gets convicted of specified crimes, or engages in criminal activity rendering them unsuitable for deferred entry of judgment, the defendant's guilty plea gets entered and the court proceeds to schedule a sentencing hearing. In the alternative, if the defendant completes the program, the criminal charges are dismissed. Under existing law the

presiding judge of the superior court, with the district attorney and public defender, may establish a pretrial diversion drug program.

THIS BILL WOULD:

1. This bill would change the existing statewide "deferred entry of judgment program" into a pretrial diversion program. Under this pretrial diversion program, a defendant qualifies if they have no prior conviction for any offense involving controlled substances (other than offenses that qualify for pretrial diversion diversion), the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies them for the diversion) and the defendant has no prior felony conviction for a serious or violent felony in the five years prior to the alleged commission of the charged offense.

2. In this pretrial diversion program, a qualifying defendant doesn't enter a guilty plea, but instead the court suspends the proceedings and places the defendant in a drug treatment program for 6 months to one year. If the defendant does not perform satisfactorily in the program or is convicted of specified crimes, the court terminates the program and the criminal proceedings are reinstated. In the alternative, if the defendant completes the program, the criminal charges are dismissed.

The most recent version of the bill allows a defendant to request and mandate that the court shall grant, for good cause shown, an extension of time to complete a pretrial diversion program.

STAFF COMMENTS:
This bill amends the Penal code that will negatively impact the Board's ability to prove in disciplinary proceedings that a licensee or applicant is engaged in illicit drug activities. The bill is likely to increase the board's costs of prosecution or lead to the dismissal of certain disciplinary charges, to the detriment of public safety. This is because the changes proposed will allow defendants to not plead guilty. This means the Board won't be able to use a guilty plea as an admission of guilt, and when a defendant participates in a pretrial diversion program, the board can't consider that an admission of guilt.

The standards for allowing defendants to participate in the deferred entry of judgment program will change, possibly increasing the number of defendants able to participate in the program. The criminal courts will dismiss charges against defendants sooner than before, and the required participation in a drug program will be for less time, possibly effecting whether adequate rehabilitation can occur. In this bill, there is no limit to the number of times an individual can cycle through pretrial diversion programs.

The prosecutor won't be able to make a motion to terminate a defendant from the program if the defendant engages in criminal conduct that makes them unsuitable for the program, or is

no longer benefitting from the program. That will leave more defendants in the program and thus still in the position of having their charges dismissed at the end of the program.

Staff has met with the author's office and has conveyed the board's Opposition. Staff offered proposed amendments, which were rejected. Staff is continuing to work with the author's office to try and find a solution to address the board's concerns.

FISCAL IMPACT ON THE BOARD:
Board staff anticipates a major fiscal impact primarily to its enforcement related costs. Due to the shortening of the diversion program (cuts the existing minimum time of 12 months in half) these types of cases would require expediting in order to take action prior to the deferred entry of judgment, which would have an impact on other cases. Likewise, for jurisdictions that take up to four months to respond to written requests for documents, the board would have to utilize staff resources to acquire the documents at the jurisdiction, thereby increasing travel costs and additional staff time.

SUPPPORT/OPPOSITION (As noted in the Senate Public Safety Analysis):
Support
American Civil Liberties Union of California (Co-Sponsor)
Coalition for Humane Immigrant Rights of Los Angeles (Co-Sponsor)
Mexican American Legal Defense and Education Fund (MALDEF) (Co-Sponsor)
National Council of La Raza (Co-Sponsor)
African Advocacy Network; Asian Americans Advancing Justice – Asian Law Caucus
Asian Americans Advancing Justice – L.A. ; Asian Law Alliance
California Attorneys for Criminal Justice
California Immigrant Policy Center; California Partnership
California Public Defenders Association; California Rural Legal Assistance Foundation
Californians for Safety and Justice; Californians United for a Responsible Budget
Central American Resource Center – Los Angeles
Chinese for Affirmative Action
Community United Against Violence
Congregations Building Community
Del Sol Group
Dolores Street Community Services
Faith in Action Kern County
Friends Committee on Legislation of California
Harvey Milk LGBT Democratic Club
Human Rights Watch
Immigration Action Group
Institute for Justice
Lawyers' Committee for Civil Rights of the San Francisco Bay Area
Legal Services for Prisoners with Children
Los Angeles Regional Reentry Partnership
Justice Not Jails
MAAC
Mujeres Unidas y Activas
National Association of Social Workers – California Chapter

National Day Laborer Organizing Network
National Immigration Law Center
Pangea Legal Services
PICO California
Placer People of Faith
Presente.org
Progressive Christians Uniting
Red Mexicana de Lideres y Organizaciones Migrantes
Santa Clara County Public Defender's Office
Silicon Valley De-Bug
Solutions for Immigrants
William C. Velasquez Institute
Vital Immigrant Defense Advocacy and Services (VIDAS)
One private individual

Opposition
California District Attorneys Association
California State Board of Pharmacy
California State Sheriffs' Association

RELATED LEGISLATION:

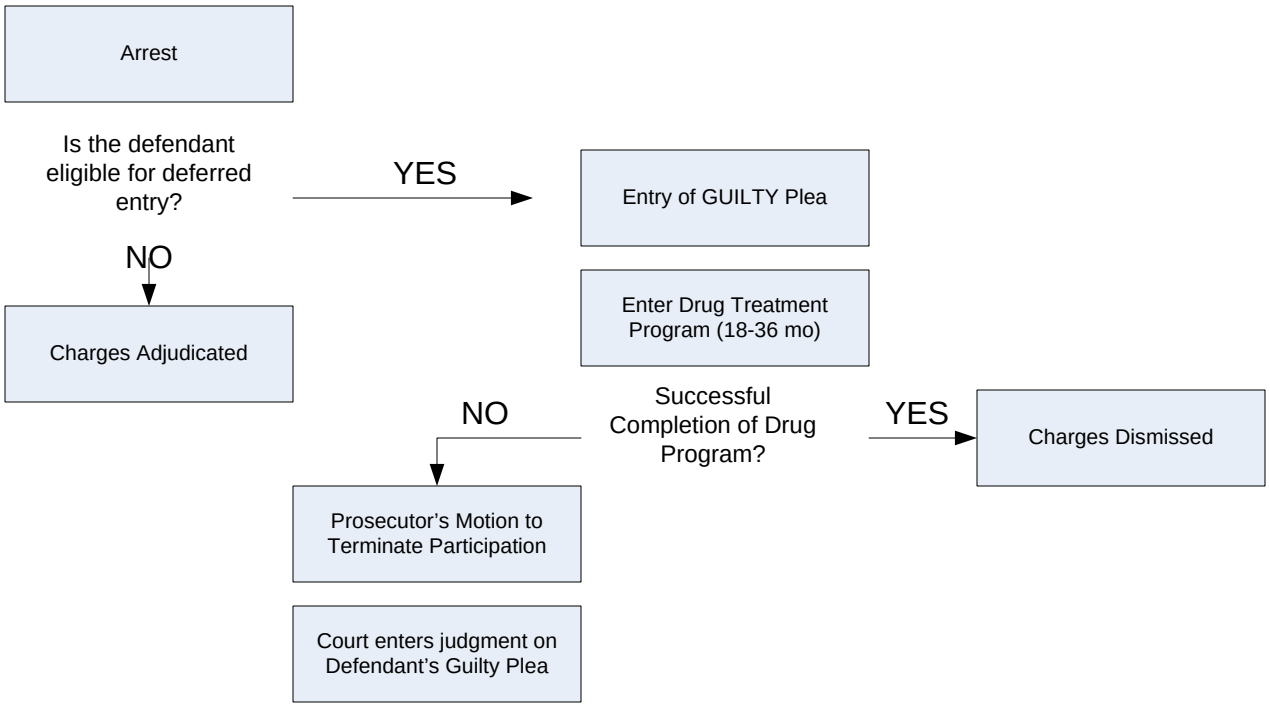
AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea
This measure would require a court to allow a defendant who was granted deferred entry of judgment to withdraw his or her plea and enter a plea of not guilty if the changed were dismissed upon successful completion of the program and the defendant shows that the plea may result in the denial or loss of the defendant's employment, benefit, license or certificate.

HISTORY:

Date	Action
07/15/15	From committee: Do pass and re-refer to Com. on APPR. (Ayes 4. Noes 2.) (July 14). Re-referred to Com. on APPR.
06/30/15	In committee: Set, first hearing. Hearing canceled at the request of author.
06/18/15	Referred to Com. on PUB. S.
06/03/15	In Senate. Read first time. To Com. on RLS. for assignment.
06/03/15	Read third time. Passed. Ordered to the Senate. (Ayes 47. Noes 30. Page 1880.)
06/02/15	Read second time. Ordered to third reading.
06/01/15	Read second time and amended. Ordered returned to second reading.
05/28/15	From committee: Amend, and do pass as amended. (Ayes 12. Noes 5.) (May 28).
05/06/15	In committee: Set, first hearing. Referred to APPR. suspense file.
04/22/15	From committee: Do pass and re-refer to Com. on APPR. (Ayes 5. Noes 2.) (April 21). Re-referred to Com. on APPR.

Date	Action
04/20/15	Re-referred to Com. on PUB. S.
04/16/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
03/23/15	Referred to Com. on PUB. S.
03/02/15	Read first time.
03/01/15	From printer. May be heard in committee March 31.

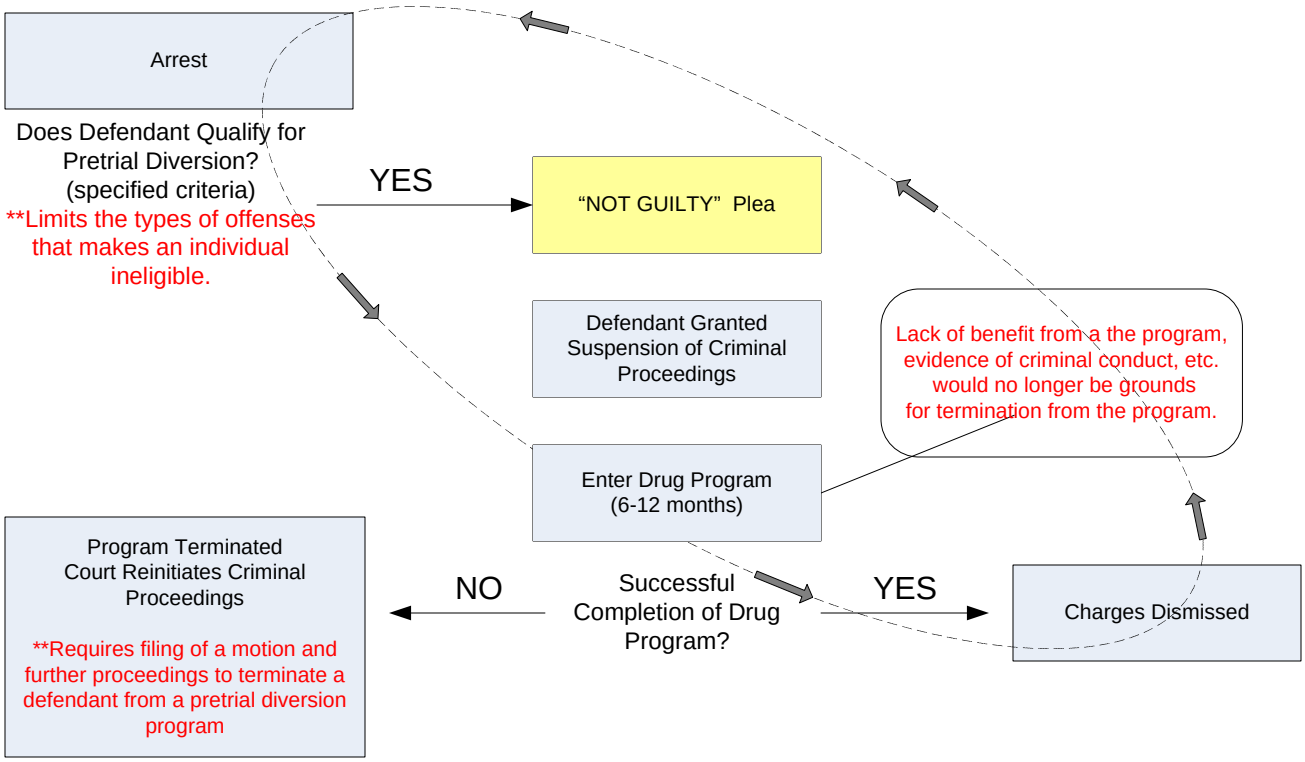
Current Deferred Entry of Judgment



AB 1351

AB 1351: The Revolving Door

- **No limit on how many times an individual can go through pretrial diversion.**



AMENDED IN SENATE MAY 19, 2015

AMENDED IN ASSEMBLY APRIL 27, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1352

Introduced by Assembly Member Eggman

February 27, 2015

An act to add Section 1203.43 to the Penal Code, relating to deferred entry of judgment.

LEGISLATIVE COUNSEL'S DIGEST

AB 1352, as amended, Eggman. Deferred entry of judgment: withdrawal of plea.

Existing law allows judgment to be deferred with respect to a defendant who is charged with certain crimes involving possession of controlled substances and who meets certain criteria, including that he or she has no prior convictions for any offense involving controlled substances and has had no felony convictions within the 5 years prior, as specified. Existing law prohibits the record pertaining to an arrest resulting in successful completion of a deferred entry of judgment program from being used in any way that could result in the denial of employment, benefit, license, or certificate.

This bill would require a court to allow a defendant who was granted deferred entry of judgment on or after January 1, 1997, after pleading guilty or nolo contendere to the charged offense, to withdraw his or her plea and enter a plea of not guilty, and would require the court to dismiss the complaint or information against the defendant, if the defendant performed satisfactorily during the deferred entry of judgment period and the defendant ~~shows~~ *attests* that the plea may result in the denial

or loss to the defendant of any employment, benefit, license, or certificate, including, but not limited to, causing a noncitizen defendant to potentially be found inadmissable, deportable, or subject to any other kind of adverse immigration consequence. *The bill would require the Judicial Council to develop a form to allow the defendant to make this attestation. Pursuant to the bill, the completion, signing, and submission of the form with specified documentation would be presumed to satisfy the requirement for the withdrawal of the plea and dismissal of the complaint.*

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1203.43 is added to the Penal Code, to read:

1203.43. (a) (1) The Legislature finds and declares that the statement in Section 1000.4, that "successful completion of a deferred entry of judgment program shall not, without the defendant's consent, be used in any way that could result in the denial of any employment, benefit, license, or certificate" constitutes misinformation about the actual consequences of making a plea in the case of some defendants, including all noncitizen defendants, because the disposition of the case may cause adverse consequences, including adverse immigration consequences.

(2) Accordingly, the Legislature finds and declares that based on this misinformation and the potential harm, the defendant's prior plea is invalid.

(b) In any case in which a defendant was granted deferred entry of judgment on or after January 1, 1997, after pleading guilty or nolo contendere to the charged offense, the defendant shall be permitted by the court to withdraw the plea of guilty or nolo contendere and enter a plea of not guilty, and thereafter the court shall dismiss the complaint or information against the defendant, if the defendant ~~shows~~ *attests to* both of the following:

(1) The charges were dismissed after the defendant performed satisfactorily during the deferred entry of judgment period.

(2) The plea of guilty or nolo contendere may result in the denial or loss to the defendant of any employment, benefit, license, or

certificate, including, but not limited to, causing a noncitizen defendant to potentially be found inadmissable, deportable, or subject to any other kind of adverse immigration consequence.

(c) The Judicial Council shall, by June 1, 2016, develop a form that allows a defendant to attest to the information described in paragraphs (1) and (2) of subdivision (b).

(d) The defendant shall submit documentation of the dismissal of charges or satisfactory participation in, or completion of, diversion programming. The completion, signing, and submission by the defendant of the form described in subdivision (c) with the documentation specified in this subdivision shall be presumed to satisfy the requirements for withdrawal of the plea and dismissal of the complaint or information against the defendant.

O

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 1352**
Current Version:	**As Amended May 19, 2015**
Board Position:	**Oppose (2/27/15)**
Author:	**Eggman**
Topic:	**Deferred Entry of Judgment: withdrawal of plea**

Affected Section(s): Section 1203.43 of the Penal Code

Status: Hearing: Senate Appropriations – August 17

SUMMARY:
This measure would require a court to allow a defendant who was granted deferred entry of judgment on or after January 1, 1997, after pleading guilty or nolo contendere to the charged offense, to withdraw his or her plea and enter a plea of not guilty if the charges were dismissed after the defendant performed satisfactorily during the deferred entry of judgment period and the defendant shows that the plea may result in the denial or loss to the defendant of any employment, benefit, license, or certificate, including, but not limited to, causing a noncitizen defendant to potentially be found in-admissable, deportable, or subject to any other kind of adverse immigration consequence.

EXISTING LAW:
Existing law allows judgment to be deferred with respect to a defendant who is charged with certain crimes involving possession of controlled substances and who meets certain criteria, including that he or she has no prior convictions for any offense involving controlled substances and has had no felony convictions within the 5 years prior. Existing law prohibits the record pertaining to an arrest resulting in successful completion of a deferred entry of judgment program from being used in any way that could result in the denial of employment, benefit, license, or certificate.

THIS BILL WOULD:
This bill would require a court to allow a defendant who was granted deferred entry of judgment on or after January 1, 1997, after pleading guilty or nolo contendere to the charged offense, to withdraw his or her plea and enter a plea of not guilty – and thereafter require the court to dismiss the complaint or information against the defendant – if the charges were dismissed after the defendant performed satisfactorily during the deferred entry of judgment period and the defendant shows that the plea may result in the denial or loss to the defendant of any employment, benefit, license, or certificate, including, but not limited to, causing a

noncitizen defendant to potentially be found inadmissible, deportable, or subject to any other kind of adverse immigration consequence.

The most recent amendments to the bill would (a) require the court to dismiss the complaint or information against the defendant where the defendant withdrew the plea of guilty or nolo contendere and entered a please of not guilty, and specified and (b) require the Judicial Council to develop a form by June 1, 2016, that an individual would use to so attest.

STAFF COMMENTS:

This bill adds to the Penal code in such a way as to strongly impact the Board's ability to prove in disciplinary proceedings that a licensee or applicant is engaged, or has been engaged, in illicit drug activities. The bill is likely to increase the board's costs of prosecution or could lead to the dismissal of certain disciplinary charges, to the detriment of public safety. The changes proposed will allow a defendant to change a prior guilty plea, and since no guilty plea will be made going forward to get into the pretrial diversion program, the Board can't view participation in the pretrial diversion program as an admission of guilt.

The standards for allowing defendants to participate in the pre-trial diversion program will change, possibly increasing the number of defendants able to participate in the program. The criminal courts will dismiss charges against defendants sooner than before, and the required participation in a drug program will be for less time, possibly effecting whether adequate rehabilitation occurs.

The prosecutor won't be able to make a motion to terminate a defendant from the program if the defendant engages in criminal conduct that makes them unsuitable for the program, or is no longer benefitting from the program, that is now for the court to monitor. That will leave more defendants in the program and thus still in the position of having their charges dismissed at the end of the program.

FISCAL IMPACT ON THE BOARD:
Board staff anticipates a major fiscal impact.

SUPPPORT/OPPOSITION (According to the Senate Public Safety Analysis)**:**
Support
American Civil Liberties Union of California (Co-Sponsor)
Coalition for Humane Immigrant Rights of Los Angeles (Co-Sponsor)
Mexican American Legal Defense and Education Fund (MALDEF) (Co-Sponsor)
National Council of La Raza (Co-Sponsor)
African Advocacy Network; Asian Americans Advancing Justice – Asian Law Caucus
Asian Americans Advancing Justice – L.A.
Asian Law Alliance; California Attorneys for Criminal Justice
California Immigrant Policy Center; California Partnership
California Public Defenders Association
California Rural Legal Assistance Foundation
Californians for Safety and Justice
Californians United for a Responsible Budget

Central American Resource Center – Los Angeles
Chinese for Affirmative Action
Community United Against Violence
Congregations Building Community
Del Sol Group; Dolores Street Community Services
Faith in Action Kern County
Friends Committee on Legislation of California
Harvey Milk LGBT Democratic Club
Human Rights Watch
Immigration Action Group
Institute for Justice
Lawyers' Committee for Civil Rights of the San Francisco Bay Area
Legal Services for Prisoners with Children
Los Angeles Regional Reentry Partnership
Justice Not Jails
MAAC
Mujeres Unidas y Activas
National Association of Social Workers – California Chapter
National Day Laborer Organizing Network; National Immigration Law Center
Pangea Legal Services
PICO California
Placer People of Faith
Presente.org
Progressive Christians Uniting
Red Mexicana de Lideres y Organizaciones Migrantes
Santa Clara County Public Defender's Office
Silicon Valley De-Bug
Solutions for Immigrants William C. Velasquez Institute
Vital Immigrant Defense Advocacy and Services (VIDAS)
One private individual

Opposition
California District Attorneys Association
California State Board of Pharmacy
California State Sheriffs' Association

PREVIOUS/RELATED LEGISLATION:

Assembly Bill 1351 (Eggman)

AB 1351 would change the existing deferred entry of judgment program into a pretrial diversion program. Under the pretrial diversion program created by this bill, a defendant qualifies if they have no prior conviction for any offense involving controlled substances (other than the offense that qualifies for the program), the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies for the program) and the defendant has no prior conviction for a serious or violent felony in the five years prior to the alleged commission of the charged offense.

HISTORY:

Date	Action
07/15/15	From committee: Do pass and re-refer to Com. on APPR. (Ayes 5. Noes 2.) (July 14). Re-referred to Com. on APPR.
06/30/15	In committee: Set, first hearing. Hearing canceled at the request of author.
06/17/15	In committee: Hearing postponed by committee.
05/19/15	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on PUB. S.
05/14/15	Referred to Com. on PUB. S.
05/04/15	In Senate. Read first time. To Com. on RLS. for assignment.
05/04/15	Read third time. Passed. Ordered to the Senate. (Ayes 42. Noes 33. Page 1257.)
04/28/15	Read second time. Ordered to third reading.
04/27/15	Read second time and amended. Ordered returned to second reading.
04/23/15	From committee: Amend, and do pass as amended. (Ayes 5. Noes 2.) (April 21).
03/23/15	Referred to Com. on PUB. S.
03/02/15	Read first time.
03/01/15	From printer. May be heard in committee March 31.
02/27/15	Introduced. To print.

Attachment 4

Title 16. Board of Pharmacy

ORDER OF ADOPTION

To Amend 1793.5 Pharmacy Technician Application. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.
The "Pharmacy Technician Application (Form 17A-5(Rev. ~~01/11~~ 10/15)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications, and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank ~~— Healthcare Integrity and Protection Data Bank~~ (NPDB~~-HIPDB~~) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4402, and 4400, Business and Professions Code; Section 11105, Penal Code.

VIRGINIA HEROLD
Executive Officer
California State Board of Pharmacy

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

PHARMACY TECHNICIAN APPLICATION

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in an incomplete application and a deficiency letter being mailed to you. Please read all the instructions prior to completing this application. **Page 1, 2, and 3 of the application must be completed and signed by the applicant.** All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets on paper if necessary.

☐ **MILITARY (**Check here if you meet the requirements for expediting your application.)

Applicant Information – Please Type or Print

Full Legal Name: Last Name:	First Name:	Middle Name:
Previous Names (AKA, Maiden Name, Alias, etc):		
*Official Mailing/Public Address of Record (Street Address, PO Box #, etc):		
City:	State:	Zip Code:
Residence Address (if different from above):		
City:	State:	Zip Code:
Home#: ( )	Cell#: ( )	Work#: ( ) Email Address:
Date of Birth (Month/Day/Year):	**Social Security # or Individual Tax ID #:	Driver's License No: State:

Mandatory Education (check one box)

Please indicate how you satisfy the mandatory education requirement in Business and Professions Code Section 4202(a).

☐ High school graduate or foreign equivalent.
Attach ~~a certified copy~~ an official embossed transcript or notarized copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

☐ Completed a ~~G~~general ~~E~~education ~~D~~development ~~(GED)~~certificate equivalent.
Attach an official transcript ~~or~~ of your ~~GED~~ test results.

TAPE A COLOR PASSPORT STYLE PHOTOGRAPH (2"X2") TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION
NO POLAROID OR SCANNED IMAGES
PHOTO MUST BE ON PHOTO QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(a)(1)(2)(3)(4) of the Business and Professions Code.

☐ Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

☐ Attached is a certified copy of PTCB certificate – Date certified: _____

☐ Attached is a certified copy of your military training DD214

List all state(s) where you hold or held a license as a pharmacist, intern pharmacist and/or pharmacy technician and or another health care profession license, including California. Attach an additional sheet if necessary.

State	Registration Number	Active or Inactive	Issued Date	Expiration Date

Self-Query Report by the National Practitioner Data Bank (NPDB)~~Healthcare Integrity and Protection Data Bank (NPDB-HIPDB)~~

☐ Attached is the original sealed envelope containing my Self-Query Report from NPDB. (This must be submitted with your application.)

FOR BOARD USE ONLY

Photo ☐ Enf 1st Check ☐ Enf 2nd Check ☐ Qualify Code _____ Self-Query ☐	FP Cards/Live Scan ☐ FP Cards Sent _____ FP Fees ☐ DOJ Clear Date: _____ FBI Clear Date: _____	License no. _____ Date issued _____ Date expires _____	App fee no. _____ Amount _____ Date cashiered _____

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

1. Do you have a ~~medical condition~~ mental illness or physical illness ~~which~~ that in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? **If "yes," attach a statement of explanation. If "no," proceed to #2.** Are the limitations caused by your ~~medical condition~~mental illness or physical illness reduced or improved because you receive ongoing treatment or participate in a monitoring program? Yes ☐ No ☐ **If "yes," attach a statement of explanation.** If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing ~~medical condition~~mental illness or physical illness to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.	Yes ☐ No ☐
2. ~~Do you currently engage, or have~~ Have you ~~you been~~ previously engaged ~~in the past two years,~~ in the illegal use of controlled substances? If "yes," are you currently participating in a supervised ~~rehabilitation~~ substance abuse program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
3. Do you currently participate in a substance abuse program or have previously participated in a substance abuse program in the past five years? If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you to ensure you are maintaining sobriety? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
~~3~~4. Has disciplinary action ever been taken against your designated representative, pharmacist, intern pharmacist and/or pharmacy technician license in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
~~4~~5. Have you ever had an application for a designated representative, pharmacist~~.~~, intern ~~-~~pharmacist and/or pharmacy technician license denied in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
~~5~~6. ~~**Have you ever had a pharmacy permit, or any professional or vocational license or registration, denied or disciplined by a government authority in this state or any other state?**~~ Have you ever had a pharmacy license, or any professional or vocational license or registration, denied, suspended, revoked, placed on probation or had other disciplinary action taken by this or any other government authority in California or any other state? **If "yes," provide the name of company, type of permit, type of action, year of action and state.** _____	Yes ☐ No ☐

~~6~~7. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? If yes, provide company name, type of permit, permit number and state where licensed.	Yes ☐ No ☐
~~7~~8. ~~Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?~~ ~~Check the box next to **"Yes"** if, you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1210.1 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a conviction for an infraction with a fine of less than $300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea on no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1210.1 or 1203.4 of the Penal Code.~~ Have you ever been convicted of, or pleaded guilty or nolo contender/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country? Include any felony or misdemeanor offense, and any infraction involving drugs or alcohol with a fine of $500 or more. You must disclose a conviction even if it was: (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application. ~~Check the box next to "NO" if you have not been convicted of a crime.~~ NOTE: You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations with a fine of less than $500 that do not involved drugs or alcohol. You may wish to provide the following information in order to assist in the processing of your application: descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required. **Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.**	Yes ☐ No ☐

			———	~~9~~

APPLICANT AFFIDAVIT

You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete. Falsification of the information on this application may constitute ground for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being rejected as incomplete.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code Sections 4200 and 4202 and Title 16 California Code of Regulations Section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Mandatory Submission. Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by Civil Code Section 1798.40.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Act request (Government Code Section 6250 and following), as allowed by the Information Practices Act (Civil Code Section 1798 and following);
- To another government agency as required by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code Section 6250 et seq.) and will be placed on the Internet. This is where the board will mail all correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

**Disclosure of your U.S. social security account number or individual taxpayer identification number is mandatory. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

MANDATORY REPORTER

Under California law, each person licensed by the Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect purposes.

California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of Section 11166 and Section 15630 is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars ($1,000), or by both that imprisonment and fine. For further details about these requirements, consult Penal Code Section 11164 and Welfare and Institutions Code Section 15630, and subsequent sections.

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

I, _____ , hereby attest to the fact that I am the applicant whose signature appears
(Print full Legal Name)

below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. ~~I also certify that I have read the instructions attached to this application.~~ I understand that my application may be denied, or any license disciplined, for fraud or misrepresentation.

_____ _____
Original Signature of Applicant Date

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION FOR PHARMACY TECHNICIAN

Instructions: This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying). All dates must include the month, day, and year in order for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

☐ Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists as specified in Title 16 California Code of Regulations section 1793.6(a) on _____/_____/_____
(completion date must be included)

☐ Completed 240 hours of instruction as specified in Title 16 California Code of Regulations Section 1793.6(c) on _____/_____/_____
(completion date must be included)

☐ Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on _____/_____/_____
(graduation date must be included)

☐ Graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on _____/_____/_____
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: _____/_____/_____

Affix school seal here.

OR

Attach a business card of the pharmacist who provided the training pursuant to Section 1793.6(c) of the California Code of Regulation here. <u>The pharmacist's license number shall be listed.</u>

University, College, or School of Pharmacy Name: _____

Address: _____

_____

Print Name of Director, Registrar, or Pharmacist: _____

Phone Number: _____

Email: _____

Attachment 5

Amend Section 1715 in Article 2 of Division 17 of Title 16 to read:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self- assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 ~~(Rev. 01/11)~~ (Rev. 10/14) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self- Assessment" and on Form 17M-14 ~~(Rev. 01/11)~~ (Rev. 10/14) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority: Business and Professions Code §4005 and §4127. Reference: Business and Professions Code §4021, §4022, §4029, §4030, §4037, §4038, §4040, §4050, §4052, §4070, §4081, §4101, §4105, §4113, §4115, §4119, §4127, §4305, §4330, §4332 and §4333.

Amend Section 1784 in Article 10 of Division 17 of Title 16 to read:

§ 1784. Self-Assessment of a Wholesaler by the Designated Representative-In-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 ~~(Rev. 01/11)~~ (Rev. 10/14) entitled “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment” which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.

(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

Board of Pharmacy

Adopt §1746.2 of Article 5 of division 17 of Title 16 of the California Code of Regulations to read as follows:

§1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: section 4052.9(a) of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

(A) Review the patient's current tobacco use and past quit attempts.

(B) Ask the patient the following screening questions:

(i) Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)

(ii) Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)

(iii) Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)

(iv) Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)

(v) Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

(vi) Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

(C) When a nicotine replacement product is furnished:
  (i) The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
  (ii) Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.

(D) The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy's or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

Nicotine Replacement Therapy Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	**Lozenge**	**Patch**	**Nasal Spray**	**Inhaler**	
Product	**Nicorette[1], Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette Lozenge,[1] Nicorette Mini Lozenge,[1] Generic** OTC 2 mg, 4 mg cherry, mint	**NicoDerm CQ[1], Generic** OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	**Nicotrol NS[2]** Rx Metered spray 0.5 mg nicotine in 50 mcL aqueous nicotine solution	**Nicotrol Inhaler[2]** Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	**Combinations with demonstrated efficacy** Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
Precautions	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ See precautions for individual agents
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	*Reserve for patients smoking ≥10 cigarettes/day:* **Long-acting NRT**: to prevent onset of severe withdrawal symptoms ▪ **Nicotine patch** 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks **PLUS** **Short-acting NRT**: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco ▪ **Nicotine gum (2 mg)** 1 piece q 1–2 hours as needed *OR* ▪ **Nicotine lozenge (2 mg)** 1 lozenge q 1–2 hours as needed *OR* ▪ **Nicotine nasal spray** 1 spray in each nostril q 1–2 hours as needed *OR* ▪ **Nicotine inhaler** 1 cartridge q 1–2 hours as needed

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Once daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to single agent NRT ▪ Attractive option for patients who have previously failed treatment with monotherapy ▪ See advantages listed for individual agents
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F)	▪ Combination therapy is more costly than monotherapy ▪ See disadvantages listed for individual agents

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Pfizer.
[3] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

Authority: Sections 4005, 4052(a)(10) and 4052.9, Business and Professions Code. Reference: Sections 4052(a)(10) and §4052.9, Business and Professions Code.

californiapharmacistsassociation

June 22, 2015

California State Board of Pharmacy
Attn: Karen Halbo
1625 N. Market Blvd., N-219
Sacramento, CA 95834

Re: Protocol for Furnishing Nicotine Replacement Products

Dear Ms. Halbo:

Thank you for the opportunity to submit written comments to the Board of Pharmacy's (Board) proposed regulations relating to the protocol for pharmacist furnishing of nicotine replacement products. The California Pharmacists Association (CPhA) was a co-sponsor of SB 493 (Hernandez, 2013), the bill that enacted the enabling statute for these proposed regulations and is pleased to support the Board's draft protocol.

CPhA and other stakeholders worked with the Board's SB 493 Implementation Committee as that committee crafted a protocol that will improve access to tobacco cessation therapy and ensure that patients receive nicotine replacement products and counseling in a safe and appropriate manner. The protocol contained in this proposed rulemaking reflects these goals.

Thank you again for the opportunity to provide written comments on this important rulemaking package. If you have any questions, please do not hesitate to contact me at (916) 779-4517.

Sincerely,

Brian Warren
Vice President, Center for Advocacy

Sally Huston, MS, PhD Associate Professor, Clinical and Administrative Sciences Keck Graduate Institute School of Pharmacy		
Section, Subdivision	**Proposed Language**	**Recommendation, Comments**
16 CCR § 1746(2)(b)(4)(B)(v)	Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid ~~nasal spray~~ recommending a nicotine replacement product that is administered nasally)	
16 CCR § 1746(2)(b)(4)(B)	These screening questions shall be made available in alternate languages used in the local geographic area of the pharmacy for patients whose primary language is not English.	I think this is problematic because it seems to suggest a pharmacist should be able to provide it for anyone whose primary language is not English. This is not really reasonable in my opinion.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 22, 2015

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, CA 95834

RE: 1746.1 & 1726.2 –Nicotine Replacement Products & Self-Administered Hormonal Contraception

Fax No.: 916-574-8616

E-Mail: Karen.Halbo@DCA.ca.gov; Lori.Martinez@DCA.ca.gov

Dear Executive Officer Herold:

On behalf of our 19 member companies operating more than 3,900 community pharmacies throughout the state of California, the National Association of Chain Drug Stores (NACDS) urges the Board of Pharmacy to finalize its proposed rules on nicotine replacement products and self-administered hormonal contraception. These proposed rules promote public health by expanding patient access to nicotine replacement products and hormonal contraception.

Starting with nicotine replacement products, the corresponding proposed rule makes it easier for pharmacists to dispense such products to patients. These products have proven invaluable in reducing the rate of smoking and will help to further promote a smoke free California. Reducing the number of smokers correspondingly reduces the costs associated with smoking related diseases, such as lung cancer.

Similarly, the proposed rule allowing pharmacists to more freely dispense self-administered hormonal contraception promotes the public health by targeting women's health. Providing women with broader access to contraceptives reduces the number of unwanted pregnancies, which is associated with improved maternal health and safer pregnancies. As a matter of public health and maternal safety, improved access to self-administered hormonal contraception is critical.

For the reasons outlined above, we urge the Board to finalize the proposed rules on nicotine replacement products and self-administered hormone replacement therapy.

Sincerely,

Mary Staples

Mary Staples

State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
Director and State Health Officer

EDMUND G. BROWN JR.
Governor

June 18, 2015

Ms. Karen Halbo
Board of Pharmacy
1625 N. Market Boulevard, N219
Sacramento, CA 95834

Dear Ms. Halbo:

The California Department of Public Health (CDPH) supports the California State Board of Pharmacy's proposed action to adopt Title 16, California Code of Regulations Section 1746.2, which would establish a standard protocol for pharmacists to furnish prescription nicotine replacement products without a doctor's prescription. The proposed protocol would significantly expand access to treatment for smokers statewide since over 90 percent of people live within five miles of a pharmacy and most pharmacies are open beyond normal business hours. Pharmacists are highly qualified and trained in direct patient care, and disease prevention and management. Additionally pharmacists rank as one of the most trusted professions for Americans (Gallup).

CDPH supports the provision that requires pharmacists to take an additional two hours of continuing education on smoking cessation and nicotine replacement therapy to ensure a pharmacist proficiently provides cessation services. The provision of cessation services by pharmacists is consistent with the growing trend of pharmacies to eliminate the sale of tobacco products. In 2014, CVS announced that they would no longer sell cigarettes and tobacco products. In 2015, Raley's also announced that it would stop selling tobacco products at most of its supermarkets across Northern California and Nevada. Pharmacies such as CVS and Target have set up basic health clinics where customers can have basic health needs met.

If you need further information regarding this matter, please contact April Roeseler, M.S.P.H., Chief, California Tobacco Control Program at April.Roeseler@cdph.ca.gov or (916) 449-5504.

Sincerely,

Karen L. Smith, MD, MPH
Director and State Health Officer

Board of Pharmacy

Proposed Regulation

Adopt §1746.3 of Article 5 of Division 7 of Title 16 of the California Code of Regulations to read as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:
(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.
(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.
(1) Before providing naloxone hydrochloride, the pharmacist shall:

(A) Screen the potential recipient by asking the following questions:
(i) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids? (If the recipient answers yes, the pharmacist may skip screening question ii.);
(ii) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. If the recipient answers yes, the pharmacist may continue.
(iii) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. If the recipient answers yes, the pharmacist may not provide the naloxone. If the recipient responds no, the pharmacist may continue.
The screening questions shall be made available by the board on its website in alternate languages for recipients and patients whose primary language is not English.

(B) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(2) When naloxone hydrochloride is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(3) Product Selection: The pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or any other FDA-approved products. A pharmacist shall provide advice to the recipient to how to choose the route of administration of naloxone based on the formulation available, how well it can likely be administered, the setting, and local context.

(4) Product Labeling: A pharmacist shall label each container consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(5) Fact Sheet: The pharmacist shall provide the recipient with a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English and made available on the board's website.

(6) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or

health care facility for a period of at least three years from the date of dispensing. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Authority and Reference: Section 4052.01, Business and Professions Code.

From: Jacobson, Jody <j3jacobs@uci.edu>
Sent: Friday, May 22, 2015 4:03 PM
To: Halbo, Karen@DCA
Subject: naloxone comments

I'm wondering how one complies with this allergy screening when if the person getting the naloxone isn't the patient, chances are the person isn't able to come in themselves. If the person is the patient, how will one safely administer IM when they are "out' which would be the indication?

So, in support of perhaps saving a life, maybe the regulation should read 'make a best effort to obtain," advise possible administrators, or ??? Otherwise having this isn;t going to be helpful. This is a rescue agent used in the health care setting when a patient is unresponsive. Getting it for one's self will not help when one's self is unresponsive.
J Jacobson

BOARD OF PHARMACY

Proposed Regulation

Adopt §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

(A) Oral;
(B) Transdermal;
(C) Vaginal;
(D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

(A) Ask the patient to use and complete the self-screening tool;
(B) Review the self-screening answers and clarify responses if needed;
(C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
(D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.
(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

(i) Dosage;
(ii) Effectiveness;
(iii) Potential side effects;
(iv) Safety;
(v) The importance of receiving recommended preventative health screenings;
(vi) That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the

pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
	If yes, list them here:		

Authority: Sections 4005, 4052(a)(10), and 4052.3, Business and Professions Code.
Reference: Sections 4052(a)(10) and §4052.3, Business & Professions Code.

Proposal to Add Section 1746.1 to Title 16 of the California Code of Regulations Related to the Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

Summary of Comments to the 45-Day Comment Period

Written Comments from Brian Warren, California Pharmacists Association

Mr. Warren does not suggest any amendments to the regulation. Mr. Warren writes in support of the Board's draft protocol.

Comment #1: Mr. Warren and the California Pharmacists Association (CPhA) supports all elements contained in the Board's protocol, including the requirement to measure and record a patient's seated blood pressure prior to furnishing estrogen-progestin combination products.

Written Comments from Mary Staples, National Association of Chain Drug Stores

Ms. Staples does not suggests any amendments to the regulation. Ms. Staples urges the Board to finalize the proposed rules on self-administered hormonal contraception.

Comment #2: Ms. Staples speaks to the public health benefit stemming from expanded patient access. Ms. Staples cites benefits to maternal health, safe pregnancies, and reduced unwanted pregnancies.

Written Comments from Bonnie Zell, MD, MPH, FACOG, Icebreaker Health

Ms. Zell requests modification of the protocol, striking the pharmacists requirement to take seated blood pressure. Alternatively, she requests modification of the language such that it is up the professional judgment of the pharmacist whether to require seated blood pressure or allow self-reported blood pressure. Ms. Zell states the blood pressure requirement is unnecessary and inconsistent with SB 493 (Hernandez), the statute that authorizes this rulemaking.

Comment #3: Ms. Zell states that the seated blood pressure requirement will limit access to hormonal contraception.

Comment #4: Ms. Zell states that blood pressure can be adequately obtained and communicated to a healthcare provider through self-reporting tools.

Comment #5: Ms. Zell states that other comparable healthcare providers are not required to obtain a seated blood pressure before providing hormonal contraceptives.

Comment #6: Ms. Zell states that other organizations do not recommend a seated blood pressure. Ms. Zell also states that these organizations call for hormonal contraception to be classified as over-the-counter.

Written Comments from Beth H. Parker, Planned Parenthood Affiliates of California

Ms. Parker requests modification of the protocol language to permit women to self-report blood pressure. Ms. Parker opines that self-reporting will ensure maximum access to contraception without compromising patient safety.

Comment #7: Ms. Parker states that blood pressure can be adequately obtained through self-reporting tools.

Comment #8: Ms. Parker states that hormonal contraception is very safe and promotes women's health.

Comment #9: Ms. Parker states that self-reporting of blood pressure will increase access to contraception for women.

Comment #10: Ms. Parker states that access to contraception is crucial for women's economic opportunity and equality.

Written Comments from Mitchell D. Crenin, MD, Catherine Cansino, MD, MPH, Melody Hou, MD, MPH, and Juliana Melo, MD, MSCS, Division of Family Planning, Department of Obstetrics & Gynecology, University of California, Davis

Drs. Cenin, Cansino, Hou, and Melo provided comment that the requirement for a pharmacist to take seated blood pressure is not necessary and should be removed from the protocol.

Comment #11: Drs. Cenin, Cansino, Hou, and Melo state that requiring any evaluation of blood pressure for women seeking progestin-only pills is beyond CDC recommendation.

Comment #12: Drs. Cenin, Cansino, Hou, and Melo state that blood pressure can be adequately obtained and communicated to a pharmacist through self-reporting tools, and blood pressure reporting can be "optional" if the pharmacist feels it is indicated based on other factors such as obesity.

Comment #13: Drs. Cenin, Cansino, Hou, and Melo state the seated blood pressure requirement is beyond the recommendation of ACOG's over-the-counter initiative.

californiapharmacistsassociation

June 22, 2015

California State Board of Pharmacy
Attn: Karen Halbo
1625 N. Market Blvd., N-219
Sacramento, CA 95834

Re: Protocol for Furnishing Self-Administered Hormonal Contraceptives

Dear Ms. Halbo:

Thank you for the opportunity to submit written comments to the Board of Pharmacy's (Board) proposed regulations relating to the protocol for pharmacist furnishing of self-administered hormonal contraceptives. The California Pharmacists Association (CPhA) was a co-sponsor of SB 493 (Hernandez, 2013), the bill that enacted the enabling statute for these proposed regulations and is pleased to support the Board's draft protocol.

CPhA and other stakeholders worked with the Board's SB 493 Implementation Committee as that committee crafted a protocol that will improve access to hormonal contraceptives and ensure that women receive hormonal contraceptives in a safe and appropriate manner. The protocol contained in this proposed rulemaking reflects these goals, placing California at the forefront of improved access to hormonal contraceptives.

We support all elements contained in the Board's protocol, including the requirement to measure and record a patient's seated blood pressure prior to furnishing estrogen-progestin combination products. This requirement is appropriate in the protocol and does not harm patient access to hormonal contraceptives for the following reasons:

- Measurement of seated blood pressure is only required when estrogen-progestin combination products are recommended or requested.
- Hypertension is a known contraindication for estrogen-progestin combination products.
- Pharmacists have limited access to interoperable electronic health records that contain patient blood pressure history and the reliability of self-reported seated blood pressure is unknown.
- Measurement of seated blood pressure is unobtrusive, quick, can easily be performed in a pharmacy, and pharmacists are qualified to measure seated blood pressure.
- The protocol is not prescriptive on the device with which seated blood pressure should be measured; a pharmacist can utilize a machine, automated cuff, or manual sphygmomanometer.
- Patients unwilling or unable to have their blood pressure measured can be furnished progestin-only products or depo provera.

Although other provider types are not statutorily required to measure seated blood pressure prior to prescribing hormonal contraceptives, neither are pharmacists. This requirement will be placed in the statewide protocol. The Board of Pharmacy-Medical Board protocol is intended to be more prescriptive than statute and is intended to be as detailed as any other clinical protocol.

Thank you again for the opportunity to provide written comments on this important rulemaking package. If you have any questions, please do not hesitate to contact me at (916) 779-4517.

Sincerely,

Brian Warren
Vice President, Center for Advocacy

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 22, 2015

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, CA 95834

RE: 1746.1 & 1726.2 –Nicotine Replacement Products & Self-Administered Hormonal Contraception

Fax No.: 916-574-8616

E-Mail: Karen.Halbo@DCA.ca.gov; Lori.Martinez@DCA.ca.gov

Dear Executive Officer Herold:

On behalf of our 19 member companies operating more than 3,900 community pharmacies throughout the state of California, the National Association of Chain Drug Stores (NACDS) urges the Board of Pharmacy to finalize its proposed rules on nicotine replacement products and self-administered hormonal contraception. These proposed rules promote public health by expanding patient access to nicotine replacement products and hormonal contraception.

Starting with nicotine replacement products, the corresponding proposed rule makes it easier for pharmacists to dispense such products to patients. These products have proven invaluable in reducing the rate of smoking and will help to further promote a smoke free California. Reducing the number of smokers correspondingly reduces the costs associated with smoking related diseases, such as lung cancer.

Similarly, the proposed rule allowing pharmacists to more freely dispense self-administered hormonal contraception promotes the public health by targeting women's health. Providing women with broader access to contraceptives reduces the number of unwanted pregnancies, which is associated with improved maternal health and safer pregnancies. As a matter of public health and maternal safety, improved access to self-administered hormonal contraception is critical.

For the reasons outlined above, we urge the Board to finalize the proposed rules on nicotine replacement products and self-administered hormone replacement therapy.

Sincerely,

Mary Staples

Mary Staples

ICE BREAKER HEALTH

June 8, 2015

Attn: Karen Halbo
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Comments in Response to Board of Pharmacy's Draft Hormonal Contraception Protocol – 45 Day Public Comment Period

Dear Mrs. Halbo:

On behalf of Icebreaker Health, we appreciate this opportunity to comment on the joint Board of Pharmacy ("BOP") and Medical Board of California ("MBC") draft hormonal contraception protocol. Icebreaker Health is a California-based health care technology company focused on transforming the delivery of healthcare, with the goal of ensuring ubiquitous access to primary care services. Icebreaker Health aims to empower patient access to the right care, at the right place, and at the right time using innovative technologies, including smartphone applications.

Executive Summary

Icebreaker Health applauds legislation such as SB 493 (Hernandez) that recognizes the critical role pharmacists play in ensuring access to care, including access to hormonal contraception. To remain consistent with the goals of SB 493 and current standards of care, we respectfully request that the draft BOP/MBC protocol language requiring a pharmacist to take a seated blood pressure be stricken or, in the alternative, be replaced with language saying it is up to the professional judgment of the pharmacist whether to require seated blood pressure or allow self-reported blood pressure.

This seated blood pressure requirement is unnecessary and inconsistent with SB 493 for the following reasons: **1)** a seated blood pressure requirement will limit access to hormonal contraception; **2)** blood pressure can be adequately obtained and communicated to a healthcare provider through self-reporting tools; **3)** other comparable healthcare providers like physicians and nurse practitioners are not required to obtain a seated blood pressure before providing hormonal contraceptives; and **4)** respected organizations such as the American Congress of Obstetricians and Gynecologists ("ACOG") do not recommend a seated blood pressure and have even called for hormonal contraceptives to be classified as "over the counter". We expand on each of these reasons below.

A Seated Blood Pressure Requirement Will Limit Access

There is an immediate and urgent need to expand access to hormonal contraceptives. Unplanned pregnancies present a major ongoing public health challenge for the US, and current statistics regarding unintended pregnancies are alarming. An estimated 49 percent of pregnancies in the United States are unplanned. This leads to dramatically increased risk of health complications and significant unnecessary burdens on the healthcare safety net.

Multiple studies indicate the obvious: women would utilize contraceptives at higher rates if they had easier access to obtaining them. Creating easier access requires addressing numerous barriers, including: California's dramatic provider shortage, geographic inequities that lead to many women in inner-city and rural locations not having access to contraceptive service facilities, language and cultural barriers, inability to leave work or secure childcare during medical office or clinic office hours, and a lack of perceived privacy when obtaining contraception.

Being able to access hormonal contraception through a local pharmacy will clearly afford far greater access to hormonal contraceptives than is currently available, but not all pharmacies have blood pressure machines onsite. Under the draft protocol, individuals would not be able to obtain hormonal contraception at pharmacies that do not have blood pressure machines. And as discussed in more detail below, the draft protocol fails to recognize that healthcare providers are able to increase access to hormonal contraception through new technologies.

Blood Pressure Can Be Adequately Obtained Via Self-Reporting Tools

Self-reporting of biometrics is common practice today and has been for many years. Examples of self-reporting include temperature, urine dipstick for glucose or protein, weight, height, and self-monitored blood glucose for medication and dietary management decisions. Another common self-reported biometric is blood pressure. For example, many patients monitor their blood pressure at home to self-manage their hypertension and provide this information to their providers for medication or lifestyle management, while others monitor their blood pressure as a trigger for management of stress. Home monitoring of blood pressure can also be a key component in post myocardial infraction or stroke management. Prenatal patients at risk for preeclampsia perform home blood pressure monitoring as a screen to detect an increase in blood pressure that would initiate need for further evaluation.

Multiple self-reported data elements impact diagnosis and treatment decisions such as smoking status and history, current medication list, alcohol use, medication allergies, recreational drug use, family history of significant medical consequence and personal

health history. This information is accepted as accurate and utilized by healthcare providers, with significant impact on treatment planning decisions.

In the context of hormonal contraception, technologies exist and are in use throughout the world that let women obtain contraception by using smartphone applications that allow for interaction with healthcare professionals who are able to determine eligibility for hormonal contraception and provide it directly to patients. These technologies often rely on self-reporting of blood pressure. For example, an individual may call their primary care physician to obtain their last blood pressure reading and simply provide that reading to the healthcare professional who is determining eligibility through the smartphone application. Another example is when an individual accesses her blood pressure reading online through an electronic health record and then self-reports the reading to the healthcare professional that is determining eligibility through the smartphone application. In yet another example, an individual could adequately obtain and report her own blood pressure at a non-pharmacy setting that provides for blood pressure readings – at fire stations, for example. In any of these situations, it is perfectly safe and perfectly adequate for the blood pressure reading to be self-reported as opposed to being obtained through a seated blood pressure requirement.

Because the draft protocol requires pharmacists to obtain a seated blood pressure, pharmacists would be unable to serve as the healthcare professional interacting with patients through the smartphone application. By preventing pharmacists from serving in this capacity, the protocol is again limiting access to care.

Other Healthcare Providers Are Not Required to Obtain Seated Blood Pressure

We have conducted research of requirements on other California healthcare providers and have not located any similar statutory or regulatory requirement for seated blood pressure on physicians, nurse practitioners or other comparable authorized providers of hormonal contraceptives. It makes no sense to place such a requirement on pharmacists when it does not appear to apply to others, especially when you take into account that pharmacists have more education in pharmacotherapy than other healthcare providers.

Respected Healthcare Organizations Do Not Call For Seated Blood Pressure

There are numerous studies that document the safety of hormonal contraceptives. In fact, multiple studies confirm there is a greater complication risk from pregnancy than there is from using oral contraceptives. After over 30 years of research verifying oral contraceptive safety, the American Congress of Obstetricians and Gynecologists (ACOG) released a Committee Opinion supporting over-the-counter oral contraceptives based on the need for increased access. In addition, based on several studies demonstrating that women correctly self-identify contraindications to oral contraceptives through the use of self-administered standardized checklists, ACOG now advocates for the use of

self-screening checklists. Several key professional organizations support this approach, including the American Academy of Family Physicians and the American College of Clinical Pharmacy.

Their safety, combined with the health risks of unintended pregnancies, have compelled respected organizations such as ACOG to call for all contraceptives to be made available over the counter in order to make contraceptives as easy to access as possible and boost utilization rates. In other words, instead of calling for access limiting requirements like seated blood pressure, organizations like ACOG are moving care in the opposite direction by seeking increased access without any prior healthcare provider review of patient eligibility.

Conclusion

For all the reasons stated above, we strongly urge BOP to strike the seated blood pressure requirement in its draft protocol. At a minimum, BOP should modify the draft protocol language to state that it is up to the professional judgment of the pharmacist to determine whether to obtain a seated blood pressure or rely on a self-reported blood pressure measurement.

We truly appreciate your consideration of our views on this important issue. For questions or more information, please feel free to contact me at bonnie@polkadoc.com or Mark Weideman at mark@weidemangroup.com.

Sincerely,

Bonnie Zell

Bonnie Zell, MD, MPH, FACOG
Chief Quality Officer
Icebreaker Health

Planned Parenthood®
Act. No matter what.

Planned Parenthood Affiliates of California

VIA EMAIL

June 22, 2015

Board of Pharmacy
Attn: Karen Halbo
1625 N. Market Blvd., N219
Sacramento, CA 95834
916-574-7948
Karen.Halbo@DCA.ca.gov

Re: Notice of Proposed Action to add Section 1746.1 to Title 16 of the California Code of Regulations related to Self-Administered Hormonal Contraception

Dear Ms. Halbo:

Thank you for the opportunity to submit comments on behalf of Planned Parenthood Affiliates of California on the proposed action related to self-administered hormonal contraception. We support the Board's efforts to make contraception more accessible to women in California. We would ask that you revise § 1746.1(b)(4)(C) to permit women to self-report blood pressure as this will ensure maximum access to contraception without compromising patient safety.

Planned Parenthood is California's leading women's health care provider and a trusted, nonprofit source of primary and preventive care for women, men, and young people in communities across the state. Our mission is to ensure that all individuals have the freedom to make reproductive decisions. For people to make healthy decisions, they need access to comprehensive information and services related to sexuality, reproduction, methods of contraception, fertility control, and parenthood. We work with our member affiliates and coalition partners to improve California's public policy climate through a program of policy analysis, coalition building, public education, legal research, and grassroots and community organizing with the goal of increasing access to comprehensive reproductive health services.

Blood Pressure Can Be Adequately Obtained Via Self-Reporting Tools

We strongly support the Board's efforts to allow pharmacists to dispense hormonal contraceptives. We believe this is a much needed step to expand women's access to essential health care. We are concerned, however, by the requirement that the pharmacist take the patient's blood pressure when she is in the pharmacy. (§ 1746.1(b)(4)(C)). Allowing patients to self-report blood pressure is medically safe, cost-effective, and promotes greater access to care. Being able to access hormonal contraception through a local pharmacy will clearly afford far greater access to hormonal contraceptives than is currently available, but not all pharmacies have blood pressure machines onsite. Under the proposed language, individuals would not be able to obtain hormonal contraception at pharmacies that do not have blood pressure machines.

Self-reported blood pressure is an acceptable medical alternative to seated blood pressure. Significantly, the American College of Obstetricians and Gynecologists (ACOG) Committee Opinion that recommended over-the-counter access to oral contraceptives also recommends allowing women to self-screen for most contraindications using self-reporting checklists.[1] The CDC Medical Eligibility Criteria specifically states that although blood pressure is required for combined hormonal contraceptive prescriptions, if a patient is not able to access an appointment for measuring blood pressure, obtaining a blood pressure reading and self-reporting to a provider is acceptable.[2]

Studies have shown that women self-report as well as, if not better than, their provider's assessment. One study evaluated the participant-provider agreement rate for women taking part in both a self-screening and a same-day provider screening that assessed risk factors for hormonal birth control use. The study found that the results of the self-screening questionnaire highly corresponded with the providers' assessments. The estimated proportion of overall agreement was 96%.[3] The agreement rate on important contraindications such as hypertension was above 90%[4]. Notably, when there was disagreement on certain criteria, women were more likely to indicate contraindications than providers.[5] The study concluded that "self-reported

[1] Comm. on Gynecologic Practice, *Over-the-Counter Access to Oral Contraceptives*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, n. 544, Dec. 2012, Reaffirmed 2014, at 1, *available at* http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Over-the-Counter-Access-to-Oral-Contraceptives (stating no pelvic exam, cervical cancer screening (Pap test) or sexually transmitted infection testing is required before prescribing hormonal contraceptives, emphasizing that a physical exam should not be a prerequisite to obtaining oral contraceptives).
[2] Ctrs. for Disease Control and Prevention, Morbidity and Mortality Weekly Rep., U.S. SELECTED PRACTICE RECOMMENDATIONS FOR CONTRACEPTIVE USE, 2013 23, (vol. 62, n. 5 2013), *available at* http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf.
[3] Solmaz Shotorbania et al., *Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors*, 73 CONTRACEPTION 501– 506 (2006).
[4] *Id.*
[5] *Id.*

medical history is a valuable epidemiologic and diagnostic tool of increasing importance as health care efficiencies are being sought in various clinical settings." [6]

Another study found that as long as a detailed medical checklist of contraindications was used, women were able to complete an accurate self-assessment.[7] The study also found that the women most likely to seek contraception, in particular younger women, were best able to identify any possible contraindications.[8] The women (6.6%) who wrongly thought they were eligible to use hormonal contraceptives were largely ineligible due to unknown hypertension. [9]

In addition to being medically acceptable, self-reported blood pressure supports and builds on person-centered care and patient self-management, and continues the trend of relying on patient-reported data. Self-reporting of biometrics, including blood pressure, is common practice today and has been for many years. For example, an individual may call their primary care physician to obtain her last blood pressure reading. An individual can access her blood pressure reading online through an electronic health record. In yet another example, an individual could adequately obtain and report her own blood pressure at a non-pharmacy setting that provides for blood pressure readings – at fire stations or dental offices, for example. In any of these situations, it is perfectly safe and perfectly adequate for the blood pressure reading to be self-reported as opposed to being obtained through a seated blood pressure requirement.

Hormonal Contraception is Very Safe and Promotes Women's Health

Oral hormonal contraceptives are very safe for most women. Many studies have shown that the benefits of contraceptive use outweigh the risks.[10] One study found a very low rate of only 2% of participants seeking contraception who had a potential medical contraindication.[11] ACOG has concluded that contraceptive use is very safe for most women,[12] with studies showing virtually no increase in death from cardiovascular disease.[13] Additionally, pregnancy poses a much

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[6] *Id.* at 505.
[7] Daniel Grossman et al., *Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use*, 112 JOURNAL OF OBSTETRICS AND GYNECOLOGY n.3 572, 577 (2008).
[8] *Id.* at 578.
[9] *Id*. at 572.
[10] U.N. Population Info. Network, U.N. Population Div., Dep't of Econ. and Soc. Affairs, *Oral Contraceptives Are Safe, Very Effective*, 16 NETWORK (1996), http://www.un.org/popin/popis/journals/network/network164/aoc164.html.
[11] Hanna Xu et al., *Medical Contraindications in Women Seeking Combined Hormonal Contraception*, 210 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY, Mar. 2014, at 2, *available at* http://www.ajog.org/article/S0002-9378(13)02035-8/pdf.
[12] Comm. on Gynecologic Practice, *supra* note 1, at 1.
[13] Pamela J. Schwingl et al., *Estimates of the Risk of Cardiovascular Death Attributable to Low-dose Oral Contraceptives in the United States*, 180 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 241-249 (1999). The study notes that smokers above the age of 35 should use nonestrogen based contraceptive. *Id.*

greater risk to women's health than contraceptive use,[14] particularly in terms of the risk of venous thromboembolism,[15] one of the most-cited risks of contraceptive use.

Additionally, access to contraception is crucial to promoting women's health and preventing unintended pregnancy. Unintended pregnancy remains a persistent problem in the United States, comprising approximately 50% of all pregnancies, and resulting in multiple health complications for women and infants.[16] Unnecessary and burdensome requirements that restrict access, such as a seated blood pressure requirement, limit the ability of many women to obtain the contraceptives they need.

Allowing Pharmacists to Dispense Contraception Based on Self-Reported Blood Pressure Would Increase Access for Women

There is an ever-increasing need for contraceptive services among women, with more than half of all women of reproductive age in need of contraceptive services in 2012, an 11% increase from 2000.[17] Women are at risk of getting pregnant for approximately 30 years of their life and will seek access to contraceptive services during much of that time period. Seventy percent of women of reproductive age are sexually active and do not want to become pregnant, but are at risk for an unintended pregnancy without proper contraceptive use.[18]

ACOG has found that practical issues with access often contribute to problems with adherence in the use of oral contraceptives, and that allowing over-the-counter access to oral contraceptives could improve access and decrease the rate of unintended pregnancy. [19] According to a study published recently in the journal Contraception, the rate of unintended pregnancies among low-income women could drop by as much as 25 percent if birth control pills were made available over-the-counter while still being covered by insurance with no copay. The study also found that the number of women using oral contraception could increase by as much as 21 percent.[20] Other studies have found that streamlined dispensing protocols that require only one visit reduce barriers and help to ensure that clients start on their method right away.[21] Thus, ensuring that a woman only has to make one visit to a pharmacist will help guarantee that women can start and continue to use a contraceptive method effectively.

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[14] U.N. Population Info. Network, *supra* note 10.
[15] Comm. on Gynecologic Practice, *supra* note 1, at 1-2.
[16] Comm. on Gynecologic Practice, *supra* note 1, at 1.
[17] JENNIFER J. FROST ET AL., GUTTMACHER INSTITUTE, CONTRACEPTIVE NEEDS AND SERVICES, 2012 UPDATE (2014), *available at* https://www.guttmacher.org/pubs/win/contraceptive-needs-2012.pdf.
[18] GUTTMACHER INSTITUTE, FACT SHEET: CONTRACEPTIVE USE IN THE U.S. (2014), *available at* http://www.guttmacher.org/pubs/fb_contr_use.html.
[19] Comm. on Gynecologic Practice, *supra* note 1, at 1.
[20] Diana G. Foster et al., *Potential Public Sector Cost-savings from Over-the-counter Access to Oral Contraceptives*, 91 Contraception 373-379 (2015), *available at* http://www.contraceptionjournal.org/article/S0010-7824(15)00011-6/fulltext.
[21] JENNIFER J. FROST ET AL., GUTTMACHER INSTITUTE, VARIATION IN SERVICE DELIVERY PRACTICES AMONG CLINICS PROVIDING PUBLICLY FUNDED FAMILY PLANNING SERVICES IN 2010 (2012), *available at* http://www.guttmacher.org/pubs/clinic-survey-2010.pdf.

Access to Contraception is Crucial for Women's Economic Opportunity and Equality

Access to contraception is crucial to women's education and economic attainment. Women are able to stay in school longer, earn advanced degrees, and participate at greater rates in the workforce due to increased access to contraception.[22] Highlighting the fact that birth control is a top economic driver for women, Bloomberg Businessweek recently listed contraception as one of the most transformational developments in the business sector in the last 85 years. Fully one-third of the wage gains women have made since the 1960s are the result of access to oral contraceptives.[23] Being able to get the pill before age 21 has been found to be the most influential factor in enabling women already in college to stay in college.[24] Birth control has been estimated to account for more than 30 percent of the increase in the proportion of women in skilled careers from 1970 to 1990.[25] Promoting greater access to contraception is key to ensuring the continuation of these economic gains for women.

Conclusion

For all the reasons stated above, we strongly urge the Board to strike the seated blood pressure requirement from the proposed language.

Thank you for the opportunity to comment on the proposed action. If you have any questions, please do not hesitate to contact me at 916-446-5247.

Respectfully submitted,

Beth H. Parker

Chief Legal Counsel
Planned Parenthood Affiliates of California

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[22] ADAM SONFIELD ET AL., GUTTMACHER INSTITUTE, THE SOCIAL AND ECONOMIC BENEFITS OF WOMEN'S ABILITY TO DETERMINE WHETHER OR WHEN TO HAVE CHILDREN (2013), *available at* https://www.guttmacher.org/pubs/social-economic-benefits.pdf.

[23] Kurt Soller, *The Birth Control Pill Advanced Women's Economic Freedom*, BLOOMBERG BUSINESSWEEK, December 4, 2014, http://www.businessweek.com/articles/2014-12-04/birth-control-pill-advanced-womens-economic-freedom.

[24] HEINRICH HOCK, FLORIDA STATE UNIVERSITY, THE PILL AND THE COLLEGE ATTAINMENT OF AMERICAN WOMEN AND MEN (2007), *available at* https://ideas.repec.org/p/fsu/wpaper/wp2007_10_01.html, citing Sonfield, *supra* note 22.

[25] Claudia Goldin and Lawrence F. Katz, *The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions*, 110 JOURNAL OF POLITICAL ECONOMY n.4 730–770 (2002), *available at http://dash.harvard.edu/bitstream/handle/1/2624453/Goldin_PowerPill.pdf?sequence=4*, citing Sonfield, *supra* note 22.

UNIVERSITY OF CALIFORNIA, DAVIS

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June 18, 2015

California Board of Pharmacy
Attn: Karen Halbo
1625 N. Market Boulevard
Suite N219
Sacramento, CA 95834

Re: Comments on Board of Pharmacy's Draft Hormonal Contraception Protocol

Dear Mrs. Halbo,

We write you as members of the Division of Family Planning in the Department of Obstetrics and Gynecology at the University of California, Davis to comment on the joint Board of Pharmacy (BOP) and Medical Board of California (MBC) hormonal contraception screening protocol. We appreciate the opportunity to provide our thoughts during this open public comment period.

We applaud the legislation (SB 493) that brought this issue to your Board.

As Family Planning specialists, we are amongst the academic leaders in women's reproductive health. The Division of Family Planning at the University of California, Davis boasts some of the world's leaders in contraceptive research, policy and clinical teaching. We are proud to live in California where legislation such as SB 493 that brought this issue to the BOP is supported as a means for our citizens to have better lives. Public health is improved when we maximize access to primary care services, which includes contraceptive services for women. We must be innovators to keep up with our rapidly changing society.

As leaders in healthcare, we feel compelled to comment on the draft BOP/MBC protocol language that requires a pharmacist to take a seated blood pressure. We believe that such a requirement is not necessary for the following reasons:

1. According to the Centers for Disease Control and Prevention, a blood pressure measurement is not indicated at all for a woman requesting progestin-only oral contraceptives. There are significant differences in the risks and medical exclusions for use between combined (estrogen-containing) oral contraceptives and progestin-only contraceptives. Requiring any evaluation of blood pressure for a woman seeking progestin-only pills limits access beyond the CDC recommendations or any medical eligibility criteria.

2. The requirement for a seated blood pressure to be taken by the pharmacist exceeds what is required for appropriate evaluation in this new paradigm of medical care. In our medical practices, we already trust women to provide accurate histories related to past problems, family history and current

medications. In a similar manner, many of the items we typically measure can be trusted in the same way to be provided by patients. It is essential for us to identify and clarify how patients can be active participants in their own healthcare, and respect their autonomy in medical decision-making. In a medical office, blood pressure evaluation is standard of care for any visit, whether the woman is seeking combined oral contraceptives or is getting a skin evaluation of her moles. However, in the pharmacy, we believe that women are capable of reporting to the pharmacist if they have had a blood pressure measurement in the past year and if it was normal. With this option, the pharmacist can offer the woman an optional blood pressure evaluation or decide if she or he feels a blood pressure is still indicated based on other screening factors (e.g., obesity).

3. The requirement for a seated blood pressure is beyond the recommendations of the American College of Obstetricians and Gynecologists (ACOG) in their Committee Opinion supporting over-the-counter access to oral contraceptives. ACOG advocates for a self-screening checklist based on the best available research studies and medical evidence which would include a self-reported blood pressure.

The need for an accurate history related to venous thromboembolic (VTE) disease is just as important as blood pressure evaluation in establishing appropriateness of estrogen-containing combined hormonal methods. Women are trusted to provide a history related to VTE and can equally be trusted to relay such information about blood pressure. The process encourages more people to be an active part of their own healthcare so that 100% of the burden is not solely on the shoulders of the provider. Increasing women's participation in their own healthcare can only improve access and contribute to a healthier California.

This program will allow continued expansion of contraceptive services through this unique and important direct access programs. However, limiting access by requiring a seated blood pressure creates an unnecessary barrier for pharmacists and women.

We hope that you will consider our position and remove the requirement for a seated blood pressure by a pharmacist before provision of hormonal contraceptives. We believe that the pharmacist and woman should have the option for having a blood pressure evaluation which is different than a mandated evaluation.

If you have any questions, please feel free to contact any of us at (916) 734-6670. We would also be happy to meet with you or any of your staff to discuss our comments.

Sincerely,

Mitchell D. Creinin, MD
Professor
Director of Family Planning

Catherine Cansino, MD, MPH
Associate Professor

Melody Hou, MD, MPH
Assistant Professor

Juliana Melo, MD, MSCS
Assistant Professor

cc: Senator Ed Hernandez, OD

Attachment 6

Board of Pharmacy

Proposal to Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of
licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010~~.

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . ~~omitting t~~Traffic infractions under ~~$300~~ $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014. (1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision
(a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014. (1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority : Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Board of Pharmacy

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority: Section 4005, Business and Professions Code.
Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

BOARD OF PHARMACY

Proposal to amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.05. Accreditation Agencies for Continuing Education

(a) The following organizations are approved accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six (6) hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six (6) hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two (2) hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three (3) hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

Proposal to amend § 1732.5 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.5 Renewal Requirements for Pharmacists

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six (6) of the thirty (30) units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy's Drug Inventory
4. Ethics
5. Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility
6. Compounding

Pharmacists renewing their licenses which expire on or after July 1, 2016, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

BOARD OF PHARMACY

Proposal to Amend Section 1703 of Title 16 of the California Code of Regulations to read as follows:

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; and make changes to its regulations without regulatory effect pursuant to Title 1 California Code of Regulations section 100 are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

Title 16 Board of Pharmacy

Proposed Regulations

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day
(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.
(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.
(f) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

BOARD OF PHARMACY
Proposed Regulation

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

BOARD OF PHARMACY

Proposal Regulation

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

For purposes of 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty.

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, and discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:

(A) Earned the clinical experience within the required time frame;

(B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, and discontinuing drug therapy of patients; and

(i) The applicant shall provide a copy of the collaborative practice agreement or protocol.

(ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients.

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

BOARD OF PHARMACY

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars ($520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars ($325). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred fifty dollars ($150).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300*). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.*

(g)(1) The fee for the biennial renewal of a pharmacist's license is one hundred fifty dollars ($150). The penalty fee for failure to renew is seventy-five dollars ($75).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). *The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.*

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars ($165). The penalty for failure to renew is eighty two dollars fifty cents ($82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars ($195). The penalty for failure to renew is ninety seven dollars and fifty cents ($97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(*l*) The fee for an intern pharmacist license is one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).
(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(o) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325) . The penalty for failure to renew is one hundred fifty dollars ($150).
(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars ($195). The penalty for failure to renew is ninety-seven dollars and fifty cents ($97.50).
(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars ($325). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred twenty-five dollars ($125).
(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).
(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be $800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be $800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4400, 4401 and 4403, Business and Professions Code.

Title 16. BOARD OF PHARMACY

Proposed Text

Proposal to add §1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) Completion of an approved immunization training program, and

(2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 30 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 30 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide

the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

Title 16. BOARD OF PHARMACY
Proposed Text

Proposal to add §1746.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

(a) For purposes of Business and Professions Code Section 4052(a)(10)(A)(3), "not requiring a diagnosis" means either:

(1) A self-diagnosable and self-treatable condition under the federal Centers for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to Section 4052(a)(10) of the Business and Professions Code shall follow the requirements specified in subdivisions (c) through (f) of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of:

(1) Completion of an approved travel medicine training program, which must consist of at least 20 hours and cover the International Society of Travel Medicine's body of knowledge,

(2) Completion of the CDC Yellow Fever Vaccine Course, and

(3) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history form using a destination-specific travel database. The travel history form must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of

an appropriate and comprehensive travel history form is available on the Board of Pharmacy's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of dispense, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, and title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel plan. An example of an appropriate and comprehensive progress note is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052, Business and Professions Code.

Title 16. Board of Pharmacy

Proposed Language

To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because ~~T~~the following classes of drugs may impair a person's ability to ~~drive~~ operate a motor vehicle or vessel~~ operate machinery when taken alone or in combination with alcohol~~ a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel:

(1) Muscle relaxants.

(2) ~~Analgesics with central nervous system depressant effects.~~

~~(3)~~ Antipsychotic drugs with central nervous system depressant effects ~~including phenothiazines~~

(4~~3~~) Antidepressants with central nervous system depressant effects.

(5~~4~~) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.

(6~~5~~) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~

(7~~6~~) Anticholinergic agents ~~and other drugs which~~ that may impair vision.

(7) Any other drug which, based on the pharmacist's professional judgment, may impair a patient's ability to operate a vehicle or vessel

(b) Because ~~T~~the following ~~are examples~~ classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall provide a written warning notice on the label to alert the patient about possible potentiating effects: which may have harmful effects when taken in combination with alcohol: ~~which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:~~

(1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine.

(5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

(6) Any other drug which, based upon a pharmacist profession judgment, may pose a substantial risk to the person consuming the drug when take in combination with alcohol.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022, 4055 and 4074, Business and Professions Code.