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

LEGISLATION AND REGULATION COMMITTEE

Greg Lippe, CPA, Chairperson, Public Member
Ryan Brooks, Public Member
Deborah Veale, RPh, Professional Member
Albert Wong, PharmD, Professional Member

Part 1: LEGISLATION REPORT

a. Board Sponsored Legislation — Attachment 1

1. AB 1073 (Ting) Pharmacy: Prescription Drug Labels
   Version: As Amended April 28, 2015
   Location: Senate Rules
   Status: Awaiting assignment

   Summary: This bill would require dispensers to use a standardized direction for use on a label of a prescription container when applicable and would require a dispenser, upon request, to select the appropriate translated directions for use to include on the prescription label or supplemental information. This bill allows for a dispenser to provide his or her own translated directions. The bill specifies that a dispenser using board provided translated directions will not be liable for civil damages for any error in the "cutting and pasting" of the translated directions.

   Recent Update: This bill passed out of the Assembly on May 14, 2015. To date there have been no nay votes on the measure. Staff continues to work with the author's office and address any concerns or respond to inquiries regarding this measure. Board staff recently received possible amendments for consideration from interested parties. Staff will be working with the author's office to secure any additional amendments that are necessary to ensure successful enactment of the measure.

   A copy of the bill in its current form is provided.

2. SB 590 (Stone) Pharmacy: Intern Licenses
   Version: As Amended April 22, 2015
   Location: Assembly Business and Professions
   Status: Hearing not yet scheduled.

   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 Senate on April 30, 2015. To date there has been no nay votes on the measure. Staff continues to address any concerns or respond to inquiries regarding this measure.

A copy of the bill in its current form is provided.

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

   Summary: Would establish the regulatory framework for licensure of outsourcing facilities that would compound non-patient specific medications for administration to California patients.

   Recent Update: Board staff continues to work with the author's office and stakeholders to address comments and concerns about the measure. Board staff anticipates additional amendments to further refine the language may be necessary as the measure continues through the legislative process.

   A copy of the bill in its current form is provided.

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 are provided in **Attachment 2.**

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

   Summary: 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.

Recent Update: 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, but this has not occurred.

2. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels
   Version: As introduced February 23, 2015
   Location: Senate Rules
   Status: Awaiting assignment
   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. This bill 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 board's support position was conveyed to the author's office.

3. AB 623 (Wood) Abuse-Deterrent Opioid Analgesic Drug Products
   Version: As amended May 4, 2015
   Location: Asm Appropriations
   Status: Awaiting committee date
   Board Position: Oppose

   Summary: Would require a pharmacist to inform a patient receiving an opioid analgesic drug product on the proper storage and disposal of the drug. Further this measure would prohibit a health care service plan from requiring the use of opioid analgesic drug products without the abuse-deterrent properties.

   Recent Update: Board staff has been in contact with the author's office who has indicated a willingness to consider and address concerns the board may have.

4. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
   Version: As amended May 6, 2015
   Location: Assembly
   Status: Third Reading
   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 amendments to address many of the legal conflicts the measure initially contained. The amended version is significantly scaled back from the prior version. There are still some concerns with the bill in its current form. The author's office has indicated that they would like to explore some additional possible amendments, but will work with board staff in advance. Board staff will continue to work with the author's office.

5. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
   Version: As Amended April 16, 2015
   Location: Asm Appropriations
   Status: Appropriations suspense file
   Board Position: Oppose

   Summary: Would significantly change the deferred entry of judgment program into a pretrial diversion program, expand the conditions under which an individual could be granted deferred entry of judgment, and reduce the duration of the program to as little as six months.

   Recent Update: Board staff advised the author's office of our concerns with the measure and how it will significantly impact the board's ability to take appropriate action against an applicant or licensee that is granted.

6. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea
   Version: As amended May 19, 2015
   Location: Senate Public Safety Committee
   Status: Re-referred to PUB. S.
   Board Position: Oppose

   Summary: 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 defendant performed satisfactorily during the deferred entry of judgment period, and if the defendant attests on a form developed by the Judicial Council that the plea may result in the denial or loss of the defendant's employment, benefit, license or certificate.

   Recent Update: Board staff advised the author's office of our concerns with this measure including the concern that this bill would eliminate the board's discretion in making licensing decisions based upon prior criminal convictions that have been withdrawn.

7. SB 671 (Hill) Pharmacy: Biological Product
   Version: As Amended May 5, 2015
   Location: Assembly
   Status: Held at desk.
   Board Position: Oppose Unless Amended

   Summary: Would authorize a pharmacist to select an alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable and the prescriber does not personally indicate "Do not substitute."

   Recent Update: Board staff conveyed the board's position and requested that the pharmacist notification requirement be removed from the bill. The author's office has indicated that this requirement is a core component of the bill and will not be eliminated.

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

1. AB 12 (Cooley) State Government: Administrative Regulations: Review
   Version: Amended April 22, 2015
   Location: Asm Appropriations
   Status: Suspense file
   Board Position: The board did not previously discuss this measure.

   Summary: 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. This measure also would establish notice and reporting requirements.

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.

   Recent Update: 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 been identified.

3. AB 1060 (Bonilla) Professions and Vocations: Licensure
   Version: As amended March 26, 2015
   Location: Senate Business, Professions and Economic Development Committee
   Status: Awaiting hearing date
   Board Position: Oppose

   Summary: This measure would require the board to advise an ex-licensee with certain information pertaining to rehabilitation, reinstatement, or reduction of penalty by first-class mail and by email if the board has an email address on file for the ex-licensee.

   Recent Update: Board staff advised the author's office of the board's position as well as basis for our oppose position.

4. SB 467 (Hill) Professions and Vocations
   Version: As amended April 21, 2015
   Location: Senate Appropriations
   Status: Appropriations suspense file
   Board Position: None, the board has not previously discussed this measure.

   Summary: Would require pro rata assessed by the Department of Consumer Affairs to be approved by the legislature, would require the Attorney General to submit an annual report on various workload measures and would direct the director of DCA to work with healing arts boards to standardize referral of complaints consistent with a memo issued under a prior DCA director.

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.

Attachment 1

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 add Section 4076.6 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. A violation of that law is a crime.

This bill would require a ~~dispenser~~ *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. 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 as an alternative to the above-described procedure. 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 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,~~ *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.

(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 label. 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 as an alternative to 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. 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 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.

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.

O

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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Attachment 2

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: Committee hearing scheduled for May 28, 2015, Asm Appropriations

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
05/20/2015	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.

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 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: Senate Rules – Awaiting committee assignment

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	
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.

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 623**
Current Version:	**As Amended May 4, 2015**
Author:	**Wood**
Topic:	**Abuse-deterrent Opioid Drugs**
Board Position:	**Oppose**

Affected Section(s): Section 4069 of the Business & Professions Code, Section 1367.217 of the Health and Safety Code, and Section 10123.203 of the Insurance Code

Status: Hearing scheduled for May 27, 2015, Asm Appropriations

SUMMARY:
Where an abuse-deterrent opioid analgesic drug product is available, this measure would prohibit a health care service plan or insurer from requiring the use of opioid analgesic drug products without abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products. The bill would require a health care service plan or insurer to allow a provider to prescribe, and if otherwise covered, to provide coverage for, a less than 30-day supply of an opioid analgesic drug product. This bill would also require the board to adopt regulations regarding patient consultation provisions.

EXISTING LAW:
Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. This measure would require specified services and drugs be covered by the various plans.

THIS BILL WOULD:

1. Add B&PC Section 4069 to require a pharmacist to information a patient receiving an opioid analgesic drug product on proper storage and disposal of the drug and require the board to adopt regulations specific to this patient consultation.
2. Add H&SC 1367.217 to
    a. Prohibit a health care service plan or insurer from requiring the use of opioid analgesic drug products without the abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products when an abuse-deterrent opioid analgesic drug product is available.
    b. Require a health care service plan to allow a provider to prescribe less than a 30-day supply of an opioid analgesic as specified.

   c. Define "Abuse-deterrent opioid analgesic drug product" as a brand or generic opioid analgesic drug product approved by the FDA, as specified.
   d. Define "Opioid analgesic drug product" as a drug product in the opioid analgesic drug class, as specified.
3. Add Section 10123.203 to the Insurance Code to make conforming changes with H&SC 1367.217

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.

STAFF COMMENTS:
During its last meeting, the Legislation and Regulation Committee members expressed concern that this measure was, at its core, a product protection measure. Since that time board staff has briefly expressed this concern with the author's office and has been reassured that this is not the intent of the legislation. A representative from the author's office hopes to attend the meeting and directly address board concerns with this measure.

SUPPPORT/OPPOSITION:

Support
Patient Organizations:
Power of Pain Foundation (Sponsor)
U.S. Pain Foundation (Sponsor)
Biocom
Partnership for Drug Free Kids
The Wall Las Memorias
Healthy African American Families
Lupus Foundation of Southern CA
Neuropathy Action Foundation
International Foundation of Autoimmune Arthritis
CA Hepatitis C Task Force
The Western Neuropathy Association
Spondylitis Association of America
Providers:
California Pharmacists Association
CA Society of Physical Medicine and Rehabilitation
CA Academy of Physician Assistants
California Urological Association
CA Academy of Family Physicians
American Academy of Pain Management
American College of Private Physicians
Alliance of Patient Access

Law Enforcement:
CA State Sheriffs Association
Veteran Groups:
American GI Forum of California

Opposition
California Retailers Association
California Chamber of Commerce
California Association of Health Plans
Pharmaceutical Management Association

HISTORY:

Date	Action
05/05/2015	May 5 Re-referred to Com. on APPR.
05/04/2015	May 4 Read second time and amended.
04/30/2015	Apr. 30 From committee: Amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 13. Noes 1.) (April 28).
04/23/2015	Apr. 23 From committee: Do pass and re-refer to Com. on B. & P. (Ayes 15. Noes 4.) (April 21). Re-referred to Com. on B. & P.
04/06/2015	Apr. 6 Re-referred to Com. on HEALTH.
03/26/2015	Mar. 26 Referred to Coms. on HEALTH and B. & P. From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
02/25/2015	Feb. 25 From printer. May be heard in committee March 27.
02/24/2015	Feb. 24 Read first time. To print.

AMENDED IN ASSEMBLY MAY 4, 2015

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 623

Introduced by Assembly Member Wood
(Coauthor: Assembly Member Waldron)

February 24, 2015

An act to add Section 4069 to the Business and Professions Code, to add Section 1367.217 to the Health and Safety Code, and to add Section 10123.203 to the Insurance Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 623, as amended, Wood. Abuse-deterrent opioid analgesic drug products.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. These provisions require specified services and drugs to be covered by the various plans.

This bill would, where an abuse-deterrent opioid analgesic drug product, as defined, is available, prohibit a health care service plan or insurer from requiring the use of opioid analgesic drug products without the abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products. The bill would require a health care service plan or insurer to allow a provider to prescribe, and if otherwise covered, to provide coverage for, a less than 30-day supply of an opioid analgesic drug product. Because a willful violation of these requirements with

respect to health care service plans would be a crime, this bill would impose a state-mandated local program.

Existing law, the Pharmacy Law, the knowing violation of which is a crime, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy. Existing regulations require a pharmacist to provide oral consultation to his or her patient or the patient's agent in all care settings upon request or whenever the pharmacist deems it warranted.

This bill would require a pharmacist to inform a patient receiving an opioid analgesic drug product on proper storage and disposal of the drug, and ~~authorizes this information to be included as part of the required oral consultation.~~ *would require the board to adopt regulations to implement that provision.* Because a violation of this requirement 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.

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. The Legislature finds and declares the following:

(a) Prescription and over-the-counter (OTC) drugs are, after marijuana and alcohol, the most commonly abused substances by Americans over 14 years of age.

(b) Over two million people in the United States suffer from substance use disorders related to prescription opioid pain relievers.

(c) More people die from overdoses of prescription opioid pain relievers than from all other drugs combined, including heroin and cocaine.

(d) Prescription opioid pain relievers can have effects similar to heroin when taken in doses or in ways other than prescribed, and research now suggests that abuse of these drugs may lead to heroin abuse.

(e) Prescription opioid pain relievers can be particularly dangerous when snorted, injected, or combined with other drugs or alcohol.

SEC. 2. Section 4069 is added to the Business and Professions Code, to read:

4069. (a) A pharmacist shall inform a patient receiving an opioid analgesic drug product on proper storage and disposal of the drug. ~~This information may be included as part of the oral consultation required under Section 1707.2 of Title 17 of the California Code of Regulations.~~ *The board shall adopt regulations to implement this section.*

(b) For purposes of this section, "opioid analgesic drug product" has the same meaning as defined in Section 1367.217 of the Health and Safety Code.

SEC. 3. Section 1367.217 is added to the Health and Safety Code, to read:

1367.217. (a) Where an abuse-deterrent opioid analgesic drug product is available, a health care service plan shall not require the use of opioid analgesic drug products without the abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products.

(b) This section shall not be construed to prevent a health care service plan from applying prior authorization requirements to abuse-deterrent opioid analgesic drug products, provided that those same requirements are applied to versions of those opioid analgesic drug products without the abuse-deterrent properties.

(c) A health care service plan shall allow a provider to prescribe, and if otherwise covered, shall provide coverage for, a less than 30-day supply of an opioid analgesic drug product.

(d) For purposes of this section, the following definitions shall apply:

(1) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product approved by the federal Food and Drug Administration with abuse-deterrence labeling claims that indicate the drug product is expected to result in a meaningful reduction in abuse.

(2) "Opioid analgesic drug product" means a drug product in the opioid analgesic drug class that is prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release or long-acting form and whether or not combined with other drug substances to form a single drug product or dosage form.

SEC. 4. Section 10123.203 is added to the Insurance Code, to read:

10123.203. (a) Where an abuse-deterrent opioid analgesic drug product is available, an insurer shall not require the use of opioid analgesic drug products without the abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products.

(b) This section shall not be construed to prevent an insurer from applying prior authorization requirements to abuse-deterrent opioid analgesic drug products, provided that those same requirements are applied to versions of those opioid analgesic drug products without the abuse-deterrent properties.

(c) An insurer shall allow a provider to prescribe, and if otherwise covered, shall provide coverage for, a less than 30-day supply of an opioid analgesic drug product.

(d) For purposes of this section, the following definitions shall apply:

(1) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product approved by the federal Food and Drug Administration with abuse-deterrence labeling claims that indicate the drug product is expected to result in a meaningful reduction in abuse.

(2) "Opioid analgesic drug product" means a drug product in the opioid analgesic drug class that is prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release or long-acting form and whether or not combined with other drug substances to form a single drug product or dosage form.

SEC. 5. 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:	**AB 1069**
Current Version:	**As amended March 26, 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: Assembly Third Reading File

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 program to another.
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.

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 bill in its current form reflects much of this effort.

Board staff continues to question the need to expand the transfer provisions of the current law given that only one county is California is currently operating a program; likewise, staff has concerns about the repackaging provisions in its current form as there are no guidelines for this.

Board staff continues to work with the author's office and sponsors. The author's office has stated a commitment to continue to work with board staff.

FISCAL IMPACT ON THE BOARD:

Board staff does not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

HISTORY:

Date	Action
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.

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 ~~Sections 150201 and~~ *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 define "tamper-evident packaging" for purposes of the program. The bill would require a county that establishes a medication repository and donation program to develop written procedures ensuring that manufacturer recalls are handled appropriately for medications with and without lot numbers. The bill would delete the requirement that a donated medication container have a lot number. The~~ bill would authorize a county-owned pharmacy participating in the medication repository and distribution program to transfer eligible donated medication to a participating county-owned pharmacy in any other county, as specified. The bill would authorize medication donated to a medication repository and distribution program to be maintained in new, properly labeled containers. *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 150201 of the Health and Safety Code is amended to read:~~

~~150201. For purposes of this division:~~

~~(a) "Donor organization" means an entity described in subdivision (a) of Section 150202.~~

~~(b) "Eligible entity" means all of the following:~~

~~(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.~~

~~(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and~~

~~operated by a primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and is not on probation with the California State Board of Pharmacy.~~

~~(3) A primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.~~

~~(c) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.~~

~~(d) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.~~

~~(e) "Tamper-evident packaging" means an immediate, outer, or secondary container that is sealed by an organization eligible to donate medication pursuant to this division and that has a seal that must be broken in order to gain access to the container's medication.~~

~~SEC. 2.~~

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.

~~(6) Ensuring manufacturer recalls are handled appropriately for medications with and without lot numbers.~~

(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 may transfer eligible donated medication to a participating county-owned pharmacy within another county that has adopted a program pursuant to this division, if the pharmacies 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.

(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) 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.*

(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 1351**
Current Version:	**As Amended April 16, 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: On Asm Appropriations Suspense File

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.

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 the offense that qualifies them 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 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 specifies the five-year time frame as it relates to a conviction for a serious or violent felony prior to the alleged commission of the charged offense.

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.

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 conveyed to the author's office the board's Opposition.

FISCAL IMPACT ON THE BOARD:
Board staff anticipates a major fiscal impact primarily to its enforcement related costs.

SUPPPORT/OPPOSITION:
Support
Drug Policy Alliance (Sponsor)
Immigrant Legal Resource Center (Sponsor)
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 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
ConXión to Community
Del Sol Group
Dolores Street Community Services
Faith in Action Kern County
Harvey Milk LGBT Democratic Club
Human Rights Watch
Immigration Action Group
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
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)
Two private individuals

Opposition
Board of Pharmacy

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
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.
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 Public Safety.
03/02/15	Read first time.
03/1/15	From printer. May be heard in committee March 31.
02/24/15	Introduced. To print.

AMENDED IN ASSEMBLY APRIL 16, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1351

Introduced by Assembly Member Eggman

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.

~~(1) Existing~~

Existing law allows individuals ~~convicted of~~ *charged with* specified crimes to qualify for deferred entry of judgment. A defendant qualifies if ~~they have~~ *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, ~~defendants can plead guilty and~~ *an eligible defendant may* have entry of judgment deferred, ~~in return for~~ *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 ~~them~~ *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.

~~(2) This~~

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 ~~qualifies if they have~~ *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 ~~felony~~ conviction for a serious or violent ~~felony.~~ *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 would suspend the proceedings in order to enter 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 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 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 ~~in lieu of trial,~~ 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 ~~waive~~ *waives* the right to a speedy ~~trial and~~ 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 ~~deferred entry of judgment~~ *pretrial diversion* following successful completion of the program.

(b) If the defendant consents and waives his or her right to a speedy trial ~~or~~ *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 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. 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 ~~(b)~~ *(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 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.

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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: Re-referred to Committee on Public Safety

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:
Support
ACLU (Co-sponsor)
CHIRLA (Co-sponsor)
Drug Policy Alliance (Co-sponsor)
Immigrant Legal Resource Center (Co-sponsor)
NCLR (Co-sponsor)
California Immigrant Policy Center
California Rural Assistance Foundation
Harvey Milk LGBT Democratic Club
Lawyers' Committee for Civil Rights of the San Francisco Bay Area
Placer People of Faith Together

Opposition

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
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.
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.

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.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 671**
Current Version:	**As Amended May 5, 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: In Assembly (5/22). Held at desk.

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 most recent amendment does not substantially alter the content of the bill.

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 amendments of 4/14/15 changed the time for notice from "within a reasonable time following the dispensing" to "within five days following the dispensing." Along with that change, the amendment made two non-substantive citation corrections. The most recent version of the bill does not make any substantive changes.

Staff has notified the author of the board's position;; however, 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:
Support
AIM at Melanoma
Alliance for Patient Access
Alliance of Specialty Medicine which includes the American Academy of Facial Plastic & Reconstructive Surgery, American Association of Neurological Surgeons, American College of Mohs Surgery, American Gastroenterological Association, American Society of Cataract and Refractive Surgery, American Society of Echocardiography, American Society of Plastic Surgeons, Coalition of State Rheumatology Organizations, Congress of Neurological Surgeons, North American Spine Society, Society for Cardiovascular Angiography and Interventions and Society for Excellence in Eyecare
American Cancer Society
Amgen
Arthritis Foundation
Association of Northern California Oncologists
Biotechnology Industry Organization (BIO) BIOCOM
California Healthcare Institute
California Rheumatology Alliance

Crohn's & Colitis Foundation of America
Express Scripts
Genentech
Hospira
International Cancer Advocacy Network
Johnson & Johnson
Kidney Cancer Association
Lilly USA
Medical Oncology Association of Southern California
Merck
National Black Nurses Association
National Kidney Foundation
Novartis
Novo Nordisk
Pharmaceutical Research and Manufacturers of America
Sandoz
Sanofi
State Building and Construction Trades Council
UCB, Inc.
U.S. Pain Foundation

Opposition
California Pharmacists Association
Academy of Managed Care Pharmacy
America's Health Insurance Plans
California Association of Health Plans
California Retailers Association
CVS Health
Kaiser Permanente
National Community Pharmacists Association
National Association of Chain Drug Stores
Pharmaceutical Care Management Association
Walgreens

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
05/22/15	In Assembly. Read first time. Held at Desk.
05/22/15	Read third time. Passed. (Ayes 31. Noes 5.) Ordered to the Assembly.
05/19/15	Read second time. Ordered to third reading.
05/18/15	From committee: Be ordered to second reading pursuant to Senate Rule 28.8.
05/08/15	Set for hearing May 18.
05/05/15	Read second time and amended. Re-referred to Com. on APPR.
05/04/15	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 9. Noes 0. Page 862.) (April 29).
04/15/15	Set for hearing April 29.
04/14/15	From committee with author's amendments. Read second time and amended. Re-referred to Com. on HEALTH.
04/14/15	From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 7. Noes 0. Page 591.) (April 13). Re-referred to Com. on HEALTH.
03/24/15	Set for hearing April 13.
03/12/15	Referred to Coms. on B., P. & E.D. and HEALTH.
03/02/15	Read first time.
03/02/15	From printer. May be acted upon on or after April 1.
02/27/15	Introduced. To Com. on RLS. for assignment. To print.

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, 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 the Pharmacy Law is guilty of a misdemeanor, as specified.

This bill would authorize a pharmacist, in his or her discretion, except as specified, 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. The bill would also require a pharmacist or his or her designee 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. 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, as defined in paragraph (2) of subdivision (h).~~ *interchangeable.*

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

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall communicate to the prescriber 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, 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 ~~FDA-approved~~ interchangeable biological ~~product, as defined in subdivision (h),~~ *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) 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) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (c). A pharmacist who selects ~~the~~ *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) 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) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

(g) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the ~~FDA~~ *federal Food and Drug Administration* to be ~~interchangeable, as defined in paragraph (2) of subdivision (h).~~ *interchangeable.*

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

(j) 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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Attachment 3

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:	**None, the board did not previously consider this measure**

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

Status: Assembly Appropriations Committee – Suspense file

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.

HISTORY:

Date	Action
05/13/2015	May 13 In committee: Set, first hearing. Referred to APPR. suspense file.
04/29/2015	Apr. 29 From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (April 29). Re-referred to Com. on APPR.
04/23/2015	Apr. 23 Re-referred to Com. on A. & A.R.
04/22/2015	Apr. 22 From committee chair, with author's amendments: Amend, and re-refer to Com. on A. & A.R. Read second time and amended.
03/23/2015	Mar. 23 In committee: Set, first hearing. Hearing canceled at the request of author.
01/16/2015	Jan. 16 Referred to Com. on A. & A.R.
12/02/2014	Dec. 2 From printer. May be heard in committee January 1.
12/01/2014	Dec. 1 Read first time. To print.

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 85**
Current Version:	**As Amended April 15, 2015**
Author:	**Wilk**
Topic:	**Open Meetings**

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

Status: ASM Appropriations – Suspense file

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
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 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 1060**
Current Version:	**As Amended March 26, 2015**
Author:	**Bonilla**
Topic:	**Professions and Vocations: Licensure**

Affected Section(s): Section 491 of the Business and Professions Code

Status: In SEN Business Professions and Economic Development

SUMMARY:

This measure would require the board to advise an ex-licensee with certain information pertaining to rehabilitation, reinstatement, or reduction of penalty by first-class mail *and* by email if the board has an email address on file for the ex-licensee.

EXISTING LAW:

1. Requires the board, upon suspension or revocation of a license, to provide the ex-licensee with information mandated by the Government Code relating to the provisions for reinstatement of a license, as well as information on criteria relating to rehabilitation.
2. Requires that this notification may be satisfied through first-class mail.

THIS BILL WOULD:

Amend B&PC Section 491 to require the board to satisfy the notification requirements through first-class mail and by e-mail if the board has an email address on file for the ex-licensee.

STAFF COMMENTS:

The intent of the bill is to require boards to notify an individual by mail and by email. The board does not currently require an individual to file or maintain an email address as part of the individual's official address of record, nor does the board's existing computer system enable the board to log or track an email address. The author's office has stated their willingness to work with the board to resolve any issues of concern.

FISCAL IMPACT ON THE BOARD:

Board staff is seeking information from the department on the costs to modify its computer systems to comply with AB 1060.

SUPPPORT/OPPOSITION:

Support

Opposition

PREVIOUS/RELATED LEGISLATION:

HISTORY:

Date	Action
05/21/15	Referred to Com. on B., P. & E.D.
05/07/15	In Senate. Read first time. To Com. on RLS. for assignment.
05/07/15	Read third time. Passed. Ordered to the Senate.
04/30/15	Read second time. Ordered to Consent Calendar.
04/29/15	From committee: Do pass. To Consent Calendar. (Ayes 17. Noes 0.) (April 29).
04/14/15	From committee: Do pass and re-refer to Com. on APPR. with recommendation: To Consent Calendar. (Ayes 14. Noes 0.) (April 14). Re-referred to Com. on APPR.
04/06/15	Re-referred to Com. on B. & P.
03/26/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/19/15	Referred to Com. on B. & P.
02/27/15	From printer. May be heard in committee March 29.
02/26/15	Read first time. To print.

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1060

Introduced by Assembly Member Bonilla

February 26, 2015

An act to amend Section 491 of the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 1060, as amended, Bonilla. Professions and vocations: licensure.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to suspend or revoke a license on the ground that the licensee has been convicted of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law requires the board, upon suspension or revocation of a license, to provide the ex-licensee with certain information pertaining to rehabilitation, reinstatement, or reduction of penalty, as specified.

This bill would ~~authorize~~ *require* the board to provide that information through first-class mail and by ~~electronic means.~~ *email if the board has an email address on file for the ex-licensee.*

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 491 of the Business and Professions Code is amended to read:

491. (a) Upon suspension or revocation of a license by a board on one or more of the grounds specified in Section 490, the board shall:

(1) Send a copy of the provisions of Section 11522 of the Government Code to the ex-licensee.

(2) Send a copy of the criteria relating to rehabilitation formulated under Section 482 to the ex-licensee.

(b) Subdivision (a) ~~may~~ *shall* be satisfied through first-class mail and by ~~electronic means.~~ *email if the board has an email address on file for the ex-licensee.*

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 467**
Current Version:	**As amended April 21, 2015**
Author:	**Hill**
Topic:	**Professions and Vocations**
Board Position:	**None, the board did not previously consider this measure**

Affected Sections: Amend Section 201 of the Business and Professions Code (B&PC) and add sections 312.2 and 328 to the B&PC. This measure also affects other sections of B&PC that have no impact to the board.

Status: Assembly Third Reading File

SUMMARY: Would require pro rata assessed by the Department of Consumer Affairs to be approved by the legislature, would require the Attorney General to submit an annual report on various workload measures and would direct the director of DCA to work with healing arts boards to standardize referral of complaints consistent with a memo issued under a prior DCA director.

EXISTING LAW:
B&PC Section 201 sets forth the provisions that allow establishment of pro rata against boards and other programs under the DCA at the discretion of the director with the approval of the Department of Finance.

THIS BILL WOULD:
Amend B&PC Section 201 to provide that the establishment of pro rata against boards and programs with the approval of the Legislature.

Add B&PC Section 312.2 to require the Attorney General's Office to report to the DCA, the Governor, and appropriation policy committees of the Legislature several specified workload elements including, but not limited to the below:

- Number of cases referred by each constituent entity within the department
- Number of such cases returned with no further action
- Number of cases re-referred after to the AG's Office after supplemental investigation
- Number of accusations filed as well as the number of accusations withdrawn
- Average days to file an accusation
- Average days to transmit a stipulated settlement, default decision or to schedule a hearing.

Add B&PC Section 328 to require the Division of Investigation to work cooperatively with health care board to implement the compliant prioritization guidelines described in a memo dated August 31, 2009 from Brian J. Stiger, the Director at the time.

STAFF COMMENTS:
In August 2009, Brian Stiger released a memo to all healing arts boards within the DCA encouraging such boards to consider using the complaint prioritization guidelines contained in the memo. This memo included three categories of complaints: Urgent; High and Routine. This memo further indicated that the department recognized that each agency may have complaint categories unique to its subject area.

The board has historically maintained its own prioritization of complaints ranging from 1 to 4, with one being the highest priority. While some of the categories of complaints detailed in Mr. Stiger's memo were consistent, some deviated from the board's prioritization. One such example is provided below.

> DCA established "diversion drop outs" as a high priority.
> The board would consider this a priority one, a higher prioritization than the DCA memo.

Board staff does not believe it is appropriate to modify its current categorization of cases if it would result in the compromising of public safety. The example above is one area where such could occur. Although the memo noted that each board may have unique complaint categories, this measure does not account for these differences.

A copy of this memo is provided.

FISCAL IMPACT ON THE BOARD:

This measure could have a fiscal impact on the board it is required to overall is current system of prioritizing complaints.

HISTORY:

Date	Action
05/11/2015	May 11 May 11 hearing: Placed on APPR. suspense file.
05/01/2015	May 1 Set for hearing May 11.
04/28/2015	Apr. 28 From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0. Page 793.) (April 27). Re-referred to Com. on APPR.
04/21/2015	Apr. 21 From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/26/2015	Mar. 26 Set for hearing April 27.
03/05/2015	Mar. 5 Referred to Com. on B., P. & E.D.
02/26/2015	Feb. 26 From printer. May be acted upon on or after March 28.
02/25/2015	Feb. 25 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 21, 2015

SENATE BILL No. 467

Introduced by Senator Hill

February 25, 2015

An act to amend Sections ~~5000 and~~ *201, 5000, and* 5015.6 ~~of~~ *of, and to add Sections 312.2, 328, and 5100.5 to,* the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 467, as amended, Hill. ~~Accountants.~~ *Professions and vocations.*

Existing law provides for the licensure and regulation of various professions and vocations by boards, bureaus, commissions, divisions, and other agencies within the Department of Consumer Affairs. Existing law authorizes the department to levy a pro rata share of the department's administrative expenses against any of these constituent agencies at the discretion of the Director of Consumer Affairs and with the approval of the Department of Finance.

This bill would eliminate the requirement that the levy described above be at the discretion of the Director of Consumer Affairs and with the approval of the Department of Finance, and would instead require the levy to be approved by the Legislature.

Existing law requires an agency within the department to investigate a consumer accusation or complaint against a licensee and, where appropriate, the agency is authorized to impose disciplinary action against a licensee. Under existing law, an agency within the department may refer a complaint to the Attorney General or Office of Administrative Hearings for further action.

This bill would require the Attorney General to submit a report to the department, the Governor, and the appropriate policy committees

of the Legislature, on or before January 1, 2017, and on or before January 1 of each subsequent year, that includes specified information regarding the actions taken by the Attorney General pertaining to accusations and cases relating to consumer complaints against a person whose profession or vocation is licensed by an agency within the department.

Existing law creates the Division of Investigation within the department and requires investigators who have the authority of peace officers to be in the division to investigate the laws administered by the various boards comprising the department or commencing directly or indirectly any criminal prosecution arising from any investigation conducted under these laws.

This bill would, in order to implement specified complaint prioritization guidelines, require the Director of Consumer Affairs, through the Division of Investigation, to work cooperatively with the health care boards to standardize referral of complaints to the division and those that are retained by the health care boards for investigation.

Under existing law, the California Board of Accountancy within the ~~Department of Consumer Affairs~~ *department* is responsible for the licensure and regulation of accountants and is required to designate an execute officer. Existing law repeals these provisions on January 1, 2016.

This bill would extend the repeal date to January 1, 2020.

Existing law authorizes the California Board of Accountancy, after notice and hearing, to revoke, suspend, or refuse to renew any permit or certificate, as specified, or to censure the holder of that permit or certificate for unprofessional conduct.

This bill would additionally authorize the board, after notice and hearing, to permanently restrict or limit the practice of a licensee or impose a probationary term or condition on a licence for unprofessional conduct. This bill would authorize a licensee to petition the board for reduction of penalty or reinstatement of the privilege, as specified, and would provide that failure to comply with any restriction or limitation imposed by the board is grounds for revocation of the license.

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 201 of the Business and Professions Code is amended to read:

201. (a) (1) A charge for the estimated administrative expenses of the department, not to exceed the available balance in any appropriation for any one fiscal year, may be levied in advance on a pro rata share basis against any of the boards, bureaus, commissions, divisions, and agencies, ~~at the discretion of the director and with the approval of the Department of Finance.~~ *with the approval of the Legislature.*

(2) The department shall submit a report of the accounting of the pro rata calculation of administrative expenses to the appropriate policy committees of the Legislature on or before July 1, 2015, and on or before July 1 of each subsequent year.

(b) The department shall conduct a one-time study of its current system for prorating administrative expenses to determine if that system is the most productive, efficient, and cost-effective manner for the department and the agencies comprising the department. The study shall include consideration of whether some of the administrative services offered by the department should be outsourced or charged on an as-needed basis and whether the agencies should be permitted to elect not to receive and be charged for certain administrative services. The department shall include the findings in its report pursuant to paragraph (2) of subdivision (a) that it is required to submit on or before July 1, 2015.

SEC. 2. Section 312.2 is added to the Business and Professions Code, to read:

312.2. (a) The Attorney General shall submit a report to the department, the Governor, and the appropriate policy committees of the Legislature on or before January 1, 2017, and on or before January 1 of each subsequent year that includes, at a minimum, all of the following for the previous fiscal year:

(1) The number of cases referred to the Attorney General by each constituent entity within the department.

(2) The number of cases referred by the Attorney General back to each constituent entity with no further action.

(3) The number of cases rereferred by a constituent entity to the Attorney General after each constituent entity or the Division of Investigation completes a supplemental investigation.

(4) The number of accusations filed by each constituent entity.

(5) The number of accusations a constituent entity withdraws.

(6) The average number of days from the Attorney General receiving a case to filing an accusation on behalf of each constituent entity.

(7) The average number of days to prepare an accusation for a case that is rereferred to the Attorney General after a supplemental investigation is conducted by staff of a constituent entity or the Division of Investigation for each constituent entity.

(8) The average number of days from filing an accusation to transmitting a stipulated settlement for each constituent entity.

(9) The average number of days from filing an accusation to transmitting a default decision for each constituent entity.

(10) The average number of days from filing an accusation to scheduling a hearing for each constituent entity.

(11) The average number of days from scheduling a hearing to conducting a hearing for each constituent entity.

(b) A report to be submitted pursuant to subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

SEC. 3. Section 328 is added to the Business and Professions Code, to read:

328. In order to implement the complaint prioritization guidelines as described in the memorandum dated August 31, 2009, by Brian J. Stiger titled "Complaint Prioritization Guidelines for Health Care Agencies," the director, through the Division of Investigation, shall work cooperatively with the health care boards to standardize referral of complaints to the division and those that are retained by the health care boards for investigation.

~~SECTION 1.~~

SEC. 4. Section 5000 of the Business and Professions Code is amended to read:

5000. (a) There is in the Department of Consumer Affairs the California Board of Accountancy, which consists of 15 members, 7 of whom shall be licensees, and 8 of whom shall be public members who shall not be licentiates of the board or registered by the board. The board has the powers and duties conferred by this chapter.

(b) The Governor shall appoint four of the public members, and the seven licensee members as provided in this section. The Senate

Committee on Rules and the Speaker of the Assembly shall each appoint two public members. In appointing the seven licensee members, the Governor shall appoint individuals representing a cross section of the accounting profession.

(c) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.

(d) Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature. However, the review of the board shall be limited to reports or studies specified in this chapter and those issues identified by the appropriate policy committees of the Legislature and the board regarding the implementation of new licensing requirements.

~~SEC. 2.~~

SEC. 5. Section 5015.6 of the Business and Professions Code is amended to read:

5015.6. The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.

SEC. 6. Section 5100.5 is added to the Business and Professions Code, to read:

5100.5. (a) After notice and hearing the board may, for unprofessional conduct, permanently restrict or limit the practice of a licensee or impose a probationary term or condition on a license, which prohibits the licensee from performing or engaging in any of the acts or services described in Section 5051.

(b) A licensee may petition the board pursuant to Section 5115 for reduction of penalty or reinstatement of the privilege to engage in the service or act restricted or limited by the board.

(c) The authority or sanctions provided by this section are in addition to any other civil, criminal, or administrative penalties or sanctions provided by law, and do not supplant, but are cumulative to, other disciplinary authority, penalties, or sanctions.

(d) Failure to comply with any restriction or limitation imposed by the board pursuant to this section is grounds for revocation of the license.

(e) For purposes of this section, both of the following shall apply:

(1) "Unprofessional conduct" includes, but is not limited to, those grounds for discipline or denial listed in Section 5100.

(2) "Permanently restrict or limit the practice of" includes, but is not limited to, the prohibition on engaging in or performing any attestation engagement, audits, or compilations.

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