California State Board of Pharmacy
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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 6, 2015
   Location: Asm Business and Professions
   Status: Scheduled for hearing on April 21, 2015

   Summary: This bill would require dispensers to use a standardized direction for use on the 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.

   A copy of the bill in its current form as well as the fact sheet is provided.

2. SB 590 (Stone) Pharmacy: Intern Licenses
   Version: As introduced February 26, 2015
   Location: Sen Appropriations
   Status: Scheduled for hearing on April 20, 2015

   During the October 2014 Meeting, the board voted to amend Business and Professions Code section 4209 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. Senator Jeff Stone is authoring this bill. Board staff received comments from a group representing the deans of the California Schools of Pharmacy. In response to those comments, the measure was amended to clarify the intent of legislation.

   The first hearing of this measure occurred on April 6, 2015 and was a consent item.

A copy of the bill in its current form, the proposed amendments as well as the fact sheet is provided.

3. SB 619 (Morrell) Pharmacy: Outsourcing Facilities: Licensure
   Version: As Amended April 6, 2015
   Location: Senate Rules

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

   A copy of the bill in its current form is provided. The provisions are preliminary at this point. Ms. Herold will discuss this proposal in further detail during the committee and board meeting.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
Unless otherwise noted, a copy of the bill in its current form and an analysis are provided in **Attachment 2.**

1. AB 45 (Mullin) Household Hazardous Waste
   Version: Amended April 13, 2015
   Location: Asm Local Government
   Status: Hearing scheduled for April 22, 2015

   Summary: Would require each jurisdiction that provides for residential collection and disposal of solid waste, on or before an unspecified date, to increase the collection and diversion of household hazardous waste in its service area by a yet to be specified percentage.

2. AB 333 (Melendez) Healing Arts, Continuing Education
   Version: Amended March 26, 2015
   Location: Asm Business and Professions
   Status: Hearing scheduled for April 28, 2015

   Summary: Would allow specified healing arts licensees to apply one unit of continuing education credit for attending a course that results in the licensee becoming a certified instructor of cardiopulmonary resuscitation (CPR) or the proper use of an automated external defibrillator (AED) and would allow to up two units of continuing education credit for conducting CPR or AED training sessions as specified.

3. AB 463 (Chiu) Pharmaceutical Cost Transparency Act of 2015
   Version: As introduced February 23, 2015
   Location: Asm Health
   Status: Hearing Scheduled for April 21, 2015

Summary: Would establish an annual reporting requirement for each manufacturer of a prescription drug, made available in California, that has wholesale acquisition cost of $10,000 or more annually or per course of treatment.

A copy of the author's fact sheet is included along with the bill and analysis.

4. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels
   Version: As introduced February 23, 2015
   Location: Asm Health
   Status: Hearing scheduled for April 21, 2015

   Summary: Would alter 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.

5. AB 611 (Dahle) Controlled Substances: Prescriptions: Reporting
   Version: As amended April 15, 2015
   Location: Asm Business and Professions
   Status: Hearing scheduled for April 21, 2015

   Summary: Would authorize an individual designated to investigate a holder of a professional license to apply to the Department of Justice to obtain approval to access information contained in the CURES PDMP regarding the controlled substance history of an applicant or licensee for the purpose of investigating the alleged substance abuse of a licensee.

6. AB 623 (Wood) Abuse-Deterrent Opioid Analgesic Drug Products
   Version: As amended March 26, 2015
   Location: Asm Health
   Status: Hearing scheduled for April 21, 2015

   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.

7. AB 684 (Bonilla) Pharmacy
   Version: As introduced February 25, 2015
   Location: Asm Business and Professions
   Status: Hearing held April 14, 2015, "Do pass and re-refer to Appropriations."

   Summary: This is currently a spot bill making changes to section 4200.3 of the Business and Professions Code. Board staff has been in contact with legislative staff and will

provide an update during the meeting if available. Given that the measure is a spot bill currently a bill analysis was not prepared.

8. AB 750 (Low) Business and Professions: Licenses
   Version: As amended April 6, 2015
   Location: Asm Business and Professions
   Status: April 15, 2015 Hearing result, "Do pass as amended "

   Summary: This measure would allow boards and bureaus within the DCA to establish, by regulation, a system for a retired category of licensure for persons who are not actively engaged in the practice of profession or vocation.

   Staff will provide a copy of the amended language if available.

9. AB 788 (Chu) Prescriptions
   Version: As amended March 26, 2015
   Location: Asm Health
   Status: Hearing Cancelled

   Summary: This measure would have provided provisions to require for the condition or purpose of a medication to be included on a prescription.

   Board staff was advised that the measure will not be moving forward. As such neither a copy of the bill nor a bill analysis is provided.

10. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
    Version: As amended March 26, 2015
    Location: Asm Health
    Status: Hearing scheduled for May 5, 2015

    Summary: Would expand the provisions under which a county established repository and distribution program including allow the transfer of drugs to other counties not just currently adjacent counties and would allow for the advance repackaging of the donated medications. Further, this measure would define "tamper-evident packaging" for purposes of a county established repository and distribution program and would require policies and procedures that address how to handle manufacturer recalls for medications without lot numbers.

11. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
    Version: As introduced February 27, 2015
    Location: Asm Public Safety
    Status: Hearing scheduled for April 21, 2015

    Summary: Would change the deferred entry of judgment program into a pretrial diversion program.

12. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea
    Version: As introduced February 27, 2015
    Location: Asm Public Safety
    Status: Hearing scheduled for April 21, 2015

    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 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.

13. SB 396 (Hill) Health and Care Facilities, Outpatient Settings and Surgical Clinics
    Version: As introduced February 25, 2015
    Location: Senate Business, Professions and Economic Development
    Status: Hearing scheduled for April 20, 2015

    Summary: Would clarify that a surgical clinic is eligible for licensure by the State Department of Public Health regardless of physician or dentist ownership.

    This measure is being brought to the board for information only as it will allow for a podiatrist owned surgical center, which would then allow the board to issue a clinic license. As such no bill analysis was prepared.

14. SB 423 (Bates) Pharmaceutical Waste: Over-the-Counter Drugs and Nutritional Supplements
    Version: As introduced February 25, 2015
    Location: Sen Environmental Quality
    Status: Hearing cancelled at request of author

    Summary: Would exclude from the definition of "pharmaceutical waste." For purposes of regulation under the Medical Waste Management Act, any over-the-counter human or veterinary drug or dietary supplement that is characterized and managed as a hazardous or solid waste.

    This measure is being brought to the board for information only. As such no bill analysis was prepared.

15. SB 587 (Stone) Pharmacy: Compounding
    Version: As amended April 9, 2015
    Location: Senate Rules
    Status: Awaiting committee assignment

    Summary: Would specify that a pharmacist may initiate or adjust the drug regimen of a patient undergoing treatment of hypertension or hyperlipidemia as authorized

16. SB 671 (Hill) Pharmacy: Biological Product
    Version: As introduced February 27, 2015
    Location: Senate Health
    Status: Hearing scheduled for April 29, 2015

    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."

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

1. AB 85 (Wilk) Open Meetings
   Version: As Amended April 15, 2015
   Location: Asm Appropriations
   Status:

   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.

2. AB 410 (Obernolte) Documents Submitted to Legislative Committees
   Version: As amended March 26, 2015
   Location: Asm Accountability and Administrative Review
   Status: Hearing scheduled for April 29, 2015

   Summary: This measure would require the board to post on its website any document that is required or requested by law to submit to a committee of the Legislature.

   This measure is being brought to the board for information only. As such no bill analysis was prepared.

3. AB 507 (Olsen) Department of Consumer Affairs: BreEZe System: Annual Report
   Version: As amended March 26, 2015
   Location: Asm Business and Professions
   Status: April 15, 2015 hearing outcome, "Do pass as amended"

   Summary: This measure would require the Department of Consumer Affairs to submit an annual report to the Legislature and the Department of Finance that includes the department's plans for implementing the BreEZe system for programs in the 3rd phase of the implementation project.

This measure is being brought to the board for information only. As such no bill analysis was prepared.

4. AB 797 (Steinorth) Regulations: Effective Dates and Legislative Review
   Version: As amended April 6, 2015
   Location: Asm Accountability and Administrative Review
   Status: Hearing outcome, "Do pass and re-refer to Appropriations Committee"

   Summary: As amended this measure would require the Office of Administrative Law to submit a copy of each major regulation submitted to the Secretary of State to the appropriate policy committee with responsibility for the subject matter and would specify that a regulation would not take effect if the Legislature passes a statute to override the regulation.

   This measure is being brought to the board for information only. As such no bill analysis was prepared.

5. AB 1060 (Bonilla) Professions and Vocations: Licensure
   Version: As amended March 26, 2015
   Location: Asm Business and Professions
   Status: Hearing outcome, "Do pass and re-refer to Appropriations Committee"

   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.

Part 2: Regulation Report

a. Newly Effective Regulation – Amendment to Title 16 California Code of Regulations Section 1707.5 Regarding Patient-Centered Labeling Requirements

In 2013, the board voted to modify the board's patient-centered prescription label requirements at 16 CCR Section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point san serif typeface.

The rulemaking was noticed on April 14, 2014, and following the 45-day comment period, adopted by the board in June. Pursuant to the Administrative Procedure Act, following review and approval by Agency, the rulemaking was submitted to the Office of Administrative Law (OAL) for final review. OAL approved the rulemaking on January 8, 2015, and the regulation became effective on April 1, 2015. Following approval by OAL, the board issued a Subscriber Alert announcing the approval of the regulation, and

encouraged pharmacies to conform their prescription container labels to the new minimum font size requirement.

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

b. Currently Noticed: Proposal to Amend Title 16 California Code of Regulations Sections 1715, 1735.2, and 1784 to Update Self-Assessment Forms 17M-13, 17M-14, and 17M-26

At the October 2014 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the text of 16 California Code of Regulations Sections 1715, 1735.2 and 1784 and to amend the Self-Assessment Forms incorporated by reference in those sections. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s). The 45 day comment period began on March 20, 2015 and ends on May 6, 2015.

A copy of the noticed text is provided in **Attachment 5**.

c. For Board Action: Proposal to Amend Title 16 California Code of Regulations Section 1793.5, Pharmacy Technician Application

At the July 2014 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations Section 1793.5 to change the wording of the criminal conviction question on the Pharmacy Technician Application, which is incorporated by reference in the regulation. The 45 day comment period ran from February 20, 2015 – April 6, 2015. No comments were received during the 45-day comment period. Board approval is necessary for minor amendments to the application to conform to statute.

<u>Recent Update</u>
As a result of a meeting with counsel and review of additional questions and the attestation on the application, additional suggested changes were identified. A brief justification for each of the changes is below.

Question 1: Requires modification to confirm to the language in CCR 1769(2)

Question 2: Requires modification to remove the portion of the question that requires disclosure if someone is "currently" engaged in the illegal use of controlled substances as the question violates their 5th amendment right.

Question 3: Is being added to request information about participation in a substance abuse program. This is a new question that will provide the board with additional information and possible mitigation to consider.

Attestation: Requires changes to specify that the applicant understands that the application may be denied, or any license disciplined, for fraud or misrepresentation.

A copy of the regulation language and amended application is provided in **Attachment 6**.

d. Board Approve – Awaiting Notice

1. **Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements**

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

2. **Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education**

   In 2013, the board approved a proposal to initial a formal rulemaking to amend the text of 16 California Code of Regulations Sections 1732.05. 1732.2, and 1732.5 relative to continuing education. At the October 2014 board meeting, the board discussed and thereafter voted to add "compounding education" as a sixth area of subject-specific continuing education in Section 1732.5. Staff is preparing the required notice documents and will be noticing these proposals as a combined rulemaking with other board-approved proposals.

3. **Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to "Section 100" Regulatory Actions**

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

   Copies of each board-approved proposal are provided in **Attachment 7**.

4. **Proposal to Add Title 16 California Code of Regulations Section 1746.1 Protocol for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives**

   At the January 2015 Board Meeting, the board approved a proposal to add Section 1746.1 to Title 16 of the California Code of Regulations. At the January 2015 Medical Board Meeting, the Medical Board also approved the Protocol. Staff is preparing the required notice documents. Any updates from the SB-493 committee meeting will be provided during the SB-493 discussion.

   Copy of the board-approved Protocol is provided in **Attachment 8.**

5. **Proposal to Add Title 16 California Code of Regulations Section 1746.2 Protocol of Pharmacists Who Furnish Nicotine Replacement Products**

   At the January 2015 Board Meeting, the board approved a proposal to add Section 1746.2 to Title 16 of the California Code of Regulations. At the January 2015 Medical Board Meeting, the Medical Board also approved the Protocol. Staff is preparing the required notice documents. Any updates from the SB-493 committee meeting will be provided during the SB-493 discussion.

   Copy of the board-approved Protocol is provided in **Attachment 8.**

Attachment 1

AB 1073 (Ting)

Providing Translations on Prescription Medication Labels

Purpose

This bill will benefit limited-English and non-English speaking patients by increasing opportunities for them to obtain translated directions for use on their prescription container labels. According to 2010 census data, forty-six percent of Californians speak English less than "very well." Directions provided on prescription container labels are a primary and necessary reference for patients and their caregivers on how to take prescription medications outside a health care setting. The bill will provide an exemption from liability for inadvertent mistakes in transcriptions on prescription labels downloaded from the Board of Pharmacy's website that go undetected because the pharmacy staff is unable to read the translated language.

The Problem

For four years, the board has made community-vetted translations available in five languages as part of its efforts to provide patient-centered prescription container labels. However, pharmacists have stated their reluctance to use these translations because pharmacists cannot read the translated language to be certain it is accurate. This has been a deterrent to widespread use of the board's translated standardized directions for use. Additionally, this bill specifies that pharmacies that currently provide their own translations of directions for use on prescription container labels (as many pharmacies do) may continue to do so.

Background Information

Prescription labels contain information for pharmacies, for regulators and for patients, but it is the patient or the patient's caregiver who relies on the label for essential information on what the medication is, who it is for and the appropriate way to take the medication. In 2007, legislation was enacted that required the Board of Pharmacy to develop patient-centered prescription labels. Through California Business and Professions Code section 4076.5, the board was directed to develop prescription container labels that address six needs:

1. Medical literacy research on increased understandability of labels,
2. Improved directions for use,
3. Improved font types and sizes,
4. Placement of information that is patient-centered,
5. The needs of patients with limited English proficient,
6. The needs of senior citizens,
7. Technology requirements necessary to implement the standards.

The board worked with nationally recognized experts in the field of label design and literacy to develop California's requirements. The parameters adopted by the board also became standards recognized by national entities for prescription container labels.

Current Law

In the area of addressing the needs of limited-English and non-English speaking patients, the board requires pharmacies to provide oral translation services in at least 12 languages via personnel or telephone language assistance lines in the pharmacies. The board also has secured translations in five languages of the English standardized directions for use that were developed by national experts for improved clarity and patient comprehension. These translations have been vetted by researchers in communities in California to ensure their precision and accuracy. However, the translations have not been widely adopted because pharmacies are concerned a transcription error could inadvertently occur and go undetected because the pharmacy staff cannot read the language.

Below is an example of standardized direction for use and the translation in Russian and Chinese.

English:	Russian:	Chinese:
Take 2 pills in the morning	Принимать по 2 таблетки утром	早上服兩粒藥丸

What This Bill Does

AB 1073 is a first step to improving the ability of certain limited-English and non-English speaking patients to better understand how to take their medications.

This bill is intended to promote use of the standardized directions and use of the vetted translations so pharmacists can provide better services and protection for consumers. It is a first step towards full achievement of the 2007 statutory mandate, and balances the needs of patients with expenses to the pharmacies.

The Board of Pharmacy's paramount mandate is consumer protection.

For More Information

Materials regarding this proposal can be found at www.pharmacy.ca.gov. Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

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Sacramento, CA 95834
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AMENDED IN ASSEMBLY APRIL 6, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1073

Introduced by Assembly Member Ting

February 27, 2015

An act to ~~amend~~ *add* Section ~~4076.5 of~~ *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 ~~remove that obsolete date.~~ *require a dispenser 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: ~~no~~ *yes*. State-mandated local program: ~~no~~ *yes*.

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

1 *SECTION 1. Section 4076.6 is added to the Business and*
2 *Professions Code, to read:*
3 *4076.6. (a) For all dangerous drugs dispensed to patients in*
4 *this state, when applicable, a dispenser shall use a standardized*
5 *direction for use on the label of the prescription container from*
6 *the list in subdivision (a) of Section 1707.5 of Title 16 of the*
7 *California Code of Regulations.*
8 *(b) The board shall make available translations, in a minimum*
9 *of five languages other than English, of the standardized directions*
10 *for use that are listed in subdivision (a) of Section 1707.5 of Title*
11 *16 of the California Code of Regulations. These translations shall*
12 *be approved by qualified translators, as determined by the board.*
13 *The board shall post these translated standardized directions for*
14 *use on its Internet Web site.*
15 *(c) Upon the request of a patient for a translated direction for*
16 *use, a dispenser shall select the appropriate translated*
17 *standardized direction for use from those established in accordance*
18 *with subdivision (b), if available, and append it to the label on the*
19 *patient's prescription container or provide it on a supplemental*
20 *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.

~~SECTION 1. Section 4076.5 of the Business and Professions Code is amended to read:~~

~~4076.5. (a) The board shall promulgate regulations that require a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.~~

~~(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of~~

~~pharmacy, other health care professionals, and other interested parties.~~

~~(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:~~

~~(1) Medical literacy research that points to increased understandability of labels.~~

~~(2) Improved directions for use.~~

~~(3) Improved font types and sizes.~~

~~(4) Placement of information that is patient-centered.~~

~~(5) The needs of patients with limited English proficiency.~~

~~(6) The needs of senior citizens.~~

~~(7) Technology requirements necessary to implement the standards.~~

~~(d) The board may exempt from the regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.~~

~~(e) (1) The board may exempt from the regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:~~

~~(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.~~

~~(B) The patient receives health-professional-directed education before the beginning of therapy by a nurse or pharmacist.~~

~~(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.~~

~~(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.~~

~~(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of~~

~~administration that require regular laboratory and patient monitoring.~~

O

Senator Jeff Stone

28th Senate District

Fact Sheet
SB 590

What is the origin of the proposal?

This idea was brought to the attention of Senator Stone on behalf of the California Board of Pharmacy. As part of the Board's regulatory oversight, it evaluates licensing requirements to ensure they remain relevant and appropriate.

What is the background of this proposal?

As a consumer protection agency, one of the key functions of the Board of Pharmacy is to ensure that applicants seeking licensure satisfy at least the minimum requirements for licensure set forth in law. Pharmacy Law establishes the requirements for pharmacist applicants, including the number of pharmacy practice hours that must be earned, currently 1500 hours. The law also prescribes the acceptable methods to document how the experience was earned. Although there are some exceptions, for the majority of California graduates, this includes that such experience must be documented and signed under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by another designated pharmacist.

What deficiency in current law does this bill seek to remedy?

Providing such documentation can be administratively difficult for many students who gain experience in several pharmacies and different pharmacy settings as part of their pharmacy practice experience, generally over a three to four year period. Given that all schools of pharmacy recognized by the board meet the same standards of curriculum (including pharmacy practice experience) by law, the current method of documentation required does not appear to add value to the application process or the board's consumer protection mandate.

What specifically will this bill do?

This proposal will streamline the application process for graduates from all schools recognized by the board, by allowing the Board to accept a transcript from the school, that includes the degree posted and date conferred, as proof that the applicant meets the pharmacy practice hours requirement if the student graduates after January 1, 2016.

Which code sections does this bill affect?

SB 590 amends Section 4209 of the Business and Professions Code, relating to pharmacy.

Who are the proponents of this legislation?

California Board of Pharmacy

Who is the main contact for this bill?

Chris Norden, Legislative Director
Phone: (916) 651-4028
Fax: (916) 651-4928
Email: Chris.norden@sen.ca.gov

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 introduced, 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 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 college of pharmacy or department of pharmacy of a university recognized by the board, be deemed by the board to have satisfied the 1,500 hours of pharmacy practice experience.

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 ~~such~~ *the* experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. ~~Intern hours~~ *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 ~~intern~~ *pharmacy practice* experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a ~~pharmacist.~~ *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 college of pharmacy or department of pharmacy of a university recognized by the board shall be deemed to have satisfied the 1,500 hours of pharmacy practice experience.

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.

CORRECTIONS:

Text—Page 1.

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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 ~~such~~ *the* experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. ~~Intern hours~~ *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 ~~intern~~ *pharmacy practice* experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a ~~pharmacist.~~ *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~~ 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~~ pharmacy practice 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.

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 13, 2015**
Author:	**Mullin**
Topic:	**Household Hazardous Waste**

Affected Sections: Public Resources Code

Status: Committee hearing scheduled for April 22, 2015, Asm Local Government

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, yet to be determined, 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 yet to be determined percentage 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) Allow additional time (also not specified) for a jurisdiction meet the collection and diversion objective.

(b) Establish a reporting timeframe (not yet specified).

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.

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) available. 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 recommends that the board offer amendments to address the security concerns.

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.

HISTORY:

Date	Action
04/14/2015	Re-referred to Com. On L. GOV.
04/13/2015	From committee chair, with author's amendments: Amend, and re-refer to Com. on L. GOV. Read second time and amended.
03/23/2015	Re-referred to Com. on L. GOV.
03/19/2015	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	From printer. May be heard in committee January 1.
12/01/2014	Dec. 1 Read first time. To print.

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, on or before an unspecified date, to increase the collection and diversion of household hazardous waste in its service area by an unspecified percentage 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 ~~door-to-door collection and diversion program~~ *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, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.~~

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, but ultimately these piecemeal and truncated approaches have not proved effective. These approaches~~ *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 ~~the closest and most practical point of disposal: the consumer's residence.~~ *consumer convenience.*

(3) ~~A~~ *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 ~~and services have found them to be successful and inexpensive.~~ *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 ~~Diversion~~ *Reduction*

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

~~(a) "Door-to-door collection and diversion program" means a curbside household hazardous waste collection program, door-to-door household hazardous waste collection program, or household hazardous waste residential pickup service administered by a jurisdiction that allows a resident to arrange, by appointment, for the collection of household hazardous waste at his or her~~

~~residence in accordance with all applicable state and federal laws and regulations.~~

(a) "Comprehensive program for the collection of household hazardous waste" means a local program that includes 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 _____, each jurisdiction shall increase its collection and diversion of household hazardous waste in its service area by _____ percent over its baseline amount, as established in subdivision (b).

(2) Notwithstanding paragraph (1), a jurisdiction that *has in place or* adopts an ordinance implementing a ~~household hazardous waste collection program identified in subdivision (b) or (c) of Section 25218.1 of the Health and Safety Code for~~ *comprehensive program for the collection of* household hazardous waste shall have an additional _____ years to meet the collection and diversion objective in paragraph (1).

(b) No later than _____, 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.* The department shall approve or disapprove of a jurisdiction's baseline amount no later than _____.

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

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

47123. Commencing ____, 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. If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.~~

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 333**
Current Version:	**As Amended March 26, 2015**
Author:	**Melendez**
Topic:	**Healing Arts, Continuing Education**

Affected Sections: Add Section 856 of the Business and Professions Code (B&PC)

Status: Committee hearing scheduled for April 28, 2015, Asm Business and Professions

SUMMARY: Would allow specified healing arts licensees to apply one unit of continuing education credit for attending a course that results in the licensee becoming a certified instructor of cardiopulmonary resuscitation (CPR) or the proper use of an automated external defibrillator (AED) and would allow to up two units of continuing education credit for conducting CPR or AED training sessions as specified.

EXISTING LAW: Existing law establishes the continuing education requirements for various boards within the Department of Consumer Affairs.

B&PC Section 4231 establishes these requirements for pharmacists, including 30 hours of approved coursework during the two years preceding the application renewal.

B&PC Section 4232 specifies that the coursed shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other methods of conveying continuing professional pharmacy education. Further, this section specifies the content areas including socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and the characteristics and therapeutics of the disease state. This section also includes the subject matter of the courses including pharmacology, biochemistry, physiology, anatomy, etc.

Title 16, California Code of Regulations Sections 1732-1732.7 establishes the board's regulations to specify definitions, accreditation agencies, requirements for accredited providers, petitioning the board for credit, general requirements for coursework, provide audit requirements, renewal requirements and exemptions.

THIS BILL WOULD:
Add Section 856 to the Business and Professions Code to allow a specified individual to, as a condition of renewing his or her license,

1. apply one unit of continuing education credit towards that requirement to attending a course that results in the licensee becoming a certified instructor of CPR or AED
2. apply up to two units of CE towards the requirement for conducting CPR and AED training sessions for employees of school districts and community college districts in the state.

STAFF COMMENTS:
According to the author, with AED's becoming more common K-12 and college school facilities, it is important that adequate training resources and instructors are available to school administrators and staff should they seek it. The author notes that pro bono instructors and training resources are in short supply and many private alternatives are cost prohibitive.

The board has discussed continuing education requirements and currently has approved a regulation change that would amend section 1732.5 to require, among other things, that a pharmacist complete six of the 30 units required for pharmacist license renewal in one or more of the following areas:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Substance Abuse
- Compounding

A copy of the proposed regulation change is attached to this bill analysis.

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 As of 4/7/2015
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.
03/26/15	Referred to Com. on B. & P.
02/17/15	From printer. May be heard in committee March 19.
02/13/15	Read first time. To print.

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 333

Introduced by Assembly Member Melendez

February 13, 2015

~~An act to amend Section 49417 of the Education Code, relating to pupil health.~~ *An act to add Section 856 to the Business and Professions Code, relating to healing arts.*

LEGISLATIVE COUNSEL'S DIGEST

AB 333, as amended, Melendez. ~~Pupil health: automated external defibrillators.~~ *Healing arts: continuing education.*

Existing law provides for the licensure and regulation of various healing arts licensees by various boards, as defined, within the Department of Consumer Affairs and imposes various continuing education requirements for license renewal.

This bill would allow specified healing arts licensees to apply one unit, as defined, of continuing education credit towards any required continuing education units for attending a course that results in the licensee becoming a certified instructor of cardiopulmonary resuscitation (CPR) or the proper use of an automated external defibrillator (`AED), and would allow specified healing arts licensees to apply up to 2 units of continuing education credit towards any required continuing education units for conducting CPR or AED training sessions for employees of school districts and community college districts in the state.

~~Existing law authorizes a public school to solicit and receive nonstate funds to acquire and maintain an automated external defibrillator (AED). Existing law provides that the employees of the school district are not~~

~~liable for civil damages resulting from certain uses, attempted uses, or nonuses of an AED, except as provided. Existing law provides that a public school or school district that complies with certain requirements related to an AED is not liable for any civil damages resulting from any act or omission in the rendering of the emergency care or treatment, except as provided.~~

~~This bill would make a nonsubstantive change to these provisions.~~

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 856 is added to the Business and Professions Code, to read:

856. (a) A person licensed pursuant to this division who is required to complete continuing education units as a condition of renewing his or her license may apply one unit of continuing education credit towards that requirement for attending a course that results in the licensee becoming a certified instructor of cardiopulmonary resuscitation (CPR) or the proper use of an automated external defibrillator (AED).

(b) A person licensed pursuant to this division who is required to complete continuing education units as a condition of renewing his or her license may apply up to two units of continuing education credit towards that requirement for conducting CPR or AED training sessions for employees of school districts and community college districts in the state.

(c) For purposes of this section, "unit" means any measurement for continuing education, such as hours or course credits.

~~SECTION 1. Section 49417 of the Education Code is amended to read:~~

~~49417. (a) A public school may solicit and receive nonstate funds to acquire and maintain an automated external defibrillator (AED). These funds shall only be used to acquire and maintain an AED and to provide training to school employees regarding the use of an AED.~~

~~(b) Except as provided in subdivision (d), if an employee of a school district complies with Section 1714.21 of the Civil Code in rendering emergency care or treatment through the use, attempted use, or nonuse of an AED at the scene of an emergency,~~

~~the employee shall not be liable for any civil damages resulting from any act or omission in the rendering of the emergency care or treatment.~~

~~(c) Except as provided in subdivision (d), if a public school or school district complies with the requirements of Section 1797.196 of the Health and Safety Code, the public school or school district shall be covered by Section 1714.21 of the Civil Code and shall not be liable for any civil damages resulting from any act or omission in the rendering of the emergency care or treatment.~~

~~(d) Subdivisions (b) and (c) do not apply in the case of personal injury or wrongful death that results from gross negligence or willful or wanton misconduct on the part of the person who uses, attempts to use, or maliciously fails to use an AED to render emergency care or treatment.~~

~~(e) This section does not alter the requirements of Section 1797.196 of the Health and Safety Code.~~

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To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy's Drug Inventory
4. Ethics
5. Substance Abuse
6. Compounding

Pharmacists renewing their licenses which expire on or after July 1, 201~~5~~6, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

ASSEMBLY BILL 463

PRESCRIPTION DRUG PRICING TRANSPARENCY

ASSEMBLYMEMBER DAVID CHIU

SUMMARY

This bill would address the high-cost of specialty medications and bring more transparency to prescription drug pricing in California.

BACKGROUND

Through the Affordable Care Act (ACA), millions more Californians have comprehensive health coverage with access to a wide range of benefits and services, including prescription drugs. Medi-Cal now covers one in three Californians. Nine out of ten enrollees in Covered California are eligible for subsidies to lower the cost of their health care.

The ACA's long-term success, however, hinges on affordability. High-priced drugs, particularly specialty drugs, threaten to derail the progress California has made in expanding coverage. Escalating prices for new blockbuster medications present challenges for payers and patients alike.

Payers and patients are grappling with six-figure price tags for medications that treat complex chronic diseases such as rheumatoid arthritis, multiple sclerosis, cancer, and Hepatitis C. The $1,000-per-pill Hepatitis C drug Sovaldi (which costs $84,000 for a regular course of treatment) and Harvoni (which costs $94,500) represent important breakthroughs in treatments for patients with these conditions. But the prices for these drugs are a significant burden on the health care system and ultimately unsustainable in the long-term.

Already the costs for specialty medications are impacting state budgets across the nation and are threatening to drive up premiums for consumers and purchasers of health coverage. Governor Jerry Brown's proposed 2015-16 state budget includes $300 million for Hepatitis C treatments across state programs, but the non-partisan Legislative Analyst's Office has questioned whether that amount is sufficient given the lack of knowledge on the number of Hepatitis C patients covered by state programs and the cost per treatment for those patients. The costs to the state could be far higher.

Pharmaceutical companies often assert that prescription drug prices reflect the cost of research and development (R&D), but evidence is mounting that many drug companies spend more on marketing than they do on R&D. It is estimated that manufacturers of orphan drugs, or medications that treat extremely rare diseases with smaller patient populations, save as much as 50% to 75% on R&D costs due to federal tax incentives. The maker of Sovaldi acknowledged at a recent legislative hearing on health care cost drivers that its products are not priced based on the cost of R&D nor the cost to manufacture the medications.

And the problem is not limited to Hepatitis C treatments or specialty drugs alone. These are industry-wide practices, and the recent trends are deeply concerning:

- Prices for 1,200 existing generic drugs increased 450%, on average, in a single year (2013-2014);
- Prices for 73 existing brand name drugs have increased 75% or more since 2007;
- The average price for oncology medications has doubled over the past decade, from $5,000 per month to $10,000 per month ($120,000 per year);
- Of the 12 oncology drugs approved by the FDA in 2013, 11 were priced at more than $100,000 per year;
- 12 new "blockbuster" medications are expected to launch in 2015 alone; and,
- Spending on specialty drugs is expected to more than quadruple from $87 billion in 2012 to $400 billion in 2020 if nothing is done to address current and future prices.

These figures – combined with the fact that specialty and orphan drugs enjoy long patent protections and that no generic alternatives are currently available for biologic drugs – highlight the need for increased scrutiny about how drugs are priced and the rationale

behind charging governments, taxpayers, purchasers, and patients prices that are beyond the threshold needed to ensure the affordability and sustainability of our health care system.

AB 463

As prices for both new and existing prescription drugs continue to rise, it is critically important to analyze drug price and underlying costs associated with individual medicines to inform the development of policies that will ensure access to affordable medications.

Legislation is needed to enhance transparency in prescription drug pricing so policymakers and purchasers can deliver on the promise of health care coverage and affordability.

AB 463 requires pharmaceutical manufacturers to report data to the State of California in order to provide taxpayers, policymakers and consumers with insight into cost centers associated with drug development and availability.

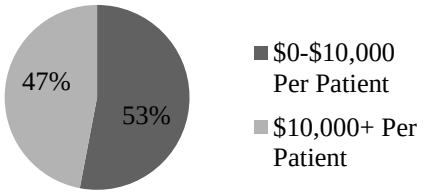
Specifically, AB 463 will:

- Require each manufacturer of a high-cost prescription drug to file a report with the Office of Statewide Health Planning and Development (OSHPD) documenting and itemizing specified cost information, including, but not limited, to:
  - total research and development costs paid by the manufacturer or any predecessor manufacturer in the development of the qualifying drug;
  - total marketing and advertising costs;
  - total cost for materials and manufacturing;
  - total costs paid by government sources in the development of the drug, including subsidies and grants;
  - cumulative history of the Average Wholesale Price and Wholesale Acquisition Costs for the drug; and,
  - total profit attributable to the drug; and,
- Require OSHPD to issue an annual report to the Legislature outlining the cost information submitted by the manufacturers and to post this report on their Website for the public to review.

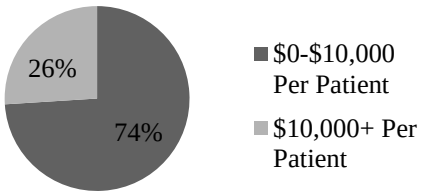
The bill defines high-cost drugs or treatments as one that is priced at $10,000 or higher. This threshold will help the public and policymakers begin to demystify the price of drugs.

The problem of high-cost drugs is not limited to any one disease or drug class, but rather spans the entire spectrum of generic, brand name, and specialty medications. The health care system must have the ability to treat all patients, and it cannot do so if current trends in prescription drug pricing continue unabated. The median price for the top 100 medications in the United States has increased from $1,258 in 2010 to $9,396 in 2014.

Top 100 Drugs by Sales Volume in US, 2010



Top 100 Drugs by Sales Volume in US, 2014



Source: Evaluate Pharma 2015

Meanwhile, pharmaceutical companies are earning profits far above any sector of the health care industry. The maker of Sovaldi doubled its profit margin – to 49% – the first year Sovaldi was on the market and within the first quarter of Harvoni's launch.

Industry	Net Profit Margin, 2015
Doctors/Practitioners	-1.5%
Health Plans	3.3%
Generic Drug Manufacturers	4%
Hospitals	4%
Labs & Medical Research	7.5%
Biotechnology	8.4%
Medical Equipment	9.1%
Brand Drug Manufacturers	16.7%
Top Drug Manufacturers	**19.9%**

Source: Yahoo! Finance 2/20/15

CONTACT

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 463**
Current Version:	**As introduced February 23, 2015**
Author:	**Chiu**
Topic:	**Pharmaceutical Cost Transparency Act of 2015**

Affected Sections: Add Chapter 9 (commencing with Section 127675) to Part 2 of Division 107 of the Health and Safety Code

Status: Committee hearing scheduled for April 21, 2015, ASM Heath

SUMMARY: Would establish the "Pharmaceutical Cost Transparency Act of 2015" as an annual reporting requirement for each manufacturer of a prescription drug, made available in California, that has wholesale acquisition cost of $10,000 or more annually or per course of treatment.

EXISTING LAW: According to the author's office, this is not currently addressed in existing law.

THIS BILL WOULD:
Add Section 127675 which includes legislative intent language to make information available to the public about the cost of ultra-high-priced pharmaceuticals, in order to make the pricing transparent and the need to establish annual cost reporting to fulfill this goal.

Add Section 127676 which would require each manufacturer of a prescription drug, as specified, that has a wholesale acquisition cost of (WAC) of ten thousand dollars or more annually or per course of treatment, to file a report that includes:

- Total costs for the production of the drug
- Cumulative annual history of average wholesale price (AWP) and WAC increases as specified
- Total profit attributable to the drug are representative in total dollars and percentage of total company profits that were derived from the sale of the drug
- Total amount of financial assistance the manufacturer has provided

Further requires that the report be filed annually with the Office of Statewide Health Planning and Development (OSHPD) and requires OSHPD to post the report on its internet site as well as provide a copy to the legislature.

STAFF COMMENTS:

The author notes that as the prices for both new and existing prescription drugs continue to rise, it is important to analyze drug price and underlying costs associated with individual medicines to inform the development of policies that will ensure access to affordable medications.

The board has discussed the issue of prescription medications publicly as a concern on more than one occasion. Further, board staff notes that the board has conducted investigation alleging fraud and drug recycling of very expensive medications.

FISCAL IMPACT ON THE BOARD:

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

SUPPORT/OPPOSITION:

Support

America's Health Insurance Plans (AHIP)
Anthem Blue Cross
California Association of Health Plans
California Labor Federation
California PACE Association for California Seniors
California School Employees Association
California Senior Legislature
East Bay Leadership Council
Fresno Chamber of Commerce
Health Access
Industry Manufacturers Council
Kaiser Permanente
Los Angeles Chamber of Commerce
Molina Healthcare
SEIU California
Small Business Majority
VICA Health Committee

Opposition

Pharmaceutical Research and Manufactures of America

BILL HISTORY:

Date	Action As of 3/5/2015
03/05/15	Referred to Com. on HEALTH.
02/24/15	From printer. May be heard in committee March 26.
02/23/15	Read first time. To print.

ASSEMBLY BILL No. 463

Introduced by Assembly Member Chiu

February 23, 2015

An act to add Chapter 9 (commencing with Section 127675) to Part 2 of Division 107 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 463, as introduced, Chiu. Pharmaceutical Cost Transparency Act of 2015.

Existing law establishes the Office of Statewide Health Planning and Development, which is vested with all the duties, powers, responsibilities, and jurisdiction of the State Department of Public Health relating to health planning and research development.

This bill would require each manufacturer of a prescription drug, made available in California, that has a wholesale acquisition cost of $10,000 or more annually or per course of treatment to file a report, no later than May 1 of each year, with the Office of Statewide Health Planning and Development on the costs for each qualifying drug, as specified. The bill would require the office to issue a report annually to the Legislature outlining the information submitted pursuant to this act, and the office would be required to post the report on its Internet Web site. The bill would also require the office to convene an advisory workgroup, as provided, to develop the reporting form required by this act.

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. Chapter 9 (commencing with Section 127675) is added to Part 2 of Division 107 of the Health and Safety Code, to read:

Chapter 9. Pharmaceutical Cost Transparency Act of 2015

127675. The Legislature finds and declares all of the following:

(a) It is the intent of the Legislature to make information available to the public about the cost of ultra-high-priced pharmaceuticals, in order to make pharmaceutical pricing as transparent as the pricing in other sectors of the health care industry.

(b) To fulfill this goal, the Legislature finds that there should be annual cost reporting on the most expensive drugs that would be of use by policymakers, government agencies, and others to understand costs for these important products.

127676. (a) Each manufacturer of a prescription drug, made available in California, that has a wholesale acquisition cost (WAC) of ten thousand dollars ($10,000) or more annually or per course of treatment, shall file a report pursuant to this section on the costs for each qualifying drug.

(b) The report shall include all of the following for each drug:

(1) The total costs for the production of the drug, including all of the following:

(A) The total research and development costs paid by the manufacturer, and separately, the total research and development costs paid by any predecessor in the development of the drug.

(B) The total costs of clinical trials and other regulatory costs paid by the manufacturer, and separately, the total costs of clinical trials and other regulatory costs paid by any predecessor in the development of the drug.

(C) The total costs for materials, manufacturing, and administration attributable to the drug.

(D) The total costs paid by any entity other than the manufacturer or predecessor for research and development, including any amount from federal, state, or other governmental programs or any form of subsidies, grants, or other support.

(E) Any other costs to acquire the drug, including costs for the purchase of patents, licensing or acquisition of any corporate entity owning any rights to the drug while in development, or all of these.

(F) The total marketing and advertising costs for the promotion of the drug directly to consumers, including, but not limited to, costs associated with direct to consumer coupons and amount redeemed, total marketing and advertising costs for promotion of the drug directly or indirectly to prescribers, and any other advertising for the drug.

(2) A cumulative annual history of average wholesale price (AWP) and WAC increases for the drug (expressed as percentages), including the months each increase in each category, AWP and WAC, took effect.

(3) The total profit attributable to the drug as represented in total dollars and represented as a percentage of the total company profits that were derived from the sale of the drug.

(4) The total amount of financial assistance the manufacturer has provided through patient prescription assistance programs, if available.

(c) All of the information in subdivision (b) shall be itemized and documented by the manufacturer, and audited by a fully independent third-party auditor prior to filing.

(d) The information required by this section shall be filed annually with the Office of Statewide Health Planning and Development on a form prescribed by the office and shall be submitted no later than May 1 of each year.

(e) (1) Notwithstanding Section 10231.5 of the Government Code, the Office of Statewide Health Planning and Development shall issue a report annually to the Legislature outlining the information submitted pursuant to this section, and the office shall post the report publicly on its Internet Web site.

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

(f) The Office of Statewide Health Planning and Development shall convene an advisory workgroup to develop the form required by this section. The workgroup shall include, but is not limited to, representatives from the pharmaceutical industry, health care

service plans and insurers, pharmacy benefit managers, governmental agencies, consumer advocates, and physicians.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 486**
Current Version:	**As Introduced February 23, 2015**
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: Hearing Scheduled for April 21, 2015, Asm Health

SUMMARY:

The measure 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 other information must be retrievable by the pharmacist by 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 the 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. These provisions were included in SB 377, Solorio, Statutes of 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, 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)

Opposition
None

PREVIOUS/RELATED LEGISLATION:
AB 377 (Solario) 2011- 2012 Legislative Session, Chapter 687, Statutes of 2012. This bill established the licensing category of a "centralized hospital pharmacy" (a pharmacy which prepares medications for hospitals under common ownership or control within a 100 mile geographic radius). One of the reasons cited to establish the need for AB 377 in the Fact Sheet was that requiring all medications be prepared by an on-site hospital pharmacy "limits the opportunity to invest in expensive technology that would improve efficiency and enhance patient safety." Underpinning AB 486 is the presumption, which may be accurate, that the present cost of developing the technology needed for bedside reading of barcoded medicines is too high for even commonly owned groups of hospitals to bear.

HISTORY:

Date	Action
04/14/2015	Apr. 14 In committee: Set, first hearing. Hearing canceled at the request of author.
03/05/2015	Mar. 5 Referred to Coms. on HEALTH and B. & P.
02/24/2015	Feb. 24 From printer. May be heard in committee March 26.
02/23/2015	Feb. 23 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 611**
Current Version:	**As amended April 15, 2015**
Author:	**Dahle**
Topic:	**Controlled Substances: Prescriptions: Reporting**

Affected Sections: Amend Section 11165.1 of the Health and Safety Code (H&SC)

Status: Committee hearing scheduled for April 21, 2015, ASM Business and Professions

SUMMARY: Would authorize an individual designated to investigate a holder of a professional license to apply to the Department of Justice to obtain approval to access information contained in the CURES PDMP regarding the controlled substance history of an applicant or licensee for the purpose of investigating the alleged substance abuse of a licensee.

EXISTING LAW:
H&SC Section 11165 Establishes the Controlled Substances Utilization Review and Evaluation System (CURES);
Specifies that data obtained from CURES shall only be used for the following purposes:

1. Provided to appropriate state, locate and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice.
2. Educating practitioners and others in lieu of disciplinary, civil or criminal actions.
3. Educational, peer review, statistical, or research purposes, provided that patient information is not compromised; and

Details the reporting requirements and elements

H&SC 11165.1 Establishes the application requirements for healthcare practitioners to access the system and established a mandatory application deadline for all such practitioners to be registered to access information in the CURES system. Further this section sets for the criteria that will be used to determine if an application will be denied or suspended.

THIS BILL WOULD:
Amend H&SC Section 11165.1 to:

1. Provide that an individual designed by a board, bureau, or program within the Department of Consumer Affairs to investigate a holder of a professional license may submit an application to the DOJ to access CURES information.
2. Specify that an application for an individual designated for a program that does not regulate health care practitioners authorized to prescribe, order, administer, furnish, or

dispense Schedule II, Schedule III or Schedule IV controlled substances shall contain facts demonstrating the probable cause to believe the licensee has violated a law governing controlled substances.

3. Specifies that the application provisions would not require an individual designated by a board, bureau, or program within the DCA that regulates health care practitioners to submit an application to access the information stored within the CURES PDMP.

STAFF COMMENTS:
Board staff questions the need for this legislation, given the authority established in H&SC 11165 relating to access to the CURES system. Although the recent amendments exempt the board from the application requirement, staff remains concerned about the necessity of this measure. As the law is currently structured, H&SC 11165 establishes the CURES program and grants the board the authority to use the program for disciplinary, civil or criminal purposes, as specified. B&SC 11165.1 provides for the application requirement for practitioners to apply and use the CURES system. If, in fact, it is determined that sufficient authority does not exist for other programs within the DCA to use this system, the proposed amendments may be better placed in 11165.

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
04/15/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/14/15	Re-referred to Com. on B. & P.
04/13/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/25/15	Re-referred to Com. on B. & P.
03/24/15	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/09/15	Referred to Com. on B. & P.
02/25/15	From printer. May be heard in committee March 27.
02/24/15	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 13, 2015

AMENDED IN ASSEMBLY MARCH 24, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 611

Introduced by Assembly Member Dahle

February 24, 2015

An act to amend Section 11165.1 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 611, as amended, Dahle. Controlled substances: prescriptions: reporting.

Existing law requires certain health care practitioners and pharmacists to apply to the Department of Justice to obtain approval to access information contained in the Controlled Substance Utilization Review and Evaluation System (CURES) Prescription Drug Monitoring Program (PDMP) regarding the controlled substance history of a patient under his or her care. Existing law requires the Department of Justice, upon approval of an application, to provide the approved health care practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care. Existing law authorizes an application to be denied, or a subscriber to be suspended, for specified reasons, including, among others, a subscriber accessing information for any reason other than caring for his or her patients.

This bill would also authorize an individual designated to investigate a holder of a professional license to apply to the Department of Justice to obtain approval to access information contained in the CURES PDMP regarding the controlled substance history of an applicant or a licensee

for the purpose of investigating the alleged substance abuse of a licensee. The bill would, upon approval of an application, require the department to provide to the approved individual the history of controlled substances dispensed to the licensee. The bill would clarify that only a subscriber who is a health care practitioner or a pharmacist may have an application denied or be suspended for accessing subscriber information for any reason other than caring for his or her patients. The bill would also specify that an application may be denied, or a subscriber may be suspended, if a subscriber who has been designated to investigate the holder of a professional license accesses information for any reason other than investigating the holder of a professional 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 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before January 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before January 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled

substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(iii) An individual designated by a board, bureau, or program within the Department of Consumer Affairs to investigate a holder of a professional license may, for the purpose of investigating the alleged substance abuse of a licensee, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a licensee that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that individual the electronic history of controlled substances dispensed to the licensee based on data contained in the CURES PDMP. ~~The application~~ *An application for an individual designated by a board, bureau, or program that does not regulate health care practitioners authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150* shall contain facts demonstrating the probable cause to believe the licensee has violated a law governing controlled substances.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber described in clause (i) or (ii) of subparagraph (A) accessing information for any other reason than caring for his or her patients.

(vi) Any subscriber described in clause (iii) of subparagraph (A) accessing information for any other reason than investigating the holder of a professional license.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or

Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by an authorized subscriber from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to an authorized subscriber pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 623**
Current Version:	**As Amended March 26, 2015**
Author:	**Wood**
Topic:	**Abuse-deterrent Opioid Drugs**

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 April 21, 2015, Asm Health

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

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.
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 prescriber less than 30-day supply of an opioid analgesic as specified
    c. Define “Abuse-deterrent opioid analgesic drug product” means 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.

SUPPPORT/OPPOSITION:

Support

Patient Organizations:
American Chronic Pain Association
Power of Pain Foundation
U.S. Pain Foundation
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

None

HISTORY:

Date	Action
04/08/15	Re-referred to Com. on HEALTH.
03/26/15	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.
02/25/15	From printer. May be heard in committee March 27.
02/24/15	Read first time. To print.

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 623

Introduced by Assembly Member Wood

February 24, 2015

An act to ~~amend Section 1367.22 of~~ *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. ~~Prescription drugs.~~ *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. ~~The act prohibits specified health care service plan contracts that cover prescription drug benefits from limiting or excluding coverage for a drug for an enrollee under specified conditions, including if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee.~~

~~This bill would make technical, nonsubstantive changes to that provision. This bill would also state the intent of the Legislature to enact legislation to address the problem of prescription opioid pain reliever abuse and would make related findings and declarations.~~

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. 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: ~~no~~ *yes*. State-mandated local program: ~~no~~ *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.

(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.

~~SEC. 2. It is the intent of the Legislature to enact legislation to address the problem of prescription opioid pain reliever abuse.~~

~~SEC. 3. Section 1367.22 of the Health and Safety Code is amended to read:~~

~~1367.22. (a) A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. This section shall not preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate for the enrollee, nor shall anything in this section be construed to prohibit generic drug substitutions as authorized by Section 4073 of the Business and Professions Code. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4059 of the Business and Professions Code, to treat a medical condition of an enrollee.~~

~~(b) This section does not apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration. Coverage for different-use drugs is subject to Section 1367.21.~~

~~(c) This section shall not be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367, which includes among its requirements that plans furnish services in a manner providing continuity of care and demonstrate that medical decisions are rendered by qualified medical providers unhindered by fiscal and administrative management.~~

~~(d) This section does not prohibit a health care service plan from charging a subscriber or enrollee a copayment or a deductible for~~

~~prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.~~

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ASSEMBLY BILL No. 684

Introduced by Assembly Member Bonilla

February 25, 2015

An act to amend Section 4200.3 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 684, as introduced, Bonilla. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy within the Department of Consumer Affairs. Existing law authorizes the board to license as a pharmacist an applicant who meets specified requirements, including passage of the North American Pharmacist Licensure Examination. Existing law requires the examination process to meet specified standards and federal guidelines and requires the board to terminate use of that examination if the department determines that the examination fails to meet those standards. Existing law requires the board to report to the now obsolete Joint Committee on Boards, Commissions, and Consumer Protection and the department specified examination pass rate information.

This bill would instead require the board to report that pass rate information to the appropriate policy committees of the Legislature and the department. The bill would also make nonsubstantive changes to those provisions.

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 4200.3 of the Business and Professions Code is amended to read:

4200.3. (a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the ~~Federal~~ *federal* Uniform Guidelines ~~for~~ *on* Employee Selection Procedures. The board shall work with the Office of Professional Examination Services of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American ~~Pharmacy~~ *Pharmacist* Licensure Examination and shall use only the written and practical examination developed by the board.

(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) The board shall work with the Office of Professional Examination Services or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.

(f) *(1)* The board shall report to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *appropriate policy committees of the Legislature* and the department as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

(2) This subdivision shall become inoperative on January 1, 2020, pursuant to Section 10231.5 of the Government Code.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 750**
Current Version:	**As Amended April 6, 2015**
Author:	**Low**
Topic:	**Retired Category: Licenses**

Affected Section(s): Section 463 of the Business and Professions Code

Status: Referred to Ams Appropriations

SUMMARY:
This measure would allow boards and bureaus within the DCA to establish, by regulation, a system for a retired category of licensure for persons who are not actively engaged in the practice of profession or vocation.

EXISTING LAW:

1. Established the regulation of several licensing and regulatory programs under various boards, bureaus, commissions and programs within the Department of Consumer Affairs.
2. Section 4200.5 of the Business and Professions Code establishes the authority for the board to issue a retired pharmacist license under specified conditions, specifies that an individual with a retired license may not practice and sets forth the conditions to restore the license.

THIS BILL WOULD:
Add Section 463 to the Business and Professions Code and provide for the following

(a) Allow any board, bureau, commission or program within the department to establish, by regulation, a system for a retired category of licensure for persons not actively engaged in the practice of their profession or vocation.

(b) (1) Would specify that any regulation would need to prohibit the holder of the retired license from engaging in any activity for which a license is required unless the board specifies criteria under which certain activities may be performed.

(2) Would specify that the holder of the retired licensed shall not be required to renew the license.

(3) Would set forth the provisions to restore the licensee shall meet including the following:

- Payment of a fee
- Not have committed an act or crime constituting grounds for denial
- Comply with the fingerprint submission requirements
- Completion of CE, unless a different requirement is specified by the board
- Complete any additional requirements established by regulation

(c) Allow the board the authority to investigate actions of any licensee, including a license that is retired, inactive, cancelled, revoked or suspended.

STAFF COMMENTS:
The board currently has provisions to establish a retired pharmacist license, however it does not have similar provisions for any additional license types. Should this measure be enacted as currently drafted, the board would have the option to determine if other categories of licensure under the board's jurisdiction should be provided the option of a retired license and if so, under what conditions.

FISCAL IMPACT ON THE BOARD:
Board staff to do anticipate any major fiscal impact on measure specifically, however should the board subsequently elect to pursue additional categories of licensure with a retired status, the board could experience significant fiscal impact given the necessary programming changes that would be involved.

HISTORY:

Date	Action
04/07/2015	Apr. 7 Re-referred to Com. on B. & P. In committee: Hearing postponed by committee.
04/06/2015	Apr. 6 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/12/2015	Mar. 12 Referred to Com. on B. & P.
02/26/2015	Feb. 26 From printer. May be heard in committee March 28.
02/25/2015	Feb. 25 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 6, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 750

Introduced by Assembly Member Low

February 25, 2015

An act to ~~amend~~ *add* Section ~~462 of~~ *463 to* the Business and Professions Code, relating to business and professions.

LEGISLATIVE COUNSEL'S DIGEST

AB 750, as amended, Low. Business and professions: *retired category:* licenses.

Existing law provides for numerous boards, bureaus, commissions, or programs within the Department of Consumer ~~Affairs,~~ *Affairs* that administer the licensing and regulation of various businesses and professions. Existing law authorizes any of the boards, bureaus, commissions, or programs within the department, except as specified, to establish by regulation a system for an inactive category of license for persons who are not actively engaged in the practice of their profession or vocation. Under existing law, the holder of an inactive license is prohibited from engaging in any activity for which a license is required. *Existing law defines "board" for these purposes to include, unless expressly provided otherwise, a bureau, commission, committee, department, division, examining committee, program, and agency.*

This bill would additionally authorize any of the boards, bureaus, commissions, or programs within the ~~department, except as specified,~~ *department* to establish by regulation a system for a retired category of license for persons who are not actively engaged in the practice of their profession or vocation, and would prohibit the holder of a retired license from engaging in any activity for which a license is ~~required.~~ *required,*

unless regulation specifies the criteria for a retired licensee to practice his or her profession. The bill would authorize a board upon its own determination, and would require a board upon receipt of a complaint from any person, to investigate the actions of any licensee, including, among others, a person with a license that is retired or inactive.

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

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

1 *SECTION 1. Section 463 is added to the Business and*
2 *Professions Code, to read:*
3 *463. (a) Any of the boards, bureaus, commissions, or programs*
4 *within the department may establish, by regulation, a system for*
5 *a retired category of licensure for persons who are not actively*
6 *engaged in the practice of their profession or vocation.*
7 *(b) The regulation shall contain the following:*
8 *(1) The holder of a retired license issued pursuant to this section*
9 *shall not engage in any activity for which a license is required,*
10 *unless the board, by regulation, specifies the criteria for a retired*
11 *licensee to practice his or her profession or vocation.*
12 *(2) The holder of a retired license shall not be required to renew*
13 *that license.*
14 *(3) In order for the holder of a retired license issued pursuant*
15 *to this section to restore his or her license to an active status, the*
16 *holder of that license shall meet all the following:*
17 *(A) Pay a fee established by regulation.*
18 *(B) Not have committed an act or crime constituting grounds*
19 *for denial of licensure.*
20 *(C) Comply with the fingerprint submission requirements*
21 *established by regulation.*
22 *(D) If the board requires completion of continuing education*
23 *for renewal of an active license, complete continuing education*
24 *equivalent to that required for renewal of an active license, unless*
25 *a different requirement is specified by the board.*
26 *(E) Complete any other requirements as specified by the board*
27 *by regulation.*
28 *(c) A board may upon its own determination, and shall upon*
29 *receipt of a complaint from any person, investigate the actions of*
30 *any licensee, including a person with a license that either restricts*

or prohibits the practice of that person in his or her profession or vocation, including, but not limited to, a license that is retired, inactive, canceled, revoked, or suspended.

~~SECTION 1. Section 462 of the Business and Professions Code is amended to read:~~

~~462. (a) Any of the boards, bureaus, commissions, or programs within the department may establish, by regulation, a system for an inactive and a retired category of licensure for persons who are not actively engaged in the practice of their profession or vocation.~~

~~(b) The regulation shall contain the following provisions:~~

~~(1) The holder of an inactive or retired license issued pursuant to this section shall not engage in any activity for which a license is required.~~

~~(2) An inactive license issued pursuant to this section shall be renewed during the same time period in which an active license is renewed. The holder of an inactive license need not comply with any continuing education requirement for renewal of an active license.~~

~~(3) The renewal fee for a license in an active status shall apply also for a renewal of a license in an inactive status, unless a lesser renewal fee is specified by the board.~~

~~(4) In order for the holder of an inactive license issued pursuant to this section to restore his or her license to an active status, the holder of an inactive license shall comply with all the following:~~

~~(A) Pay the renewal fee.~~

~~(B) If the board requires completion of continuing education for renewal of an active license, complete continuing education equivalent to that required for renewal of an active license, unless a different requirement is specified by the board.~~

~~(c) This section shall not apply to any healing arts board as specified in Section 701.~~

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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**

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

Status: Committee hearing scheduled for May 5, 2015, Asm Health

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 the donated medication in advance of a prescription. Further, this measure would define "tamper-evident packaging" for purposes of a county established repository and distribution program and would require policies and procedures that address how to handle manufacturer recalls for medications that are labeled with lot numbers.

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 provide 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:

1. Amend H&SC 150201 to include a definition of "tamper-evident packaging" to mean an immediate, outer or secondary container that is sealed by an organization eligible to donate medication pursuant to this division that has a seal that must be broken in order to gain access to the containers medication.
2. Amend H&SC Section 150204
    a. To specify that the written procedures must also include ensuring manufacturer recalls are handled appropriately for medications with and without lot numbers.
    b. To remove the requirement that the lot number be required on the donated medication packaging.
    c. To allow for the transfer of donated medications from one county program to another.
    d. To allow for medications to be repackaged into new, properly labeled containers until dispensed.

STAFF COMMENTS:

Board staff has identified several concerns with the proposed expansion of this program. The most significant concerns include the repackaging of the medications in advance of the medication being dispensed as well as the removal of the lot number from a unit dose container. Drugs that are repackaged in quantities suitable for dispensing to patients of the pharmacy must be performed according to Current Good Manufacturing Practice (CGMP) and the drugs must be labeled with specified elements included the lot number.

The exemption of the lot number requirement alone would immediately create conflict with federal law and make them unlawful to dispense. Staff notes that based upon discussion with the sponsor's many of the donated unit dose medications that are donated do not include the lot number currently which is why they are seeking the amendment. Such medications are deemed misbranded under Section 502 of the Act as they deviate from the unit dose labeling requirements.

In addition to the conflict with federal law, the loss of the lot number would make it extremely difficult for the receiving pharmacy to have the necessary information to effectively manage the recall of a drug product. Absent the lot number, all drugs affected by a recall would need to be destroyed, which seems to run contrary to the overall intent of this program, which is the redistribution of medications. Although the sponsors appear to be attempting to address this concern by establishing a recall requirement, the provision is very vague and only requires policies to address the issue, not what the policies must include.

Board staff further question the need to expand the transfer provisions of the current law given that only one county is California is currently. Board staff is also concerned with the lack of specificity on the labeling requirements and questions the necessity to define tamper-evident packaging when the term is already defined in federal law.

Board staff has conveyed reservations to the sponsors related to the packaging of donated prescription drugs that either do not bear or will eliminate the use of the lot number(s) of donated drugs.

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
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 MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1069

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

February 26, 2015

An act to amend ~~Section~~ *Sections 150201 and* 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. ~~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 is eligible for donation to the program.~~ *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. 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.

~~SECTION 1.~~

SEC. 2. 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 ~~subdivision (a) of~~ 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 ~~paragraph (3) of subdivision (a) of~~ Section ~~150201~~ *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 ~~adjacent~~ 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.

(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 Introduced February 27, 2015**
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: Hearing Scheduled for April 21, 2015

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 felony conviction for a serious or violent felony.

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 within 5 years prior to the alleged commission of the charged offense.

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, <u>may</u> 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.

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.

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.

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

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
Dolores Street Community Services
Harvey Milk LGBT Democratic Club
Human Rights Watch
Justice Not Jails
Lawyers' Committee for Civil Rights of the San Francisco Bay Area
Legal Services for Prisoners with Children
Placer People of Faith Together
William C. Velasquez Institute

Opposition

None on file

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
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.

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 introduced, Eggman. Deferred entry of judgment: pretrial diversion.

(1) Existing law allows individuals convicted of specified crimes to qualify for deferred entry of judgment. A defendant qualifies if they have 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 have entry of judgment deferred, in return for 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 unsuitable for deferred entry of judgment, the defendant's guilty plea is entered and the court 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 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 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.

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 ~~prior to the alleged commission of the charged offense.~~ *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's record does not indicate that probation or parole has ever been revoked without thereafter being completed.~~

~~(5) The defendant's record does not indicate that he or she has successfully completed or been terminated from diversion or deferred entry of judgment pursuant to this chapter within five years prior to the alleged commission of the charged offense.~~

~~(6)~~

(4) The defendant has no prior ~~felony~~ 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 ~~(6),~~ *(4),* inclusive, of subdivision (a) apply to the defendant. ~~Upon the agreement of the prosecuting attorney, law enforcement, the public defender, and the presiding judge of the criminal division of the superior court, or a judge designated by the presiding judge, this procedure shall be completed as soon as possible after the initial filing of the charges.~~ 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 ~~deferred entry~~ *pretrial diversion* of judgment at the arraignment. If the defendant is found ineligible for ~~deferred entry~~

~~of judgment,~~ *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 ~~deferred entry of judgment~~ *pretrial diversion* is a postconviction appeal.

(c) All referrals for ~~deferred entry of judgment~~ *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) ~~Deferred entry of judgment~~ *Pretrial diversion* for ~~a~~ *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 ~~deferred entry of judgment.~~ *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 ~~deferred entry of judgment~~ *pretrial diversion* with respect to any

crime specified in subdivision (a) of Section 1000 that is charged, provided that the defendant ~~pleads guilty to each of these charges and waives time for the pronouncement of judgment,~~ *waive 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 ~~18~~ *six* months and no later than ~~three years~~ *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 ~~for entry of judgment and the court shall render a finding of guilt to the charge or charges pled, enter judgment,~~ *to terminate pretrial diversion* and schedule ~~a sentencing hearing~~ *further proceedings* as otherwise provided in this code.

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

(b) If the defendant consents and waives his or her right to a speedy trial or a speedy preliminary hearing, the court may refer the case to the probation department or the court may summarily grant ~~deferred entry of judgment if the defendant pleads guilty to the charge or charges and waives time for the pronouncement of judgment.~~ *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 ~~deferred entry of judgment~~ *pretrial diversion* if the defendant ~~pleads guilty to the charge or charges and waives time for the pronouncement of judgment.~~ *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.

~~No~~

(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 ~~deferred entry of judgment,~~ *pretrial diversion* shall be admissible in any action or ~~proceeding, including a sentencing hearing.~~ *proceeding.*

(d) A defendant's ~~plea of guilty~~ *participation in pretrial diversion* pursuant to this chapter shall not constitute a conviction *or an admission of guilt* for any ~~purpose unless a judgment of guilty is entered pursuant to Section 1000.3.~~ *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 ~~deferred entry of judgment.~~ *pretrial diversion.* If ~~the court does not deem the defendant a person who would be benefited by deferred entry of judgment, or if~~ the defendant does not consent to ~~participate,~~ *participate in pretrial diversion* the proceedings shall continue as in any other case.

~~At~~

(b) At the time that ~~deferred entry of judgment~~ *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.

~~The~~

(c) The period during which ~~deferred entry of judgment~~ *pretrial diversion* is granted shall be for no less than ~~18~~ *six* months nor longer than ~~three years.~~ *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 not benefiting from education, treatment, or rehabilitation,~~ or that the defendant is convicted of ~~a misdemeanor~~ *an offense* that reflects the defendant's propensity for violence, or the defendant is convicted of a felony, ~~or the defendant has engaged in criminal conduct rendering him or her unsuitable for deferred entry of judgment,~~ the prosecuting attorney, the court on its own, or the probation department may make a motion for ~~entry of judgment.~~ *termination from pretrial diversion.*

~~After~~

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

~~If~~

(c) If the court finds that the defendant is not performing satisfactorily in the assigned program, ~~or that the defendant is not benefiting from education, treatment, or rehabilitation,~~ or the court finds that the defendant has been convicted of a crime as indicated ~~above, or that the defendant has engaged in criminal conduct rendering him or her unsuitable for deferred entry of judgment,~~ *in subdivision (b)* the court shall ~~render a finding of guilt to the charge or charges pled, enter judgment,~~ *reinstate the criminal charge or charges* and schedule ~~a sentencing hearing~~ *the matter for further proceedings* as otherwise provided in this code.

~~If~~

(d) If the defendant has ~~performed satisfactorily during the period in which deferred entry of judgment was granted,~~ *completed pretrial diversion,* at the end of that period, the criminal charge or charges shall be dismissed.

~~Prior~~

(e) Prior to dismissing the charge or charges or ~~rendering a finding of guilt and entering judgment,~~ *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 ~~deferred~~ *referred to pretrial diversion* pursuant to this chapter. Upon successful completion of a ~~deferred entry of judgment~~ *pretrial diversion* program, the arrest upon which the ~~judgment was deferred~~ *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 ~~deferred entry of judgment~~ *pretrial diversion* for the offense, except as specified in subdivision (b). A record pertaining to an arrest resulting in successful completion of a ~~deferred entry of judgment~~ *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 ~~deferred entry of judgment~~ *pretrial diversion* program, the arrest upon which ~~the judgment was deferred~~ *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 ~~deferred entry of judgment~~ *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 ~~deferred entry of judgment~~ *pretrial diversion* program or a preguilty plea program pursuant to this chapter, the person ~~may also participate in a licensed methadone~~ *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) ~~program~~ *to treat substance use disorders* if the ~~following conditions are met:~~

~~(1) The sheriff allows a methadone program to operate in the county jail.~~

~~(2) The~~ participant allows release of his or her medical records to the court presiding over the participant's preguilty *plea* or ~~deferred entry~~ *pretrial diversion* program for the limited purpose

of determining whether or not the participant is ~~duly enrolled in the licensed methadone or LAAM program~~ *using such medications under the direction of a licensed health care practitioner* and is in compliance with ~~deferred entry~~ *the pretrial diversion* or preguilty plea program rules.

(b) If the conditions specified in ~~paragraphs (1) and (2) of~~ subdivision (a) are met, ~~participation in a methadone or LAAM treatment program~~ *using medications to treat substance use disorders* shall not be the sole reason for exclusion from a ~~deferred entry~~ *pretrial diversion* or preguilty plea program. A ~~methadone or LAAM~~ patient who *uses medications to treat substance use disorders and* participates in a preguilty *plea* or ~~deferred entry~~ *pretrial diversion* program shall comply with all court program rules.

(c) A person who is participating in a ~~deferred entry of judgment~~ *pretrial diversion* program or preguilty plea program pursuant to this chapter who ~~participates in a licensed methadone or LAAM program~~ *uses medications to treat substance use disorders* shall present to the court a declaration from ~~the director of the methadone or LAAM program, or the director's~~ *their health care practitioner, or their health care practitioner's* authorized representative, that the person is currently ~~enrolled and in good standing in the program.~~ *under their care.*

(d) Urinalysis results that only establish that a person described in this section has ingested ~~or taken the methadone administered or prescribed by a licensed methadone or LAAM program~~ *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 ~~deferred entry of judgment~~ *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 ~~deferred entry and~~ diversion programs.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 1352**
Current Version:	**As Introduced February 27, 2015**
Author:	**Eggman**
Topic:	**Deferred Entry of Judgment: withdrawal of plea**

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

Status: Hearing scheduled for April 21, 2015, Asm 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 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.

STAFF COMMENTS:
The additions proposed to the Penal code would negatively 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, primarily in enforcement related costs.

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
None on file

RELATED LEGISLATION:
AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
This measure would change the deferred entry of judgment program into a pretrial diversion program.

HISTORY:

Date	Action
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.

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 introduced, 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 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 inadmissable, deportable, or subject to any other kind of adverse immigration consequence.

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 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 if the defendant shows 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.

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AMENDED IN SENATE APRIL 14, 2015

SENATE BILL No. 396

Introduced by Senator Hill

February 25, 2015

An act to amend Sections 805 and 805.5 of, and to add Section 2216.5 to, the Business and Professions Code, *to amend Section 12529.7 of the Government Code,* and to amend Sections 1204, 1248.15, 1248.3, and 1248.35 of the Health and Safety Code, relating to health ~~and care facilities.~~ *care.*

LEGISLATIVE COUNSEL'S DIGEST

SB 396, as amended, Hill. Health ~~and care facilities:~~ *care:* outpatient settings and surgical ~~clinics.~~ *clinics: facilities: licensure and enforcement.*

Existing law provides for the licensure and regulation of clinics by the State Department of Public Health. A violation of those provisions is a misdemeanor. Existing law provides that certain types of specialty clinics, including surgical clinics, as defined, are eligible for licensure. *Existing law excludes from the definition of surgical clinic any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice. Existing law requires a surgical clinic that is licensed or seeking licensure to comply with federal certification standards for an ambulatory surgical clinic until the department adopts regulations relating to the provision of services by a surgical clinic.*

This bill would ~~clarify~~ *provide* that a surgical clinic *that has met the federal certification standards and requirements for an ambulatory surgical clinic* is eligible for licensure by the department regardless of physician, *podiatrist,* or dentist ownership. *The bill would provide that*

a surgical clinic is deemed to have met the licensure requirements under the chapter upon presenting documentation, within a 3-year period, that the surgical clinic has met the federal certification requirements for an ambulatory surgical clinic.

The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Existing law provides that it is unprofessional conduct for a physician and surgeon to perform procedures in any outpatient setting except in compliance with specified provisions. Existing law prohibits an association, corporation, firm, partnership, or person from operating, managing, conducting, or maintaining an outpatient setting in the state unless the setting is one of the specified settings, which includes, among others, *an ambulatory surgical clinic that is certified to participate in the Medicare program,* a surgical clinic licensed by the State Department of Public ~~Health~~ *Health,* or an outpatient setting accredited by an accreditation agency approved by the Division of Licensing of the Medical Board of California.

Existing law provides that an outpatient setting that is accredited shall be inspected by the accreditation agency and may be inspected by the Medical Board of California. Existing law requires that the inspections be conducted no less often than once every 3 years by the accreditation agency and as often as necessary by the Medical Board of California to ensure quality of care provided. Existing law requires that certificates for accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than 3 years.

This bill would require that all subsequent inspections after the initial inspection for accreditation be unannounced. This bill would require an outpatient setting accredited by the division *and a facility certified to participate in the federal Medicare program as an ambulatory surgical center* to pay certain fees and to comply with certain data submission requirements. The bill would also instead require that an initial certificate of accreditation by an accreditation agency be valid for not more than 2 years and that a renewal certificate be valid for not more than 3 years.

Existing law requires members of the medical staff and other practitioners who are granted clinical privileges in an outpatient setting to be professionally qualified and appropriately credentialed for the performance of privileges granted and requires the outpatient setting to grant privileges in accordance with recommendations from qualified

health professionals, and credentialing standards established by the outpatient setting.

This bill would additionally require that each ~~physician and surgeon~~ *licensee* who performs procedures in an outpatient setting that requires the outpatient setting to be accredited be peer reviewed*, at least every 2 years,* by ~~California licensed physicians~~ *licensees* who are qualified by education *and* experience to perform the same types of*, or similar* procedures. *The bill would require the findings of the peer review to be reported to the accrediting body who shall determine if the licensee continues to be professionally qualified and appropriately credentialed for the performance of privileges granted.* By expanding the scope of a crime, this bill would impose a state-mandated local program.

Existing law requires specified entities, including any health care service plan or medical care foundation, to request a report from the Medical Board of California, the Board of Psychology, the Osteopathic Medical Board of California, or the Dental Board of California, prior to granting or renewing staff privileges, to determine if a certain report has been made indicating that the applying physician and surgeon, psychologist, podiatrist, or dentist has been denied staff privileges, been removed from a medical staff, or had his or her staff privileges restricted.

This bill would also require an outpatient setting and a facility certified to participate in the federal Medicare program as an ambulatory surgical center to request that report. By expanding the scope of a crime, this bill would impose a state-mandated local program.

Existing law establishes a vertical enforcement and prosecution model for cases before the Medical Board of California, and requires the board to report to the Governor and the Legislature on that model by March 1, 2015.

This bill would extend the date that report is due to March 1, 2016.

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

805. (a) As used in this section, the following terms have the following definitions:

(1) (A) "Peer review" means both of the following:

(i) A process in which a peer review body reviews the basic qualifications, staff privileges, employment, medical outcomes, or professional conduct of licentiates to make recommendations for quality improvement and education, if necessary, in order to do either or both of the following:

(I) Determine whether a licentiate may practice or continue to practice in a health care facility, clinic, or other setting providing medical services, and, if so, to determine the parameters of that practice.

(II) Assess and improve the quality of care rendered in a health care facility, clinic, or other setting providing medical services.

(ii) Any other activities of a peer review body as specified in subparagraph (B).

(B) "Peer review body" includes:

(i) A medical or professional staff of any health care ~~facility or~~ *facility, of a* clinic licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, of a facility certified to participate in the federal Medicare program as an ambulatory surgical center, or of an outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code.

(ii) A health care service plan licensed under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer that contracts with licentiates to provide services at alternative rates of payment pursuant to Section 10133 of the Insurance Code.

(iii) Any medical, psychological, marriage and family therapy, social work, professional clinical counselor, dental, or podiatric professional society having as members at least 25 percent of the eligible licentiates in the area in which it functions (which must include at least one county), which is not organized for profit and which has been determined to be exempt from taxes pursuant to Section 23701 of the Revenue and Taxation Code.

(iv) A committee organized by any entity consisting of or employing more than 25 licentiates of the same class that functions for the purpose of reviewing the quality of professional care provided by members or employees of that entity.

(2) "Licentiate" means a physician and surgeon, doctor of podiatric medicine, clinical psychologist, marriage and family therapist, clinical social worker, professional clinical counselor, dentist, or physician assistant. "Licentiate" also includes a person authorized to practice medicine pursuant to Section 2113 or 2168.

(3) "Agency" means the relevant state licensing agency having regulatory jurisdiction over the licentiates listed in paragraph (2).

(4) "Staff privileges" means any arrangement under which a licentiate is allowed to practice in or provide care for patients in a health facility. Those arrangements shall include, but are not limited to, full staff privileges, active staff privileges, limited staff privileges, auxiliary staff privileges, provisional staff privileges, temporary staff privileges, courtesy staff privileges, locum tenens arrangements, and contractual arrangements to provide professional services, including, but not limited to, arrangements to provide outpatient services.

(5) "Denial or termination of staff privileges, membership, or employment" includes failure or refusal to renew a contract or to renew, extend, or reestablish any staff privileges, if the action is based on medical disciplinary cause or reason.

(6) "Medical disciplinary cause or reason" means that aspect of a licentiate's competence or professional conduct that is reasonably likely to be detrimental to patient safety or to the delivery of patient care.

(7) "805 report" means the written report required under subdivision (b).

(b) The chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed health care facility or clinic shall file an 805 report with the relevant agency within 15 days after the effective date on which any of the following occur as a result of an action of a peer review body:

(1) A licentiate's application for staff privileges or membership is denied or rejected for a medical disciplinary cause or reason.

(2) A licentiate's membership, staff privileges, or employment is terminated or revoked for a medical disciplinary cause or reason.

(3) Restrictions are imposed, or voluntarily accepted, on staff privileges, membership, or employment for a cumulative total of 30 days or more for any 12-month period, for a medical disciplinary cause or reason.

(c) If a licentiate takes any action listed in paragraph (1), (2), or (3) after receiving notice of a pending investigation initiated for a medical disciplinary cause or reason or after receiving notice that his or her application for membership or staff privileges is denied or will be denied for a medical disciplinary cause or reason, the chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed health care facility or clinic where the licentiate is employed or has staff privileges or membership or where the licentiate applied for staff privileges or membership, or sought the renewal thereof, shall file an 805 report with the relevant agency within 15 days after the licentiate takes the action.

(1) Resigns or takes a leave of absence from membership, staff privileges, or employment.

(2) Withdraws or abandons his or her application for staff privileges or membership.

(3) Withdraws or abandons his or her request for renewal of staff privileges or membership.

(d) For purposes of filing an 805 report, the signature of at least one of the individuals indicated in subdivision (b) or (c) on the completed form shall constitute compliance with the requirement to file the report.

(e) An 805 report shall also be filed within 15 days following the imposition of summary suspension of staff privileges, membership, or employment, if the summary suspension remains in effect for a period in excess of 14 days.

(f) A copy of the 805 report, and a notice advising the licentiate of his or her right to submit additional statements or other information, electronically or otherwise, pursuant to Section 800, shall be sent by the peer review body to the licentiate named in the report. The notice shall also advise the licentiate that information submitted electronically will be publicly disclosed to those who request the information.

The information to be reported in an 805 report shall include the name and license number of the licentiate involved, a description of the facts and circumstances of the medical disciplinary cause or reason, and any other relevant information deemed appropriate by the reporter.

A supplemental report shall also be made within 30 days following the date the licentiate is deemed to have satisfied any terms, conditions, or sanctions imposed as disciplinary action by the reporting peer review body. In performing its dissemination functions required by Section 805.5, the agency shall include a copy of a supplemental report, if any, whenever it furnishes a copy of the original 805 report.

If another peer review body is required to file an 805 report, a health care service plan is not required to file a separate report with respect to action attributable to the same medical disciplinary cause or reason. If the Medical Board of California or a licensing agency of another state revokes or suspends, without a stay, the license of a physician and surgeon, a peer review body is not required to file an 805 report when it takes an action as a result of the revocation or suspension.

(g) The reporting required by this section shall not act as a waiver of confidentiality of medical records and committee reports. The information reported or disclosed shall be kept confidential except as provided in subdivision (c) of Section 800 and Sections 803.1 and 2027, provided that a copy of the report containing the information required by this section may be disclosed as required by Section 805.5 with respect to reports received on or after January 1, 1976.

(h) The Medical Board of California, the Osteopathic Medical Board of California, and the Dental Board of California shall disclose reports as required by Section 805.5.

(i) An 805 report shall be maintained electronically by an agency for dissemination purposes for a period of three years after receipt.

(j) No person shall incur any civil or criminal liability as the result of making any report required by this section.

(k) A willful failure to file an 805 report by any person who is designated or otherwise required by law to file an 805 report is punishable by a fine not to exceed one hundred thousand dollars ($100,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any

agency having regulatory jurisdiction over the person regarding whom the report was or should have been filed. If the person who is designated or otherwise required to file an 805 report is a licensed physician and surgeon, the action or proceeding shall be brought by the Medical Board of California. The fine shall be paid to that agency but not expended until appropriated by the Legislature. A violation of this subdivision may constitute unprofessional conduct by the licentiate. A person who is alleged to have violated this subdivision may assert any defense available at law. As used in this subdivision, "willful" means a voluntary and intentional violation of a known legal duty.

(*l*) Except as otherwise provided in subdivision (k), any failure by the administrator of any peer review body, the chief executive officer or administrator of any health care facility, or any person who is designated or otherwise required by law to file an 805 report, shall be punishable by a fine that under no circumstances shall exceed fifty thousand dollars ($50,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any agency having regulatory jurisdiction over the person regarding whom the report was or should have been filed. If the person who is designated or otherwise required to file an 805 report is a licensed physician and surgeon, the action or proceeding shall be brought by the Medical Board of California. The fine shall be paid to that agency but not expended until appropriated by the Legislature. The amount of the fine imposed, not exceeding fifty thousand dollars ($50,000) per violation, shall be proportional to the severity of the failure to report and shall differ based upon written findings, including whether the failure to file caused harm to a patient or created a risk to patient safety; whether the administrator of any peer review body, the chief executive officer or administrator of any health care facility, or any person who is designated or otherwise required by law to file an 805 report exercised due diligence despite the failure to file or whether they knew or should have known that an 805 report would not be filed; and whether there has been a prior failure to file an 805 report. The amount of the fine imposed may also differ based on whether a health care facility is a small or rural hospital as defined in Section 124840 of the Health and Safety Code.

(m) A health care service plan licensed under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer that negotiates and enters into a contract with licentiates to provide services at alternative rates of payment pursuant to Section 10133 of the Insurance Code, when determining participation with the plan or insurer, shall evaluate, on a case-by-case basis, licentiates who are the subject of an 805 report, and not automatically exclude or deselect these licentiates.

SEC. 2. Section 805.5 of the Business and Professions Code is amended to read:

805.5. (a) Prior to granting or renewing staff privileges for any physician and surgeon, psychologist, podiatrist, or dentist, any health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, any health care service plan or medical care foundation, the medical staff of the institution, a facility certified to participate in the federal Medicare program as an ambulatory surgical center, or an outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code shall request a report from the Medical Board of California, the Board of Psychology, the Osteopathic Medical Board of California, or the Dental Board of California to determine if any report has been made pursuant to Section 805 indicating that the applying physician and surgeon, psychologist, podiatrist, or dentist has been denied staff privileges, been removed from a medical staff, or had his or her staff privileges restricted as provided in Section 805. The request shall include the name and California license number of the physician and surgeon, psychologist, podiatrist, or dentist. Furnishing of a copy of the 805 report shall not cause the 805 report to be a public record.

(b) Upon a request made by, or on behalf of, an institution described in subdivision (a) or its medical staff the board shall furnish a copy of any report made pursuant to Section 805 as well as any additional exculpatory or explanatory information submitted electronically to the board by the licensee pursuant to subdivision (f) of that section. However, the board shall not send a copy of a report (1) if the denial, removal, or restriction was imposed solely because of the failure to complete medical records, (2) if the board has found the information reported is without merit, (3) if a court finds, in a final judgment, that the peer review, as defined in Section 805, resulting in the report was conducted in bad faith and

the licensee who is the subject of the report notifies the board of that finding, or (4) if a period of three years has elapsed since the report was submitted. This three-year period shall be tolled during any period the licentiate has obtained a judicial order precluding disclosure of the report, unless the board is finally and permanently precluded by judicial order from disclosing the report. If a request is received by the board while the board is subject to a judicial order limiting or precluding disclosure, the board shall provide a disclosure to any qualified requesting party as soon as practicable after the judicial order is no longer in force.

If the board fails to advise the institution within 30 working days following its request for a report required by this section, the institution may grant or renew staff privileges for the physician and surgeon, psychologist, podiatrist, or dentist.

(c) Any institution described in subdivision (a) or its medical staff that violates subdivision (a) is guilty of a misdemeanor and shall be punished by a fine of not less than two hundred dollars ($200) nor more than one thousand two hundred dollars ($1,200).

SEC. 3. Section 2216.5 is added to the Business and Professions Code, to read:

2216.5. An outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code ~~is~~ *and a facility certified to participate in the federal Medicare program as an ambulatory surgical center are* subject to the requirements of Section ~~1216,~~ *1216 of,* subdivision (f) of Section ~~127280,~~ *127280 of, Section 127285 of,* and Section 128737 ~~of~~ *of,* the Health and Safety Code. *Any fees collected pursuant to subdivision (f) of Section 127280 of the Health and Safety Code shall not exceed the reasonable costs incurred by the Office of Statewide Health Planning and Development in regulating the outpatient setting and the facility.*

SEC. 4. Section 12529.7 of the Government Code is amended to read:

12529.7. By March 1, ~~2015,~~ *2016,* the Medical Board of California, in consultation with the Department of Justice and the Department of Consumer Affairs, shall report and make recommendations to the Governor and the Legislature on the vertical enforcement and prosecution model created under Section 12529.6.

~~SEC. 4.~~

SEC. 5. Section 1204 of the Health and Safety Code is amended to read:

1204. Clinics eligible for licensure pursuant to this chapter are primary care clinics and specialty clinics.

(a) (1) Only the following defined classes of primary care clinics shall be eligible for licensure:

(A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.

(B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.

(2) Nothing in this subdivision shall prohibit a community clinic or a free clinic from providing services to patients whose services are reimbursed by third-party payers, or from entering

into managed care contracts for services provided to private or public health plan subscribers, as long as the clinic meets the requirements identified in subparagraphs (A) and (B). For purposes of this subdivision, any payments made to a community clinic by a third-party payer, including, but not limited to, a health care service plan, shall not constitute a charge to the patient. This paragraph is a clarification of existing law.

(b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter:

(1) (A) A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians, *podiatrists,* or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment.

(B) A physician, *podiatrist,* or dentist may, at his or her option, apply for licensure. A surgical clinic shall be eligible for licensure by the department regardless of physician, *podiatrist,* or dentist ownership. *A surgical clinic that has met the federal certification standards and requirements for an ambulatory surgical clinic, as specified in Part 416 of Title 42 of the Code of Federal Regulations, shall be eligible for licensure by the department pursuant to this chapter.*

(C) Until the department adopts regulations relating to the provision of services by a surgical clinic pursuant to Section 1225, a surgical clinic is deemed to have met the licensure requirements under this chapter upon presenting documentation, within a three-year period, that the surgical clinic has met the federal certification standards for an ambulatory surgical clinic.

(2) A "chronic dialysis clinic" means a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services.

(3) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation

clinic does not include the offices of a private physician in individual or group practice.

(4) An "alternative birth center" means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility.

~~SEC. 5.~~

SEC. 6. Section 1248.15 of the Health and Safety Code is amended to read:

1248.15. (a) The board shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:

(1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.

(2) (A) Outpatient settings shall have a system for facility safety and emergency training requirements.

(B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.

(C) In order for procedures to be performed in an outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:

(i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.

(ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.

(iii) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.

(D) The outpatient setting shall submit for approval by an accreditation agency at the time of accreditation a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations. The plan shall include, at a minimum, that if a patient is being transferred to a local accredited or licensed acute care hospital, the outpatient setting shall do all of the following:

(i) Notify the individual designated by the patient to be notified in case of an emergency.

(ii) Ensure that the mode of transfer is consistent with the patient's medical condition.

(iii) Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.

(iv) Continue to provide appropriate care to the patient until the transfer is effectuated.

(E) All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body or in accordance with existing law.

(3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code.

(4) Outpatient settings shall have a system for maintaining clinical records.

(5) Outpatient settings shall have a system for patient care and monitoring procedures.

(6) (A) Outpatient settings shall have a system for quality assessment and improvement.

(B) (i) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.

(ii) Each ~~physician and surgeon~~ *licensee* who performs procedures in an outpatient setting that requires the outpatient setting to be accredited shall be, *at least every two years*, peer reviewed, as described in *subparagraph (A) of paragraph (1) of subdivision (a) of* Section 805 of the Business and Professions Code, including when the outpatient setting has only ~~one physician and surgeon.~~ *one licensee.* The peer review shall be performed by ~~California licensed physicians~~ *licensees* who are qualified by education *and* experience to perform the same types of, *or similar* procedures. *The findings of the peer review shall be reported to the accrediting body who shall determine if the licensee continues to meet the requirements described in clause (i).*

(C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.

(7) Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.

(8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.

(9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.

(10) Outpatient settings shall have a written discharge criteria.

(b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who

does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.

(c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.

(d) No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency approved by the board, shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.

(e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.

(f) The board may adopt regulations it deems necessary to specify procedures that should be performed in an accredited outpatient setting for facilities or clinics that are outside the definition of outpatient setting as specified in Section 1248.

(g) As part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, "conducting a reasonable investigation" means querying the Medical Board of California and the Osteopathic Medical Board of California to ascertain if either the outpatient setting has, or, if its owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision.

~~SEC. 6.~~

SEC. 7. Section 1248.3 of the Health and Safety Code is amended to read:

1248.3. (a) An initial certificate of accreditation issued to an outpatient setting by an accreditation agency shall be valid for not

more than two years, and a renewal certificate shall be valid for not more than three years.

(b) The outpatient setting shall notify the accreditation agency within 30 days of any significant change in ownership, including, but not limited to, a merger, change in majority interest, consolidation, name change, change in scope of services, additional services, or change in locations.

(c) Except for disclosures to the division or to the Division of Medical Quality under this chapter, an accreditation agency shall not disclose information obtained in the performance of accreditation activities under this chapter that individually identifies patients, individual medical practitioners, or outpatient settings. Neither the proceedings nor the records of an accreditation agency or the proceedings and records of an outpatient setting related to performance of quality assurance or accreditation activities under this chapter shall be subject to discovery, nor shall the records or proceedings be admissible in a court of law. The prohibition relating to discovery and admissibility of records and proceedings does not apply to any outpatient setting requesting accreditation in the event that denial or revocation of that outpatient setting's accreditation is being contested. Nothing in this section shall prohibit the accreditation agency from making discretionary disclosures of information to an outpatient setting pertaining to the accreditation of that outpatient setting.

~~SEC. 7.~~

SEC. 8. Section 1248.35 of the Health and Safety Code is amended to read:

1248.35. (a) Every outpatient setting that is accredited shall be inspected by the accreditation agency and may also be inspected by the Medical Board of California. The Medical Board of California shall ensure that accreditation agencies inspect outpatient settings.

(b) Unless otherwise specified, the following requirements apply to inspections described in subdivision (a).

(1) The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.

(2) Inspections shall be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board of California to ensure the quality of care

provided. After the initial inspection for accreditation, all subsequent inspections shall be unannounced.

(3) The Medical Board of California or the accreditation agency may enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of this chapter.

(c) If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance with the standards under which it was approved, the accreditation agency may do any of the following:

(1) Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the outpatient setting's accreditation.

(2) Issue a reprimand.

(3) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the board or the accreditation agency, to correct the deficiencies.

(4) Suspend or revoke the outpatient setting's certification of accreditation.

(d) (1) Except as is otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the accreditation agency shall provide the outpatient setting with notice of any deficiencies and the outpatient setting shall agree with the accreditation agency on a plan of correction that shall give the outpatient setting reasonable time to supply information demonstrating compliance with the standards of the accreditation agency in compliance with this chapter, as well as the opportunity for a hearing on the matter upon the request of the outpatient setting. During the allotted time to correct the deficiencies, the plan of correction, which includes the deficiencies, shall be conspicuously posted by the outpatient setting in a location accessible to public view. Within 10 days after the adoption of the plan of correction, the accrediting agency shall send a list of deficiencies and the corrective action to be taken to the board and to the California State Board of Pharmacy if an outpatient setting is licensed pursuant to Article 14 (commencing with Section 4190)

of Chapter 9 of Division 2 of the Business and Professions Code. The accreditation agency may immediately suspend the certificate of accreditation before providing notice and an opportunity to be heard, but only when failure to take the action may result in imminent danger to the health of an individual. In such cases, the accreditation agency shall provide subsequent notice and an opportunity to be heard.

(2) If an outpatient setting does not comply with a corrective action within a timeframe specified by the accrediting agency, the accrediting agency shall issue a reprimand, and may either place the outpatient setting on probation or suspend or revoke the accreditation of the outpatient setting, and shall notify the board of its action. This section shall not be deemed to prohibit an outpatient setting that is unable to correct the deficiencies, as specified in the plan of correction, for reasons beyond its control, from voluntarily surrendering its accreditation prior to initiation of any suspension or revocation proceeding.

(e) The accreditation agency shall, within 24 hours, report to the board if the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation. If an outpatient setting has been issued a license by the California State Board of Pharmacy pursuant to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code, the accreditation agency shall also send this report to the California State Board of Pharmacy within 24 hours.

(f) The accreditation agency, upon receipt of a complaint from the board that an outpatient setting poses an immediate risk to public safety, shall inspect the outpatient setting and report its findings of inspection to the board within five business days. If an accreditation agency receives any other complaint from the board, it shall investigate the outpatient setting and report its findings of investigation to the board within 30 days.

(g) Reports on the results of any inspection shall be kept on file with the board and the accreditation agency along with the plan of correction and the comments of the outpatient setting. The inspection report may include a recommendation for reinspection. All final inspection reports, which include the lists of deficiencies, plans of correction or requirements for improvements and

correction, and corrective action completed, shall be public records open to public inspection.

(h) If one accrediting agency denies accreditation, or revokes or suspends the accreditation of an outpatient setting, this action shall apply to all other accrediting agencies. An outpatient setting that is denied accreditation is permitted to reapply for accreditation with the same accrediting agency. The outpatient setting also may apply for accreditation from another accrediting agency, but only if it discloses the full accreditation report of the accrediting agency that denied accreditation. Any outpatient setting that has been denied accreditation shall disclose the accreditation report to any other accrediting agency to which it submits an application. The new accrediting agency shall ensure that all deficiencies have been corrected and conduct a new onsite inspection consistent with the standards specified in this chapter.

(i) If an outpatient setting's certification of accreditation has been suspended or revoked, or if the accreditation has been denied, the accreditation agency shall do all of the following:

(1) Notify the board of the action.

(2) Send a notification letter to the outpatient setting of the action. The notification letter shall state that the setting is no longer allowed to perform procedures that require outpatient setting accreditation.

(3) Require the outpatient setting to remove its accreditation certification and to post the notification letter in a conspicuous location, accessible to public view.

(j) The board may take any appropriate action it deems necessary pursuant to Section 1248.7 if an outpatient setting's certification of accreditation has been suspended or revoked, or if accreditation has been denied.

~~SEC. 8.~~

SEC. 9. 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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SENATE BILL No. 423

Introduced by Senator Bates

February 25, 2015

An act to amend Section 117690 of the Health and Safety Code, relating to medical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 423, as introduced, Bates. Pharmaceutical waste: over-the-counter drugs and nutritional supplements.

The existing law, the Medical Waste Management Act, administered by the State Department of Public Health, regulates the management, handling, and disposal of medical waste, as defined, including pharmaceutical waste. For purposes of that act, "pharmaceutical waste" is defined as a prescription or over-the counter human or veterinary drug, as specified, that is waste, as defined, but excludes from that definition certain pharmaceuticals being sent out of state to a reverse distributor, or being sent by a reverse distributor offsite for treatment and disposal, as prescribed.

This bill would additionally exclude from the definition of "pharmaceutical waste," for purposes of regulation under the act, any over-the-counter human or veterinary drug or dietary supplement that is, among other things, characterized and managed as a hazardous or solid waste and, with respect to an over-the-counter human or veterinary drug, is not disposed of on land within the state.

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 117690 of the Health and Safety Code is amended to read:

117690. (a) "Medical waste" means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes. Biohazardous, pathology, pharmaceutical, sharps, and trace chemotherapy wastes that meet the conditions of this section are not subject to any of the hazardous waste requirements found in Chapter 6.5 (commencing with Section 25100) of Division 20.

(b) For purposes of this part the following definitions apply:

(1) "Biohazardous waste" includes all of the following:

(A) (i) Regulated medical waste, clinical waste, or biomedical waste that is a waste or reusable material derived from the medical treatment of a human or from an animal that is suspected by the attending veterinarian of being infected with a pathogen that is also infectious to humans, which includes diagnosis and immunization; or from biomedical research, which includes the production and testing of biological products.

(ii) Regulated medical waste or clinical waste or biomedical waste suspected of containing a highly communicable disease.

(B) Laboratory waste such as human specimen cultures or animal specimen cultures that are infected with pathogens that are also infectious to humans; cultures and stocks of infectious agents from research; wastes from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including Brucellosis

and Contagious Ecthyma, as defined by the department; culture dishes, devices used to transfer, inoculate, and mix cultures; and wastes identified by Section 173.134 of Title 49 of the Code of Federal Regulations as Category B "once wasted" for laboratory wastes.

(C) Waste that, at the point of transport from the generator's site or at the point of disposal contains recognizable fluid human blood, fluid human blood products, containers, or equipment containing human blood that is fluid, or blood from animals suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.

(D) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans or animals that are required to be isolated by the infection control staff, the attending physician and surgeon, the attending veterinarian, or the local health officer, to protect others from highly communicable diseases or diseases of animals that are communicable to humans.

(2) Pathology waste includes both of the following:

(A) Human body parts, with the exception of teeth, removed at surgery and surgery specimens or tissues removed at surgery or autopsy that are suspected by the health care professional of being contaminated with infectious agents known to be contagious to humans or having been fixed in formaldehyde or another fixative.

(B) Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.

(3) "Pharmaceutical waste" means a pharmaceutical, as defined in Section 117747, including trace chemotherapy waste, that is a waste, as defined in Section 25124. For purposes of this part, "pharmaceutical waste" does not include a pharmaceutical that meets ~~either~~ *any* of the following criteria:

(A) The pharmaceutical is being sent out of the state to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4161 of the Business and Professions Code.

(B) The pharmaceutical is being sent by a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, offsite for treatment and disposal in accordance with applicable laws, or to a reverse distributor that is licensed as a wholesaler of

dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station if the reverse distributor is located within the state.

(C) The pharmaceutical is an over-the-counter human or veterinary drug or dietary supplement that meets all of the following requirements:

(i) Is offered for sale without a prescription.

(ii) Is labeled with information entitled "Drug Facts" or "Supplement Facts," in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, (21 U.S.C.A. Sec. 321 et seq.).

(iii) Is characterized and managed as either a hazardous waste pursuant to Chapter 6.5 (commencing with Section 25100) of Division 20, or a solid waste pursuant to Division 30 (commencing with Section 40000) of the Public Resources Code.

(iv) With respect to an over-the-counter human or veterinary drug, is not disposed of on land within the state.

(4) "Sharps waste" means a device that has acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, acupuncture needles, root canal files, broken glass items used in health care such as Pasteur pipettes and blood vials contaminated with biohazardous waste, and any item capable of cutting or piercing from trauma scene waste.

(5) "Trace chemotherapeutic waste" means waste that is contaminated through contact with, or having previously contained, chemotherapeutic agents, including, but not limited to, gloves, disposable gowns, towels, and intravenous solution bags and attached tubing that are empty. A biohazardous waste that meets the conditions of this paragraph is not subject to the hazardous waste requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.

(6) "Trauma scene waste" means waste that is a regulated waste, as defined in Section 5193 of Title 8 of the California Code of Regulations, and that has been removed, is to be removed, or is in

the process of being removed, from a trauma scene by a trauma scene waste management practitioner.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 587**
Current Version:	**As Amended April 9, 2015**
Author:	**Stone**
Topic:	**Pharmacy: Drug Regimens: Hypertension and Hyperlipidemia**

Affected Sections: Amend Business and Professions Code (B&PC) Section 4052.2

Status: Committee hearing has not been set.

SUMMARY: Would specify that a pharmacist may initiate or adjust the drug regimen of a patient undergoing treatment of hypertension or hyperlipidemia as authorized.

EXISTING LAW:

B&PC 4052.2 establishes the authority for a pharmacist to perform specified procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic with physician oversight as specified including the following:

- Ordering or performing routine drug therapy-related patient assessment procedures, as specified
- Ordering drug therapy-related laboratory tests
- Administering drugs and biological by injection pursuant to a prescriber's order
- Initiating or adjusting the drug regimen of a patient pursuant to a specific written order of authorization, as specified.

THIS BILL WOULD:

Amend B&PC Section 4052.2 (a)(4) to specifically include the treatment of hypertension and hyperlipidemia in the provisions that authorize a pharmacist to initiate or adjust the drug regimen of a patient.

STAFF COMMENTS:

Board staff has requested the fact sheet for this measure and will provide it during the meeting, if available.

FISCAL IMPACT ON THE BOARD:

Board staff to do anticipate any major fiscal impact on measure. Any minor impact could be absorbed within existing resources.

HISTORY:

Date	Action
04/09/15	From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS.
03/12/15	Referred to Com. on RLS.
02/27/15	From printer. May be acted upon on or after March 29.
02/26/15	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 9, 2015

SENATE BILL No. 587

Introduced by Senator Stone

February 26, 2015

An act to amend Section ~~4127.1~~ *4052.2* of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 587, as amended, Stone. Pharmacy: ~~compounding.~~ *drug regimens: hypertension and hyperlipidemia.*

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.~~ *That law authorizes a pharmacist to perform listed procedures or functions as part of the care provided by specified health care entities, including initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care entity.*

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

This bill would specifically include the treatment of hypertension and hyperlipidemia in the authorized initiation or adjustment of a patient's drug regimen.

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 4052.2 of the Business and Professions Code is amended to read:

4052.2. (a) Notwithstanding any other ~~provision of~~ law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours. *This function may include, but is not limited to, treatment of hypertension and hyperlipidemia.*

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, ~~and shall,~~ *and*, at a minimum, *shall* do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

~~SECTION 1. Section 4127.1 of the Business and Professions Code, as added by Section 5 of Chapter 565 of the Statutes of 2013, is amended to read:~~

~~4127.1. (a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable.~~

~~(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.~~

~~(c) A license to compound sterile drug products 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) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:~~

~~(1) Reviews a current copy of the pharmacy's procedures and policies for sterile compounding.~~

~~(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.~~

~~(3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.~~

~~(4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.~~

~~(e) A pharmacy licensed pursuant to this section shall do all of the following:~~

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

~~(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.~~

~~(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.~~

~~(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.~~

~~(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:~~

~~(1) The sterile powder was obtained from a manufacturer.~~

~~(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.~~

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

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 671**
Current Version:	**As Amended April 14, 2015**
Author:	**Hill**
Topic:	**Biosimilar Drug Substitution**

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

Status: Hearing scheduled for April 29, 2015, Senate Health

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.

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, within five days of 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.
3. Require the board to maintain on its website a link to the current list, if available, of biological products determined by the FDA to be interchangeable as defined.

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.

The measure was amended during a committee hearing on April 14, 2015, however those 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.

FISCAL IMPACT ON THE BOARD:

As introduced, SB 671 would not have any significant fiscal impact. Any minor impact could be absorbed within existing resources

SUPPPORT/OPPOSITION:

Support
Unknown

Opposition
California Pharmacists Association (Oppose Unless Amended)

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 Subsitute." 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
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) (April 13), Re-referred to Com. on Health
03/24/15	Set for hearing April 13
03/12/15	Referred to Committees 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 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).

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

(b) Within ~~a reasonable time~~ *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), 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 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 to be interchangeable, as defined in paragraph (2) of subdivision (h).

(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 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 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 ~~503B~~ *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 ~~Section 4052.~~ *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 85**
Current Version:	**As Amended April 15, 2015**
Author:	**Wilk**
Topic:	**Open Meetings**

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

Status: Referred to ASM Appropriations

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.

FISCAL IMPACT ON THE BOARD:
Board staff do 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

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.

Date	Action As of 4/15/2015
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.

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 introduced, 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 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.~~ *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. 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 act take effect immediately

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AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 410

Introduced by Assembly Member ~~Lackey~~ *Obernolte*
(Principal coauthor: Assembly Member Lackey)

February 19, 2015

An act to ~~amend Section 11341 of~~ *add Section 9796 to* the Government Code, relating to state government.

LEGISLATIVE COUNSEL'S DIGEST

AB 410, as amended, ~~Lackey~~ *Obernolte*. ~~Administrative procedures.~~ *Documents submitted to legislative committees.*

Existing law requires a report required or requested by law to be submitted by a state or local agency to the Members of either house of the Legislature, generally, to be submitted in a specified manner, including, but not limited to, a requirement that a report submitted by a state agency be posted on the state agency's Internet Web site.

This bill would require a state agency to post on its Internet Web site any document it is required or requested by law to submit to a committee of the Legislature.

~~The Administrative Procedure Act governs the procedure for the adoption, amendment, or repeal of regulations by state agencies and for the review of those regulatory actions by the Office of Administrative Law. Existing law requires that office to establish a unique numbering system for each regulatory action for identification and tracking purposes.~~

~~This bill would make technical, nonsubstantive changes to this provision.~~

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 9796 is added to the Government Code, to read:

9796. A state agency shall post on its Internet Web site any document the state agency is required or requested by law to submit to a committee of the Legislature, including, but not limited to, material submitted pursuant to subdivision (f) of Section 13337 or a report.

~~SECTION 1. Section 11341 of the Government Code is amended to read:~~

~~11341. (a) The office shall establish a system to provide a unique identification number to each regulatory action.~~

~~(b) The office and the state agency taking the regulatory action shall use the identification number provided by the office pursuant to subdivision (a) to refer to the regulatory action for which a notice already has been published in the California Regulatory Notice Register.~~

~~(c) The identification number shall be sufficient information for a member of the public to identify and track a regulatory action both with the office and the state agency taking the regulatory action. No other information pertaining to the regulatory action shall be required of a member of the public if the identification number of the regulatory action has been provided.~~

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AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 507

Introduced by Assembly Member Olsen
(Principal coauthor: Assembly Member Gray)

February 23, 2015

An act to ~~amend~~ *add* Section ~~106 of~~ *210.5 to* the Business and Professions Code, relating to the Department of Consumer Affairs.

LEGISLATIVE COUNSEL'S DIGEST

AB 507, as amended, Olsen. Department of Consumer ~~Affairs.~~ *Affairs: BreEZe system: annual report.*

Existing law authorizes the Department of Consumer Affairs to enter into a contract with a vendor for the licensing and enforcement of the BreEZe system, which is a specified integrated, enterprisewide enforcement case management and licensing system, no sooner than 30 days after written notification to certain committees of the Legislature. Existing law requires the amount of contract funds for the system to be consistent with costs approved by the office of the State Chief Information Officer, based on information provided by the department in a specified manner.

This bill would, on and after January 31, 2016, require the department to submit an annual report to the Legislature and the Department of Finance that includes, among other things, the department's plans for implementing the BreEZe system at specified regulatory entities included in the department's's 3rd phase of the BreEZe implementation project, including, but not limited to, a timeline for the implementation.

~~Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer~~

~~Affairs. Existing law authorizes the Governor to remove from office any member of any board within the department appointed by him or her for, among other things, unprofessional or dishonorable conduct.~~

~~This bill would make nonsubstantive changes to these provisions.~~

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 210.5 is added to the Business and Professions Code, immediately following Section 210, to read:

210.5. (a) On and after January 31, 2016, the department shall submit an annual report to the Legislature and the Department of Finance that includes all of the following:

(1) The department's plan for implementing the BreEZe system at the regulatory entities in the department's third phase of the implementation project, including, but not limited to, a timeline for implementation.

(2) The total estimated costs of implementation of the BreEZe system at the regulatory entities in the department's third phase of the implementation project and the results of any cost-benefit analysis the department conducted for the third phase of the implementation project.

(3) A description of whether and to what extent the BreEZe system will achieve any operational efficiencies resulting from implementation by the boards and regulatory entities within the department's jurisdiction.

(b) The report described in subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

(c) For purposes of this section, "the regulatory entities in the department's third phase of the implementation project" includes all of the following:

(1) Acupuncture Board.

(2) Board for Professional Engineers, Land Surveyors, and Geologists.

(3) Bureau of Automotive Repair.

(4) Bureau of Electronic and Appliance Repair, Home Furnishings, and Thermal Insulation.

(5) Bureau for Private Postsecondary Education.

(6) California Architects Board.

(7) California Board of Accountancy.
(8) California State Board of Pharmacy.
(9) Cemetery and Funeral Bureau.
(10) Contractors' State License Board.
(11) Court Reporters Board of California.
(12) Landscape Architects Technical Committee.
(13) Professional Fiduciaries Bureau.
(14) Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.
(15) State Athletic Commission.
(16) State Board of Chiropractic Examiners.
(17) State Board of Guide Dogs for the Blind.
(18) Structural Pest Control Board.
(19) Telephone Medical Advice Services Bureau.

~~SECTION 1. Section 106 of the Business and Professions Code is amended to read:~~

~~106. The Governor has power to remove from office at any time, any member of any board appointed by him or her for continued neglect of duties required by law, for incompetence, or unprofessional or dishonorable conduct. This section shall not be construed as a limitation or restriction on the power of the Governor, conferred on him or her by any other law, to remove any member of any board.~~

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AMENDED IN ASSEMBLY APRIL 6, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 797

Introduced by Assembly Member Steinorth

February 26, 2015

An act to amend Sections 11343.4 and 11349.3 of the Government Code, relating to regulations.

LEGISLATIVE COUNSEL'S DIGEST

AB 797, as amended, Steinorth. Regulations: effective dates and legislative review.

The Administrative Procedure Act governs the procedure for the adoption, amendment, or repeal of regulations by state agencies and for the review of those regulatory actions by the Office of Administrative Law. That act requires an agency, prior to submitting a proposal to adopt, amend, or repeal an administrative regulation, to determine the economic impact of that regulation, in accordance with certain procedures. The act defines a major regulation as a regulation that the agency determines has an expected economic impact on California business enterprises and individuals estimated to exceed $50,000,000. The act requires the office to transmit a copy of a regulation to the Secretary of State for filing if the office approves the regulation or fails to act on it within 30 days. The act provides that a regulation or an order of repeal of a regulation becomes effective on a quarterly basis, as prescribed, except in specified ~~instances, including if a regulation adopted by the Fish and Game Commission requires a different effective date to conform with federal law.~~ *instances.*

This bill would require the office to submit to *the appropriate policy committees of* each house of the Legislature for review a copy of each

major regulation that it submits to the Secretary of State. ~~The bill would eliminate the quarterly schedule pursuant to which regulations and orders of repeal become effective, as well as the provisions specifically addressing the effective dates of regulations adopted by the Fish and Game Commission. The bill would, instead, provide that a regulation or order of repeal required to be filed with the Secretary of State generally becomes effective the 90th day after the date of filing, subject to certain exceptions.~~ The bill would add another exception to those currently provided that specifies that a regulation does not become effective if the Legislature passes a statute to override the regulation.

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 11343.4 of the Government Code is amended to read:~~

~~11343.4. A regulation or an order of repeal required to be filed with the Secretary of State shall become effective on the 90th day after the date of filing unless any of the following occur:~~

~~(a) The statute pursuant to which the regulation or order of repeal was adopted specifically provides otherwise, in which event it becomes effective on the day prescribed by the statute.~~

~~(b) A later date is prescribed by the state agency in a written instrument filed with, or as part of, the regulation or order of repeal.~~

~~(c) The agency makes a written request to the office demonstrating good cause for an earlier effective date, in which case the office may prescribe an earlier date.~~

~~(d) The Legislature passes a statute to override the regulation.~~

SECTION 1. Section 11343.4 of the Government Code is amended to read:

11343.4. (a) Except as otherwise provided in subdivision (b), a regulation or an order of repeal required to be filed with the Secretary of State shall become effective on a quarterly basis as follows:

(1) January 1 if the regulation or order of repeal is filed on September 1 to November 30, inclusive.

(2) April 1 if the regulation or order of repeal is filed on December 1 to February 29, inclusive.

(3) July 1 if the regulation or order of repeal is filed on March 1 to May 31, inclusive.

(4) October 1 if the regulation or order of repeal is filed on June 1 to August 31, inclusive.

(b) The effective dates in subdivision (a) shall not apply in all of the following:

(1) The effective date is specifically provided by the statute pursuant to which the regulation or order of repeal was adopted, in which event it becomes effective on the day prescribed by the statute.

(2) A later date is prescribed by the state agency in a written instrument filed with, or as part of, the regulation or order of repeal.

(3) The agency makes a written request to the office demonstrating good cause for an earlier effective date, in which case the office may prescribe an earlier date.

(4) (A) A regulation adopted by the Fish and Game Commission pursuant to Article 1 (commencing with Section 200) of Chapter 2 of Division 1 of the Fish and Game Code.

(B) A regulation adopted by the Fish and Game Commission that requires a different effective date in order to conform to a federal regulation.

(5) The Legislature passes a statute to override the regulation.

SEC. 2. Section 11349.3 of the Government Code is amended to read:

11349.3. (a) (1) The office shall either approve a regulation submitted to it for review and transmit it to the Secretary of State for filing or disapprove it within 30 working days after the regulation has been submitted to the office for review. If the office fails to act within 30 days, the regulation shall be deemed to have been approved and the office shall transmit it to the Secretary of State for filing.

(2) The office shall submit a copy of each major regulation submitted to the Secretary of State pursuant to paragraph (1) to *the appropriate policy committees with responsibility for the subject matter of the regulation of* each house of the Legislature for review.

(b) If the office disapproves a regulation, it shall return it to the adopting agency within the 30-day period specified in subdivision (a) accompanied by a notice specifying the reasons for disapproval. Within seven calendar days of the issuance of the notice, the office

shall provide the adopting agency with a written decision detailing the reasons for disapproval. No regulation shall be disapproved except for failure to comply with the standards set forth in Section 11349.1 or for failure to comply with this chapter.

(c) If an agency determines, on its own initiative, that a regulation submitted pursuant to subdivision (a) should be returned by the office prior to completion of the office's review, it may request the return of the regulation. All requests for the return of a regulation shall be memorialized in writing by the submitting agency no later than one week following the request. Any regulation returned pursuant to this subdivision shall be resubmitted to the office for review within the one-year period specified in subdivision (b) of Section 11346.4 or shall comply with Article 5 (commencing with Section 11346) prior to resubmission.

(d) The office shall not initiate the return of a regulation pursuant to subdivision (c) as an alternative to disapproval pursuant to subdivision (b).

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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: Referred to ASM Appropriations

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:

Board staff has confirmed with the author's office that the intent is to require boards to send this notification to *any* email address ever on file with the board, which could require significant research on behalf of board staff. Current computer systems used by the board do not have a specified area to store such information. As such, modifications to computer systems may be necessary to comply with these provisions.

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
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. 1069

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

February 26, 2015

An act to amend ~~Section~~ *Sections 150201 and* 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. ~~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 is eligible for donation to the program.~~ *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. 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.

~~SECTION 1.~~

SEC. 2. 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 ~~subdivision (a) of~~ 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 ~~paragraph (3) of subdivision (a) of~~ Section ~~150201~~ *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 ~~adjacent~~ 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.

(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.

O

Attachment 4

Order of Adoption
Board of Pharmacy
California Code of Regulations

To Amend Section 1707.5 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~10-point sans serif typeface or, if requested by the consumer, at least a~~ 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

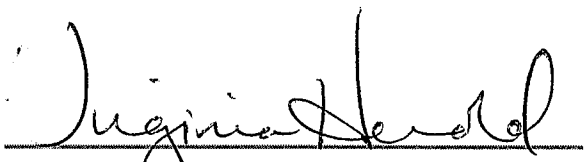
(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.



Virginia Herold
Executive Officer
Board of Pharmacy

Attachment 5

BOARD OF PHARMACY

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

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

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

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

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

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

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

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

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

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:

4113, 4115, 4119, 4127, 4305, 4330, 4332 and 4333, Business and Professions Code.

Proposal to Amend Section 1735.2 in Article 4.5 of Division 17 of Title 16 to read:

§ 1735.2. Compounding Limitations and Requirements; Self-Assessment

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the

compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "~~Community Pharmacy & Hospital Outpatient Pharmacy~~ Compounding Self-Assessment" Form 17M-39 Rev. ~~02/12.)~~ 10/14.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

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

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

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

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

(1) A new wholesaler permit is issued, or

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

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

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

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

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

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections

Professions Code.

Attachment 6

Title 16. Board of Pharmacy

PROPOSED LANGUAGE

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

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

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

(1) Information sufficient to identify the applicant.

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

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

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

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

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

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

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

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

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

PHARMACY TECHNICIAN APPLICATION

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

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

Applicant Information – Please Type or Print

Full Legal Name: Last Name: First Name: Middle Name:

Previous Names (AKA, Maiden Name, Alias, etc):

*Official Mailing/Public Address of Record (Street Address, PO Box #, etc):

City: State: Zip Code:

Residence Address (if different from above):

City: State: Zip Code:

Home#: ( ) Cell#: ( ) Work#: ( ) Email Address:

Date of Birth (Month/Day/Year): **Social Security # or Individual Tax ID #: Driver's License No: State:

Mandatory Education (check one box)

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

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

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

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

Pharmacy Technician Qualifying Method (check one box)

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

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

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

☐ Attached is a certified copy of your military training DD214

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

State	Registration Number	Active or Inactive	Issued Date	Expiration Date

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

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

FOR BOARD USE ONLY

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

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

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

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

Arrest Date	Conviction Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)~~9~~

APPLICANT AFFIDAVIT

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

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

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

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

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

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

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

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

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

MANDATORY REPORTER

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

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

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

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

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

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

_____ _____
Original Signature of Applicant Date

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

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

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION FOR PHARMACY TECHNICIAN

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

This is to certify that _____ has
Print Name of Applicant

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

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

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

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

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

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

Affix school seal here.

OR

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

University, College, or School of Pharmacy Name: _____

Address: _____

_____

Print Name of Director, Registrar, or Pharmacist: _____

Phone Number: _____

Email: _____

Attachment 7

Title 16. Board of Pharmacy
Proposed Language

To Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010~~.

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . ~~omitting t~~Traffic infractions under ~~$300~~ $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Add Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014. (1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Amend Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2014.

(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Title 16. Board of Pharmacy
Proposed Language

To Add Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4112, 4161, 4300, 4301, Business and Professions Code

Title 16. Board of Pharmacy
Proposed Language

To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy's Drug Inventory
4. Ethics
5. Substance Abuse
6. Compounding

Pharmacists renewing their licenses which expire on or after July 1, 201~~5~~6, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Draft Proposed Text

Amend Title 16 California Code of Regulations Section 1703

Related to Delegation of Certain Functions

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; ~~and~~ issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; and make changes to its regulations without regulatory effect pursuant to Title 1, California Code of Regulations section 100 are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

DRAFT

Attachment 8

Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.
- When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
    - Dosage;
    - Effectiveness;
    - Potential side effects;
    - Safety;
    - The importance of receiving recommended preventative health screenings;
    - That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

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

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

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

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
	If yes, list them here:		

Note: Authority cited: Section 4052.3, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria for Contraceptive Use," (2010) *available at* http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm.

This resources serves as the basis for which self-administered hormonal contraception medications from which a pharmacist may select.

Centers for Disease Control and Prevention, "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm.

This document from the CDC offers guidance on how to use contraceptive methods most effectively. It is adapted from a World Health Organization (WHO) publication, and endorsed by the American College of Obstetricians and Gynecologists (ACOG).

S. Shotorbani, et al., "Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors," 73 CONTRACEPTION 501, 501-506 (2006).

This article provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The article's research found 96% agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.

CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives."

This draft protocol was consulted in development of the Board's recommended protocol.

Food and Drug Administration Office of Women's Health, "HPV, HIV, Birth Control" (last updated June 24, 2014), *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117971.htm

This site contains a consumer-friendly birth control guide recommended for patient education.

Office on Women's Health, U.S. Department of Health and Human Services, "Birth Control Methods" (last updated Nov. 21, 2011), *available at* http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf.

This fact sheet was consulted in development of the Board's recommended fact sheet.

Division of Reproductive Health, Centers for Disease Control and Prevention, "Contraception" (last updated Oct. 14, 2014), http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm.

This website, especially the chart, is recommended as a resource for pharmacists choosing to provide additional user-friendly information on various birth control methods.

The American College of Obstetricians and Gynecologists, "Birth Control -- Especially for Teens," FAQ112 (Dec. 2013), *available at* http://www.acog.org/Patients/FAQs/Birth--Control--Especially--for--Teens.

This fact sheet was consulted in development of the Board's recommended fact sheet.

J. McIntosh et al., "Changing Oral Contraceptives from Prescription to Over--the--Counter Status: An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy," Pharmacotherapy Vol. 31, Number 4, 424--437 (2011).

This opinion paper discusses pharmacist training on page 432. Both pharmacists and pharmacy students generally expressed interest in more education specifically on appropriate product selection.

Fatim Lakha, et al., "The Acceptability of Self--Administration of Subcutaneous Depo--Provera," 72 CONTRACEPTION 14--18 (2005).

This research finds that subcutaneous self--injectable hormonal contraception is beneficial for many women with appropriate training and reminder system.

Nicole J. Monastersky Maderas & Sharon Cohen Landau, "Pharmacy and Clinic Partnerships To Expand Access to Injectable Contraception," 47 J. AM. PHARM. ASSOC. 527--531 (2007).

This research finds that pharmacy reinjection of contraception is a viable option for many women, and is most successful when combined with primary care provider support and integration.

Sujatha Prabhakaran & Ashley Sweet, "Self--Administration of Subcutaneous Depot Medroxyprogesterone Acetate for Contraception: Feasibility and Acceptability," 85 CONTRACEPTION 453--457 (2012).

This research article finds that self--administration injections were easy and convenient for women with training from two Planned Parenthood health centers.

Sharon T. Cameron, et al., "Pilot Study of Home Self--Administration of Subcutaneous Depo--Medroxyprogesterone Acetate for Contraception," 85 CONTRACEPTION 458--464 (2012).

This research concludes that self--administration is feasible and has similar continuation and satisfaction rates to clinician--administration injections.

Rebekah L. Williams, et al., "Self--Administration of Subcutaneous Depot Medroxyprogesterone Acetate by Adolescent Women," 88 CONTRACEPTION 401--407 (2013).

This research concludes that many adolescents are interested in and capable of self--administration with brief education and minimal assistance.

S. Vinker, et al., "The Effect of Drug Information Leaflets on Patient Behavior," ISR. MED. ASSOC. J. 9(5) 383--4386 (May 2007).

This research concludes that reading the leaflet did not greatly affect adherence but aroused anxiety and decreased adherence in some patients.

21 C.F.R §§ 201 "Labeling," *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201.
These FDA regulations require manufacturers to include comprehensive patient leaflets in both prescription-only and OTC products.

21 C.F.R. § 310.501 "Patient Package Inserts for Oral Contraceptives," (Apr. 1, 2014), *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.501.
These FDA regulations are specific to leaflet requirements for oral contraceptives.

FACT SHEET : PROGESTIN-ONLY/ MINI-PILL

Remember, the mini-pill **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!

HOW DOES THE MINI-PILL WORK?

- The mini-pill contains a hormone like the ones your body makes. It works by making the mucus in your cervix too thick for sperm to pass through. If sperm cannot reach the egg, you cannot get pregnant.
- No method of birth control is 100% effective. Progestin-only birth control pills are 91-99% effective.

HOW DO I START THE MINI-PILL?

- There are 2 ways to start the pill:
  - **Quick Start:** Take your first pill as soon as you get the pack.
  - **Next period:** Take your first pill soon after your next period begins.
- If you take your first pill *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you take your first pill *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE MINI-PILL?

- **Once you start using the pill**, take 1 pill each day. Take your pill at the same time each day.
- After you finish a pack of pills, you should start a new pack the next day. You should have NO day without a pill.

WHAT IF I MISS MINI-PILLS?

- **I forgot ONE pill:** Take your pill as soon as you can. If you take your pill more than 3 hours late, **use condoms for the next 7 days.**
- **I forgot TWO pills or more:** Take your pill as soon as you can. Take your next pill at the usual time. **Use condoms for the next 7 days. Use emergency contraception (EC) if you have unprotected sex.**

WHAT IF I STOPPED TAKING THE MINI-PILL AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE MINI-PILL HELP ME?

- The mini-pill is safe & effective birth control. The mini-pill is safe for you to use while breastfeeding.
- The mini-pill has **no effect** on your ability to get pregnant in the future, after you stop taking it.

HOW WILL I FEEL ON THE MINI-PILL?

- You will feel about the same. Most women notice changes in their periods. You may have spotting or no period at all. This is normal. You may have nausea, spotting, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE MINI-PILL HAVE RISKS?

- The mini-pill is very safe.

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HOJA INFORMATIVA : MINI PÍLDORA/ LA PÍLDORA SOLO DE PROGESTINA

Recuerde, la mini píldora **no la protege contra las infecciones de transmisión sexual o el VIH.** Siempre use condones para protegerse!

¿CÓMO FUNCIONA LA MINI PÍLDORA?

- La mini píldora contiene una hormona como las que produce su cuerpo. Funciona haciendo que el moco de su cuello uterino sea demasiado espeso para que los espermatozoides lo puedan atravesar. Si los espermatozoides no pueden llegar al óvulo, usted no puede quedar embarazada.
- Ningún método anticonceptivo es 100% efectivo. Las píldoras anticonceptivas de progestina son 91-99% efectivas.

¿COMO EMPIEZO A USAR LA MINI PÍLDORA?

- Hay 2 maneras de empezar las píldoras:
  - **Inicio Inmediato:** Tome la primera píldora tan pronto que obtenga el paquete.
  - **Siguiente menstruación:** Tome la primera píldora poco después de que empieze su próximo período.
- Si toma la primera píldora hasta 5 días después del inicio de su período, su protección contra el embarazo es **inmediato**.
- Si toma la primera pildora más de 5 días después del inicio de su período, **debe usar condones como método de respaldo durante los primeros 7 días**.

¿CÓMO DEBO USAR LA MINI PÍLDORA?

- **Una vez que comience a usar la píldora**, tome 1 píldora todos los días. Tómela a la misma hora cada día.
- **Use condones durante los primeros 7 días** de su *primer* paquete de píldoras anticonceptivas.
- Cuando termine un paquete de píldoras, debería comenzar un nuevo paquete al día siguiente. Usted NO debería pasar NI UN día sin una píldora.

¿QUÉ PASA SI SE ME OLVIDAN ALGUNAS PÍLDORAS?

- **Se me olvidó UNA píldora:** Tómela tan pronto como pueda. Si toma la píldora más de 3 horas de retraso, use condones durante los próximos 7 días.
- **Se me olvidaron DOS o más píldoras:** Tome su píldora tan pronto como sea posible. Tome su siguiente píldora a la hora habitual. **Use condones durante los próximos 7 días. Use anticoncepción de emergencia (AE) si tiene relaciones sexuales sin protección.**

¿QUÉ PASA SI DEJÉ DE TOMAR LAS PÍLDORAS Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) **inmediatamente**. Los AE puede prevenir el embarazo hasta 5 días después de una relación sexual, y funciona mejor cuanto más pronto la tome.

¿CÓMO ME AYUDA LA MINI PÍLDORA?

- La mini píldora es un anticonceptivo seguro y efectivo. La mini píldora es segura y usted la puede usar mientras esté amamantando porque no afecta la producción de leche. Después de que deje de tomar la mini píldora, **no tiene ningún efecto** sobre su capacidad de quedar embarazada en el futuro.

¿CÓMO ME SENTIRÉ CUANDO ESTÉ TOMANDO LA MINI PÍLDORA?

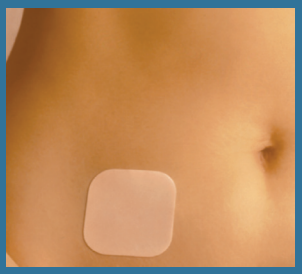
- Usted sentirá más o menos igual. La mayoría de las mujeres notan cambios en sus menstruaciones. Usted puede tener algún manchado, o no tener menstruaciones del todo. Esto es normal. En los primeros meses usted puede tener náusea, manchado, cambios de peso y/o dolor en los pechos. Estos problemas con frecuencia desaparecen a los 2-3 meses.

¿LA MINI PÍLDORA TIENE RIESGOS?

- La mini píldora es muy segura.

HOJA INFORMATIVA : SOBRE EL PARCHE

Recuerde, el parche **no la protege contra las Infecciones de Transmisión Sexual o el VIH.** Siempre use condones para protegerse!



¿CÓMO FUNCIONA EL PARCHE?

- El parche contiene hormonas como las que produce su propio cuerpo. Estas hormonas impiden que sus ovarios liberen óvulos. Sin un óvulo usted no puede quedar embarazada.
- No existe un método anticonceptivo que sea 100% efectivo. El parche es 91-99% efectivo.

¿COMO EMPIEZO A USAR EL PARCHE?

- Hay 2 maneras de empezar a usar el parche:
  - **Inicio Inmediato:** Coloquese el primer parche tan pronto que lo obtenga.
  - **Siguiente menstruación:** Coloquese el primer parche poco después de que empieze su próximo período.
- Si se coloca el primer parche hasta 5 días después del inicio de su período, su protección contra el embarazo es **inmediato**.
- Si se coloca el primer parche *más de 5 días después del inicio de su período,* **debe usar condones como método de respaldo durante los primeros 7 días.**

¿CÓMO DEBO USAR EL PARCHE?

- El parche es como una calcomanía que usted usa sobre su piel durante una semana. Usted puede usar el parche en cualquier lugar de su piel excepto en sus pechos, sus genitales, las palmas de sus manos y las plantas de sus pies.
- Escoja un lugar de su cuerpo donde usted pueda ver el parche si se cae. Coloque el parche en un área limpia y seca y asegúrese que los bordes queden bien pegados.
- Debe usar un parche nuevo cada semana durante tres semanas y no usarlo durante la cuarta semana.
- **Use condones los primeros 7 días** de su primer parche.
- Espere ver su menstruación durante la semana libre de parche. (Usted podría tener una menstruación más ligera o no tenerla del todo.)
- Comience una nueva caja de parches al final de la 4ta semana.

¿QUÉ PASA SI EL PARCHE SE CAE?

- Si el parche se cae, póngalo de vuelta inmediatamente. Si el parche no se pega, use un parche nuevo.
- Si el parche se mantiene despegado por más de un día, use un parche nuevo y condones por los siguientes 7 días.
- Colóquese su siguiente parche a la semana de haberse puesto este parche.

¿QUÉ PASA SI ME OLVIDO DE CAMBIAR EL PARCHE PASADOS LOS 7 DÍAS?

- El parche tiene hormonas suficientes para 9 días o menos, solo póngase un parche nuevo.
- Si se deja el parche puesto por más de 9 días, póngase un nuevo parche y use condones durante los siguientes 7 días.

¿QUÉ PASA SI DEJÉ DE USAR EL PARCHE Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) inmediatamente. Los AE puede prevenir el embarazo hasta 5 días después de la relación sexual, y funcionan mejor cuanto más pronto los tome.

¿CÓMO ME AYUDA/ME BENEFICIA EL PARCHE?

- El parche es anticoncepción segura y efectiva. Sus menstruaciones pueden ser más regulares, más ligeras y más cortas. Su piel se puede aclarar del acné. El parche disminuye su riesgo de desarrollar cáncer del útero y de los ovarios. El parche **no tiene nignún efecto** sobre su capacidad de quedar embarazada en el futuro, después de que deje de usarlo.

¿CÓMO ME SENTIRÉ CUANDO USE EL PARCHE?

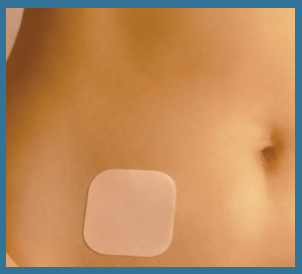
- Usted se sentirá más o menos igual que siempre. Durante los primeros 2-3 meses podría tener náusea, sangrado entre menstruaciones, cambios de peso y/o dolor en sus pechos. Estos problemas con frecuencia en 2-3 meses.

¿EL PARCHE TIENE RIESGOS?

- El parche es muy seguro. Los problemas serios son raros. Si usted tiene alguno de los síntomas enumerados abajo, llame a su proveedor de atención a la salud:
  - -Dolor, hinchazón y enrojecimiento en la pierna
  - -Debilidad o adormecimiento en un lado de su cuerpo
  - -Dolor de cabeza severo
  - -Problemas de la visión
  - -Dolor de pecho
- Su proveedor de atención a la salud puede ayudarla a determinar si estos síntomas son señales de un problema serio.

FACT SHEET : THE PATCH

Remember, the patch **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES THE PATCH WORK?

- The patch contains hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you can't get pregnant.
- No method of birth control is 100% effective. The patch is 91-99% effective.

HOW DO I START THE PATCH?

- There are 2 ways to start the patch:
  - **Quick Start:** Put on your first patch as soon as you get the pack.
  - **Next period:** Put on your first patch soon after your next period begins.
- If you put on your first patch *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you put on your first patch *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE PATCH?

- The patch is like a sticker you wear on your skin for a week. You can wear the patch anywhere on your skin except your breasts, your genitals, palms of your hands or soles of your feet.
- Choose a spot on your body where you can see the patch if it falls off. Place the patch on a clean, dry area and make sure the edges stick well.
- You will use a new patch every week for 3 weeks and no patch for the 4th week.
- Expect your period during the patch-free week. (You may have a light period or no period at all.)
- Start a new box of patches at the end of the 4th week.

WHAT IF THE PATCH COMES OFF?

- If the patch comes off, put it back on right away. If it does not stick, use a new patch.
- If the patch falls off for more than a day, put on a new patch and **use condoms for the next 7 days**.
- Put on your next patch a week from the date of this new patch.

WHAT IF I FORGET TO CHANGE THE PATCH AFTER 7 DAYS?

- The patch has enough hormones for 9 days. If you leave the patch on for 9 days or less, just put on a new patch.
- If you leave the patch on for more than 9 days, put on a new patch and **use condoms for the next 7 days**.

WHAT IF I STOPPED USING THE PATCH AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE PATCH HELP ME?

- The patch is safe and effective birth control. Your periods may be more regular, lighter, and shorter. You may have clearer skin.
- The patch lowers your risk of getting cancer of the uterus and ovaries.
- The patch has **no effect** on your ability to get pregnant in the future, after you stop using it.

HOW WILL I FEEL ON THE PATCH?

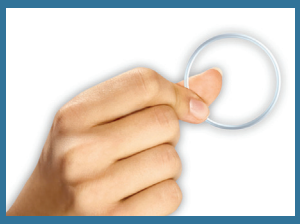
- You will feel about the same. During the first 2-3 months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE PATCH HAVE RISKS?

- The patch is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider:
  - Leg pain, swelling, and redness
  - Weakness or numbness on 1 side of your body
  - Bad headache
  - Vision problems
  - Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

FACT SHEET : THE RING

Remember, the ring **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES THE RING WORK?

- The ring contains hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective. The ring is 91-99% effective.

HOW DO I START THE RING?

- There are 2 ways to start the ring:
  - **Quick Start:** put in your first ring as soon as you get the pack.
  - **Next period:** put in your first ring soon after your next period begins.
- If you put your first ring in *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you put your first ring in *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE RING?

- The ring is a small, bendable, plastic circle that you insert into your vagina.
- You leave the ring in your vagina for 3 weeks, and remove it for the 4th week.
- Remove the ring by hooking a finger under the rim and pulling it out.
- Most women get their period during the ring-free week.
- Insert a new ring at the end of the 4th week.
- You can store the ring at room temperature up to four months. In the refrigerator, the ring lasts much longer.

DO I HAVE TO GET A PERIOD?

- Because the ring has enough hormones to last 35 days, you can leave it in for more than 3 weeks. You can change the ring on the same day of each month (for instance, March 1st, April 1st, May 1st, etc.). If you remove the old ring and insert the new ring on the same day, you may not get a period. This is ok.

WHAT IF THE RING COMES OUT?

- The ring may slip out during sex or when you use the bathroom. The ring can stay out of your body for up to 3 hours and still prevent pregnancy. If the ring is out of your body for more than 3 hours, you should put it back into your vagina and **use condoms for the next 7 days**.

WHAT IF I STOPPED USING THE RING AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE RING HELP ME?

- The ring is safe and effective birth control. Your periods may be more regular, lighter, and shorter. You may have clearer skin. The ring lowers your risk of getting cancer of the uterus and ovaries. The ring has **no effect** on your ability to get pregnant in the future, after you stop using it.

HOW WILL I FEEL ON THE RING?

- You will feel about the same. In the first few months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE RING HAVE RISKS?

- The ring is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider:
  - Leg pain, swelling, and redness
  - Weakness or numbness on 1 side of your body
  - Bad headache
  - Vision problems
  - Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

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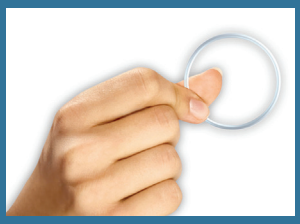
HOJA INFORMATIVA : SOBRE EL ANILLO

Recuerde, el anillo **no la protege contra las infecciones de transmisión sexual o el VIH.** Siempre use condones para protegerse!



¿CÓMO FUNCIONA EL ANILLO?

- El anillo contiene hormonas como las que su cuerpo produce. Estas hormonas impiden que sus ovarios liberen óvulos. Sin un óvulo, usted no puede quedar embarazada.
- Ningún método anticonceptivo es 100% efectivo. El anillo es 91-99% efectivo.

¿COMO EMPIEZO A USAR EL ANILLO?

- Hay 2 maneras de empezar a usar el anillo:
  - **Inicio Inmediato:** Inserte el primer anillo tan pronto que lo obtenga.
  - **Siguiente menstruación:** Inserte el primer anillo después de que empieze su próximo período.
- Si inserta el primer anillo hasta *5 días después del inicio de su período*, su protección contra el embarazo es **inmediato**.
- Si inserta el primer anillo *más de 5 días después del inicio de su período*, **debe usar condones como método de respaldo durante los primeros 7 días.**

¿CÓMO DEBO USAR EL ANILLO?

- El anillo es un círculo plástico, pequeño y flexible que usted introduce en su vagina.
- Usted deja el anillo en su vagina por 3 semanas, y lo retira para la cuarta semana.
- **Use condones por 7 días** al insertar su *primer* anillo.
- Remueva el anillo enganchándolo con el dedo y jalándolo.
- La mayoría de mujeres presentan su menstruación durante la semana libre de anillo.
- Introduzca un nuevo anillo al final de la cuarta semana.
- Usted puede almacenar el anillo a temperatura ambiente por hasta cuatro meses. En el refrigerador, el anillo dura mucho más.

¿TENGO QUE TENER UNA MENSTRUACIÓN?

- Debido a que el anillo tiene suficientes hormonas para 35 días, usted puede dejarlo puesto por más de 3 semanas. Usted puede cambiar el anillo el mismo día de cada mes (por ejemplo, 1ro de marzo, 1ro de abril, 1ro de mayo, etc.). Si usted retira el anillo Viejo y coloca uno nuevo el mismo día, es probable que no tenga una menstruación. Esto está bien.

¿QUÉ PASA SI EL ANILLO SE CAE?

- El anillo se puede deslizar durante la relación sexual o cuando usted use el baño. El anillo puede permanecer fuera de su cuerpo por hasta 3 horas y aun prevenir el embarazo. Si el anillo permanece fuera de su cuerpo por más de 3 horas, usted debe ponerlo de vuelta en su vagina y **usar condones durante los siguientes 7 días**.

¿QUÉ PASA SI DEJÉ DE USAR EL ANILLO Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) **inmediatamente**. Los AE pueden prevenir el embarazo hasta 5 días después de una relación sexual, y funciona mejor cuanto más pronto los tome.

¿CÓMO ME AYUDA/ME BENEFICIA EL ANILLO?

- El anillo es anticoncepción segura y efectiva. Sus menstruaciones podrían ser más regulares, ligeras y cortas. Su piel se podría aclarar del acné. El anillo disminuye su riesgo de desarrollar cáncer uterino y de los ovarios. El anillo no tiene **ningún efecto** sobre su capacidad de quedar embarazada en el futuro, después que usted lo deje de usar.

¿CÓMO ME SENTIRÉ CON EL ANILLO?

- Usted se sentirá más o menos igual. En los primeros meses usted podría tener náusea, sangrado entre menstruaciones, cambios de peso y/o dolor en los pechos. Estos problemas generalmente desaparecen a los 2-3 meses.

¿EXISTEN RIESGOS?

- El anillo es muy seguro. Los problemas serios son raros. Si usted tiene alguno de los síntomas enumerados abajo, llame a su proveedor de atención a la salud:
  - -Dolor, hinchazón y enrojecimiento de las piernas
  - -Debilidad o adormecimiento en un lado de su cuerpo
  - -Dolor de cabeza severo
  - -Problemas de la visión
  - -Dolor de pecho
- Su proveedor de atención a la salud puede ayudarle a determinar si estos síntomas son señales de un problema serio.

FACT SHEET : THE PILL

Remember, the pill **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!

HOW DO BIRTH CONTROL PILLS WORK?

- Birth control pills contain hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective. Birth control pills are 91-99% effective.

HOW DO I START THE PILL?

- There are 2 ways to start the pill:
  - **Quick Start:** Take your first pill as soon as you get the pack.
  - **Next period:** Take your first pill soon after your next period begins.
- If you take your first pill *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you take your first pill *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days.**

HOW DO I USE THE PILL?

- **Once you start using the pill**, take 1 pill each day. Take your pill at the same time each day.
- After you finish a pack of pills, you should start a new pack the next day. You should have NO day without a pill.

WHAT IF I MISS PILLS?

- **I forgot ONE pill:** Take your pill as soon as you can.
- **I forgot TWO pills or more:** Take your pill as soon as you can. Take your next pill at the usual time. **Use condoms for 7 days. Use emergency contraception (EC) if you have unprotected sex.**

WHAT IF I STOPPED TAKING THE PILL AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE PILL HELP ME?

- The pill is safe and effective birth control.
- Your periods may be more regular, lighter, and shorter. You may have clearer skin.
- The pill lowers your risk of getting cancer of the uterus and ovaries.
- The pill has **no effect** on your ability to get pregnant in the future, after you stop taking it.

HOW WILL I FEEL ON THE PILL?

- You will feel about the same. In the first 2-3 months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE PILL HAVE RISKS?

- The pill is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider.
- Leg pain, swelling, and redness
- Weakness or numbness on 1 side of your body
- Bad headache
- Vision problems
- Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

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HOJA INFORMATIVA : SOBRE LA PÍLDORA

Recuerde, la píldora **no la protege contra las Infecciones de Transmisión Sexual o el VIH.** Siempre use condones para protegerse!

¿CÓMO FUNCIONAN LAS PÍLDORAS ANTICONCEPTIVAS?

- Las píldoras anticonceptivas contienen hormonas como las que produce su cuerpo. Estas hormonas impiden que sus ovarios liberen óvulos. Sin óvulos usted no puede quedar embarazada.
- Ningún método es 100% efectivo. Las píldoras anticonceptivas son 91-99% efectivas.

¿COMO EMPIEZO A USAR LA PÍLDORA?

- Hay 2 maneras de empezar las píldoras:
  - **Inicio Inmediato:** Tome la primera píldora tan pronto que obtenga el paquete.
  - **Siguiente menstruación:** Tome la primera píldora poco después de que empieze su próximo período.
- Si toma la primera píldora hasta *5 días después del inicio de su período,* su protección contra el embarazo es **inmediato**.
- Si toma la primera pildora *más de 5 días después del inicio de su período,* **debe usar condones como método de respaldo durante los primeros 7 días.**

¿CÓMO DEBO USAR LAS PÍLDORAS ANTICONCEPTIVAS?

- **Una vez que comience a usar la píldora**, tome 1 píldora todos los días. Tómela a la misma hora cada día.
- Después que termine un paquete de píldoras anticonceptivas, necesita comenzar otro paquete al día siguiente. No debería tener NI UN solo día sin píldoras.

¿QUÉ PASA SI ME OLVIDAN LAS PÍLDORAS?

- **Se me olvidó UNA píldora:** Tómela tan pronto como pueda.
- **Se me olvidaron DOS o más píldoras:** Tome su píldora tan pronto como sea posible. Tome su siguiente píldora a la hora habitual. **Use condones durante 7 días. Use anticoncepción de emergencia (AE) si tiene relaciones sexuales sin protección.**

¿QUÉ PASA SI DEJÉ DE TOMAR LAS PÍLDORAS Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) **inmediatamente.** Los AE puede prevenir el embarazo hasta 5 días después de una relación sexual, y funciona mejor cuanto más pronto la tome.

¿CÓMO ME AYUDA LA PÍLDORA?

- La píldora es anticoncepción segura y efectiva.
- Sus menstruaciones pueden ser más regulares, más ligeras y más cortas.
- Su piel se podría aclarar del acné. La píldora disminuye su riesgo de desarrollar cáncer del útero y de los ovarios.
- La píldora no tiene ningún efecto sobre su capacidad de quedar embarazada en el futuro, después que deje de tomarla.

¿CÓMO ME SENTIRÉ CUANDO TOME LA PÍLDORA?

- Se sentirá más o menos igual. En los primeros 2-3 meses podría tener nausea, sangrado entre menstruaciones, cambios de peso y/o dolor en los pechos. Estos problemas generalmente desaparecen a los 2-3 meses.

¿LA PÍLDORA TIENE RIESGOS?

- La píldora es muy segura. Los problemas serios son raros. Si tiene cualquiera de los síntomas enumerados abajo, llame a su proveedor o escríbanos por medio de *mychart*:
  - -Dolor, hinchazón o enrojecimiento de las piernas
  - -Debilidad o adormecimiento en 1 lado de tu cuerpo
  - -Dolor de cabeza severo
  - -Problemas de la visión
  - -Dolor de pecho
- Nosotros podemos ayudarle a averiguar si estos síntomas son señales de un problema serio.

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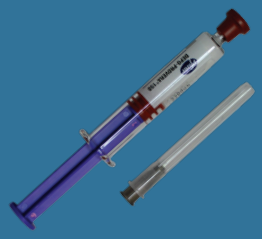
FACT SHEET : THE SHOT/DEPO-PROVERA

Remember, Depo **does not protect you from Sexually Transmitted Infections or HIV**. Always use condoms to protect yourself!



HOW DOES DEPO WORK?

- Depo contains a hormone like the ones your body makes. This hormone stops your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective. Depo is 94-99% effective.

HOW DO I USE DEPO?

- You get a Depo injection in the arm or in the buttocks.
- **Use condoms as back-up the first 7 days** after your first shot of Depo.
- You should get a shot every 3 months (every 12 weeks).

WHAT IF I AM LATE FOR THE NEXT SHOT?

- Depo works best if you get a new shot every 12 weeks.
- If your shot is more than 4 weeks late, you should get a pregnancy test before the next shot. You should **use condoms for the next 7 days**.

WHAT IF I AM LATE GETTING A SHOT AND HAD UNPROTECTED SEX?

- If your last shot was more than 16 weeks ago, take Emergency Contraception (EC) **right after** unprotected sex. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES DEPO HELP ME?

- Depo is safe & effective. It keeps you from getting pregnant for 3 months.
- The shot lowers your risk of cancer of the uterus.
- It is safe to breastfeed while on Depo.

HOW WILL I FEEL ON DEPO?

- You will most likely have spotting between periods. You may have weight gain, bloating, headaches and/or mood changes. Talk to your health care provider about treating any side effects.
- After the first 2-3 shots, you may have *no period at all*. This is normal.
- Your bones may become slightly weaker while you take Depo. Bone strength returns to normal once you stop getting the shot.
- After you stop Depo, it takes a few months for your fertility to return to normal. This means that it may take a while for you to get pregnant (even if you're trying) – but if you don't want to get pregnant, you need to use a new form of birth control after you stop Depo.

DOES DEPO HAVE RISKS?

- The shot is very safe. Severe problems are rare. If you have any of the symptoms below, call your doctor:
  - Severe headaches
  - Very heavy bleeding
- Your health care provider can help you find out if these symptoms are signs of a severe problem.

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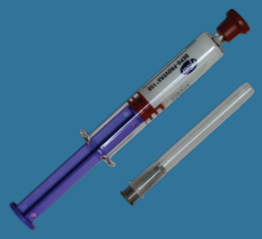
HOJA INFORMATIVA : LA INYECCIÓN/DEPO-PROVERA

Recuerde, la Depo **no la protege contra las Infecciones de Transmisión Sexual o el VIH.** ¡Siempre use condones para protegerse!



¿CÓMO FUNCIONA LA DEPO?

- La Depo contiene una hormona como las que produce su cuerpo. Esta hormona impide que sus ovarios liberen óvulos. Sin un óvulo, usted no puede quedar embarazada.
- Ningún método anticonceptivo es 100% efectivo. La Depo es 94-99% efectiva.

¿CÓMO DEBO USAR LA DEPO?

- Usted recibe una inyección de Depo en el brazo o en la cadera.
- **Use condones como método de resplando por los primeros 7 días** después que reciba su *primera* inyección de Depo.
- Usted debería recibir una inyección cada 3 meses (cada 12 semanas).

¿QUÉ PASA SI ME RETRASO PARA LA SIGUIENTE INYECCIÓN?

- La Depo funciona mejor si usted recibe una nueva inyección cada 12 semanas.
- Si su inyección está retrasada más de 4 semanas, usted debería hacerse una prueba de embarazo antes de su próxima inyección. Usted debería **usar condones durante los siguientes 7 días.**

¿QUÉ PASA SI ME RETRASO PARA LA SIGUIENTE INYECCIÓN Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Si su última inyección fue hace más de 16 semanas, tome anticonceptivos de emergencia (AE) **inmediatamente** después de la relación sexual sin protección. Los AE pueden prevenir el embarazo hasta 5 días después de la relación sexual, y funcionan mejor cuanto más pronto los tome.

¿CÓMO ME AYUDA LA DEPO?

- La Depo es segura y eficaz. Le ayuda a prevenir el embarazo por 3 meses.
- La inyección disminuye su riesgo de cáncer uterino.
- Amamantar es seguro mientras esté usando la Depo.

¿CÓMO ME SENTIRÉ AL USAR LA DEPO?

- Es muy probable que tenga algo de manchado entre sus menstruaciones. Usted podría aumentar de peso, tener hinchazón, dolores de cabeza y/o cambios en su estado de ánimo. Hable con su proveedor de salud sobre el tratamiento de cualquier efecto secundario.
- Después de las primeras 2-3 inyecciones, usted podría *no tener menstruaciones del todo*. Esto es normal.
- Sus huesos podrían debilitarse un poco mientras esté usando la Depo. La fuerza ósea regresa a lo normal una vez que usted deje de recibir las inyecciones.
- Después de que deje de usar la Depo, toma algunos meses para que su fecundidad regrese a lo normal. Esto significa que puede tomar algo de tiempo para que usted quede embarazada (aun si está tratando) –pero si no desea quedar embarazada, usted debe usar una nueva forma de anticoncepción después que deje de usar la Depo.

¿LA DEPO TIENE RIESGOS?

- La inyección es muy segura. Los problemas severos son raros. Si usted tiene cualquiera de los síntomas mencionados abajo, llame a su doctor:
  - -Dolores de cabeza severos
  - -Sangrado muy abundante
- Su proveedor de salud puede ayudarle a saber si estos síntomas son señales de un problema severo.

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Protocol for Pharmacists Furnishing Nicotine Replacement Products

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

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

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

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

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

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

- Review the patient's current tobacco use and past quit attempts.
- Ask the patient the following screening questions:
    - Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
    - Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

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

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

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

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

Generic equivalent products may be furnished.

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

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

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

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

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

10) Nicotine Replacement Therapy Medications for Smoking Cessation
Insert chart

Note: Authority cited: Section 4052.9, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "Quitting Smoking," *available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm.
This resource describes the methods of quitting smoking and their effectiveness.

CPhA/CSHP, "Pharmacists Protocol for Dispensing Nicotine Replacement Products."
This draft protocol was consulted in development of the Board's recommended protocol.

Frank Vitale, "Brief Intervention Protocol for Assisting Patients with Tobacco Cessation," 64 AM. J. HEALTH-SYST PHARM. 2583 (2007).
This commentary provides important resources and specific dialogue for a pharmacists' procedure for assisting patients with tobacco cessation.

Nicole Van Hoey, "Opportunities for Smoking Cessation Services in Emerging Models of Care," America's Pharmacist (Oct. 2014).
This Continuing Education provided helpful referral resources, especially smartphone resources.

University of California, San Francisco, "Smoking Cessation Leadership Center," http://smokingcessationleadership.ucsf.edu/.
This site offers evidence-based resources for providers as well as continuing education opportunities in smoking cessation for CME and CEU credit.

University of California, San Francisco, "Rx for Change," http://rxforchange.ucsf.edu/.
This site offers evidence-based resources for providers and non-providers.

Accreditation Council for Pharmacy Education, "Basic Tobacco Intervention Workshop," P.L.A.N. Search Detail, *available at* https://www.acpe-accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014.
This website shows ACPE-approved education involving smoking cessation.

Agency for Healthcare Research and Quality, "Treating Tobacco Use and Dependence: 2008—Clinical Practice Guideline," *available at* http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/index.html.
This site provides tobacco reference materials and guides for health care providers.

Nicotine Replacement Therapy Medications for Smoking Cessation

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

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

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

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

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

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