



## Legislation and Regulation Committee Report

Greg Lippe, CPA, Chairperson, Public Member  
Lavanza Butler, Vice Chairperson, Licensee Member  
Amy Gutierrez, Licensee Member  
Amjad Khan, Public Member  
Valerie Muñoz, Public Member  
Albert Wong, PharmD, Licensee Member

### **I. Call to Order, Establishment of Quorum and General Announcements**

### **II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings**

*Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]*

### **III. Legislation for Discussion and Consideration**

#### **a. Board Sponsored/Originated Legislation**

#### **Attachment 1**

1. **SB 1447 (Hernandez) Pharmacy: Automated Drug Delivery Systems: Licensing**  
**Version:** Amended April 17, 2018

**Status:** Senate Business, Professions and Economic Development

**Summary:** This bill would repeal the general ADDS provisions and the additional conditions for an ADDS located in a licensed clinic or a health facility. The bill instead would prohibit an ADDS from being installed or operated in the state unless specified requirements are met, including a license for the ADDS issued by the board to the holder of a current, valid, and active pharmacy license. The bill would limit the placement and operation of an ADDS to specified locations, including the licensed, pharmacy holding that ADDS license, a licensed health facility, a licensed clinic, or a specified medical office. The bill would require the pharmacy holding the ADDS license to own the ADDS and the drugs and devices located within it, and would require that pharmacy to supervise the operation of the ADDS. The bill would prescribe specified stocking and transfer requirements for those drugs and devices. The bill would require the pharmacy holding the ADDS license to provide training on the operation and use of that ADDS to specified individuals and would require the pharmacy to complete periodic self-assessments. The bill would require additional conditions for automated patient dispensing systems, as defined. The bill would also authorize a pharmacy inspector employed by the board to enter

the location, or proposed location, of an ADDS to inspect the location pursuant to these provisions.

**Staff Comments:** This measure is board sponsored and includes the provisions approved by the board during its January 2018 meeting. This proposal has been amended to better mesh with existing law.

2. AB 1751 (Low) Controlled Substances: CURES Database

**Version:** As introduced January 3, 2018

**Status:** Referred to Assembly Public Safety Committee

**Board Position:** Support

**Summary:** This measure will allow the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for purposes of interstate sharing of controlled substances reporting information

**Staff Comments:** The board is the originator of this measure. The board established a support position on this measure during the February board meeting.

3. AB 1752 (Low) Controlled Substances: CURES Database

**Version:** Introduced January 3, 2018

**Status:** Referred to Assembly Business and Professions Committee

**Summary:** This measure expands CURES reporting to also include Schedule V controlled substances and reduces the time frame for reporting to the CURES system to one working day.

**Staff Comments:** The board is the originator of some of the provisions included in this measure. During the board's February 2018 meeting, the Board voted to take a position of Support for this measure. Since that time, the measure was amended to remove the authority of the board to, through regulation, add additional medications that would be tracked in the CURES database.

4. AB 2086 (Gallagher) Controlled Substances: CURES Database

**Version:** Amended April 3, 2018

**Status:** Re-Referred to Assembly Appropriations Committee

**Summary:** Allow prescribers to request a list of patients for whom they are listed as being the prescriber in the CURES database.

**Staff Comments:** The board is the originator of this bill. During the July 2017 Board meeting it was discovered that a statutory change was needed in order to allow prescribers to access reports in CURES.

5. AB 2783 (O'Donnell) Controlled Substances: Hydrocodone Combination products: Schedules

**Version:** Amended April 11, 2018

**Status:** Re-Referred to Assembly Appropriations Committee

**Summary:** Reclassify specific hydrocodone combination products as Schedule II controlled substances.

**Staff Comments:** This is the board's measure that was initially intended to reconcile California state schedules with the Federal schedules as approved by the Board at its January 11, 2018 meeting. Although this bill does not go that far, this change does begin the reconciliation.

6. AB 2789 (Wood) Health Care Practitioners: Prescriptions: Electronic Data Transmission

**Version:** Amended April 3, 2018

**Status:** Assembly Appropriations

**Summary:** Require by January 1, 2021, all prescriptions issued by licensed prescribers in California be issued as an electronic transmission prescription (e-prescription). By January 2, 2021 all pharmacies, pharmacists or other practitioners authorized to dispense or furnish a prescription must have the capability to receive an e-prescription.

**Staff Comments:** The board is the originator of this bill. During the January 2018 Board meeting, the board discussed how the abuse of pharmaceutical drugs has skyrocketed in the United States, over the past decade, and has led to the current opioid epidemic. E-prescribing can address the opioid epidemic by substantially reducing the opportunities for persons to steal, alter, "doctor shop," or counterfeit prescriptions, thus decreasing unsupervised access to medication

A copy of each measure and bill analysis is provided in **Attachment 1**.

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

**Attachment 2**

1. AB 1753 (Low) Controlled Substances: CURES Database

**Version:** As introduced January 3, 2018

**Status:** Referred to Assembly Public Safety Committee

**Summary:** This measure would limit the number of authorized security printers approved by the DOJ to three effective January 1, 2020. Further, this measure would require security forms to contain a unique serialized number that must be reported to CURES and would establish reporting requirements to the DOJ on the

delivery of security forms to a prescriber.

**Staff Comments:** The author arrived at the number of printers based on input from the Department of Justice.

5. AB 1953 (Wood) Skilled Nursing Facilities: Disclosure of Interests in Business Providing Services

**Version:** As introduced January 29, 2018

**Status:** Referred to Assembly Health Committee

**Summary:** This bill would require disclosures by an applicant for a license to operate a skilled nursing facility or by a skilled nursing facility licensee relating to an ownership or control interest of 5% or more in a corporation, sole proprietorship, or partnership, that provides, or is proposed to provide, any service to the skilled nursing facility.

**Staff Comments:** More information regarding related party transactions and skilled nursing facilities will be available soon. Board staff recommends that amendments be offered to require a similar disclosure by anyone applying for a Pharmacy license. This additional provision would support the intent of this legislation by also highlighting any relationship between a pharmacy and a SNF.

2. AB 2037(Bonta) Pharmacy: Automated Drug Delivery Systems

**Version:** Introduced February 6, 2018

**Status:** Referred to Assembly Business, Professions and Consumer Protection

**Summary:** Allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug delivery system (ADDS)

**Staff Comments:** This measure is similar to last year's SB 528 (Stone). The board established a support if amended position on that measure. As part of its request, the board requested that the provisions not be limited to just 340B clinics. The board's amendments were not incorporated into the measure last year and the measure ultimately stalled in committee.

9. AB 2138 (Chiu/Low) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction

**Version:** Amended April 2, 2018

**Status:** Assembly Business and Professions Committee hearing April 24, 2018

**Summary:** This bill would place significant limits on the Board's enforcement process including limits on when a board can deny, revoke or suspend a license

based on a conviction or other act and limits on the length of probation. It also limits the Board's timeframe to decide on a petition to modify probation to 90 days.

**Staff Comments:** Board staff have significant policy concerns that this measure will negatively impact the board's ability to thoroughly review and consider criminal arrests and/or convictions of applicants and licensees. The policy being put forth in this measure runs contrary to the board's consumer protection mandate as well as efforts by the Legislature to strengthen the ability of programs within the DCA to more robustly protect consumers. Creating barriers or limiting information the board can consider when making a licensing decision and enforcement action will undo gains the board has made in this area and significantly undermine the board's consumer protection mandate.

11. AB 2256 (Santiago) Law Enforcement Agencies: Opioid Antagonist

**Version:** Introduced February 13, 2018

**Status:** Assembly Public Safety

**Summary:** Allow law enforcement agencies throughout the state to acquire Naloxone from a pharmacy without a prescription if it is exclusively for use by employees of the agency who have completed training in administering an opioid antagonist and acquisition and disposition records are maintained by the law enforcement agency for three years.

**Staff Comments:** This bill is consistent with the board's policy to support the availability and use of naloxone as an important tool to reduce deaths caused by opioid overdose.

3. AB 2409 (Kiley) Professions and vocations: occupational regulations

**Version:** Amended April 16, 2018

**Status:** Assembly Business and Professions

**Summary:** Establishes the right of a person to engage in a lawful profession without being subject to an occupational regulation that imposes a substantial burden on that right. Included within this right is the right to not have the person's criminal record, delinquent taxes, or student loan payments be used as grounds for an automatic denial of a license. Authorizes a person to petition a board to review an occupational regulation for compliance with the above rights. Authorize a person with a criminal record to petition a board at any time for a determination of whether the person's criminal record will automatically disqualify the person from obtaining a license from the board and would specify the criteria a board is allowed to use in making that determination.

**Staff Comments:** This bill failed Assembly B&P and will be reconsidered by committee. Board staff have concerns that establishing a statutory right to a license is counter to the Board's consumer protection mandate. Staff notes that last year

the board was successful in negotiating an amendment to changes in the deferred entry of judgement program by excluding some of the provisions from applying to healing arts licensed professional. Board staff suggest that similar amendments be requested and if not accepted the board change its positions to an oppose position.

4. AB 2576 (Aguiar-Curry) Emergencies: Healthcare

**Version:** Amended April 25,2018

**Status:** Assembly Appropriations

**Summary:** Expands the emergency provisions to authorize a clinic licensed by the Board to purchase drugs at wholesale for administration or dispensing to patients, to furnish dangerous drugs or devices in reasonable quantities without a prescription during a federal, state, or local emergency.

**Staff Comments:** The board currently has authority to issue temporary permits as well as a process to waive certain requirements in the event of a declared natural disaster. Many of these provisions currently only apply to a pharmacy. It appears that allowing greater flexibility for clinic licenses would be consistent with the board's policy of ensuring displaced patients have ready access to prescription medications. Board staff provided technical input to reconcile the provisions with current law.

16. AB 2859 (Caballero) Pharmacy: Safe Storage Products

**Version:** Amended April 12, 2018

**Status:** Assembly Appropriations Committee

**Summary:** Require community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products within the pharmacy.

**Staff Comments:** This measure appears consistent with the board's policy to combat the opioid epidemic. Board staff recommend offering amendments to remove (c)(1) and (2) as the Board already has the authority to cite and fine for noncompliance with regulations.

17. AB 2863 (Nazarian) Pharmacy: Prescriptions: Pharmacy Benefit Manager: Cost

**Version:** Amended April 11, 2018

**Status:** Assembly Business & Professions

**Summary:** This bill would limit the amount a health care service plan, health insurer, or pharmacy benefit manager may require an enrollee or insured to pay at the point of sale for a covered prescription to the lesser of the applicable cost-sharing amount or the retail price.

**Staff Comments:** This measure seems to be consistent with the Board's consumer protection mandate by ensuring the consumer be charged the lesser amount for their prescriptions.

18. SB 1021 (Wiener) Prescription Drugs

**Version:** Amended April 16, 2018

**Status:** Senate Health Committee

**Summary:** This bill would eliminate the sunset date on provisions of AB 339 (Gordon, 2015).which, added Section 1342.71 to the Health & Safety Code, capping monthly copays at \$250 total per patient; preventing discrimination against patients with specific conditions, by ensuring that all of the drugs for a given disease could not be placed in the most expensive tier; and extending all protections to plans in the large employer market as well as the individual and small employer coverage markets, of January 1, 2020.

**Staff Comments:** Amendments made in Senate Health Committee added language similar to AB 2863 capping the co pay amount at the retail price if it is lower than the co pay.

19. SB 1109 (Bates) Controlled Substances: Schedule II Drugs: Opioids

**Version:** Amended April 4, 2018

**Status:** Senate Health

**Summary:** This measure contains provisions relating to education of opioid use. Specifically related to our board, it would require a warning label on all Schedule II controlled substances.

**Staff Comments:** This bill was recently amended in committee and the resulting amendments have not been published. Generally, the amendments will remove the requirement for the Board to promulgate emergency regulations regarding an opioid warning label, as well as no longer requiring the minor and parent/guardian to sign a statement upon being informed of the risks of opioid use, rather require a consultation by the prescriber, and requiring the use of the Opioid fact sheet by the Centers for Disease control by schools and sports organizations.

20. SB 1229 (Stone) Pharmacists: Opioid Medications: Consultation

**Version:** Amended April 9, 2018

**Status:** Senate Business, Professions and Economic Development

**Summary:** Currently pharmacists are required to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription. This bill would require, except as specified, a pharmacist to provide oral consultation before dispensing any opioid medication to a patient or the patient's agent for the first

time and prohibit a pharmacist from dispensing the medication if the patient or patient's agent declines the consultation.

**Staff Comments:** The board has previously expressed concern with low patient consultation rates. The policy being offered in this measure appears to address the board's concern as it relates to patient consultation for opioids. As part of its consideration it may be appropriate to consider if the current elements for patient consultation should be more specific for opioid prescriptions and if the current fine is appropriate for such violations.

21. SB 1240 (Stone) Prescription Drugs: CURES Database

**Staff Comments:** Board staff was informed that this bill will not be moving forward, as such, no analysis is provided.

22. SB 1254 (Stone) Hospital Pharmacies: Medication Profiles or Lists for High-Risk Patients

**Version:** Amended April 2, 2018

**Status:** Senate Business, Professions and Economic Development

**Summary:** This bill would require a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge of the patient. The criteria for determining whether a patient is high risk will be established by each hospital. Additionally, this measure would allow for this duty to be performed by a pharmacy technician or a pharmacy intern, if they have successfully completed training and proctoring by a pharmacist and where a quality assurance program is used to monitor competency.

**Staff Comments:** This measure is being brought to the committee to seek input on the policy of the measure. The board previously heard a presentation on a study underway at Cedars Sinai regarding high risk patients. This bill was amended on April 23, 2018 to add a provision that the Board may adopt rules to carry out the provisions of the bill.

25. SB 1286 (Pan) Pharmacy Technicians

**Staff Comments:** Staff has been advised by the author of this measure that they will not be moving forward, as such, the analysis for this bill is not being provided.

26. SB 1373 (Stone) General Acute Care Hospitals: Minimum Levels of Pharmaceutical Staff

**Staff Comments:** This measure did not receive the votes to pass the Senate Health committee and as such no analysis is provided.

28. SB 1442 (Wiener) Pharmacies: Staffing

**Version:** Amended April 2, 2018

**Status:** Senate Appropriations

**Summary:** Specify that a pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy unless the pharmacist is assisted at all times by another employee as specified.

**Staff Comments:** This measure recently passed out of the Senate Business, Professions, and Economic Development committee. As part of the committee's discussion, concern was raised about independent pharmacies and the possible negative impact to such businesses.

A copy of each measure and bill analysis is provided in **Attachment 2**.

#### **IV. Regulations for Discussion and Consideration**

**a. Board Adopted - Submitted for Administrative Review to the Office of Administrative Law: Proposed Regulations to Amend Title 16 CCR section 1749, Related to the Board's Fees**

The board currently has one regulation undergoing review by the Department or the Office of Administrative Law, the proposed regulations to amend Title 16 CCR section 1749.

**Summary of Regulation:**

This regulation updates the board's fee schedule to incorporate changes made to pharmacy law in Business and Professions Code section 4400 on July 1, 2017.

**Timeline:**

Approved by Board: October 27, 2016

Submitted to DCA for Pre-Notice Review: November 4, 2016

Rulemaking Initiated: April 14, 2017

Adopted by Board: July 26, 2017

Submitted to DCA: October 10, 2017

Submitted to OAL: March 9, 2018

Final date for OAL review: April 20, 2018

The board-adopted text is posted on the board's website and can be obtain using the following link - - [http://www.pharmacy.ca.gov/laws\\_regs/pending\\_regs.shtml](http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml)

**b. Board Approved to Initiate Rulemaking – Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or Returned to Board Staff for Revisions Pursuant to Such Review**

**Attachment 3**

Members have previously requested that regulations without action for over 30 days be highlighted. As such, regulations with inactivity for over 30 days are indicated below in **red**.

The board has several regulations returned to board staff for modification after completion of the department's pre-notice review, including:

1. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors

**Summary of Regulation:**

This regulation establishes the regulatory framework for third-party logistics providers.

**Timeline:**

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: February 9, 2017

Returned to the board on: February 28, 2017

Re-submitted to DCA for Pre-Notice Review: October 25, 2017

**Returned to the board on: March 26, 2018**

Board staff is currently amending the rulemaking file to incorporate the changes requested by DCA Legal on March 26<sup>th</sup>.

2. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

**Summary of Regulation:**

This regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

**Timeline:**

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 23, 2017

Returned to the board: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: August 21, 2017

Returned to the board: February 24, 2018

**Modified language approved by board: March 27, 2018**

Board staff is currently amending the rulemaking file to incorporate the changes to the language approved by the board on March 27<sup>th</sup>.

3. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

**Summary of Regulation:**

This regulation amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

**Timeline:**

Approved by Board: January 24, 2017

Submitted to DCA for Pre-Notice Review: April 27, 2017

**Returned to the board: January 18, 2018**

Board staff is currently amending the rulemaking file to incorporate the changes requested by DCA Legal on January 18<sup>th</sup>.

4. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

**Summary of Regulation:**

This regulation amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

**Timeline:**

Approved by Board: May 4, 2017

Submitted to DCA for Pre-Notice Review: May 31, 2017

Returned to the board: January 18, 2018

**Modified language approved by board: March 27, 2018**

Board staff is currently amending the rulemaking file to incorporate the changes to the language approved by the board on March 27<sup>th</sup>.

5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Trusts

**Summary of Regulation:**

This regulation amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

**Timeline:**

Approved by Board: October 27, 2016

Submitted to DCA for Pre-Notice Review: January 26, 2017

**Returned to the Board on: March 28, 2017**

Board staff is currently reviewing the changes requested by DCA Legal to determine the next course of action for this rulemaking.

6. Proposed Regulations to Add Title 16 CCR section 1717.5 Related to Automatic Refill Programs

**Summary of Regulation:**

This regulation establishes regulatory requirements for automated refill programs.

**Timeline:**

Approved by Board: May 3, 2017

Submitted to DCA for Pre-Notice Review: November 7, 2017

**Returned to the Board on: March 26, 2018**

Board staff is currently amending the rulemaking file to incorporate the changes requested by DCA Legal on March 26<sup>th</sup>.

7. Proposed Regulations to Amend Title 16 CCR sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, Related to Compounding

**Summary of Regulation:**

This regulation formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system.

**Recent Update:**

As part of the discussion during the Enforcement and Compounding Committee meeting, the committee noted the need to readopt the emergency regulations given the delay in the promulgation permanent regulation.

The emergency regulations expire on June 18, 2018. Without re-adoption of the emergency regulations, there will be significant adverse impact to patients related to the current requirement for the establishment of beyond use dates for non-sterile compounded drug preparations.

Board staff recommend that the enforcement committee's recommendation to re-adopt the emergency regulations be ratified by this committee as well as the full board when considered.

**Timeline:**

Approved by Board: July 25, 2017

**Submitted to DCA for Pre-Notice Review: November 20, 2017. According to DCA, this regulation is currently under review by the DCA Budget Office.**

8. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

**Summary of Regulation:**

This regulation updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

**Timeline:**

Approved by Board: November 8, 2017

Submitted to DCA for Pre-Notice Review: February 2, 2018

Returned to the Board on: April 17, 2018

**Attachment 3** includes the board approved text for each regulation.

**c. Board Approved to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency**

**Attachment 4**

Members have previously requested that regulations without action for over 30 days be highlighted. As such, regulations with inactivity for over 30 days are indicated below in **red**.

1. Proposed Regulations to Amend Title 16 CCR section 1735.2 Related to the Compounding Self-Assessment Form 17M-39

**Summary of Regulation:**

This regulation updates the Self-Assessment form 17M-39 (rev. 12/16) as incorporated by reference in Title 16 CCR section 1735.2. Additionally, this regulation updates section 1735.2 with clarifying language as to the completion and certification requirements of the self-assessment form.

**Timeline:**

**Approved by Board: November 8, 2017**

2. Proposed Regulations to Amend Title 16 CCR section 1793.9 Related to Remote Dispensing Technicians

**Summary of Regulation:**

This regulation establishes regulatory requirements for pharmacy technicians working in a remote dispensing site pharmacy.

**Timeline:**

**Approved by Board: February 6, 2018**

3. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

**Summary of Regulation:**

This regulation updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

**Timeline:**

**Approved by Board: February 6, 2018**

4. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update Self-Assessment Form 17M-26

**Summary of Regulation:**

This regulation updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

**Timeline:**

**Approved by Board: November 8, 2017**

**Attachment 4** includes the board approved text for each regulation.

**V. Future Committee Meeting Dates**

- July 10, 2018
- October 23, 2018

# **Attachment 1**

AMENDED IN SENATE APRIL 17, 2018

**SENATE BILL**

**No. 1447**

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**Introduced by Senator Hernandez**

February 16, 2018

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An act to amend Sections 4008 and 4400 of, to add Section 4017.3 to, to add Article 25 (commencing with Section 4427) to Chapter 9 of Division 2 of, and to repeal ~~Section 4105.5~~ *Sections 4105.5, 4119.1, and 4186* of, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1447, as amended, Hernandez. Pharmacy: automated drug delivery ~~systems: licensing: systems.~~ *systems.*

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy, within the Department of Consumer Affairs, to license and regulate the practice of pharmacy. Existing law makes any violation of the Pharmacy Law punishable as a crime.

Existing law generally requires a pharmacy that owns or provides dangerous drugs *or devices* dispensed through an automated drug delivery system (ADDS) to register the system, as provided, and authorizes the pharmacy to use the ADDS only if certain conditions are satisfied. Existing law authorizes the board to prohibit a pharmacy from using an ADDS if the board determines that those conditions are not satisfied. Existing law exempts from these requirements an ADDS operated by a licensed hospital pharmacy for doses administered in a facility operated under a consolidated license. Existing law specifies additional conditions for an ADDS located in a licensed clinic or a health facility, as defined. Existing law authorizes a pharmacy or licensed wholesaler that is also an emergency medical services provider

agency to restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system that is licensed by the board, as provided. Existing law authorizes an inspector employed by the board to enter specified locations to inspect those locations for compliance with the Pharmacy Law.

This bill would repeal the general ADDS ~~provisions~~. *provisions and the additional conditions for an ADDS located in a licensed clinic or a health facility.* The bill instead would prohibit an ADDS ~~unit~~ from being installed or operated in the state unless specified requirements are met, including a license for the ADDS ~~unit~~ issued by the board to the holder of a current, valid, and active pharmacy ~~license~~, and would ~~require the pharmacy holding the license to complete periodic self-assessments~~. *license.* The bill would limit the placement and operation of an ADDS ~~unit~~ to specified locations, including ~~a the licensed pharmacy, pharmacy holding that ADDS license, a licensed health facility, a licensed clinic, or a specified medical office.~~ The bill would require the pharmacy holding the ADDS license to own the *ADDS and the drugs and devices located within the ADDS unit and it, and would require that pharmacy to supervise the operation of the ADDS.* The bill would prescribe specified stocking and transfer requirements for those drugs and devices. *The bill would require the pharmacy holding the ADDS license to provide training on the operation and use of that ADDS to specified individuals and would require the pharmacy to complete periodic self-assessments.* The bill would require additional conditions for automated patient dispensing systems, as defined. The bill would also authorize a pharmacy inspector employed by the board to enter the location, or proposed location, of an ADDS ~~unit~~ to inspect the location pursuant to these provisions. Because a violation of the Pharmacy Law is punishable as a crime, the bill would expand the scope of an existing crime, thereby imposing 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:*

1 SECTION 1. Section 4008 of the Business and Professions  
2 Code is amended to read:

3 4008. (a) Except as provided by Section 159.5, the board may  
4 employ legal counsel and inspectors of pharmacy. The inspectors,  
5 whether the inspectors are employed by the board or the  
6 department's Division of Investigation, may inspect during business  
7 hours all pharmacies, wholesalers, dispensaries, stores, or places  
8 where drugs or devices are compounded, prepared, furnished,  
9 dispensed, or stored.

10 (b) Notwithstanding subdivision (a), a pharmacy inspector may  
11 inspect or examine a physician's office or clinic that does not have  
12 a permit under Section 4180 or 4190 only to the extent necessary  
13 to determine compliance with and to enforce either Section 4080  
14 or 4081.

15 (c) (1) (A) A pharmacy inspector employed by the board or in  
16 the department's Division of Investigation shall have the authority,  
17 as a public officer, to arrest, without warrant, any person whenever  
18 the officer has reasonable cause to believe that the person to be  
19 arrested has, in his or her presence, violated a provision of this  
20 chapter or of Division 10 (commencing with Section 11000) of  
21 the Health and Safety Code.

22 (B) If the violation is a felony, or if the arresting officer has  
23 reasonable cause to believe that the person to be arrested has  
24 violated any provision that is declared to be a felony, although no  
25 felony has in fact been committed, he or she may make an arrest  
26 although the violation or suspected violation did not occur in his  
27 or her presence.

28 (2) In any case in which an arrest authorized by this subdivision  
29 is made for an offense declared to be a misdemeanor, and the  
30 person arrested does not demand to be taken before a magistrate,  
31 the arresting inspector may, instead of taking the person before a  
32 magistrate, follow the procedure prescribed by Chapter 5C  
33 (commencing with Section 853.5) of Title 3 of Part 2 of the Penal  
34 Code. That chapter shall thereafter apply with reference to any  
35 proceeding based upon the issuance of a citation pursuant to this  
36 authority.

37 (d) There shall be no civil liability on the part of, and no cause  
38 of action shall arise against, a person, acting pursuant to subdivision

1 (a) within the scope of his or her authority, for false arrest or false  
2 imprisonment arising out of an arrest that is lawful, or that the  
3 arresting officer, at the time of the arrest, had reasonable cause to  
4 believe was lawful. An inspector shall not be deemed an aggressor  
5 or lose his or her right to self-defense by the use of reasonable  
6 force to effect the arrest, to prevent escape, or to overcome  
7 resistance.

8 (e) Any inspector may serve all processes and notices throughout  
9 the state.

10 (f) A pharmacy inspector employed by the board may enter a  
11 facility licensed pursuant to subdivision (c) or (d) of Section 1250  
12 of the Health and Safety Code to inspect an automated drug  
13 delivery system operated pursuant to Section ~~4119 or 4119.1~~ 4119.

14 (g) A pharmacy inspector employed by the board may enter the  
15 location, or proposed location, of an automated drug delivery  
16 system to inspect that automated drug delivery system pursuant  
17 to Article 25 (commencing with Section 4427).

18 SEC. 2. Section 4017.3 is added to the Business and Professions  
19 Code, to read:

20 4017.3. (a) “Automated Drug Delivery System” (ADDS) ~~has~~  
21 ~~the same meaning as paragraph (1) of subdivision (a) of Section~~  
22 ~~1261.6 of the Health and Safety Code:~~ *means a mechanical system*  
23 *that performs operations or activities, other than compounding or*  
24 *administration, relative to the storage, dispensing, or distribution*  
25 *of drugs. An ADDS shall collect, control, and maintain all*  
26 *transaction information to accurately track the movement of drugs*  
27 *into and out of the system for security, accuracy, and*  
28 *accountability.*

29 (b) An “Automated Unit Dose System” (AUDS) is an ADDS  
30 ~~unit from which health care providers with appropriate authority~~  
31 ~~retrieve unit doses of drugs for administration to patients. for~~  
32 *storage and retrieval of unit doses of drugs for administration to*  
33 *patients by persons authorized to perform these functions.*

34 (c) An “Automated Patient Dispensing System” (APDS) is an  
35 ~~ADDS unit from which drugs and devices may be dispensed to~~  
36 ~~patients pursuant to authorization by a pharmacist. for storage and~~  
37 *dispensing of prescribed drugs directly to patients pursuant to*  
38 *prior authorization by a pharmacist.*

39 SEC. 3. Section 4105.5 of the Business and Professions Code  
40 is repealed.

1     *SEC. 4. Section 4119.1 of the Business and Professions Code*  
2     *is repealed.*

3     ~~4119.1. (a) A pharmacy may provide pharmacy services to a~~  
4     ~~health facility licensed pursuant to subdivision (c), (d), or both, of~~  
5     ~~Section 1250 of the Health and Safety Code, through the use of~~  
6     ~~an automated drug delivery system that need not be located at the~~  
7     ~~same location as the pharmacy.~~

8     ~~(b) Drugs stored in an automated drug delivery system shall be~~  
9     ~~part of the inventory of the pharmacy providing pharmacy services~~  
10    ~~to that facility, and drugs dispensed from the pharmacy system~~  
11    ~~shall be considered to have been dispensed by that pharmacy.~~

12    ~~(c) (1) The pharmacy shall maintain records of the acquisition~~  
13    ~~and disposition of dangerous drugs and dangerous devices stored~~  
14    ~~in the automated drug delivery system separate from other~~  
15    ~~pharmacy records.~~

16    ~~(2) The pharmacy shall own and operate the automated drug~~  
17    ~~delivery system.~~

18    ~~(3) The pharmacy shall provide training regarding the operation~~  
19    ~~and use of the automated drug delivery system to both pharmacy~~  
20    ~~and health facility personnel using the system.~~

21    ~~(4) The pharmacy shall operate the automated drug delivery~~  
22    ~~system in compliance with Section 1261.6 of the Health and Safety~~  
23    ~~Code.~~

24    ~~(d) The operation of the automated drug delivery system shall~~  
25    ~~be under the supervision of a licensed pharmacist. To qualify as a~~  
26    ~~supervisor for an automated drug delivery system, the pharmacist~~  
27    ~~need not be physically present at the site of the automated drug~~  
28    ~~delivery system and may supervise the system electronically.~~

29    ~~(e) This section shall not be construed to revise or limit the use~~  
30    ~~of automated drug delivery systems as permitted by the board in~~  
31    ~~any licensed health facility other than a facility defined in~~  
32    ~~subdivision (c) or (d), or both, of Section 1250 of the Health and~~  
33    ~~Safety Code.~~

34    *SEC. 5. Section 4186 of the Business and Professions Code is*  
35    *repealed.*

36    ~~4186. (a) Automated drug delivery systems, as defined in~~  
37    ~~subdivision (h), may be located in any clinic licensed by the board~~  
38    ~~pursuant to Section 4180. If an automated drug delivery system is~~  
39    ~~located in a clinic, the clinic shall develop and implement written~~  
40    ~~policies and procedures to ensure safety, accuracy, accountability,~~

1 security, patient confidentiality, and maintenance of the quality,  
2 potency, and purity of drugs. All policies and procedures shall be  
3 maintained at the location where the automated drug system is  
4 being used.

5 (b) ~~Drugs shall be removed from the automated drug delivery~~  
6 ~~system only upon authorization by a pharmacist after the~~  
7 ~~pharmacist has reviewed the prescription and the patient's profile~~  
8 ~~for potential contraindications and adverse drug reactions. Drugs~~  
9 ~~removed from the automated drug delivery system shall be~~  
10 ~~provided to the patient by a health professional licensed pursuant~~  
11 ~~to this division.~~

12 (c) ~~The stocking of an automated drug delivery system shall be~~  
13 ~~performed by a pharmacist.~~

14 (d) ~~Review of the drugs contained within, and the operation and~~  
15 ~~maintenance of, the automated drug delivery system shall be the~~  
16 ~~responsibility of the clinic. The review shall be conducted on a~~  
17 ~~monthly basis by a pharmacist and shall include a physical~~  
18 ~~inspection of the drugs in the automated drug delivery system, an~~  
19 ~~inspection of the automated drug delivery system machine for~~  
20 ~~cleanliness, and a review of all transaction records in order to~~  
21 ~~verify the security and accountability of the system.~~

22 (e) ~~The automated drug delivery system used at the clinic shall~~  
23 ~~provide for patient consultation pursuant to Section 1707.2 of Title~~  
24 ~~16 of the California Code of Regulations with a pharmacist via a~~  
25 ~~telecommunications link that has two-way audio and video.~~

26 (f) ~~The pharmacist operating the automated drug delivery system~~  
27 ~~shall be located in California.~~

28 (g) ~~Drugs dispensed from the automated drug delivery system~~  
29 ~~shall comply with the labeling requirements in Section 4076.~~

30 (h) ~~For purposes of this section, an "automated drug delivery~~  
31 ~~system" means a mechanical system controlled remotely by a~~  
32 ~~pharmacist that performs operations or activities, other than~~  
33 ~~compounding or administration, relative to the storage, dispensing,~~  
34 ~~or distribution of prepackaged dangerous drugs or dangerous~~  
35 ~~devices. An automated drug delivery system shall collect, control,~~  
36 ~~and maintain all transaction information to accurately track the~~  
37 ~~movement of drugs into and out of the system for security,~~  
38 ~~accuracy, and accountability.~~

1     ~~SEC. 4.~~

2     *SEC. 6.* Section 4400 of the Business and Professions Code is  
3 amended to read:

4     4400. The amount of fees and penalties prescribed by this  
5 chapter, except as otherwise provided, is that fixed by the board  
6 according to the following schedule:

7     (a) The fee for a nongovernmental pharmacy license shall be  
8 five hundred twenty dollars (\$520) and may be increased to five  
9 hundred seventy dollars (\$570). The fee for the issuance of a  
10 temporary nongovernmental pharmacy permit shall be two hundred  
11 fifty dollars (\$250) and may be increased to three hundred  
12 twenty-five dollars (\$325).

13     (b) The fee for a nongovernmental pharmacy license annual  
14 renewal shall be six hundred sixty-five dollars (\$665) and may be  
15 increased to nine hundred thirty dollars (\$930).

16     (c) The fee for the pharmacist application and examination shall  
17 be two hundred sixty dollars (\$260) and may be increased to two  
18 hundred eighty-five dollars (\$285).

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

23     (e) The fee for a pharmacist license shall be one hundred  
24 ninety-five dollars (\$195) and may be increased to two hundred  
25 fifteen dollars (\$215). The fee for a pharmacist biennial renewal  
26 shall be three hundred sixty dollars (\$360) and may be increased  
27 to five hundred five dollars (\$505).

28     (f) The fee for a nongovernmental wholesaler or third-party  
29 logistics provider license and annual renewal shall be seven  
30 hundred eighty dollars (\$780) and may be increased to eight  
31 hundred twenty dollars (\$820). The application fee for any  
32 additional location after licensure of the first 20 locations shall be  
33 three hundred dollars (\$300) and may be decreased to no less than  
34 two hundred twenty-five dollars (\$225). A temporary license fee  
35 shall be seven hundred fifteen dollars (\$715) and may be decreased  
36 to no less than five hundred fifty dollars (\$550).

37     (g) The fee for a hypodermic license shall be one hundred  
38 seventy dollars (\$170) and may be increased to two hundred forty  
39 dollars (\$240). The fee for a hypodermic license renewal shall be

1 two hundred dollars (\$200) and may be increased to two hundred  
2 eighty dollars (\$280).

3 (h) (1) The fee for application, investigation, and issuance of  
4 a license as a designated representative pursuant to Section 4053,  
5 as a designated representative-3PL pursuant to Section 4053.1, or  
6 as a designated representative-reverse distributor pursuant to  
7 Section 4053.2 shall be one hundred fifty dollars (\$150) and may  
8 be increased to two hundred ten dollars (\$210).

9 (2) The fee for the annual renewal of a license as a designated  
10 representative, designated representative-3PL, or designated  
11 representative-reverse distributor shall be two hundred fifteen  
12 dollars (\$215) and may be increased to three hundred dollars  
13 (\$300).

14 (i) (1) The fee for the application, investigation, and issuance  
15 of a license as a designated representative for a veterinary  
16 food-animal drug retailer pursuant to Section 4053 shall be one  
17 hundred fifty dollars (\$150) and may be increased to two hundred  
18 ten dollars (\$210).

19 (2) The fee for the annual renewal of a license as a designated  
20 representative for a veterinary food-animal drug retailer shall be  
21 two hundred fifteen dollars (\$215) and may be increased to three  
22 hundred dollars (\$300).

23 (j) (1) The application fee for a nonresident wholesaler or  
24 third-party logistics provider license issued pursuant to Section  
25 4161 shall be seven hundred eighty dollars (\$780) and may be  
26 increased to eight hundred twenty dollars (\$820).

27 (2) For nonresident wholesalers or third-party logistics providers  
28 that have 21 or more facilities operating nationwide the application  
29 fees for the first 20 locations shall be seven hundred eighty dollars  
30 (\$780) and may be increased to eight hundred twenty dollars  
31 (\$820). The application fee for any additional location after  
32 licensure of the first 20 locations shall be three hundred dollars  
33 (\$300) and may be decreased to no less than two hundred  
34 twenty-five dollars (\$225). A temporary license fee shall be seven  
35 hundred fifteen dollars (\$715) and may be decreased to no less  
36 than five hundred fifty dollars (\$550).

37 (3) The annual renewal fee for a nonresident wholesaler license  
38 or third-party logistics provider license issued pursuant to Section  
39 4161 shall be seven hundred eighty dollars (\$780) and may be  
40 increased to eight hundred twenty dollars (\$820).

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

4 (l) The fee for an intern pharmacist license shall be one hundred  
5 sixty-five dollars (\$165) and may be increased to two hundred  
6 thirty dollars (\$230). The fee for transfer of intern hours or  
7 verification of licensure to another state shall be twenty-five dollars  
8 (\$25) and may be increased to thirty dollars (\$30).

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

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

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

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

24 (q) The fee for any applicant for a nongovernmental clinic  
25 license shall be five hundred twenty dollars (\$520) for each license  
26 and may be increased to five hundred seventy dollars (\$570). The  
27 annual fee for renewal of the license shall be three hundred  
28 twenty-five dollars (\$325) for each license and may be increased  
29 to three hundred sixty dollars (\$360).

30 (r) The fee for the issuance of a pharmacy technician license  
31 shall be one hundred forty dollars (\$140) and may be increased to  
32 one hundred ninety-five dollars (\$195). The fee for renewal of a  
33 pharmacy technician license shall be one hundred forty dollars  
34 (\$140) and may be increased to one hundred ninety-five dollars  
35 (\$195).

36 (s) The fee for a veterinary food-animal drug retailer license  
37 shall be four hundred thirty-five dollars (\$435) and may be  
38 increased to six hundred ten dollars (\$610). The annual renewal  
39 fee for a veterinary food-animal drug retailer license shall be three

1 hundred thirty dollars (\$330) and may be increased to four hundred  
2 sixty dollars (\$460).

3 (t) The fee for issuance of a retired license pursuant to Section  
4 4200.5 shall be thirty-five dollars (\$35) and may be increased to  
5 forty-five dollars (\$45).

6 (u) The fee for issuance of a nongovernmental sterile  
7 compounding pharmacy license or a hospital satellite compounding  
8 pharmacy shall be one thousand six hundred forty-five dollars  
9 (\$1,645) and may be increased to two thousand three hundred five  
10 dollars (\$2,305). The fee for a temporary license shall be five  
11 hundred fifty dollars (\$550) and may be increased to seven hundred  
12 fifteen dollars (\$715). The annual renewal fee of the license shall  
13 be one thousand three hundred twenty-five dollars (\$1,325) and  
14 may be increased to one thousand eight hundred fifty-five dollars  
15 (\$1,855).

16 (v) The fee for the issuance of a nonresident sterile compounding  
17 pharmacy license shall be two thousand three hundred eighty  
18 dollars (\$2,380) and may be increased to three thousand three  
19 hundred thirty-five dollars (\$3,335). The annual renewal of the  
20 license shall be two thousand two hundred seventy dollars (\$2,270)  
21 and may be increased to three thousand one hundred eighty dollars  
22 (\$3,180). In addition to paying that application fee, the nonresident  
23 sterile compounding pharmacy shall deposit, when submitting the  
24 application, a reasonable amount, as determined by the board,  
25 necessary to cover the board's estimated cost of performing the  
26 inspection required by Section 4127.2. If the required deposit is  
27 not submitted with the application, the application shall be deemed  
28 to be incomplete. If the actual cost of the inspection exceeds the  
29 amount deposited, the board shall provide to the applicant a written  
30 invoice for the remaining amount and shall not take action on the  
31 application until the full amount has been paid to the board. If the  
32 amount deposited exceeds the amount of actual and necessary  
33 costs incurred, the board shall remit the difference to the applicant.

34 (w) The fee for the issuance of an outsourcing facility license  
35 shall be two thousand two hundred seventy dollars (\$2,270) and  
36 may be increased to up to three thousand one hundred eighty  
37 dollars (\$3,180) by the board. The fee for the renewal of an  
38 outsourcing facility license shall be one thousand three hundred  
39 twenty-five dollars (\$1,325) and may be increased to up to one  
40 thousand eight hundred fifty-five dollars (\$1,855) by the board.

1 The fee for a temporary outsourcing facility license shall be seven  
2 hundred fifteen dollars (\$715).

3 (x) The fee for the issuance of a nonresident outsourcing facility  
4 license shall be two thousand three hundred eighty dollars (\$2,380)  
5 and may be increased to up to three thousand three hundred  
6 thirty-five dollars (\$3,335) by the board. The fee for the renewal  
7 of a nonresident outsourcing facility license shall be two thousand  
8 two hundred seventy dollars (\$2,270) and may be increased to up  
9 to three thousand one hundred eighty dollars (\$3,180) by the board.  
10 In addition to paying that application fee, the nonresident  
11 outsourcing facility shall deposit, when submitting the application,  
12 a reasonable amount, as determined by the board, necessary to  
13 cover the board's estimated cost of performing the inspection  
14 required by Section 4129.2. If the required deposit is not submitted  
15 with the application, the application shall be deemed to be  
16 incomplete. If the actual cost of the inspection exceeds the amount  
17 deposited, the board shall provide to the applicant a written invoice  
18 for the remaining amount and shall not take action on the  
19 application until the full amount has been paid to the board. If the  
20 amount deposited exceeds the amount of actual and necessary  
21 costs incurred, the board shall remit the difference to the applicant.

22 (y) The fee for the issuance of a centralized hospital packaging  
23 license shall be eight hundred twenty dollars (\$820) and may be  
24 increased to one thousand one hundred fifty dollars (\$1,150). The  
25 annual renewal of the license shall be eight hundred five dollars  
26 (\$805) and may be increased to one thousand one hundred  
27 twenty-five dollars (\$1,125).

28 (z) The fee for an automated drug delivery system license shall  
29 be two hundred dollars (\$200) and may be increased to two  
30 hundred fifty dollars (\$250). The annual renewal of the license  
31 shall be two hundred dollars (\$200) and may be increased to two  
32 hundred fifty dollars (\$250).

33 (aa) This section shall become operative on July 1, 2017.

34 ~~SEC. 5.~~

35 *SEC. 7.* Article 25 (commencing with Section 4427) is added  
36 to Chapter 9 of Division 2 of the Business and Professions Code,  
37 to read:

1 Article 25. Automated Drug Delivery System ~~Units~~

2  
3 4427. An ADDS ~~unit~~ shall not be installed or operated in the  
4 State of California unless it meets the requirements of this article.

5 4427.1. (a) An ADDS ~~unit~~ installed or operated in the State  
6 of California shall be licensed by the board.

7 (b) An ADDS license ~~may~~ *shall* only be issued to the holder of  
8 a current, valid, and active pharmacy license.

9 (c) A separate application and license shall be required for each  
10 ~~ADDS unit.~~ *ADDS.*

11 ~~(d) A pharmacy may only obtain five simultaneous ADDS~~  
12 ~~licenses.~~

13 *(d) An ADDS license shall only be issued when the following*  
14 *conditions are met:*

15 *(1) Use of the ADDS is consistent with legal requirements.*

16 *(2) The proposed location for installation of the ADDS meets*  
17 *the requirements of Section 4427.2 and the ADDS is secure from*  
18 *access and removal by unauthorized individuals.*

19 *(3) The pharmacy's policies and procedures related to the ADDS*  
20 *include appropriate security measures and monitoring of the*  
21 *inventory to prevent theft and diversion.*

22 *(4) The pharmacy's policies and procedures include provisions*  
23 *for reporting to the board drug losses from the ADDS inventory,*  
24 *as required by law.*

25 *(5) The pharmacy license is not subject to suspension or*  
26 *disciplinary conditions.*

27 (e) Prior to issuance of the license, the board shall conduct a  
28 precensure inspection at the proposed location of the ~~ADDS unit.~~  
29 *ADDS. Relocation or replacement of the ADDS shall require a*  
30 *new application for licensure.*

31 (f) The ADDS license shall be canceled by operation of law if  
32 the underlying pharmacy license is not ~~in good standing.~~ *current,*  
33 *valid, and active.* Upon reissuance or reinstatement of the  
34 underlying pharmacy license, a new application for an ADDS  
35 license may be submitted to the board.

36 (g) The holder of an ADDS license shall advise the board in  
37 writing within 30 days if the use of the ~~ADDS unit~~ is discontinued.

38 (h) The ADDS license shall be renewed annually, and the  
39 renewal date shall be the same as the underlying pharmacy license.

40 ~~The ADDS license is nontransferable.~~

1 (i) An ADDS-unit operated by a licensed hospital pharmacy, as  
2 defined in Section 4029, and used solely to provide doses  
3 administered to inpatients while in a facility operated under a  
4 license pursuant to Section 1250.8 of the Health and Safety Code,  
5 shall be exempt from the requirement of obtaining an ADDS  
6 license pursuant to this section.

7 4427.2. (a) An ADDS-unit shall be placed and operated-in  
8 *inside or contiguous to an enclosed-building building, with a*  
9 *premise address, at a location approved by the board.*

10 (b) An ADDS-unit ~~may~~ shall be placed and operated in ~~any one~~  
11 of the following locations:

12 ~~(1) A pharmacy licensed by the board.~~

13 *(1) The pharmacy holding the ADDS license.*

14 ~~(2) A health facility as defined in licensed pursuant to Section~~  
15 ~~1250 of the Health and Safety Code. Code that complies with~~  
16 *Section 1261.6 of the Health and Safety Code.*

17 ~~(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the~~  
18 ~~Health and Safety Code, or Section 4180 or 4190 of this Code.~~

19 ~~(4) A medical office or other location where patients are~~  
20 ~~regularly seen for purposes of diagnosis and treatment, and where~~  
21 ~~drugs and devices are routinely dispensed pursuant to Section~~  
22 ~~4170. in compliance with Section 4170, except that paragraph (5)~~  
23 ~~of subdivision (a) of Section 4170, requiring prescriber ownership~~  
24 ~~of any dispensing device and its contents, shall not apply to that~~  
25 ~~office or location.~~

26 ~~(c) Prior to installation, the pharmacy holding the ADDS license~~  
27 ~~and the location where the ADDS is placed pursuant to subdivision~~  
28 ~~(b) shall jointly develop and implement written policies and~~  
29 ~~procedures to ensure safety, accuracy, accountability, security,~~  
30 ~~patient confidentiality, and maintenance of the ADDS, as well as~~  
31 ~~quality, potency, and purity of the drugs and devices. These policies~~  
32 ~~and procedures shall be maintained at the location of the ADDS.~~

33 4427.3. (a) ~~Drugs-~~The ADDS, and drugs and devices located  
34 within the ~~ADDS-unit~~ ADDS, shall be owned by the pharmacy  
35 holding ~~that ADDS-unit's license.~~ *the license for the ADDS.*

36 ~~(b) Each ADDS shall only be operated under the supervision~~  
37 ~~of the pharmacy holding the ADDS license.~~

38 ~~(c) An ADDS shall be considered an extension and part of the~~  
39 ~~pharmacy holding the ADDS license, regardless of the ADDS~~

1 location, and shall be subject to inspection pursuant to Section  
2 4008.

3 (d) Drugs and devices stored in an ADDS shall be deemed part  
4 of the inventory and the responsibility of the pharmacy holding  
5 the ADDS license, and drugs and devices dispensed from the ADDS  
6 shall be considered to have been dispensed by that pharmacy.

7 ~~(b)~~

8 (e) The stocking and restocking of an ADDS-unit shall be  
9 performed by licensed pharmacy staff unless otherwise specified  
10 by law. a pharmacist, except for an ADDS located in a health  
11 facility licensed pursuant to Section 1250 of the Health and Safety  
12 Code, where the stocking and restocking of the ADDS may be  
13 performed in compliance with Section 1261.6 of the Health and  
14 Safety Code.

15 ~~(e)~~

16 (f) If drugs or devices are not immediately transferred into an  
17 ADDS-unit upon arrival at the ADDS-unit location, the drugs and  
18 devices shall be stored for no longer than 48 hours in a secured  
19 room. Upon retrieval of these drugs and devices from secured  
20 storage, an inventory shall be taken to detect any losses or  
21 overages.

22 4427.4. Prior to installation, and annually thereafter, the  
23 pharmacy holding the ADDS license shall provide training on the  
24 operation and use of the ADDS to pharmacy personnel and to  
25 personnel using the ADDS at the location where the ADDS is  
26 placed pursuant to subdivision (b) of Section 4427.2.

27 ~~4427.4. When an APDS unit is used to dispense drugs or~~  
28 ~~devices directly to patients, the following conditions shall~~  
29 ~~additionally apply:~~

30 4427.5. In addition to any other requirements imposed by this  
31 article, an APDS shall additionally meet the following  
32 requirements:

33 (a) The pharmacy shall develop and implement, and review  
34 annually, written policies and procedures pertaining to the APDS,  
35 including all of the following:

36 (1) Maintaining the security of the APDS and the dangerous  
37 drugs and devices within that APDS.

38 (2) Determining and applying inclusion criteria regarding which  
39 drugs and devices are appropriate for placement in the APDS and  
40 for which patients.

1     (3) *Ensuring that patients are aware that consultation with a*  
2 *pharmacist is available for any prescription medication, including*  
3 *for those delivered via the APDS.*

4     (4) *Describing assignment of responsibilities to, and training*  
5 *of, pharmacy personnel, and other personnel using the ADDS at*  
6 *the location where the ADDS is placed pursuant to subdivision*  
7 *(b) of Section 4427.2, regarding maintenance and filing procedures*  
8 *for the APDS.*

9     (5) *Orienting participating patients on the use of the APDS,*  
10 *notifying patients when expected prescription medications are not*  
11 *available in the APDS, and ensuring that patient use of the APDS*  
12 *does not interfere with delivery of drugs and devices.*

13     (6) *Ensuring delivery of drugs and devices to patients expecting*  
14 *to receive them from the APDS in the event the APDS is disabled*  
15 *or malfunctions.*

16     (b) *The APDS shall only be used for patients who have signed*  
17 *a written consent form demonstrating their informed consent to*  
18 *receive prescribed drugs from an APDS, and whose use of the*  
19 *device meets inclusion criteria established pursuant to subdivision*  
20 *(a).*

21     (c) *The APDS shall have a means to identify each patient and*  
22 *only release the identified patient's drugs and devices.*

23     ~~(a)~~  
24     (d) *A pharmacist licensed by the board shall perform all clinical*  
25 *services conducted as part of the dispensing process, including,*  
26 *but not limited to, drug utilization review and consultation.*

27     (e) *Drugs shall be dispensed from the APDS only upon*  
28 *authorization by a licensed pharmacist after the pharmacist has*  
29 *reviewed the prescription and the patient's profile for potential*  
30 *contraindications and adverse drug reactions.*

31     ~~(b)~~  
32     (f) *All drugs and devices dispensed from an APDS-unit shall*  
33 *be accompanied by a consultation conducted by a pharmacist*  
34 *licensed by the board and consistent with Duty to Consult*  
35 ~~*regulations promulgated by the board.*~~ *via a telecommunications*  
36 *link that has two-way audio and video.*

37     ~~(e)~~  
38     (g) *The APDS-unit shall include a notice, prominently posted*  
39 *on the-APDS-unit, APDS, providing the name of the pharmacy*  
40 *that holds that APDS-unit's license. The notice shall comply with*

1 ~~Notice to Consumers regulations promulgated by the board. the~~  
2 ~~ADDS license for that APDS.~~

3 ~~(d)~~

4 (h) The labels on all medications dispensed by the APDS ~~unit~~  
5 shall comply with Section 4076 and with ~~Patient-Centered Labels~~  
6 ~~of Prescription Drug Containers Requirement regulations~~  
7 ~~promulgated by the board. Section 1707.5 of Title 16 of the~~  
8 ~~California Code of Regulations.~~

9 (i) Any incident involving the APDS where a complaint, error,  
10 or omission has occurred shall be reviewed as part of the  
11 pharmacy’s quality assurance program pursuant to Section 4125.

12 (j) The pharmacy holding the ADDS license for an APDS shall  
13 maintain the policies and procedures developed pursuant to  
14 subdivision (a) for three years after the last date of use of that  
15 APDS.

16 ~~4427.5.~~

17 4427.6. (a) ~~The pharmacist-in-charge of a~~ A pharmacy holding  
18 an ADDS ~~unit~~ license shall complete a self-assessment, ~~annually~~  
19 ~~or upon designation of a new pharmacist-in-charge, an annual~~  
20 ~~self-assessment, performed pursuant to Section 1715 of Title 16~~  
21 ~~of the California Code of Regulations, evaluating the pharmacy’s~~  
22 ~~compliance with pharmacy law relating to the use of the ADDS~~  
23 ~~unit. ADDS. All information regarding operation, maintenance,~~  
24 ~~compliance, error, omissions, or complaints pertaining to the~~  
25 ~~ADDS shall be included in the self-assessment.~~

26 (b) The pharmacy shall comply with all recordkeeping and  
27 quality assurance requirements established in pharmacy law and  
28 regulation, and shall maintain those records within the licensed  
29 pharmacy holding the ADDS license and separate from other  
30 pharmacy records.

31 ~~SEC. 6.~~

32 SEC. 8. No reimbursement is required by this act pursuant to  
33 Section 6 of Article XIII B of the California Constitution because  
34 the only costs that may be incurred by a local agency or school  
35 district will be incurred because this act creates a new crime or  
36 infraction, eliminates a crime or infraction, or changes the penalty  
37 for a crime or infraction, within the meaning of Section 17556 of  
38 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California  
2 Constitution.

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<b>Bill Number:</b>	<b>SB 1447</b>
<b>Current Version:</b>	<b>As amended April 17, 2018</b>
<b>Author:</b>	<b>Hernandez</b>
<b>Topic:</b>	<b>Pharmacy: Automated Drug Delivery Systems</b>
<b>Board Position:</b>	<b>Board Sponsored</b>

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**AFFECTED SECTIONS:** Amend sections 4008 and 4400 of the Business & Professions Code. Add sections 4017.3 and add Article 25 (commencing with section 4427), Repeal sections 4105.5, 4119.1, and 4186.

**STATUS:** Senate Business and Profession Committee Hearing April 23, 2018

**CURRENT LAW:**

- Establishes the authority to use automated drug delivery systems (ADDS) in specified settings.
- Except for ADDS devices used for emergency medical services prescription drug stock, requires notification to the board where ADDS are used and prohibit the use of ADDS if a pharmacy license is on probation.
- Requires licensure of ADDS devices used for emergency medical services prescription drugs

**THIS BILL WOULD:**

- Establish a licensing framework for ADDS and expand the settings were such a system can be used.
- Provide definitions for the systems including distinctions between ADDS used for purposed of administration to a patient and those used to dispense medications to a patient.
- Establishes the conditions that must be satisfied to use an ADDS including a fee.

**STAFF COMMENTS:**

This measure is board sponsored and includes the provisions approved by the board during its January 2018 meeting. The elements of the proposal need to be amended to better mesh with existing law. It is anticipated that the measure will be amended as part of the Senate Business, Professions and Economic Development committee.

**FISCAL IMPACT ON THE BOARD:**

Board staff believe that this measure will be cost neutral.

**SUPPORT / OPPOSITION:**SUPPORT:

None on file

OPPOSITION:

None on file

**BILL HISTORY:**

04/17/18	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/10/18	Set for hearing April 23.
04/09/18	April 16 set for first hearing canceled at the request of author.
03/20/18	Set for hearing April 16.
03/08/18	Referred to Com. on B., P. & E.D.
02/20/18	From printer. May be acted upon on or after March 22.
02/16/18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

**ASSEMBLY BILL**

**No. 1751**

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**Introduced by Assembly Member Low**

January 3, 2018

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An act to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1751, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance.

This bill would authorize the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for the purposes of participating in interjurisdictional information sharing between prescription drug monitoring programs across state lines. The bill would require any agreement entered into by the Department of Justice for those purposes to ensure that all access to data within CURES complies with California law and meets the same patient privacy and data security standards employed and required for direct access of CURES.

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 11165 of the Health and Safety Code is  
2 amended to read:

3 11165. (a) To assist health care practitioners in their efforts  
4 to ensure appropriate prescribing, ordering, administering,  
5 furnishing, and dispensing of controlled substances, law  
6 enforcement and regulatory agencies in their efforts to control the  
7 diversion and resultant abuse of Schedule II, Schedule III, and  
8 Schedule IV controlled substances, and for statistical analysis,  
9 education, and research, the Department of Justice shall, contingent  
10 upon the availability of adequate funds in the CURES Fund,  
11 maintain the Controlled Substance Utilization Review and  
12 Evaluation System (CURES) for the electronic monitoring of, and  
13 Internet access to information regarding, the prescribing and  
14 dispensing of Schedule II, Schedule III, and Schedule IV controlled  
15 substances by all practitioners authorized to prescribe, order,  
16 administer, furnish, or dispense these controlled substances.

17 (b) The Department of Justice may seek and use grant funds to  
18 pay the costs incurred by the operation and maintenance of  
19 CURES. The department shall annually report to the Legislature  
20 and make available to the public the amount and source of funds  
21 it receives for support of CURES.

22 (c) (1) The operation of CURES shall comply with all  
23 applicable federal and state privacy and security laws and  
24 regulations.

25 (2) (A) CURES shall operate under existing provisions of law  
26 to safeguard the privacy and confidentiality of patients. Data  
27 obtained from CURES shall only be provided to appropriate state,  
28 local, and federal public agencies for disciplinary, civil, or criminal  
29 purposes and to other agencies or entities, as determined by the  
30 Department of Justice, for the purpose of educating practitioners  
31 and others in lieu of disciplinary, civil, or criminal actions. Data  
32 may be provided to public or private entities, as approved by the  
33 Department of Justice, for educational, peer review, statistical, or  
34 research purposes, provided that patient information, including  
35 any information that may identify the patient, is not compromised.  
36 Further, data disclosed to any individual or agency as described  
37 in this subdivision shall not be disclosed, sold, or transferred to  
38 any third party, unless authorized by, or pursuant to, state and

1 federal privacy and security laws and regulations. The Department  
2 of Justice shall establish policies, procedures, and regulations  
3 regarding the use, access, evaluation, management, implementation,  
4 operation, storage, disclosure, and security of the information  
5 within CURES, consistent with this subdivision.

6 (B) Notwithstanding subparagraph (A), a regulatory board whose  
7 licensees do not prescribe, order, administer, furnish, or dispense  
8 controlled substances shall not be provided data obtained from  
9 CURES.

10 (3) In accordance with federal and state privacy laws and  
11 regulations, a health care practitioner may provide a patient with  
12 a copy of the patient's CURES patient activity report as long as  
13 no additional CURES data is provided and keep a copy of the  
14 report in the patient's medical record in compliance with  
15 subdivision (d) of Section 11165.1.

16 (d) For each prescription for a Schedule II, Schedule III, or  
17 Schedule IV controlled substance, as defined in the controlled  
18 substances schedules in federal law and regulations, specifically  
19 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21  
20 of the Code of Federal Regulations, the dispensing pharmacy,  
21 clinic, or other dispenser shall report the following information to  
22 the Department of Justice as soon as reasonably possible, but not  
23 more than seven days after the date a controlled substance is  
24 dispensed, in a format specified by the Department of Justice:

25 (1) Full name, address, and, if available, telephone number of  
26 the ultimate user or research subject, or contact information as  
27 determined by the Secretary of the United States Department of  
28 Health and Human Services, and the gender, and date of birth of  
29 the ultimate user.

30 (2) The prescriber's category of licensure, license number,  
31 national provider identifier (NPI) number, if applicable, the federal  
32 controlled substance registration number, and the state medical  
33 license number of any prescriber using the federal controlled  
34 substance registration number of a government-exempt facility.

35 (3) Pharmacy prescription number, license number, NPI number,  
36 and federal controlled substance registration number.

37 (4) National Drug Code (NDC) number of the controlled  
38 substance dispensed.

39 (5) Quantity of the controlled substance dispensed.

1 (6) International Statistical Classification of Diseases, 9th  
2 revision (ICD-9) or 10th revision (ICD-10) Code, if available.

3 (7) Number of refills ordered.

4 (8) Whether the drug was dispensed as a refill of a prescription  
5 or as a first-time request.

6 (9) Date of origin of the prescription.

7 (10) Date of dispensing of the prescription.

8 (e) The Department of Justice may invite stakeholders to assist,  
9 advise, and make recommendations on the establishment of rules  
10 and regulations necessary to ensure the proper administration and  
11 enforcement of the CURES database. All prescriber and dispenser  
12 invitees shall be licensed by one of the boards or committees  
13 identified in subdivision (d) of Section 208 of the Business and  
14 Professions Code, in active practice in California, and a regular  
15 user of CURES.

16 (f) The Department of Justice shall, prior to upgrading CURES,  
17 consult with prescribers licensed by one of the boards or  
18 committees identified in subdivision (d) of Section 208 of the  
19 Business and Professions Code, one or more of the boards or  
20 committees identified in subdivision (d) of Section 208 of the  
21 Business and Professions Code, and any other stakeholder  
22 identified by the department, for the purpose of identifying  
23 desirable capabilities and upgrades to the CURES Prescription  
24 Drug Monitoring Program (PDMP).

25 (g) The Department of Justice may establish a process to educate  
26 authorized subscribers of the CURES PDMP on how to access and  
27 use the CURES PDMP.

28 (h) (1) *The Department of Justice may enter into an agreement*  
29 *with an entity operating an interstate data share hub for purposes*  
30 *of participating in interjurisdictional information sharing between*  
31 *prescription drug monitoring programs across state lines.*

32 (2) *Any agreement entered into by the Department of Justice*  
33 *for purposes of interstate data sharing shall ensure that all access*  
34 *to data within CURES complies with California law and meets the*  
35 *same patient privacy and data security standards employed and*  
36 *required for direct access of CURES.*



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**Bill Number:** AB 1751

**Current Version:** As Introduced January 3, 2018

**Author:** Low

**Topic:** Controlled Substances: CURES database

**Board Position:** Support

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**AFFECTED SECTIONS:** Amend HSC sections 11165

**STATUS:** Referred to Assembly Public Safety Committee

**THIS BILL WOULD:**

Allow the Department of Justice to enter into an agreement with another entity operating an interstate hub for allowing sharing of prescription drug monitoring information across state lines. Under the provisions of this measure, the interstate data sharing must meet all the patient privacy and data security measures of the CURES system.

**STAFF COMMENTS:**

The board is the originator of this measure. The board voted to pursue a statutory change to allow interstate data exchange of prescription drug monitoring programs during its November Board Meeting.

The board has a long history of supporting CURES and its use and has supported the concept of sharing prescription drug monitoring information across state lines. The board established a support position on this measure during the February board meeting.

**SUPPORT / OPPOSITION:**

SUPPORT:

America's Physician Groups  
Biocom  
California Association of Health Underwriters  
California Chiropractic Association  
California Dental Association  
California District Attorneys Association  
CaliforniaHealth+ Advocates  
California Life Sciences Association  
California Pharmacists Association  
California Police Chiefs Association  
California State Board of Pharmacy  
California State Sheriffs' Association  
Consumer Attorneys of California  
County Health Executives Association of California

Kaiser Permanente  
Medical Board of California  
OCHIN  
San Diego County District Attorney Summer Stephan  
Troy and Alana Pack Foundation

OPPOSITION:

American Civil liberties Union  
California medical Association

**BILL HISTORY:**

01/16/2018	Referred to Coms. on B. & P. and PUB. S.
01/04/2018	From printer. May be heard in committee February 3.
01/03/2018	Read first time. To print.

**ASSEMBLY BILL**

**No. 1752**

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**Introduced by Assembly Member Low**

January 3, 2018

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An act to amend Sections 11165 and 11165.1 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1752, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the Department of Justice as soon as reasonably possible, but not more than 7 days after the date a controlled substance is dispensed.

This bill would add Schedule V controlled substances to the CURES database. The bill would additionally authorize the California State Board of Pharmacy, through regulation, to add additional medications to be tracked in the CURES database. The bill would require a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than one working day after a controlled substance is dispensed. The bill would change what

information is required to be reported by deleting references to classification codes and adding the date of sale of the prescription.

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 11165 of the Health and Safety Code is  
2 amended to read:

3 11165. (a) To assist health care practitioners in their efforts  
4 to ensure appropriate prescribing, ordering, administering,  
5 furnishing, and dispensing of controlled substances, law  
6 enforcement and regulatory agencies in their efforts to control the  
7 diversion and resultant abuse of Schedule II, Schedule III,~~and~~  
8 ~~Schedule IV~~ IV, and Schedule V controlled substances, and for  
9 statistical analysis, education, and research, the Department of  
10 Justice shall, contingent upon the availability of adequate funds  
11 in the CURES Fund, maintain the Controlled Substance Utilization  
12 Review and Evaluation System (CURES) for the electronic  
13 monitoring of, and Internet access to information regarding, the  
14 prescribing and dispensing of Schedule II, Schedule III,~~and~~  
15 ~~Schedule IV~~ IV, and Schedule V controlled substances by all  
16 practitioners authorized to prescribe, order, administer, furnish, or  
17 dispense these controlled substances. *The California State Board*  
18 *of Pharmacy may add through regulation additional medications*  
19 *determined to pose a substantial risk of abuse or diversion that*  
20 *shall be tracked in CURES.*

21 (b) The Department of Justice may seek and use grant funds to  
22 pay the costs incurred by the operation and maintenance of  
23 CURES. The department shall annually report to the Legislature  
24 and make available to the public the amount and source of funds  
25 it receives for support of CURES.

26 (c) (1) The operation of CURES shall comply with all  
27 applicable federal and state privacy and security laws and  
28 regulations.

29 (2) (A) CURES shall operate under existing provisions of law  
30 to safeguard the privacy and confidentiality of patients. Data  
31 obtained from CURES shall only be provided to appropriate state,  
32 local, and federal public agencies for disciplinary, civil, or criminal  
33 purposes and to other agencies or entities, as determined by the

1 Department of Justice, for the purpose of educating practitioners  
2 and others in lieu of disciplinary, civil, or criminal actions. Data  
3 may be provided to public or private entities, as approved by the  
4 Department of Justice, for educational, peer review, statistical, or  
5 research purposes, provided that patient information, including  
6 any information that may identify the patient, is not compromised.  
7 Further, data disclosed to any individual or agency as described  
8 in this subdivision shall not be disclosed, sold, or transferred to  
9 any third party, unless authorized by, or pursuant to, state and  
10 federal privacy and security laws and regulations. The Department  
11 of Justice shall establish policies, procedures, and regulations  
12 regarding the use, access, evaluation, management, implementation,  
13 operation, storage, disclosure, and security of the information  
14 within CURES, consistent with this subdivision.

15 (B) Notwithstanding subparagraph (A), a regulatory board whose  
16 licensees do not prescribe, order, administer, furnish, or dispense  
17 controlled substances shall not be provided data obtained from  
18 CURES.

19 (3) In accordance with federal and state privacy laws and  
20 regulations, a health care practitioner may provide a patient with  
21 a copy of the patient's CURES patient activity report as long as  
22 no additional CURES data is provided and keep a copy of the  
23 report in the patient's medical record in compliance with  
24 subdivision (d) of Section 11165.1.

25 (d) For each prescription for a Schedule II, Schedule III, ~~or~~  
26 ~~Schedule IV~~ *IV, or Schedule V* controlled substance, as defined in  
27 the controlled substances schedules in federal law and regulations,  
28 specifically Sections 1308.12, 1308.13, ~~and~~ 1308.14, *and 1308.15*,  
29 respectively, of Title 21 of the Code of Federal Regulations, *and*  
30 *for any additional medications of concern added by the California*  
31 *State Board of Pharmacy through regulation*, the dispensing  
32 pharmacy, clinic, or other dispenser shall report the following  
33 information to the Department of Justice as soon as reasonably  
34 possible, but not more than ~~seven days~~ *one working day* after the  
35 date a controlled substance is dispensed, in a format specified by  
36 the Department of Justice:

37 (1) Full name, address, and, if available, telephone number of  
38 the ultimate user or research subject, or contact information as  
39 determined by the Secretary of the United States Department of

- 1 Health and Human Services, and the gender, and date of birth of  
2 the ultimate user.
- 3 (2) The prescriber's category of licensure, license number,  
4 national provider identifier (NPI) number, if applicable, the federal  
5 controlled substance registration number, and the state medical  
6 license number of any prescriber using the federal controlled  
7 substance registration number of a government-exempt facility.
- 8 (3) Pharmacy prescription number, license number, NPI number,  
9 and federal controlled substance registration number.
- 10 (4) National Drug Code (NDC) number of the controlled  
11 substance dispensed.
- 12 (5) Quantity of the controlled substance dispensed.
- 13 ~~(6) International Statistical Classification of Diseases, 9th~~  
14 ~~revision (ICD-9) or 10th revision (ICD-10) Code, if available.~~
- 15 ~~(7)~~
- 16 (6) Number of refills ordered.
- 17 ~~(8)~~
- 18 (7) Whether the drug was dispensed as a refill of a prescription  
19 or as a first-time request.
- 20 ~~(9)~~
- 21 (8) Date of origin of the prescription.
- 22 ~~(10)~~
- 23 (9) Date of dispensing of the prescription.
- 24 *(10) Date of sale of the prescription.*
- 25 (e) The Department of Justice may invite stakeholders to assist,  
26 advise, and make recommendations on the establishment of rules  
27 and regulations necessary to ensure the proper administration and  
28 enforcement of the CURES database. All prescriber and dispenser  
29 invitees shall be licensed by one of the boards or committees  
30 identified in subdivision (d) of Section 208 of the Business and  
31 Professions Code, in active practice in California, and a regular  
32 user of CURES.
- 33 (f) The Department of Justice shall, prior to upgrading CURES,  
34 consult with prescribers licensed by one of the boards or  
35 committees identified in subdivision (d) of Section 208 of the  
36 Business and Professions Code, one or more of the boards or  
37 committees identified in subdivision (d) of Section 208 of the  
38 Business and Professions Code, and any other stakeholder  
39 identified by the department, for the purpose of identifying

1 desirable capabilities and upgrades to the CURES Prescription  
2 Drug Monitoring Program (PDMP).

3 (g) The Department of Justice may establish a process to educate  
4 authorized subscribers of the CURES PDMP on how to access and  
5 use the CURES PDMP.

6 SEC. 2. Section 11165.1 of the Health and Safety Code is  
7 amended to read:

8 11165.1. (a) (1) (A) (i) A health care practitioner authorized  
9 to prescribe, order, administer, furnish, or dispense Schedule II,  
10 Schedule III,~~or~~ ~~Schedule IV~~, *or Schedule V* controlled  
11 substances pursuant to Section 11150 shall, before July 1, 2016,  
12 or upon receipt of a federal Drug Enforcement Administration  
13 (DEA) registration, whichever occurs later, submit an application  
14 developed by the department to obtain approval to electronically  
15 access information regarding the controlled substance history of  
16 a patient that is maintained by the department. Upon approval, the  
17 department shall release to that practitioner the electronic history  
18 of controlled substances dispensed to an individual under his or  
19 her care based on data contained in the CURES Prescription Drug  
20 Monitoring Program (PDMP).

21 (ii) A pharmacist shall, before July 1, 2016, or upon licensure,  
22 whichever occurs later, submit an application developed by the  
23 department to obtain approval to electronically access information  
24 regarding the controlled substance history of a patient that is  
25 maintained by the department. Upon approval, the department  
26 shall release to that pharmacist the electronic history of controlled  
27 substances dispensed to an individual under his or her care based  
28 on data contained in the CURES PDMP.

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

32 (i) Materially falsifying an application to access information  
33 contained in the CURES database.

34 (ii) Failing to maintain effective controls for access to the patient  
35 activity report.

36 (iii) Having his or her federal DEA registration suspended or  
37 revoked.

38 (iv) Violating a law governing controlled substances or any  
39 other law for which the possession or use of a controlled substance  
40 is an element of the crime.

1 (v) Accessing information for a reason other than to diagnose  
2 or treat his or her patients, or to document compliance with the  
3 law.

4 (C) An authorized subscriber shall notify the department within  
5 30 days of any changes to the subscriber account.

6 (D) Commencing no later than October 1, 2018, an approved  
7 health care practitioner, pharmacist, and any person acting on  
8 behalf of a health care practitioner or pharmacist pursuant to  
9 subdivision (b) of Section 209 of the Business and Professions  
10 Code may use the department's online portal or a health  
11 information technology system that meets the criteria required in  
12 subparagraph (E) to access information in the CURES database  
13 pursuant to this section. A subscriber who uses a health information  
14 technology system that meets the criteria required in subparagraph  
15 (E) to access the CURES database may submit automated queries  
16 to the CURES database that are triggered by predetermined criteria.

17 (E) Commencing no later than October 1, 2018, an approved  
18 health care practitioner or pharmacist may submit queries to the  
19 CURES database through a health information technology system  
20 if the entity that operates the health information technology system  
21 can certify all of the following:

22 (i) The entity will not use or disclose data received from the  
23 CURES database for any purpose other than delivering the data  
24 to an approved health care practitioner or pharmacist or performing  
25 data processing activities that may be necessary to enable the  
26 delivery unless authorized by, and pursuant to, state and federal  
27 privacy and security laws and regulations.

28 (ii) The health information technology system will authenticate  
29 the identity of an authorized health care practitioner or pharmacist  
30 initiating queries to the CURES database and, at the time of the  
31 query to the CURES database, the health information technology  
32 system submits the following data regarding the query to CURES:

33 (I) The date of the query.

34 (II) The time of the query.

35 (III) The first and last name of the patient queried.

36 (IV) The date of birth of the patient queried.

37 (V) The identification of the CURES user for whom the system  
38 is making the query.

1 (iii) The health information technology system meets applicable  
2 patient privacy and information security requirements of state and  
3 federal law.

4 (iv) The entity has entered into a memorandum of understanding  
5 with the department that solely addresses the technical  
6 specifications of the health information technology system to  
7 ensure the security of the data in the CURES database and the  
8 secure transfer of data from the CURES database. The technical  
9 specifications shall be universal for all health information  
10 technology systems that establish a method of system integration  
11 to retrieve information from the CURES database. The  
12 memorandum of understanding shall not govern, or in any way  
13 impact or restrict, the use of data received from the CURES  
14 database or impose any additional burdens on covered entities in  
15 compliance with the regulations promulgated pursuant to the  
16 federal Health Insurance Portability and Accountability Act of  
17 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal  
18 Regulations.

19 (F) No later than October 1, 2018, the department shall develop  
20 a programming interface or other method of system integration to  
21 allow health information technology systems that meet the  
22 requirements in subparagraph (E) to retrieve information in the  
23 CURES database on behalf of an authorized health care practitioner  
24 or pharmacist.

25 (G) The department shall not access patient-identifiable  
26 information in an entity's health information technology system.

27 (H) An entity that operates a health information technology  
28 system that is requesting to establish an integration with the  
29 CURES database shall pay a reasonable fee to cover the cost of  
30 establishing and maintaining integration with the CURES database.

31 (I) The department may prohibit integration or terminate a health  
32 information technology system's ability to retrieve information in  
33 the CURES database if the health information technology system  
34 fails to meet the requirements of subparagraph (E), or the entity  
35 operating the health information technology system does not fulfill  
36 its obligation under subparagraph (H).

37 (2) A health care practitioner authorized to prescribe, order,  
38 administer, furnish, or dispense Schedule II, Schedule III, ~~or~~  
39 ~~Schedule IV~~ *Schedule IV, or Schedule V* controlled substances pursuant to  
40 Section 11150 or a pharmacist shall be deemed to have complied

1 with paragraph (1) if the licensed health care practitioner or  
 2 pharmacist has been approved to access the CURES database  
 3 through the process developed pursuant to subdivision (a) of  
 4 Section 209 of the Business and Professions Code.

5 (b) A request for, or release of, a controlled substance history  
 6 pursuant to this section shall be made in accordance with guidelines  
 7 developed by the department.

8 (c) In order to prevent the inappropriate, improper, or illegal  
 9 use of Schedule II, Schedule III, ~~or Schedule IV~~ *IV, or Schedule*  
 10 *V* controlled substances, the department may initiate the referral  
 11 of the history of controlled substances dispensed to an individual  
 12 based on data contained in CURES to licensed health care  
 13 practitioners, pharmacists, or both, providing care or services to  
 14 the individual.

15 (d) The history of controlled substances dispensed to an  
 16 individual based on data contained in CURES that is received by  
 17 a practitioner or pharmacist from the department pursuant to this  
 18 section is medical information subject to the provisions of the  
 19 Confidentiality of Medical Information Act contained in Part 2.6  
 20 (commencing with Section 56) of Division 1 of the Civil Code.

21 (e) Information concerning a patient’s controlled substance  
 22 history provided to a practitioner or pharmacist pursuant to this  
 23 section shall include prescriptions for controlled substances listed  
 24 in Sections 1308.12, 1308.13, ~~and 1308.14~~ *1308.14, and 1308.15*  
 25 of Title 21 of the Code of Federal Regulations.

26 (f) A health care practitioner, pharmacist, and any person acting  
 27 on behalf of a health care practitioner or pharmacist, when acting  
 28 with reasonable care and in good faith, is not subject to civil or  
 29 administrative liability arising from any false, incomplete,  
 30 inaccurate, or misattributed information submitted to, reported by,  
 31 or relied upon in the CURES database or for any resulting failure  
 32 of the CURES database to accurately or timely report that  
 33 information.

34 (g) For purposes of this section, the following terms have the  
 35 following meanings:

36 (1) “Automated basis” means using predefined criteria to trigger  
 37 an automated query to the CURES database, which can be  
 38 attributed to a specific health care practitioner or pharmacist.

39 (2) “Department” means the Department of Justice.

1 (3) “Entity” means an organization that operates, or provides  
2 or makes available, a health information technology system to a  
3 health care practitioner or pharmacist.

4 (4) “Health information technology system” means an  
5 information processing application using hardware and software  
6 for the storage, retrieval, sharing of or use of patient data for  
7 communication, decisionmaking, coordination of care, or the  
8 quality, safety, or efficiency of the practice of medicine or delivery  
9 of health care services, including, but not limited to, electronic  
10 medical record applications, health information exchange systems,  
11 or other interoperable clinical or health care information system.

12 (5) “User-initiated basis” means an authorized health care  
13 practitioner or pharmacist has taken an action to initiate the query  
14 to the CURES database, such as clicking a button, issuing a voice  
15 command, or taking some other action that can be attributed to a  
16 specific health care practitioner or pharmacist.

O



<b>Bill Number:</b>	<b>AB 1752</b>
<b>Current Version:</b>	<b>As amended April 5, 2018</b>
<b>Author:</b>	<b>Low</b>
<b>Topic:</b>	<b>Controlled Substances: CURES database</b>
<b>Board Position:</b>	<b>Support</b>

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**AFFECTED SECTIONS:** Amend HSC sections 11165 & 11165.1

**STATUS:** Referred to Assembly Public Safety Committee

**CURRENT LAW:**

Current law establishes the Controlled Substance Utilization Review and Evaluation System (CURES) to provide for a means of electronic monitoring of all prescribing and dispensing of schedule II – schedule IV controlled substances per the federal controlled substances schedule. The dispensing of such controlled drugs must be reported within seven work days after the drug has been dispensed.

**THIS BILL WOULD:**

Expand the requirements of CURES to also include the reporting of schedule V drugs, as well as any other drug identified by the board through regulation. Further, under the provisions of this measure, dispensing would be required to be reported within one working day and date of the sale of the drug would also be reported to the CURES system. The diagnosis code would no longer be required to be reported.

**STAFF COMMENTS:**

The board is the originator of some of the provisions included in this measure. During the board's February 2018 meeting, the Board voted to take a position of Support for this measure. Since that time, the measure was amended to remove the authority of the board to, through regulation, add additional medications that would be tracked in the CURES database.

At the Board's November 2017 meeting, the board voted to pursue a statutory proposal that would expand CURES reporting to encompass schedule V drugs and other drugs of concern. Further, the board voted to reduce the reporting time to CURES to the next business day.

**SUPPORT / OPPOSITION:**

SUPPORT:

California State Board of Pharmacy (Sponsor)  
California Association of Health Underwriters  
California Chiropractic Association

California District Attorneys Association  
 California Medical Association  
 California Police Chiefs Association  
 California Society of Anesthesiologists  
 California State Sheriffs' Association  
 Consumer Attorneys of California  
 Medical Board of California  
 Troy and Alana Pack Foundation

**OPPOSITION:**

American Civil Liberties Union

**BILL HISTORY:**

04/10/18	From committee: Do pass and re-refer to Com. on PUB. S. (Ayes 16. Noes 0.) (April 10). Re-referred to Com. on PUB. S.
04/09/18	Re-referred to Com. on B. & P.
04/05/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
01/16/18	Referred to Coms. on B. & P. and PUB. S.
01/04/18	From printer. May be heard in committee February 3.
01/03/18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 3, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2086**

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**Introduced by Assembly Member Gallagher  
(Coauthors: Assembly Members Gipson and Mathis)**

February 7, 2018

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An act to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2086, as amended, Gallagher. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance.

This bill would allow prescribers to ~~request from the Department of Justice~~ *access the CURES database* for a list of patients for whom that prescriber is listed as a prescriber in the CURES database.

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 11165 of the Health and Safety Code is  
2 amended to read:

3 11165. (a) To assist health care practitioners in their efforts  
4 to ensure appropriate prescribing, ordering, administering,  
5 furnishing, and dispensing of controlled substances, law  
6 enforcement and regulatory agencies in their efforts to control the  
7 diversion and resultant abuse of Schedule II, Schedule III, and  
8 Schedule IV controlled substances, and for statistical analysis,  
9 education, and research, the Department of Justice shall, contingent  
10 upon the availability of adequate funds in the CURES Fund,  
11 maintain the Controlled Substance Utilization Review and  
12 Evaluation System (CURES) for the electronic monitoring of, and  
13 Internet access to information regarding, the prescribing and  
14 dispensing of Schedule II, Schedule III, and Schedule IV controlled  
15 substances by all practitioners authorized to prescribe, order,  
16 administer, furnish, or dispense these controlled substances.

17 (b) The Department of Justice may seek and use grant funds to  
18 pay the costs incurred by the operation and maintenance of  
19 CURES. The department shall annually report to the Legislature  
20 and make available to the public the amount and source of funds  
21 it receives for support of CURES.

22 (c) (1) The operation of CURES shall comply with all  
23 applicable federal and state privacy and security laws and  
24 regulations.

25 (2) (A) CURES shall operate under existing provisions of law  
26 to safeguard the privacy and confidentiality of patients. Data  
27 obtained from CURES shall only be provided to appropriate state,  
28 local, and federal public agencies for disciplinary, civil, or criminal  
29 purposes and to other agencies or entities, as determined by the  
30 Department of Justice, for the purpose of educating practitioners  
31 and others in lieu of disciplinary, civil, or criminal actions. Data  
32 may be provided to public or private entities, as approved by the  
33 Department of Justice, for educational, peer review, statistical, or  
34 research purposes, provided that patient information, including  
35 any information that may identify the patient, is not compromised.  
36 Further, data disclosed to any individual or agency as described  
37 in this subdivision shall not be disclosed, sold, or transferred to  
38 any third party, unless authorized by, or pursuant to, state and

1 federal privacy and security laws and regulations. The Department  
2 of Justice shall establish policies, procedures, and regulations  
3 regarding the use, access, evaluation, management, implementation,  
4 operation, storage, disclosure, and security of the information  
5 within CURES, consistent with this subdivision.

6 (B) Notwithstanding subparagraph (A), a regulatory board whose  
7 licensees do not prescribe, order, administer, furnish, or dispense  
8 controlled substances shall not be provided data obtained from  
9 CURES.

10 (C) A prescriber ~~may request from the Department of Justice~~  
11 *shall be allowed to access the CURES database* for a list of patients  
12 for whom that prescriber is listed as a prescriber in the CURES  
13 database.

14 (3) In accordance with federal and state privacy laws and  
15 regulations, a health care practitioner may provide a patient with  
16 a copy of the patient's CURES patient activity report as long as  
17 no additional CURES data is provided and keep a copy of the  
18 report in the patient's medical record in compliance with  
19 subdivision (d) of Section 11165.1.

20 (d) For each prescription for a Schedule II, Schedule III, or  
21 Schedule IV controlled substance, as defined in the controlled  
22 substances schedules in federal law and regulations, specifically  
23 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21  
24 of the Code of Federal Regulations, the dispensing pharmacy,  
25 clinic, or other dispenser shall report the following information to  
26 the Department of Justice as soon as reasonably possible, but not  
27 more than seven days after the date a controlled substance is  
28 dispensed, in a format specified by the Department of Justice:

29 (1) Full name, address, and, if available, telephone number of  
30 the ultimate user or research subject, or contact information as  
31 determined by the Secretary of the United States Department of  
32 Health and Human Services, and the gender, and date of birth of  
33 the ultimate user.

34 (2) The prescriber's category of licensure, license number,  
35 national provider identifier (NPI) number, if applicable, the federal  
36 controlled substance registration number, and the state medical  
37 license number of any prescriber using the federal controlled  
38 substance registration number of a government-exempt facility.

39 (3) Pharmacy prescription number, license number, NPI number,  
40 and federal controlled substance registration number.

- 1 (4) National Drug Code (NDC) number of the controlled  
2 substance dispensed.
- 3 (5) Quantity of the controlled substance dispensed.
- 4 (6) International Statistical Classification of Diseases, 9th  
5 revision (ICD-9) or 10th revision (ICD-10) Code, if available.
- 6 (7) Number of refills ordered.
- 7 (8) Whether the drug was dispensed as a refill of a prescription  
8 or as a first-time request.
- 9 (9) Date of origin of the prescription.
- 10 (10) Date of dispensing of the prescription.
- 11 (e) The Department of Justice may invite stakeholders to assist,  
12 advise, and make recommendations on the establishment of rules  
13 and regulations necessary to ensure the proper administration and  
14 enforcement of the CURES database. All prescriber and dispenser  
15 invitees shall be licensed by one of the boards or committees  
16 identified in subdivision (d) of Section 208 of the Business and  
17 Professions Code, in active practice in California, and a regular  
18 user of CURES.
- 19 (f) The Department of Justice shall, prior to upgrading CURES,  
20 consult with prescribers licensed by one of the boards or  
21 committees identified in subdivision (d) of Section 208 of the  
22 Business and Professions Code, one or more of the boards or  
23 committees identified in subdivision (d) of Section 208 of the  
24 Business and Professions Code, and any other stakeholder  
25 identified by the department, for the purpose of identifying  
26 desirable capabilities and upgrades to the CURES Prescription  
27 Drug Monitoring Program (PDMP).
- 28 (g) The Department of Justice may establish a process to educate  
29 authorized subscribers of the CURES PDMP on how to access and  
30 use the CURES PDMP.



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<b>Bill Number:</b>	<b>AB 2086</b>
<b>Current Version:</b>	<b>As amended April 3, 2018</b>
<b>Author:</b>	<b>Gallagher</b>
<b>Topic:</b>	<b>Controlled substances: CURES database.</b>
<b>Staff Recommendation:</b>	<b>Support</b>

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**AFFECTED SECTIONS:** Adds Chapter 3.6 to Part 1 of Division 3 of Title 2 of the Government Code and subsequent repeal.

**STATUS:** Re-Referred to Assembly Appropriations

**EXISTING LAW:**

Establishes required elements a dispenser must report to the Controlled Substance Utilization Review and Evaluation System (CURES) database regarding the distribution of controlled substances.

**THIS BILL WOULD:**

Allow prescribers to request a list of patients for whom they are listed as being the prescriber in the CURES database.

**STAFF COMMENTS:**

The board is the originator of this bill. The board has a long history of supporting CURES and its use. The Board had a presentation from Department of Justice for an update on CURES at its July 2017 meeting and discussed the feasibility of allowing a prescriber to run a report to monitor prescriptions of controlled substances dispensed under their prescription authority. The presenter stated that a statutory change was needed in order to allow prescribers to access reports in CURES.

**SUPPORT / OPPOSITION:**

SUPPORT:

California Dental Association  
California District Attorneys Association  
California Health+ Advocates  
California Hospital Association  
California Medical Association  
California Police Chiefs Association  
California Society of Anesthesiologists

OPPOSITION:

None on file

**BILL HISTORY:**

04/10/18	From committee: Do pass and re-refer to Com. on APPR. (Ayes 16. Noes 0.) (April 10). Re-referred to Com. on APPR.
04/04/18	In committee: Set, first hearing. Referred to suspense file.
03/20/18	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (March 20). Re-referred to Com. on APPR.
02/16/18	Referred to Com. on B. & P.
02/07/18	From printer. May be heard in committee March 9.
02/07/18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 11, 2018

AMENDED IN ASSEMBLY MARCH 22, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2783**

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**Introduced by Assembly Member O'Donnell**

February 16, 2018

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An act to amend ~~Section 4021 of the Business and Professions Code,~~ and to amend ~~Section 11007 Sections 11055 and 11056~~ of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2783, as amended, O'Donnell. Controlled substances: *hydrocodone combination products*: schedules.

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. *Existing law classifies hydrocodone as a Schedule II controlled substance. Existing law classifies specified compounds, including some hydrocodone compounds, as Schedule III controlled substances. Existing law imposes stringent prescription requirements on drugs classified as Schedule II, including a limitation on refills, the violation of which are crimes.*

~~Existing federal law classifies controlled substances into 5 designated schedules, similar to the state schedules. Federal law authorizes updates of the substances on the federal schedules administratively by the federal Drug Enforcement Agency.~~

~~Existing law creates various crimes based on the schedule on which a controlled substance is placed, including prohibiting possession, transportation, and sale of a Schedule III, IV, or V controlled substance without a prescription.~~

~~This bill would define controlled substances for the purposes of California law as any of the substances listed on the California and federal schedules, including substances that have been added to the federal schedules in regulations. The bill would provide that when the state and federal controlled substances schedules conflict, the schedule that is more closely regulated shall control. By expanding the definition of a crime, this 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 reclassify specified hydrocodone combination products as Schedule II controlled substances. By expanding the scope of the existing crimes that apply to Schedule II controlled substances, this bill would impose a state-mandated local program.*

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

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

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

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

- 1 *SECTION 1. Section 11055 of the Health and Safety Code is*
- 2 *amended to read:*
- 3 11055. (a) The controlled substances listed in this section are
- 4 included in Schedule II.
- 5 (b) Any of the following substances, except those narcotic drugs
- 6 listed in other schedules, whether produced directly or indirectly
- 7 by extraction from substances of vegetable origin, or independently
- 8 by means of chemical synthesis, or by combination of extraction
- 9 and chemical synthesis:

- 1 (1) Opium, opiate, and any salt, compound, derivative, or  
2 preparation of opium or opiate, with the exception of naloxone  
3 hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone  
4 hydrochloride), but including the following:
- 5 (A) Raw opium.
  - 6 (B) Opium extracts.
  - 7 (C) Opium fluid extracts.
  - 8 (D) Powdered opium.
  - 9 (E) Granulated opium.
  - 10 (F) Tincture of opium.
  - 11 (G) Codeine.
  - 12 (H) Ethylmorphine.
  - 13 (I) (i) Hydrocodone.
  - 14 (ii) *Hydrocodone combination products with not more than 300*  
15 *milligrams of dihydrocodeinone per 100 milliliters or not more*  
16 *than 15 milligrams per dosage unit, with one or more active*  
17 *nonnarcotic ingredients in recognized therapeutic amounts.*
  - 18 (iii) *Oral liquid preparations of dihydrocodeinone containing*  
19 *the above specified amounts that contain, as its nonnarcotic*  
20 *ingredients, two or more antihistamines in combination with each*  
21 *other.*
  - 22 (iv) *Hydrocodone combination products with not more than 300*  
23 *milligrams of dihydrocodeinone per 100 milliliters or not more*  
24 *than 15 milligrams per dosage unit, with a fourfold or greater*  
25 *quantity of an isoquinoline alkaloid of opium.*
  - 26 (J) Hydromorphone.
  - 27 (K) Metopon.
  - 28 (L) Morphine.
  - 29 (M) Oxycodone.
  - 30 (N) Oxymorphone.
  - 31 (O) Thebaine.
- 32 (2) Any salt, compound, isomer, or derivative, whether natural  
33 or synthetic, of the substances referred to in paragraph (1), but not  
34 including the isoquinoline alkaloids of opium.
- 35 (3) Opium poppy and poppy straw.
- 36 (4) Coca leaves and any salt, compound, derivative, or  
37 preparation of coca leaves, but not including decocainized coca  
38 leaves or extractions which do not contain cocaine or ecgonine.

- 1 (5) Concentrate of poppy straw (the crude extract of poppy straw
- 2 in either liquid, solid, or powder form which contains the
- 3 phenanthrene alkaloids of the opium poppy).
- 4 (6) Cocaine, except as specified in Section 11054.
- 5 (7) Ecgonine, whether natural or synthetic, or any salt, isomer,
- 6 derivative, or preparation thereof.
- 7 (c) Opiates. Unless specifically excepted or unless in another
- 8 schedule, any of the following opiates, including its isomers, esters,
- 9 ethers, salts, and salts of isomers, esters, and ethers whenever the
- 10 existence of those isomers, esters, ethers, and salts is possible
- 11 within the specific chemical designation, dextrorphan and
- 12 levopropoxyphene excepted:
- 13 (1) Alfentanyl.
- 14 (2) Alphaprodine.
- 15 (3) Anileridine.
- 16 (4) Bezitramide.
- 17 (5) Bulk dextropropoxyphene (nondosage forms).
- 18 (6) Dihydrocodeine.
- 19 (7) Diphenoxylate.
- 20 (8) Fentanyl.
- 21 (9) Isomethadone.
- 22 (10) Levoalphacetylmethadol, also known as
- 23 levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This
- 24 substance is authorized for the treatment of narcotic addicts under
- 25 federal law (see Part 291 (commencing with Section 291.501) and
- 26 Part 1308 (commencing with Section 1308.01) of Title 21 of the
- 27 Code of Federal Regulations).
- 28 (11) Levomethorphan.
- 29 (12) Levorphanol.
- 30 (13) Metazocine.
- 31 (14) Methadone.
- 32 (15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,
- 33 4-diphenyl butane.
- 34 (16) Moramide-Intermediate, 2-methyl-3-morpholino-1,
- 35 1-diphenylpropane-carboxylic acid.
- 36 (17) Pethidine (meperidine).
- 37 (18) Pethidine-Intermediate-A,
- 38 4-cyano-1-methyl-4-phenylpiperidine.
- 39 (19) Pethidine-Intermediate-B,
- 40 ethyl-4-phenylpiperidine-4-carboxylate.

- 1 (20) Pethidine-Intermediate-C,
- 2 1-methyl-4-phenylpiperidine-4-carboxylic acid.
- 3 (21) Phenazocine.
- 4 (22) Piminodine.
- 5 (23) Racemethorphan.
- 6 (24) Racemorphan.
- 7 (25) Sufentanyl.
- 8 (d) Stimulants. Unless specifically excepted or unless listed in
- 9 another schedule, any material, compound, mixture, or preparation
- 10 which contains any quantity of the following substances having a
- 11 stimulant effect on the central nervous system:
- 12 (1) Amphetamine, its salts, optical isomers, and salts of its
- 13 optical isomers.
- 14 (2) Methamphetamine, its salts, isomers, and salts of its isomers.
- 15 (3) Dimethylamphetamine (N,N-dimethylamphetamine), its
- 16 salts, isomers, and salts of its isomers.
- 17 (4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine),
- 18 its salts, isomers, and salts of its isomers.
- 19 (5) Phenmetrazine and its salts.
- 20 (6) Methylphenidate.
- 21 (7) Khat, which includes all parts of the plant classified
- 22 botanically as *Catha Edulis*, whether growing or not, the seeds
- 23 thereof, any extract from any part of the plant, and every
- 24 compound, manufacture, salt, derivative, mixture, or preparation
- 25 of the plant, its seeds, or extracts.
- 26 (8) Cathinone (also known as alpha-aminopropiophenone,
- 27 2-aminopropiophenone, and norephedrone).
- 28 (e) Depressants. Unless specifically excepted or unless listed
- 29 in another schedule, any material, compound, mixture, or
- 30 preparation which contains any quantity of the following substances
- 31 having a depressant effect on the central nervous system, including
- 32 its salts, isomers, and salts of isomers whenever the existence of
- 33 those salts, isomers, and salts of isomers is possible within the
- 34 specific chemical designation:
- 35 (1) Amobarbital.
- 36 (2) Pentobarbital.
- 37 (3) Phencyclidines, including the following:
- 38 (A) 1-(1-phenylcyclohexyl) piperidine (PCP).
- 39 (B) 1-(1-phenylcyclohexyl) morpholine (PCM).

1 (C) Any analog of phencyclidine which is added by the Attorney  
2 General by regulation pursuant to this paragraph.

3 The Attorney General, or his or her designee, may, by rule or  
4 regulation, add additional analogs of phencyclidine to those  
5 enumerated in this paragraph after notice, posting, and hearing  
6 pursuant to Chapter 3.5 (commencing with Section 11340) of Part  
7 1 of Division 3 of Title 2 of the Government Code. The Attorney  
8 General shall, in the calendar year of the regular session of the  
9 Legislature in which the rule or regulation is adopted, submit a  
10 draft of a proposed bill to each house of the Legislature which  
11 would incorporate the analogs into this code. No rule or regulation  
12 shall remain in effect beyond January 1 after the calendar year of  
13 the regular session in which the draft of the proposed bill is  
14 submitted to each house. However, if the draft of the proposed bill  
15 is submitted during a recess of the Legislature exceeding 45  
16 calendar days, the rule or regulation shall be effective until January  
17 1 after the next calendar year.

18 (4) Secobarbital.

19 (5) Glutethimide.

20 (f) Immediate precursors. Unless specifically excepted or unless  
21 listed in another schedule, any material, compound, mixture, or  
22 preparation which contains any quantity of the following  
23 substances:

24 (1) Immediate precursor to amphetamine and methamphetamine:

25 (A) Phenylacetone. Some trade or other names: phenyl-2  
26 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

27 (2) Immediate precursors to phencyclidine (PCP):

28 (A) 1-phenylcyclohexylamine.

29 (B) 1-piperidinocyclohexane carbonitrile (PCC).

30 *SEC. 2. Section 11056 of the Health and Safety Code is*  
31 *amended to read:*

32 11056. (a) The controlled substances listed in this section are  
33 included in Schedule III.

34 (b) Stimulants. Unless specifically excepted or unless listed in  
35 another schedule, any material, compound, mixture, or preparation  
36 which contains any quantity of the following substances having a  
37 stimulant effect on the central nervous system, including its salts,  
38 isomers (whether optical, position, or geometric), and salts of those  
39 isomers whenever the existence of those salts, isomers, and salts  
40 of isomers is possible within the specific chemical designation:

1 (1) Those compounds, mixtures, or preparations in dosage unit  
2 form containing any stimulant substances listed in Schedule II  
3 which compounds, mixtures, or preparations were listed on August  
4 25, 1971, as excepted compounds under Section 1308.32 of Title  
5 21 of the Code of Federal Regulations, and any other drug of the  
6 quantitative composition shown in that list for those drugs or which  
7 is the same except that it contains a lesser quantity of controlled  
8 substances.

9 (2) Benzphetamine.

10 (3) Chlorphentermine.

11 (4) Clortermine.

12 (5) Mazindol.

13 (6) Phendimetrazine.

14 (c) Depressants. Unless specifically excepted or unless listed  
15 in another schedule, any material, compound, mixture, or  
16 preparation which contains any quantity of the following substances  
17 having a depressant effect on the central nervous system:

18 (1) Any compound, mixture, or preparation containing any of  
19 the following:

20 (A) Amobarbital

21 (B) Secobarbital

22 (C) Pentobarbital

23 or any salt thereof and one or more other active medicinal  
24 ingredients which are not listed in any schedule.

25 (2) Any suppository dosage form containing any of the  
26 following:

27 (A) Amobarbital

28 (B) Secobarbital

29 (C) Pentobarbital

30 or any salt of any of these drugs and approved by the federal Food  
31 and Drug Administration for marketing only as a suppository.

32 (3) Any substance which contains any quantity of a derivative  
33 of barbituric acid or any salt thereof.

34 (4) Chlorhexadol.

35 (5) Lysergic acid.

36 (6) Lysergic acid amide.

37 (7) Methyprylon.

38 (8) Sulfondiethylmethane.

39 (9) Sulfonethylmethane.

40 (10) Sulfonmethane.

1 (11) Gamma hydroxybutyric acid, and its salts, isomers and  
2 salts of isomers, contained in a drug product for which an  
3 application has been approved under Section 505 of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

5 (d) Nalorphine.

6 (e) Narcotic drugs. Unless specifically excepted or unless listed  
7 in another schedule, any material, compound, mixture, or  
8 preparation containing any of the following narcotic drugs, or their  
9 salts calculated as the free anhydrous base or alkaloid, in limited  
10 quantities as set forth below:

11 (1) Not more than 1.8 grams of codeine per 100 milliliters or  
12 not more than 90 milligrams per dosage unit, with an equal or  
13 greater quantity of an isoquinoline alkaloid of opium.

14 (2) Not more than 1.8 grams of codeine per 100 milliliters or  
15 not more than 90 milligrams per dosage unit, with one or more  
16 active, nonnarcotic ingredients in recognized therapeutic amounts.

17 ~~(3) Not more than 300 milligrams of dihydrocodeinone per 100~~  
18 ~~milliliters or not more than 15 milligrams per dosage unit, with a~~  
19 ~~fourfold or greater quantity of an isoquinoline alkaloid of opium.~~

20 ~~(4) Not more than 300 milligrams of dihydrocodeinone per 100~~  
21 ~~milliliters or not more than 15 milligrams per dosage unit, with~~  
22 ~~one or more active nonnarcotic ingredients in recognized~~  
23 ~~therapeutic amounts. Additionally, oral liquid preparations of~~  
24 ~~dihydrocodeinone containing the above specified amounts may~~  
25 ~~not contain as its nonnarcotic ingredients two or more~~  
26 ~~antihistamines in combination with each other.~~

27 ~~(5)~~

28 (3) Not more than 1.8 grams of dihydrocodeine per 100  
29 milliliters or not more than 90 milligrams per dosage unit, with  
30 one or more active nonnarcotic ingredients in recognized  
31 therapeutic amounts.

32 ~~(6)~~

33 (4) Not more than 300 milligrams of ethylmorphine per 100  
34 milliliters or not more than 15 milligrams per dosage unit, with  
35 one or more active, nonnarcotic ingredients in recognized  
36 therapeutic amounts.

37 ~~(7)~~

38 (5) Not more than 500 milligrams of opium per 100 milliliters  
39 or per 100 grams or not more than 25 milligrams per dosage unit,

1 with one or more active, nonnarcotic ingredients in recognized  
2 therapeutic amounts.

3 ~~(8)~~

4 (6) Not more than 50 milligrams of morphine per 100 milliliters  
5 or per 100 grams, with one or more active, nonnarcotic ingredients  
6 in recognized therapeutic amounts.

7 (f) Anabolic steroids and chorionic gonadotropin. Any material,  
8 compound, mixture, or preparation containing chorionic  
9 gonadotropin or an anabolic steroid (excluding anabolic steroid  
10 products listed in the “Table of Exempt Anabolic Steroid Products”  
11 (Section 1308.34 of Title 21 of the Code of Federal Regulations),  
12 as exempt from the federal Controlled Substances Act (Section  
13 801 and following of Title 21 of the United States Code)),  
14 including, but not limited to, the following:

- 15 (1) Androisoxazole.
- 16 (2) Androstenediol.
- 17 (3) Bolandiol.
- 18 (4) Bolasterone.
- 19 (5) Boldenone.
- 20 (6) Chlormethandienone.
- 21 (7) Clostebol.
- 22 (8) Dihydromesterone.
- 23 (9) Ethylestrenol.
- 24 (10) Fluoxymesterone.
- 25 (11) Formyldienolone.
- 26 (12) 4-Hydroxy-19-nortestosterone.
- 27 (13) Mesterolone.
- 28 (14) Methandriol.
- 29 (15) Methandrostenolone.
- 30 (16) Methenolone.
- 31 (17) 17-Methyltestosterone.
- 32 (18) Methyltrienolone.
- 33 (19) Nandrolone.
- 34 (20) Norbolethone.
- 35 (21) Norethandrolone.
- 36 (22) Normethandrolone.
- 37 (23) Oxandrolone.
- 38 (24) Oxymestronone.
- 39 (25) Oxymetholone.
- 40 (26) Quinbolone.

- 1 (27) Stanolone.
- 2 (28) Stanozolol.
- 3 (29) Stenbolone.
- 4 (30) Testosterone.
- 5 (31) Trenbolone.
- 6 (32) Chorionic Gonadotropin (HGC).
- 7 (g) Ketamine. Any material, compound, mixture, or preparation
- 8 containing ketamine.
- 9 (h) Hallucinogenic substances. Any of the following
- 10 hallucinogenic substances: dronabinol (synthetic) in sesame oil
- 11 and encapsulated in a soft gelatin capsule in a drug product
- 12 approved by the federal Food and Drug Administration.

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

22 ~~SECTION 1. Section 4021 of the Business and Professions~~  
 23 ~~Code is amended to read:~~

24 ~~4021. (a) "Controlled substance" means a substance listed in~~  
 25 ~~Chapter 2 (commencing with Section 11053) of Division 10 of the~~  
 26 ~~Health and Safety Code and a substance listed in the controlled~~  
 27 ~~substance schedules in federal law and regulations, including~~  
 28 ~~sections 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15 of Title~~  
 29 ~~21 of the Code of Federal Regulations.~~

30 ~~(b) When there is a conflict between the federal and state~~  
 31 ~~schedules, the schedule that is more closely regulated shall control.~~

32 ~~SEC. 2. Section 11007 of the Health and Safety Code is~~  
 33 ~~amended to read:~~

34 ~~11007. (a) "Controlled substance," unless otherwise specified,~~  
 35 ~~means a drug, substance, or immediate precursor that is listed in~~  
 36 ~~any schedule in Section 11054, 11055, 11056, 11057, or 11058~~  
 37 ~~and a substance listed in the controlled substance schedules in~~  
 38 ~~federal law and regulations, including Sections 1308.11, 1308.12,~~  
 39 ~~1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal~~  
 40 ~~Regulations.~~

1 ~~(b) When there is a conflict between the federal and state~~  
2 ~~schedules, the schedule that is more closely regulated shall control.~~

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



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<b>Bill Number:</b>	<b>AB 2783</b>
<b>Current Version:</b>	<b>As amended April 11, 2018</b>
<b>Author:</b>	<b>O'Donnell</b>
<b>Topic:</b>	<b>Controlled substances: hydrocodone combination products</b>
<b>Staff Recommendation:</b>	<b>Support</b>

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**AFFECTED SECTIONS:** Amends sections 11055 and 11056 of the Health and Safety Code.

**STATUS:** Assembly Appropriations

**EXISTING LAW:**

The California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law classifies hydrocodone as a Schedule II controlled substance. Existing law classifies specified compounds, including some hydrocodone compounds, as Schedule III controlled substances. Existing law imposes stringent prescription requirements on drugs classified as Schedule II, including a limitation on refills, the violation of which are crimes.

**THIS BILL WOULD:**

This bill would reclassify specific hydrocodone combination products as Schedule II controlled substances.

**STAFF COMMENTS:**

This is the board's measure that was initially intended to reconcile California state schedules with the Federal schedules as approved by the Board at its January 11, 2018 meeting. Although this measure does not meet the full policy goals of the board, it does reschedule hydrocodone in California to make it consistent with the federal classification and is a step in the direction of reconciliation.

**FISCAL IMPACT ON THE BOARD:**

Minor and absorbable.

**SUPPORT / OPPOSITION:**

SUPPORT:

California State Board of Pharmacy

OPPOSITION:

None on file

**BILL HISTORY:**

04/17/18	From committee: Do pass and re-refer to Com. on APPR. with recommendation: To Consent Calendar. (Ayes 7. Noes 0.) (April 17). Re-referred to Com. on APPR.
04/12/18	Re-referred to Com. on PUB. S.
04/11/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
04/02/18	Re-referred to Com. on PUB. S.
03/22/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
03/22/18	Referred to Com. on PUB. S.
02/17/18	From printer. May be heard in committee March 19.
02/16/18	Read first time. To print.

**ASSEMBLY BILL**

**No. 2789**

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**Introduced by Assembly Member Wood**

February 16, 2018

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An act to add Section 688 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2789, as introduced, Wood. Health care practitioners: prescriptions: electronic transmission.

Existing law provides for the regulation of health care practitioners and requires prescription drugs to be ordered and dispensed in accordance with the Pharmacy Law. Existing law, the Pharmacy Law, provides that a prescription is an oral, written, or electronic transmission order and requires electronic transmission prescriptions to be transmitted and processed in accordance with specified requirements.

This bill, on and after January 1, 2020, would require health care practitioners authorized to issue prescriptions to have the capability to transmit electronic transmission prescriptions, and would require pharmacies to have the capability to receive those transmissions. The bill, on and after January 1, 2021, would require those health care practitioners to issue prescriptions as an electronic transmission prescription, unless specified exceptions are met. The bill would not require the pharmacy to verify that a written, oral, or faxed prescription satisfies the specified exemptions. The bill would require the pharmacy receiving the electronic transmission prescription to immediately notify the prescriber if the electronic transmission prescription fails, is incomplete, or is otherwise not appropriately received. The bill would authorize the pharmacy to transmit the prescription to another pharmacy

at the request of the patient, as specified. The bill would make a violation of these provisions unprofessional conduct and would subject the health care practitioner to discipline by the board charged with regulating his or her license.

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 688 is added to the Business and  
2 Professions Code, to read:

3 688. (a) On and after January 1, 2020, a health care practitioner  
4 authorized to issue a prescription pursuant to Section 4040 shall  
5 have the capability to issue an electronic transmission prescription,  
6 as defined under Section 4040, on behalf of a patient and to  
7 transmit that electronic transmission prescription to a pharmacy  
8 selected by the patient.

9 (b) On and after January 1, 2020, a pharmacy, pharmacist, or  
10 other practitioner authorized under California law to dispense or  
11 furnish a prescription pursuant to Section 4040 shall have the  
12 capability to receive an electronic transmission prescription on  
13 behalf of a patient.

14 (c) For a prescription for a controlled substance, as defined by  
15 Section 4021, generation and transmission of the electronic  
16 transmission prescription shall comply with Parts 1300, 1304,  
17 1306, and 1311 of Title 21 of the Code of Federal Regulations, as  
18 amended from time to time.

19 (d) On and after January 1, 2021, a prescription prescribed by  
20 a health care practitioner shall be issued as an electronic  
21 transmission prescription. This subdivision shall not apply to  
22 prescriptions issued pursuant to subdivision (e).

23 (e) Subdivision (d) shall not apply to any of the following:

24 (1) The prescription is issued pursuant to Section 11159.2 of  
25 the Health and Safety Code.

26 (2) An electronic transmission prescription is not available due  
27 to a temporary technological or electrical failure. For purposes of  
28 this paragraph, “temporary technological or electrical failure”  
29 means failure of a computer system, application, or device, or the  
30 loss of electrical power to that system, application, or device, or  
31 any other service interruption affecting the certified electronic

1 transmission prescription application used to transmit the  
2 prescription.

3 (3) The prescribing health care practitioner is issuing a  
4 prescription to be dispensed by a pharmacy located outside  
5 California.

6 (4) The prescription is issued by a veterinarian.

7 (5) The prescribing health care practitioner and the dispenser  
8 are the same entity.

9 (6) The prescription is issued by a prescribing health care  
10 practitioner under circumstances whereby the practitioner  
11 reasonably determines that it would be impractical for the patient  
12 to obtain controlled substances prescribed by an electronic  
13 transmission prescription in a timely manner, and the delay would  
14 adversely impact the patient's medical condition.

15 (f) A health care practitioner who issues a prescription for a  
16 controlled substance but does not transmit the prescription as an  
17 electronic transmission prescription shall document the reason in  
18 the patient's medical record as soon as practicable and within 72  
19 hours of the end of the technological or electrical failure that  
20 prevented the electronic transmission of the prescription.

21 (g) A pharmacy that receives an electronic transmission  
22 prescription from a prescribing health care practitioner who has  
23 issued the prescription but has not dispensed the medication to the  
24 patient may, at the request of the patient or a person authorized to  
25 make a request on behalf of the patient, immediately transfer or  
26 forward the electronic transmission prescription to an alternative  
27 pharmacy designated by the requester.

28 (h) If a pharmacy, or its staff, is aware than an attempted  
29 transmission of an electronic transmission prescription failed, is  
30 incomplete, or is otherwise not appropriately received, the  
31 pharmacy shall immediately notify the prescribing health care  
32 practitioner.

33 (i) A pharmacist who receives a written, oral, or faxed  
34 prescription shall not be required to verify that the prescription  
35 properly falls under one of the exceptions in subdivision (e).  
36 Pharmacists may continue to dispense medications from legally  
37 valid written, oral, or fax prescriptions pursuant to this division.

- 1 (j) Notwithstanding any other law, a violation of this section
- 2 constitutes unprofessional conduct and grounds for disciplinary
- 3 action by the health care practitioner's licensing board.

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<b>Bill Number:</b>	<b>AB 2789</b>
<b>Current Version:</b>	<b>As amended April 3, 2018</b>
<b>Author:</b>	<b>Wood</b>
<b>Topic:</b>	<b>Health care practitioners: prescriptions: electronic data transmission.</b>
<b>Staff Recommendation:</b>	<b>Support</b>

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**AFFECTED SECTIONS:** Adds Chapter 3.6 to Part 1 of Division 3 of Title 2 of the Government Code and subsequent repeal.

**STATUS:** Assembly Appropriations

**EXISTING LAW:**

Health Care practitioners are regulated by their respective licensing boards and certain practitioners are authorized to issue prescriptions for dangerous drugs and devices.

**THIS BILL WOULD:**

- Require by January 1, 2021, all prescriptions issued by licensed prescribers in California be issued as an electronic transmission prescription (e-prescription).
- Require that on or before January 1, 2020, health care practitioners authorized to issue a prescription must have the capability to issue an electronic transmission and that
- By January 2, 2021 all pharmacies, pharmacists or other practitioners authorized to dispense or furnish a prescription must have the capability to receive an e-prescription.
- Provide for certain exemptions to this requirement including:
  - A prescription issued pursuant to Section 11159.2 (certification of a terminally ill patient);
  - Electronic transmission not available due to a temporary technological or electrical failure;
  - The prescribing practitioner is issuing a prescription; to be dispensed by a pharmacy located outside California;
  - The prescription is issued by a veterinarian;
  - The prescribing health care practitioner and the dispenser are the same entity; and,
  - The health care practitioner reasonably determines that it would be impractical for the patient to obtain the controlled substances prescribed in a timely manner, and the delay would adversely impact the patient's medical condition.
- Requires a prescriber who does not transmit a prescription for a controlled substance as an e- prescription to document the reason in the patient's medical record within 72

hours of the end of the technological or electrical failure that prevented the electronic transmission.

- Does not require a pharmacist who receives a written, oral, or faxed prescription to verify that the prescription falls under one of the exemptions from e-prescribing previously noted. The pharmacists may continue to dispense medications from written, oral or fax prescriptions that otherwise meet the requirements for a valid prescription.

**STAFF COMMENTS:**

The board is the originator of this bill. During the January 2018 Board meeting, the board discussed how the abuse of pharmaceutical drugs has skyrocketed in the United States, over the past decade, and has led to the current opioid epidemic. In California, specifically, criminal organizations have been able to exploit weaknesses and lack of oversight in the paper printing program resulting in their ability to counterfeit prescriptions. It was reported that as recently as November 29, 2017, a member of a drug trafficking organization that illegally acquired and distributed at least 50,000 oxycodone tablets valued at \$1.5 million using counterfeit security form prescriptions during a three year span was convicted in federal court in San Diego. It was further discussed how patients can alter paper prescriptions to increase the quantity, add drugs, or add refills. Patients also steal whole prescription pads from prescribers which are then sold to criminal organizations or used by addicts. Prescribers routinely report losing their pads to the Board of Pharmacy as well as to other agencies.

There are seven states that have passed legislation on e-prescribing. Minnesota requires the ability to e-prescribe but does not mandate its use, while, New York and Maine mandate the use of e-prescribing as the primary means of prescribing any medication.

In New York, which has had a mandate since March 2016 for both controlled and noncontrolled prescriptions to be e-prescribed:

- 98.1 percent of pharmacies were EPCS-enabled
- 72.1 percent of prescribers were EPCS-enabled (one year before, only 47% of New York prescribers could use EPCS)
- 91.9 percent of controlled substance prescriptions were sent electronically
- one year after the law was finalized doctor shopping was reduced by 90 percent

The use of e-prescribing in California is increasing because e-prescribing helps to:

- Reduce overall mistakes made in interpreting prescribers' handwriting
- Allow for the prescription information to auto populate in the pharmacy without staff input
- Reduce patients' wait times for filling prescriptions
- Enable fast retrieval of records
- Save space by e-storing records
- Substantially reduce the opportunities for persons to steal, alter, "doctor shop," or counterfeit prescriptions, thus decreasing unsupervised access to medication

**FISCAL IMPACT ON THE BOARD:**

Given the resources that would be required, board staff identified a fiscal to include IT costs for the establishment of new enforcement codes. Such costs would be minor and absorbable.

**SUPPORT / OPPOSITION:**

SUPPORT:

- America’s Physician Groups
- California Association of Health Underwriters
- California State Board of Pharmacy
- Healthcare Distribution Alliance
- Imprivata

OPPOSITION:

- California Medical Association

**BILL HISTORY:**

04/10/18	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 1.) (April 10). Re-referred to Com. on APPR.
04/04/18	Re-referred to Com. on B. & P.
04/03/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/08/18	Referred to Com. on B. & P.
02/17/18	From printer. May be heard in committee March 19.
02/16/18	Read first time. To print.

# **Attachment 2**

AMENDED IN ASSEMBLY APRIL 18, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1753**

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**Introduced by Assembly Member Low**

January 3, 2018

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An act to amend Sections 11161.5, 11162.1, and 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1753, as amended, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the Department of Justice, as specified. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the Department of Justice.

This bill ~~would, beginning January 1, 2020, require~~ *would authorize* the Department of Justice to *reduce or* limit the number of approved printers to 3, as specified. The bill would require prescription forms for controlled substance prescriptions to have a uniquely serialized number, in a manner prescribed by the Department of Justice, and would require a printer to submit specified information to the Department of Justice for all prescription forms delivered. The bill would require the

information submitted by a dispensing pharmacy, clinic, or other dispenser to the Department of Justice to include the serial number for the corresponding prescription ~~pad~~, *form*, if applicable.

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. The Legislature finds and declares the following:

2 (a) The prevailing use of paper prescription pads to prescribe  
3 controlled substances leads to significant instances of theft and  
4 fraud each year, contributing to the prescription drug abuse crisis  
5 and fueling criminal enterprises engaged in drug diversion.

6 (b) Prescribing controlled substances by means of electronic  
7 transmission prescription, or e-prescribing, has long been  
8 considered the most effective way to combat prescription pad theft  
9 and fraud.

10 (c) Many states have begun to require that all controlled  
11 substances must be prescribed electronically as a means of  
12 addressing the public health and public safety crises associated  
13 with prescription drug abuse and diversion.

14 (d) Until mandatory e-prescribing is established in California,  
15 it is critical that tighter restrictions be placed on the manufacturing  
16 and tracking of prescription pads used within the state.

17 SEC. 2. Section 11161.5 of the Health and Safety Code is  
18 amended to read:

19 11161.5. (a) Prescription forms for controlled substance  
20 prescriptions shall be obtained from security printers approved by  
21 the Department of Justice.

22 (b) The department may approve security printer applications  
23 after the applicant has provided the following information:

24 (1) Name, address, and telephone number of the applicant.

25 (2) Policies and procedures of the applicant for verifying the  
26 identity of the prescriber ordering controlled substance prescription  
27 forms.

28 (3) Policies and procedures of the applicant for verifying  
29 delivery of controlled substance prescription forms to prescribers.

30 (4) (A) The location, names, and titles of the applicant’s agent  
31 for service of process in this state; all principal corporate officers,  
32 if any; all managing general partners, if any; and any individual

1 owner, partner, corporate officer, manager, agent, representative,  
2 employee, or subcontractor of the applicant who has direct access  
3 to, or management or control of, controlled substance prescription  
4 forms.

5 (B) A report containing this information shall be made on an  
6 annual basis and within 30 days after any change of office,  
7 principal corporate officers, managing general partner, or of any  
8 person described in subparagraph (A).

9 (5) (A) A signed statement indicating whether the applicant,  
10 any principal corporate officer, any managing general partner, or  
11 any individual owner, partner, corporate officer, manager, agent,  
12 representative, employee, or subcontractor of the applicant who  
13 has direct access to, or management or control of, controlled  
14 substance prescription forms, has ever been convicted of, or pled  
15 no contest to, a violation of any law of a foreign country, the United  
16 States, or any state, or of any local ordinance.

17 (B) The department shall provide the applicant and any  
18 individual owner, partner, corporate officer, manager, agent,  
19 representative, employee, or subcontractor of the applicant who  
20 has direct access to, or management or control of, controlled  
21 substance prescription forms, with the means and direction to  
22 provide fingerprints and related information, in a manner specified  
23 by the department, for the purpose of completing state, federal, or  
24 foreign criminal background checks.

25 (C) Any applicant described in subdivision (b) shall submit his  
26 or her fingerprint images and related information to the department,  
27 for the purpose of the department obtaining information as to the  
28 existence and nature of a record of state, federal, or foreign level  
29 convictions and state, federal, or foreign level arrests for which  
30 the department establishes that the applicant was released on bail  
31 or on his or her own recognizance pending trial, as described in  
32 subdivision (l) of Section 11105 of the Penal Code. Requests for  
33 federal level criminal offender record information received by the  
34 department pursuant to this section shall be forwarded to the  
35 Federal Bureau of Investigation by the department.

36 (D) The department shall assess against each security printer  
37 applicant a fee determined by the department to be sufficient to  
38 cover all processing, maintenance, and investigative costs generated  
39 from or associated with completing state, federal, or foreign  
40 background checks and inspections of security printers pursuant

1 to this section with respect to that applicant; the fee shall be paid  
2 by the applicant at the time he or she submits the security printer  
3 application, fingerprints, and related information to the department.

4 (E) The department shall retain fingerprint impressions and  
5 related information for subsequent arrest notification pursuant to  
6 Section 11105.2 of the Penal Code for all applicants.

7 (c) The department may, within 60 calendar days of receipt of  
8 the application from the applicant, deny the security printer  
9 application.

10 (d) The department may deny a security printer application on  
11 any of the following grounds:

12 (1) The applicant, any individual owner, partner, corporate  
13 officer, manager, agent, representative, employee, or subcontractor  
14 for the applicant, who has direct access, management, or control  
15 of controlled substance prescription forms, has been convicted of  
16 a crime. A conviction within the meaning of this paragraph means  
17 a plea or verdict of guilty or a conviction following a plea of nolo  
18 contendere. Any action which a board is permitted to take  
19 following the establishment of a conviction may be taken when  
20 the time for appeal has elapsed, the judgment of conviction has  
21 been affirmed on appeal, or when an order granting probation is  
22 made suspending the imposition of sentence, irrespective of a  
23 subsequent order under the provisions of Section 1203.4 of the  
24 Penal Code.

25 (2) The applicant committed any act involving dishonesty, fraud,  
26 or deceit with the intent to substantially benefit himself, herself,  
27 or another, or substantially injure another.

28 (3) The applicant committed any act that would constitute a  
29 violation of this division.

30 (4) The applicant knowingly made a false statement of fact  
31 required to be revealed in the application to produce controlled  
32 substance prescription forms.

33 (5) The department determines that the applicant failed to  
34 demonstrate adequate security procedures relating to the production  
35 and distribution of controlled substance prescription forms.

36 (6) The department determines that the applicant has submitted  
37 an incomplete application.

38 (7) As a condition for its approval as a security printer, an  
39 applicant shall authorize the Department of Justice to make any  
40 examination of the books and records of the applicant, or to visit

1 and inspect the applicant during business hours, to the extent  
2 deemed necessary by the board or department to properly enforce  
3 this section.

4 (e) An approved applicant shall submit an exemplar of a  
5 controlled substance prescription form, with all security features,  
6 to the Department of Justice within 30 days of initial production.

7 (f) The department shall maintain a list of approved security  
8 printers and the department shall make this information available  
9 to prescribers and other appropriate government agencies, including  
10 the Board of Pharmacy.

11 (g) Before printing any controlled substance prescription forms,  
12 a security printer shall verify with the appropriate licensing board  
13 that the prescriber possesses a license and current prescribing  
14 privileges which permits the prescribing of controlled substances  
15 with the federal Drug Enforcement Administration (DEA).

16 (h) Controlled substance prescription forms shall be provided  
17 directly to the prescriber either in person, by certified mail, or by  
18 a means that requires a signature signifying receipt of the package  
19 and provision of that signature to the security printer. Controlled  
20 substance prescription forms provided in person shall be restricted  
21 to established customers. Security printers shall obtain a photo  
22 identification from the customer and maintain a log of this  
23 information. Controlled substance prescription forms shall be  
24 shipped only to the prescriber's address on file and verified with  
25 the federal Drug Enforcement Administration or the Medical Board  
26 of California.

27 (i) Security printers shall retain ordering and delivery records  
28 in a readily retrievable manner for individual prescribers for three  
29 years.

30 (j) Security printers shall produce ordering and delivery records  
31 upon request by an authorized officer of the law as defined in  
32 Section 4017 of the Business and Professions Code.

33 (k) Security printers shall report any theft or loss of controlled  
34 substance prescription forms to the Department of Justice via fax  
35 or ~~e-mail~~ *email* within 24 hours of the theft or loss.

36 (l) (1) The department shall impose restrictions, sanctions, or  
37 penalties, subject to subdivisions (m) and (n), against security  
38 printers who are not in compliance with this division pursuant to  
39 regulations implemented pursuant to this division and shall revoke  
40 its approval of a security printer for a violation of this division or

1 action that would permit a denial pursuant to subdivision (d) of  
2 this section.

3 (2) When the department revokes its approval, it shall notify  
4 the appropriate licensing boards and remove the security printer  
5 from the list of approved security printers.

6 (m) The following violations by security printers shall be  
7 punishable pursuant to subdivision (n):

8 (1) Failure to comply with the Security Printer Guidelines  
9 established by the Security Printer Program as a condition of  
10 approval.

11 (2) Failure to take reasonable precautions to prevent any  
12 dishonest act or illegal activity related to the access and control of  
13 security prescription forms.

14 (3) Theft or fraudulent use of a prescriber’s identity in order to  
15 obtain security prescription forms.

16 (n) A security printer approved pursuant to subdivision (b) shall  
17 be subject to the following penalties for actions leading to the  
18 denial of a security printer application specified in subdivision (d)  
19 or for a violation specified in subdivision (m):

20 (1) For a first violation, a fine not to exceed one thousand dollars  
21 (\$1,000).

22 (2) For a second or subsequent violation, a fine not to exceed  
23 two thousand five hundred dollars (\$2,500) for each violation.

24 (3) For a third or subsequent violation, a filing of an  
25 administrative disciplinary action seeking to suspend or revoke  
26 security printer approval.

27 ~~(o) Beginning January 1, 2020, the Department of Justice shall  
28 limit the number of approved printers to three. The Department of  
29 Justice shall establish policies governing the selection of the three  
30 approved vendors based on ability to meet demand and prevent  
31 fraud and theft of prescription pads and the process of revoking  
32 approval for currently authorized printers in excess of three.~~

33 *(o) In order to facilitate the standardization of all prescription  
34 forms and the serialization of prescription forms with unique  
35 identifiers, the Department of Justice may cease issuing new  
36 approvals of security printers to the extent necessary to achieve  
37 these purposes. The department may, pursuant to regulation,  
38 reduce the number of currently approved security printers to no  
39 fewer than three vendors. The department shall ensure that any  
40 reduction or limitation of approved security printers does not*

1 *impact the ability of vendors to meet demand for prescription*  
2 *forms.*

3 SEC. 3. Section 11162.1 of the Health and Safety Code is  
4 amended to read:

5 11162.1. (a) The prescription forms for controlled substances  
6 shall be printed with the following features:

7 (1) A latent, repetitive “void” pattern shall be printed across the  
8 entire front of the prescription blank; if a prescription is scanned  
9 or photocopied, the word “void” shall appear in a pattern across  
10 the entire front of the prescription.

11 (2) A watermark shall be printed on the backside of the  
12 prescription blank; the watermark shall consist of the words  
13 “California Security Prescription.”

14 (3) A chemical void protection that prevents alteration by  
15 chemical washing.

16 (4) A feature printed in thermochromic ink.

17 (5) An area of opaque writing so that the writing disappears if  
18 the prescription is lightened.

19 (6) A description of the security features included on each  
20 prescription form.

21 (7) (A) Six quantity check off boxes shall be printed on the  
22 form so that the prescriber may indicate the quantity by checking  
23 the applicable box where the following quantities shall appear:

24 1–24

25 25–49

26 50–74

27 75–100

28 101–150

29 151 and over.

30 (B) In conjunction with the quantity boxes, a space shall be  
31 provided to designate the units referenced in the quantity boxes  
32 when the drug is not in tablet or capsule form.

33 (8) Prescription blanks shall contain a statement printed on the  
34 bottom of the prescription blank that the “Prescription is void if  
35 the number of drugs prescribed is not noted.”

36 (9) The preprinted name, category of licensure, license number,  
37 federal controlled substance registration number, and address of  
38 the prescribing practitioner.

39 (10) Check boxes shall be printed on the form so that the  
40 prescriber may indicate the number of refills ordered.

- 1 (11) The date of origin of the prescription.
- 2 (12) A check box indicating the prescriber’s order not to
- 3 substitute.
- 4 (13) An identifying number assigned to the approved security
- 5 printer by the Department of Justice.
- 6 (14) (A) A check box by the name of each prescriber when a
- 7 prescription form lists multiple prescribers.
- 8 (B) Each prescriber who signs the prescription form shall
- 9 identify himself or herself as the prescriber by checking the box
- 10 by his or her name.
- 11 (15) ~~(A) A uniquely serialized number, in a manner prescribed~~
- 12 ~~by the Department of Justice.~~
- 13 ~~(B) Within the next working day following delivery, a security~~
- 14 ~~printer shall submit via Web-based application, as specified by the~~
- 15 ~~Department of Justice, all of the following information for all~~
- 16 ~~prescription forms delivered:~~
- 17 ~~(i) Serial numbers of all prescription forms delivered.~~
- 18 ~~(ii) All prescriber names and Drug Enforcement Administration~~
- 19 ~~Controlled Substance Registration Certificate numbers displayed~~
- 20 ~~on the prescription forms.~~
- 21 ~~(iii) The delivery shipment recipient names.~~
- 22 (b) Each batch of controlled substance prescription forms shall
- 23 have the lot number printed on the form and each form within that
- 24 batch shall be numbered sequentially beginning with the numeral
- 25 one.
- 26 (c) (1) A prescriber designated by a licensed health care facility,
- 27 a clinic specified in Section 1200, or a clinic specified in
- 28 subdivision (a) of Section 1206 that has 25 or more physicians or
- 29 surgeons may order controlled substance prescription forms for
- 30 use by prescribers when treating patients in that facility without
- 31 the information required in paragraph (9) of subdivision (a) or
- 32 paragraph (3) of this subdivision.
- 33 (2) Forms ordered pursuant to this subdivision shall have the
- 34 name, category of licensure, license number, and federal controlled
- 35 substance registration number of the designated prescriber and the
- 36 name, address, category of licensure, and license number of the
- 37 licensed health care facility the clinic specified in Section 1200,
- 38 or the clinic specified in Section 1206 that has 25 or more
- 39 physicians or surgeons preprinted on the form. Licensed health
- 40 care facilities or clinics exempt under Section 1206 are not required

1 to preprint the category of licensure and license number of their  
2 facility or clinic.

3 (3) Forms ordered pursuant to this section shall not be valid  
4 prescriptions without the name, category of licensure, license  
5 number, and federal controlled substance registration number of  
6 the prescriber on the form.

7 (4) (A) Except as provided in subparagraph (B), the designated  
8 prescriber shall maintain a record of the prescribers to whom the  
9 controlled substance prescription forms are issued, that shall  
10 include the name, category of licensure, license number, federal  
11 controlled substance registration number, and quantity of controlled  
12 substance prescription forms issued to each prescriber. The record  
13 shall be maintained in the health facility for three years.

14 (B) Forms ordered pursuant to this subdivision that are printed  
15 by a computerized prescription generation system shall not be  
16 subject to subparagraph (A) or paragraph (7) of subdivision (a).  
17 Forms printed pursuant to this subdivision that are printed by a  
18 computerized prescription generation system may contain the  
19 prescriber's name, category of professional licensure, license  
20 number, federal controlled substance registration number, and the  
21 date of the prescription.

22 ~~(d) This section shall become operative on January 1, 2012.~~  
23 ~~Prescription forms not in compliance with this division shall not~~  
24 ~~be valid or accepted after July 1, 2012.~~

25 *(d) Within the next working day following delivery, a security*  
26 *printer shall submit via Web-based application, as specified by*  
27 *the Department of Justice, all of the following information for all*  
28 *prescription forms delivered:*

29 *(1) Serial numbers of all prescription forms delivered.*

30 *(2) All prescriber names and Drug Enforcement Administration*  
31 *Controlled Substance Registration Certificate numbers displayed*  
32 *on the prescription forms.*

33 *(3) The delivery shipment recipient names.*

34 *(4) The date of delivery.*

35 SEC. 4. Section 11165 of the Health and Safety Code is  
36 amended to read:

37 11165. (a) To assist health care practitioners in their efforts  
38 to ensure appropriate prescribing, ordering, administering,  
39 furnishing, and dispensing of controlled substances, law  
40 enforcement and regulatory agencies in their efforts to control the

1 diversion and resultant abuse of Schedule II, Schedule III, and  
2 Schedule IV controlled substances, and for statistical analysis,  
3 education, and research, the Department of Justice shall, contingent  
4 upon the availability of adequate funds in the CURES Fund,  
5 maintain the Controlled Substance Utilization Review and  
6 Evaluation System (CURES) for the electronic monitoring of, and  
7 Internet access to information regarding, the prescribing and  
8 dispensing of Schedule II, Schedule III, and Schedule IV controlled  
9 substances by all practitioners authorized to prescribe, order,  
10 administer, furnish, or dispense these controlled substances.

11 (b) The Department of Justice may seek and use grant funds to  
12 pay the costs incurred by the operation and maintenance of  
13 CURES. The department shall annually report to the Legislature  
14 and make available to the public the amount and source of funds  
15 it receives for support of CURES.

16 (c) (1) The operation of CURES shall comply with all  
17 applicable federal and state privacy and security laws and  
18 regulations.

19 (2) (A) CURES shall operate under existing provisions of law  
20 to safeguard the privacy and confidentiality of patients. Data  
21 obtained from CURES shall only be provided to appropriate state,  
22 local, and federal public agencies for disciplinary, civil, or criminal  
23 purposes and to other agencies or entities, as determined by the  
24 Department of Justice, for the purpose of educating practitioners  
25 and others in lieu of disciplinary, civil, or criminal actions. Data  
26 may be provided to public or private entities, as approved by the  
27 Department of Justice, for educational, peer review, statistical, or  
28 research purposes, provided that patient information, including  
29 any information that may identify the patient, is not compromised.  
30 Further, data disclosed to any individual or agency as described  
31 in this subdivision shall not be disclosed, sold, or transferred to  
32 any third party, unless authorized by, or pursuant to, state and  
33 federal privacy and security laws and regulations. The Department  
34 of Justice shall establish policies, procedures, and regulations  
35 regarding the use, access, evaluation, management, implementation,  
36 operation, storage, disclosure, and security of the information  
37 within CURES, consistent with this subdivision.

38 (B) Notwithstanding subparagraph (A), a regulatory board whose  
39 licensees do not prescribe, order, administer, furnish, or dispense

1 controlled substances shall not be provided data obtained from  
2 CURES.

3 (3) In accordance with federal and state privacy laws and  
4 regulations, a health care practitioner may provide a patient with  
5 a copy of the patient's CURES patient activity report as long as  
6 no additional CURES data is provided and keep a copy of the  
7 report in the patient's medical record in compliance with  
8 subdivision (d) of Section 11165.1.

9 (d) For each prescription for a Schedule II, Schedule III, or  
10 Schedule IV controlled substance, as defined in the controlled  
11 substances schedules in federal law and regulations, specifically  
12 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21  
13 of the Code of Federal Regulations, the dispensing pharmacy,  
14 clinic, or other dispenser shall report the following information to  
15 the Department of Justice as soon as reasonably possible, but not  
16 more than seven days after the date a controlled substance is  
17 dispensed, in a format specified by the Department of Justice:

18 (1) Full name, address, and, if available, telephone number of  
19 the ultimate user or research subject, or contact information as  
20 determined by the Secretary of the United States Department of  
21 Health and Human Services, and the gender, and date of birth of  
22 the ultimate user.

23 (2) The prescriber's category of licensure, license number,  
24 national provider identifier (NPI) number, if applicable, the federal  
25 controlled substance registration number, and the state medical  
26 license number of any prescriber using the federal controlled  
27 substance registration number of a government-exempt facility.

28 (3) Pharmacy prescription number, license number, NPI number,  
29 and federal controlled substance registration number.

30 (4) National Drug Code (NDC) number of the controlled  
31 substance dispensed.

32 (5) Quantity of the controlled substance dispensed.

33 (6) International Statistical Classification of Diseases, 9th  
34 revision (ICD-9) or 10th revision (ICD-10) Code, if available.

35 (7) Number of refills ordered.

36 (8) Whether the drug was dispensed as a refill of a prescription  
37 or as a first-time request.

38 (9) Date of origin of the prescription.

39 (10) Date of dispensing of the prescription.

- 1 (11) The serial number for the corresponding prescription ~~pad,~~  
2 *form*, if applicable.
- 3 (e) The Department of Justice may invite stakeholders to assist,  
4 advise, and make recommendations on the establishment of rules  
5 and regulations necessary to ensure the proper administration and  
6 enforcement of the CURES database. All prescriber and dispenser  
7 invitees shall be licensed by one of the boards or committees  
8 identified in subdivision (d) of Section 208 of the Business and  
9 Professions Code, in active practice in California, and a regular  
10 user of CURES.
- 11 (f) The Department of Justice shall, prior to upgrading CURES,  
12 consult with prescribers licensed by one of the boards or  
13 committees identified in subdivision (d) of Section 208 of the  
14 Business and Professions Code, one or more of the boards or  
15 committees identified in subdivision (d) of Section 208 of the  
16 Business and Professions Code, and any other stakeholder  
17 identified by the department, for the purpose of identifying  
18 desirable capabilities and upgrades to the CURES Prescription  
19 Drug Monitoring Program (PDMP).
- 20 (g) The Department of Justice may establish a process to educate  
21 authorized subscribers of the CURES PDMP on how to access and  
22 use the CURES PDMP.



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**Bill Number:** AB 1753

**Current Version:** As amended April 18, 2018

**Author:** Low

**Topic:** Controlled Substances: CURES database

**Staff Recommendation:** Support

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**AFFECTED SECTIONS:** Amend sections 11161.5, 11162.1, and 11165 of the Health & Safety Code.

**STATUS:** Referred to Assembly Appropriations

**CURRENT LAW:**

Existing law requires controlled substances prescriptions to be written on prescription forms obtained from security printers approved by the Department of Justice (DOJ). Such forms must contain security features designed to prevent counterfeiting. Further, existing law establishes the required elements a dispenser must report to the CURES system.

**THIS BILL WOULD:**

1. This measure includes legislative findings regarding the use of paper prescription pads including a finding that until mandatory e-prescribing is established, it is critical that tighter restrictions be placed on the manufacturing and tracking of prescription pads used within the state.
2. Allow the DOJ to cease issuing new approvals of security printers in order to limit the number of approved printers to no more than three, as specified.
3. Require security forms to include a unique serialized number.
4. Require the security printer to submit to the DOJ, via a web-based application, information including:
  - a. Serial numbers.
  - b. Prescribers names and DEA Controlled Substance Registration Certificate number.
  - c. Delivery shipment recipient name.
5. Require inclusion of the prescription serial number into the CURES reporting system.

**STAFF COMMENTS:**

At the Board's February 2018 meeting the Board requested more information on this measure, specifically, how the number of three printers was reached. The Author's office informed board staff that the Department of Justice determined that three printers was sufficient, likely as this would provide some market competition while still allowing for adequate controls.

During its January 2018 Board Meeting, the board discussed the issue of fraudulent security forms and how their use contributed to the opioid epidemic. After discussion, the board voted to pursue a statutory proposal to require e-prescribing while allowing for some exemptions.

**Related Legislation**

The board supports the transition to mandatory e-prescribing and is the origin of AB 2789 (Wood).

**SUPPORT / OPPOSITION:**

SUPPORT:

America’s Physician Groups  
 California Association of Health Underwriters  
 California Chiropractic Association  
 California District Attorneys Association  
 California Life Sciences Association  
 California Police Chiefs Association  
 California State Board of Pharmacy  
 Consumer Attorneys of California  
 OCHIN  
 San Diego County District Attorney Summer Stephan  
 Troy and Alana Pack Foundation

OPPOSITION:

American Civil Liberties Union

**BILL HISTORY:**

04/19/18	Re-referred to Com. on PUB. S.
04/18/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
04/10/18	From committee: Do pass and re-refer to Com. on PUB. S. (Ayes 15. Noes 1.) (April 10). Re-referred to Com. on PUB. S.
01/16/18	Referred to Coms. on B. & P. and PUB. S.
01/04/18	From printer. May be heard in committee February 3.
01/03/18	Read first time. To print.

**ASSEMBLY BILL**

**No. 1953**

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**Introduced by Assembly Member Wood**

January 29, 2018

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An act to amend Section 1267.5 of the Health and Safety Code, relating to health care facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 1953, as introduced, Wood. Skilled nursing facilities: disclosure of interests in business providing services.

(1) Existing law requires each applicant for a license to operate a skilled nursing facility or intermediate care facility to disclose to the State Department of Public Health, among other things, the names and addresses of any person or organization, or both, having an ownership or control interest of 5% or more in a management company that operates, or is proposed to operate, the facility. A failure to disclose this information is a basis for an action to revoke or deny a license. Existing law requires these disclosures to be available to the public, as specified, and further requires a licensee to update these disclosures to the state department within 30 calendar days of a change.

This bill would require similar disclosures by an applicant for a license to operate a skilled nursing facility or by a skilled nursing facility licensee relating to an ownership or control interest of 5% or more in a corporation, sole proprietorship, or partnership, that provides, or is proposed to provide, any service to the skilled nursing facility. The bill would specifically require the applicant or licensee to disclose the number of individuals who are intended to provide that service at the skilled nursing facility and any other information requested by the department. By expanding the required disclosures by a licensee of a

health care facility, the bill would expand the scope of a crime, thereby imposing a state-mandated local program.

(2) 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:*

1 SECTION 1. Section 1267.5 of the Health and Safety Code is  
2 amended to read:

3 1267.5. (a) (1) Each applicant for a license to operate a  
4 skilled nursing facility or intermediate care facility shall disclose  
5 to the state department the name and business address of each  
6 general partner if the applicant is a partnership, or each director  
7 and officer if the applicant is a corporation, and each person having  
8 a beneficial ownership interest of 5 percent or more in the applicant  
9 corporation or partnership.

10 (2) If any person described in paragraph (1) has served or  
11 currently serves as an administrator, general partner, trustee or  
12 trust applicant, sole proprietor of any applicant or licensee who is  
13 a sole proprietorship, executor, or corporate officer or director of,  
14 or has held a beneficial ownership interest of 5 percent or more  
15 in, any other skilled nursing facility or intermediate care facility  
16 or in any community care facility licensed pursuant to Chapter 3  
17 (commencing with Section 1500) of this division, the applicant  
18 shall disclose the relationship to the state department, including  
19 the name and current or last address of the health facility or  
20 community care facility and the date the relationship commenced  
21 and, if applicable, the date it was terminated.

22 (3) (A) If the facility is operated by, or proposed to be operated  
23 in whole or part under, a management contract, the names and  
24 addresses of any person or organization, or both, having an  
25 ownership or control interest of 5 percent or more in the  
26 management company shall be disclosed to the state department.  
27 This provision shall not apply if the management company has

1 submitted an application for licensure with the state department  
2 and has complied with paragraph (1).

3 (B) If the management company is a subsidiary of one or more  
4 other organizations, the information shall include the names and  
5 addresses of the parent organizations of the management company  
6 and the names and addresses of any officer or director of the parent  
7 organizations. The failure to comply with this subparagraph may  
8 result in action to revoke or deny a license. However, once the  
9 information that is required under this subparagraph is provided,  
10 the action to revoke the license shall terminate.

11 *(4) Each applicant for a license to operate a skilled nursing*  
12 *facility shall disclose to the state department whether the applicant*  
13 *or a general partner, director, or officer of the applicant, has an*  
14 *ownership or control interest of 5 percent or more in a corporation,*  
15 *sole proprietorship, or partnership, that provides, or is proposed*  
16 *to provide, any service to the skilled nursing facility. If the*  
17 *applicant or general partner, director, or officer of the applicant*  
18 *has such an interest, the applicant shall disclose all services*  
19 *provided, or to be provided, to the skilled nursing facility, the*  
20 *number of individuals who are intended to provide that service at*  
21 *the skilled nursing facility, and any other information requested*  
22 *by the department.*

23 ~~(4)~~

24 (5) If the applicant or licensee is a subsidiary of one or more  
25 other organizations, the information shall include the names and  
26 addresses of the parent organizations of the subsidiary and the  
27 names and addresses of any officer or director of the parent  
28 organizations.

29 ~~(5)~~

30 (6) The information required by this subdivision shall be  
31 provided to the state department upon initial application for  
32 licensure, and any change in the information shall be provided to  
33 the state department within 30 calendar days of that change.

34 ~~(6)~~

35 (7) Except as provided in subparagraph (B) of paragraph (3),  
36 the failure to comply with this section may result in action to  
37 revoke or deny a license.

38 ~~(7)~~

39 (8) The information required by this section shall be made  
40 available to the public upon request, shall be included in the public

1 file of the facility, and by July 1, 2002, shall be included in the  
2 department's automated certification licensing administration  
3 information management system.

4 (b) On and after January 1, 1990, no person may acquire a  
5 beneficial interest of 5 percent or more in any corporation or  
6 partnership licensed to operate a skilled nursing facility or  
7 intermediate care facility, or in any management company under  
8 contract with a licensee of a skilled nursing facility or intermediate  
9 care facility, nor may any person become an officer or director of,  
10 or general partner in, a corporation, partnership, or management  
11 company of this type without the prior written approval of the state  
12 department. Each application for departmental approval pursuant  
13 to this subdivision shall include the information specified in  
14 subdivision (a) as regards the person for whom the application is  
15 made.

16 The state department shall approve or disapprove the application  
17 within 30 days after receipt thereof, unless the state department,  
18 with just cause, extends the application review period beyond 30  
19 days.

20 (c) The state department may deny approval of a license  
21 application or of an application for approval under subdivision (b)  
22 if a person named in the application, as required by this section,  
23 was an officer, director, general partner, or owner of a 5-percent  
24 or greater beneficial interest in a licensee of, or in a management  
25 company under contract with a licensee of, a skilled nursing  
26 facility, intermediate care facility, community care facility, or  
27 residential care facility for the elderly at a time when one or more  
28 violations of law were committed therein that resulted in  
29 suspension or revocation of its license, or at a time when a  
30 court-ordered receiver was appointed pursuant to Section 1327,  
31 or at a time when a final Medi-Cal decertification action was taken  
32 under federal law. However, the prior suspension, revocation, or  
33 court-ordered receivership of a license shall not be grounds for  
34 denial of the application if the applicant shows to the satisfaction  
35 of the state department (1) that the person in question took every  
36 reasonably available action to prevent the violation or violations  
37 that resulted in the disciplinary action and (2) that he or she took  
38 every reasonably available action to correct the violation or  
39 violations once he or she knew, or with the exercise of reasonable  
40 diligence should have known of, the violation or violations.

1 (d) No application shall be denied pursuant to this section until  
2 the state department first (1) provides the applicant with notice in  
3 writing of grounds for the proposed denial of application, and (2)  
4 affords the applicant an opportunity to submit additional  
5 documentary evidence in opposition to the proposed denial.

6 (e) Nothing in this section shall cause any individual to be  
7 personally liable for any civil penalty assessed pursuant to Chapter  
8 2.4 (commencing with Section 1417) or create any new criminal  
9 or civil liability contrary to general laws limiting that liability.

10 (f) This section shall not apply to a bank, trust company,  
11 financial institution, title insurer, controlled escrow company, or  
12 underwritten title company to which a license is issued in a  
13 fiduciary capacity.

14 (g) As used in this section, “person” has the same meaning as  
15 specified in Section 19.

16 (h) This section shall not apply to the directors of a nonprofit  
17 corporation exempt from taxation under Section 23701d of the  
18 Revenue and Taxation Code that operates a skilled nursing facility  
19 or intermediate care facility in conjunction with a licensed  
20 residential facility, where the directors serve without financial  
21 compensation and are not compensated by the nonprofit corporation  
22 in any other capacity.

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

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<b>Bill Number:</b>	<b>AB 1953</b>
<b>Current Version:</b>	<b>As introduced January 29, 2018</b>
<b>Author:</b>	<b>Wood</b>
<b>Topic:</b>	<b>Skilled nursing facilities: disclosure of interests in business providing services.</b>
<b>Staff Recommendation:</b>	<b>Support if amended</b>

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**AFFECTED SECTIONS:** Amends Section 1267.5 of the Health and Safety Code.

**STATUS:** Assembly Health

**SUMMARY:**

AB 1953 requires disclosures by an applicant for a license to operate a Skilled Nursing Facility (SNF) or by a SNF licensee relating to ownership of a business that provides, or is proposed to provide, any service to the SNF. The applicant or SNF owner must also disclose all services provided to the SNF, the number of individuals who provide the service, and any other information requested by DPH.

**EXISTING LAW:**

Health & Safety Codes Section 1267.s currently requires any applicant for a license to operate a Skilled Nursing Facility to disclose, to the State Department of Public Health, contact information for anyone who has a five percent or greater interest, if that person has five percent or greater interest in any other SNF and, if contracting with a management company, the parent company information.

**THIS BILL WOULD:**

Add to the above list the requirement to disclose if the applicant, general partner, director, or officer of the applicant also has a five percent or greater interest in a corporation, sole proprietorship, or partnership that provides or will provide any service to the SNF and; all services that will be provided, the number of individuals intended to provide that service, and any other information requested by the department.

**STAFF COMMENTS:**

The Author has asked for an audit of the Department of Public Health, the Department of Health Care Services, and the Office of Statewide health planning and Development to determine the impact and appropriateness of related-party transactions on skilled nursing facilities' Medi-Cal rates and reimbursements. This information has not been made public yet but will be forthcoming. Board staff recommends that amendments be offered to require a similar disclosure by anyone applying for a Pharmacy license. This additional provision would support the intent of this legislation by also highlighting any relationship between a Pharmacy and a SNF.

**SUPPORT / OPPOSITION:**

SUPPORT:

None on file

OPPOSITION:

None on file

**BILL HISTORY:**

01/16/2018	Referred to Com on Health
01/30/2018	From printer. May be heard in committee March 1
01/29/2018	Read first time. To print.

**ASSEMBLY BILL**

**No. 2037**

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**Introduced by Assembly Member Bonta**

February 6, 2018

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An act to add Section 4119.11 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2037, as introduced, Bonta. Pharmacy: automated drug delivery systems.

Existing law, the Pharmacy Law, the knowing violation of which is a crime, provides for the licensure and regulation of pharmacies, pharmacists, intern pharmacists, and pharmacy technicians by the California State Board of Pharmacy. The Pharmacy Law authorizes a pharmacy to provide pharmacy services to specified licensed health facilities through the use of an automated drug delivery system. Existing law, the Pharmacy Law, authorizes a licensed clinic to make use of an automated drug delivery system, operated under the authorization of a pharmacist, and under which the clinic is responsible for the safety and security of the drugs in the system.

This bill would provide an alternative program to authorize a pharmacy to provide pharmacy services to covered entities, as defined, that are eligible for discount drug programs under federal law, as specified, through the use of an automated drug delivery system, as defined.

This bill would provide that, under the alternative program, the responsibility for the operation, maintenance, and security of the drugs in the automated drug delivery system would be the responsibility of the pharmacy. The pharmacy would also be responsible for, among

other things, obtaining a license from the board to operate the automated drug delivery system at the covered entity and developing and implementing written policies and procedures to ensure the safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, purity, and potency of the stored drugs. The bill would require that the drugs removed from the system for a patient be labeled in accordance with existing law and that records of each transaction be maintained by the pharmacy for a minimum of 3 years. The bill would require the pharmacy to review the operation and maintenance of the automated delivery system and the drugs contained therein on a monthly basis. The bill would require that the pharmacy provide for patient consultations via 2-way audio and video, as specified.

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

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

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

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

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

1 SECTION 1. Section 4119.11 is added to the Business and  
2 Professions Code, to read:

3 4119.11. (a) A pharmacy may provide pharmacy services to  
4 a “covered entity,” as defined in Section 256b of Title 42 of the  
5 United States Code, through the use of an automated drug delivery  
6 system located on the premises of the covered entity or on the  
7 premises of medical professional practices under contract to  
8 provide medical services to covered entity patients, which need  
9 not be the same location as the pharmacy, if all of the following  
10 conditions are met:

11 (1) The pharmacy obtains a license from the board to operate  
12 the automated drug delivery system at the covered entity or  
13 affiliated site. As part of the application, the pharmacy shall provide  
14 the address at which the automated drug delivery system shall be  
15 placed and identify the covered entity. A separate license shall be  
16 required for each location and shall be renewed annually concurrent

1 with the pharmacy license. The application and renewal fee shall  
2 be two hundred dollars (\$200) and may be increased to three  
3 hundred fifty dollars (\$350).

4 (2) The pharmacy providing the pharmacy services to the  
5 covered entity shall be under contract with that covered entity as  
6 described in Section 4126 to provide pharmacy services through  
7 the use of the automated drug delivery system.

8 (3) Drugs stored in an automated drug delivery system shall be  
9 part of the inventory of the pharmacy providing pharmacy services  
10 to the covered entity and drugs dispensed from the automated drug  
11 delivery system shall be considered to have been dispensed by that  
12 pharmacy.

13 (4) The pharmacy shall maintain records of the acquisition and  
14 disposition of dangerous drugs stored in the automated drug  
15 delivery system separate from other pharmacy records.

16 (5) The pharmacy shall be solely responsible for the security,  
17 operation, and maintenance of the automated drug delivery system.

18 (6) The pharmacy shall provide training regarding the operation  
19 and use of the automated drug delivery system to both pharmacy  
20 and covered entity personnel using the system.

21 (7) The operation of the automated drug delivery system shall  
22 be under the supervision of a licensed pharmacist acting on behalf  
23 of the pharmacy providing services to the covered entity. The  
24 pharmacist need not be physically present at the site of the  
25 automated drug delivery system and may supervise the system  
26 electronically.

27 (8) Notwithstanding Section 4107, the board may issue a license  
28 for the operation of an automated drug delivery system at an  
29 address for which it has issued another site license.

30 (b) For purposes of this section, an “automated drug delivery  
31 system” has the same meaning as that term is defined in subdivision  
32 (a) of Section 4105.5.

33 (c) Transaction information shall be made readily available in  
34 a downloadable format for review and inspection by individuals  
35 authorized by law. These records shall be maintained by the  
36 pharmacy for a minimum of three years.

37 (d) Drugs removed from the automated drug delivery system  
38 shall be provided to the patient by a health professional licensed  
39 pursuant to this division or by a covered entity or contract

1 personnel acting under the supervision of persons authorized by  
2 law to administer drugs.

3 (e) (1) The pharmacy shall develop and implement written  
4 policies and procedures to ensure safety, accuracy, accountability,  
5 security, patient confidentiality, and maintenance of the quality,  
6 potency, and purity of the stored drugs. These policies and  
7 procedures shall define access to the automated drug delivery  
8 system and limits to access to equipment and drugs.

9 (2) All of these policies and procedures shall be maintained at  
10 the pharmacy operating the automated drug delivery system at the  
11 location where the automated drug delivery system is being used.

12 (f) Drugs removed from the automated drug delivery system  
13 for a patient shall be labeled pursuant to Section 4076.

14 (g) A pharmacist shall review and approve all orders prior to a  
15 drug being removed from the automated drug delivery system for  
16 a patient. The pharmacist shall review the prescriber's order and  
17 the patient's profile for potential contraindications and adverse  
18 drug reactions. Drugs shall be released from the system only upon  
19 completion of that review.

20 (h) Access to the automated drug delivery system shall be  
21 controlled and tracked using an identification or password system  
22 or biosensor. A system that is accessed via a password system shall  
23 include a camera that records a picture of the individual accessing  
24 the machine. Picture records shall be maintained for a minimum  
25 of 180 days.

26 (i) The automated drug delivery system shall make a complete  
27 and accurate record of all transactions that will include all users  
28 accessing the system and all drugs added to, or removed from, the  
29 system.

30 (j) The stocking of an automated drug delivery system shall be  
31 performed by a pharmacist. If the automated drug delivery system  
32 utilizes removable pockets, cards, drawers, similar technology, or  
33 unit of use or single dose containers as defined by the United States  
34 Pharmacopeia, the stocking system may be done outside of the  
35 facility and be delivered to the facility if all of the following  
36 conditions are met:

37 (1) The task of placing drugs into the removable pockets, cards,  
38 drawers, similar technology, or unit of use or single dose containers  
39 is performed by a pharmacist, or by an intern pharmacist or a

1 pharmacy technician working under the direct supervision of a  
2 pharmacist.

3 (2) The removable pockets, cards, drawers, similar technology,  
4 or unit of use or single dose containers are transported between  
5 the pharmacy and the facility in a secure tamper-evident container.

6 (3) The pharmacy, in conjunction with the covered entity, has  
7 developed policies and procedures to ensure that the removable  
8 pockets, cards, drawers, similar technology, or unit of use or single  
9 dose containers are properly placed into the automated drug  
10 delivery system.

11 (k) Review of the drugs contained within, and the operation and  
12 maintenance of, the automated drug delivery system shall be done  
13 in accordance with law and shall be the responsibility of the  
14 pharmacy. The review shall be conducted on a monthly basis by  
15 a pharmacist and shall include a physical inspection of the drugs  
16 in the automated drug delivery system, an inspection of the  
17 automated drug delivery system machine for cleanliness, and a  
18 review of all transaction records in order to verify the security and  
19 accountability of the system.

20 (l) The automated drug delivery system shall provide for patient  
21 consultation pursuant to Section 1707.2 of Title 16 of the California  
22 Code of Regulations with a pharmacist via a telecommunications  
23 link that has two-way audio and video.

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

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<b>Bill Number:</b>	<b>AB 2037</b>
<b>Current Version:</b>	<b>As Introduced February 6, 2018</b>
<b>Author:</b>	<b>Bonta</b>
<b>Topic:</b>	<b>Pharmacy: automated drug delivery systems</b>
<b>Staff Recommendation:</b>	<b>Support if Amended</b>

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**AFFECTED SECTIONS:** Add BPC section 4119.11

**STATUS:** Referred to Assembly Business, Professions and Consumer Protection

**EXISTING LAW:**

Allows for the use of automated drug delivery systems (ADDS) in both the clinic setting and in a skilled nursing facility.

**THIS BILL WOULD:**

Allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug delivery system (ADDS) if all of the following conditions are met:

1. The pharmacy obtains a license from the board to operate the ADDS.
2. The pharmacy providing services to the covered entity must be in contract with the covered entity in accordance with 4126.
3. Drugs stored and dispensed are considered to have been dispensed by the pharmacy.
4. The pharmacy maintains records of acquisition and disposition separate from other pharmacy records.
5. The pharmacy is solely responsible for the ADDS.
6. The pharmacy provides training to staff (both pharmacy and entity staff).
7. The operation of the ADDS shall be under the supervision of a pharmacist and may be done electronically.
8. Transaction information must be readily retrievable in a downloadable format and maintained by the pharmacy for three years.
9. Drugs removed from the ADDS must be provided to the patient by a health care professional.
10. The pharmacy must have written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality and appropriate maintenance of the drugs.
11. Labeling must be consistent with BPC 4076.
12. Drugs are only released to a patient upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for contraindications and adverse drug reactions.
13. Access to the ADDS shall be tracked using identification, password or biosensor

14. Records of transactions including all transactions, stocking and removal must be maintained.
15. Stocking of the machine must be done by a pharmacist unless specified conditions are met. (Such conditions are similar to the conditions a pharmacy must meet in using an ADDS in a skilled nursing facility.)
16. Review of drugs contained and proper maintenance of the ADDS machine shall be performed by the Pharmacy in accordance with current law.
17. Patient consultation, as required in CCR 1707.2, must be provided via telecommunication link that has two-way audio and video.

**STAFF COMMENTS:**

This measure is similar to last year's SB 528 (Stone). The board established a support if amended position on that measure. As part of its request, the board requested that the provisions not be limited to just 340B clinics. The board's amendments were not incorporated into the measure last year and the measure ultimately stalled in committee.

The new measure also does not include the amendments requested by the board last year. Also, this measure in its current form conflicts with some of the provisions of the board sponsored measure SB 1447 (Hernandez) which creates a licensing protocol and expanded use of ADDS.

Board staff met with the author's office and the measure's sponsor to discuss the overlap, however no solution was identified. If both measures move forward in their current forms, double joining language may be necessary to reconcile the difference as part of the enactment of the various sections.

**Fiscal Impact**

This measure would increase patient access to medications by authorizing pharmacies to provide pharmacy services to covered entities that are eligible for discount drug programs through the use of an ADDS. Pharmacies would be required to obtain a license to operate the ADDS within the covered entity. The board would need a 0.5 Associate Governmental Program analyst and 0.5 Pharmacy Inspector to process the additional workload associated with regulating the new license type. The cost of the new positions would be \$162,000 in FY 2018-19 and \$146,000 in FY 2019-20 and ongoing.

**REVENUE**

The Board anticipates that approximately 436 applicants/renewals will be received each year for the new license type. This bill states that the applicant/renewal fee shall be \$200 and may be increased to \$350. Therefore, the anticipated annual revenue for the new license type will be \$87,200 (436 licenses x \$200 fee). If the Board were to increase the licensing fee to \$350, the annual revenue would be \$152,600 (436 licenses x \$350 fee).

**IT IMPACT**

The It impact associated with this bill is \$72,000, which can be absorbed by redirecting existing maintenance resources. The IT work can be implemented 8 months after the board approves the final IT requirements. However, the Board may choose to do the IT implementation in phases by rolling our a more limited version initially, which would enable the Board to regulate the new license type without a delay until an IT solution is put in place. The IT work associated with this bill consists of creating a new license type, establishing relationships and creating new enforcement codes.

**SUPPORT/OPPOSITION:**

Support

IMGRX (Sponsor)

Opposition

None on file.

**BILL HISTORY:**

04/04/18	In committee: Set, first hearing. Referred to suspense file.
03/20/18	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (March 20). Re-referred to Com. on APPR.
02/16/18	Referred to Com. on B. & P.
02/07/18	From printer. May be heard in committee March 9.
02/06/18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 2, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2138**

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**Introduced by Assembly Members Chiu and Low**

February 12, 2018

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An act to amend ~~Sections 480 and~~ *Sections 7.5, 480, 481, 482, 488, 490, 492, 493, 1005, and 11345.2* ~~of of,~~ *to add Section 481.5 to,* and *to repeal Section 490.5 of,* the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 2138, as amended, Chiu. Licensing boards: denial of application: *revocation or suspension of licensure: criminal conviction.*

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs and Affairs. Existing law authorizes a board to ~~deny~~ *deny, suspend, or revoke a license or take disciplinary action against a licensee* on the grounds that the applicant *or licensee* has, among other things, been convicted of a crime, as specified. Existing law provides that a person shall not be denied a license solely on the basis that the person has been convicted of a felony if he or she has obtained a certificate of rehabilitation or that the person has been convicted of a misdemeanor if he or she has met applicable requirements of rehabilitation developed by the board, as specified. Existing law also prohibits a person from being denied a license solely on the basis of a conviction that has been dismissed, as specified. *Existing law requires a board to develop criteria to aid it when considering the denial, suspension, or revocation of a license to determine whether a crime is substantially related to the qualifications, functions, or duties of the*

*business or profession the board regulates and requires a board to develop criteria to evaluate the rehabilitation of a person when considering the denial, suspension, or revocation of a license.*

~~This bill would instead prohibit a person from being denied a license solely on the basis that he or she has been convicted of a nonviolent crime and would make conforming changes.~~ *revise and recast those provisions to instead authorize a board to, among other things, deny, revoke, or suspend a license on the grounds that the applicant or licensee has been convicted of a crime only if the applicant or licensee is presently incarcerated or if the conviction, as defined, occurred within the preceding 5 years, except for violent felonies, and would require the crime to be directly and adversely related to the qualifications, functions, or duties of the business or profession. The bill would prohibit a board from denying a person a license based on the conviction of a crime, or on the basis of acts underlying a conviction for a crime, if the conviction has been dismissed or expunged, if the person has made a showing of rehabilitation, if the person has been granted clemency or a pardon, or if an arrest resulted in a disposition other than a conviction. The bill would provide that these provisions relating to denial, revocation, or suspension of a license would supersede contradictory provisions in specified existing law.*

*The bill would require the board to develop criteria for determining whether a crime is directly and adversely related to the qualifications, functions, or duties of the business or profession. The bill would require a board to find that a person has made a showing of rehabilitation if certain conditions are met. The bill would require a board to follow certain procedures when requesting or acting on an applicant's or licensee's criminal history information. The bill would also require a board to annually submit a report to the Legislature and post the report on its Internet Web site containing specified deidentified information regarding actions taken by a board based on an applicant or licensee's criminal history information.*

*Existing law authorizes a board to deny a license on the grounds that an applicant knowingly made a false statement of fact that is required to be revealed in the application for licensure.*

*This bill would prohibit a board from denying a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had the fact been disclosed.*

*Existing law authorizes a board to suspend a license if a licensee is not in compliance with a child support order or judgment.*

*This bill would repeal that authorization.*

*Existing law authorizes specified agencies to take disciplinary action against a licensee or deny a license for professional misconduct if the licensee has successfully completed certain diversion programs or alcohol and drug problem assessment programs.*

*This bill would instead prohibit a board from taking disciplinary action against a licensee or denying a license for professional misconduct if the licensee has successfully completed certain diversion programs or alcohol and drug problem assessment programs or deferred entry of judgment.*

*Existing law authorizes a board after a specified hearing requested by an applicant for licensure to take various actions, including imposing probationary conditions on the license.*

*This bill would additionally authorize a board to grant the license and immediately issue a public reproof. The bill would limit probationary terms or restrictions placed on a license by a board to 2 years or less and would authorize additional conditions to be imposed only if the board determines that there is clear and convincing evidence that additional conditions are necessary to address a risk shown by clear and convincing evidence. The bill would require a board to develop criteria to aid it in considering the imposition of probationary conditions and to determine what conditions may be imposed. The bill would authorize a licensee or registrant whose license or registration has been placed on probation to petition the board for a change to that probation one year from the effective date of the board’s decision, would require the board to issue a decision on the petition within 90 days, and would deem the petition granted if the board does not file a decision denying the petition within 90 days.*

*This bill would also make necessary conforming changes.*

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 7.5 of the Business and Professions Code
- 2     is amended to read:
- 3     7.5. (a) A conviction within the meaning of this code means
- 4     a judgment following a plea or verdict of guilty or a conviction
- 5     following a plea of nolo contendere, contendere or finding of guilt.
- 6     Any action which a board is permitted to take following the

1 establishment of a conviction may be taken when the time for  
 2 appeal has elapsed, or the judgment of conviction has been affirmed  
 3 on appeal or when an order granting probation is made suspending  
 4 the imposition of sentence, irrespective of a subsequent order under  
 5 the provisions of Section 1203.4 of the Penal Code: *sentence*.  
 6 However, a board may not deny a license to an applicant who is  
 7 otherwise qualified pursuant to subdivision (b) *or* (c) of Section  
 8 480.

9 ~~Nothing~~

10 (b) ~~Nothing~~ in this section shall apply to the licensure of persons  
 11 pursuant to Chapter 4 (commencing with Section 6000) of Division  
 12 3.

13 (c) ~~Except as provided in subdivision (b), this section controls~~  
 14 ~~over and supersedes the definition of conviction contained within~~  
 15 ~~individual practice acts under this code.~~

16 SECTION 4.

17 SEC. 2. Section 480 of the Business and Professions Code is  
 18 amended to read:

19 480. (a) ~~A(1) Notwithstanding any other provision of this~~  
 20 ~~code, a board may deny a license regulated by this code on the~~  
 21 ~~grounds that the applicant has one of the following: been convicted~~  
 22 ~~of a crime or has been subject to formal discipline only if either~~  
 23 ~~of the following conditions are met:~~

24 (1) ~~Been convicted of a crime. A conviction within the meaning~~  
 25 ~~of this section means a plea or verdict of guilty or a conviction~~  
 26 ~~following a plea of nolo contendere. Any action that a board is~~  
 27 ~~permitted to take following the establishment of a conviction may~~  
 28 ~~be taken when the time for appeal has elapsed, or the judgment of~~  
 29 ~~conviction has been affirmed on appeal, or when an order granting~~  
 30 ~~probation is made suspending the imposition of sentence,~~  
 31 ~~irrespective of a subsequent order under the provisions of Section~~  
 32 ~~1203.4, 1203.4a, or 1203.41 of the Penal Code.~~

33 (2) ~~Done any act involving dishonesty, fraud, or deceit with the~~  
 34 ~~intent to substantially benefit himself or herself or another, or~~  
 35 ~~substantially injure another.~~

36 (3) (A) ~~Done any act that if done by a licentiate of the business~~  
 37 ~~or profession in question, would be grounds for suspension or~~  
 38 ~~revocation of license.~~

39 (B) ~~The board may deny a license pursuant to this subdivision~~  
 40 ~~only if the crime or act is substantially related to the qualifications;~~

1 ~~functions, or duties of the business or profession for which~~  
2 ~~application is made.~~

3 (A) *The applicant has been convicted of a crime for which the*  
4 *applicant is presently incarcerated or for which the conviction*  
5 *occurred within the preceding five years. However, the preceding*  
6 *five year limitation shall not apply to a conviction for a violent*  
7 *felony, as defined in Section 667.5 of the Penal Code.*

8 *The board may deny a license pursuant to this subparagraph*  
9 *only if the crime is directly and adversely related to the*  
10 *qualifications, functions, or duties of the business or profession*  
11 *for which application is made.*

12 (B) *The applicant has been subjected to formal discipline by a*  
13 *licensing board within the preceding five years based on*  
14 *professional misconduct that would have been cause for discipline*  
15 *before the board for which the present application is made and*  
16 *that is directly and adversely related to the qualifications,*  
17 *functions, or duties of the business or profession for which the*  
18 *present application is made. However, prior disciplinary action*  
19 *by a licensing board within the preceding five years shall not be*  
20 *the basis for denial of a license if the basis for that disciplinary*  
21 *action was a conviction that has been dismissed pursuant to Section*  
22 *1203.4, 1203.4a, or 1203.41 of the Penal Code or a comparable*  
23 *dismissal or expungement.*

24 (2) *Denial of a license includes denial of an unrestricted license*  
25 *by issuance of a restricted or probationary license.*

26 (b) *Notwithstanding any other provision of this code, a person*  
27 *shall not be denied a license solely on the basis that he or she has*  
28 *been convicted of a ~~nonviolent crime.~~ crime, or on the basis of*  
29 *acts underlying a conviction for a crime, if he or she has obtained*  
30 *a certificate of rehabilitation under Chapter 3.5 (commencing with*  
31 *Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been*  
32 *granted clemency or a pardon by a state or federal executive, or*  
33 *has made a showing of rehabilitation pursuant to Section 482.*

34 (c) *Notwithstanding any other provision of this code, a person*  
35 *shall not be denied a license on the basis of any conviction, or on*  
36 *the basis of the acts underlying the conviction, that has been*  
37 *dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the*  
38 *Penal Code, or a comparable dismissal or expungement. An*  
39 *applicant who has a conviction that has been dismissed pursuant*  
40 *to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code*

1 shall provide proof of the dismissal if it is not reflected on the  
 2 report furnished by the Department of Justice.

3 (d) Notwithstanding any other provision of this code, a board  
 4 shall not deny a license on the basis of an arrest that resulted in  
 5 a disposition other than a conviction, including an arrest that  
 6 resulted in an infraction, citation, or a juvenile adjudication.

7 ~~(e)~~

8 (e) A board may deny a license regulated by this code on the  
 9 ground that the applicant knowingly made a false statement of fact  
 10 that is required to be revealed in the application for the license. A  
 11 board shall not deny a license based solely on an applicant's  
 12 failure to disclose a fact that would not have been cause for denial  
 13 of the license had it been disclosed.

14 (f) A board shall follow the following procedures in requesting  
 15 or acting on an applicant's criminal history information:

16 (1) A board shall not require an applicant for licensure to  
 17 disclose any information or documentation regarding the  
 18 applicant's criminal history.

19 (2) If a board decides to deny an application based solely or in  
 20 part on the applicant's conviction history, the board shall notify  
 21 the applicant in writing of all of the following:

22 (A) The denial or disqualification of licensure.

23 (B) Any existing procedure the board has for the applicant to  
 24 challenge the decision or to request reconsideration.

25 (C) That the applicant has the right to appeal the board's  
 26 decision.

27 (D) The processes for the applicant to request a copy of his or  
 28 her complete conviction history and question the accuracy or  
 29 completeness of the record pursuant to Sections 11122 to 11127  
 30 of the Penal Code.

31 (g) (1) For a minimum of three years, each board under this  
 32 code shall retain application forms and other documents submitted  
 33 by an applicant, any notice provided to an applicant, all other  
 34 communications received from and provided to an applicant, and  
 35 criminal history reports of an applicant.

36 (2) Each board under this code shall retain the number of  
 37 applications received for each license and the number of  
 38 applications requiring inquiries regarding criminal history. In  
 39 addition, each licensing authority shall retain all of the following  
 40 information:

1 (A) *The number of applicants with a criminal record who*  
2 *received notice of denial or disqualification of licensure.*

3 (B) *The number of applicants with a criminal record who*  
4 *provided evidence of mitigation or rehabilitation.*

5 (C) *The number of applicants with a criminal record who*  
6 *appealed any denial or disqualification of licensure.*

7 (D) *The final disposition and demographic information,*  
8 *including, but not limited to, voluntarily provided information on*  
9 *race or gender, of any applicant described in subparagraph (A),*  
10 *(B), or (C).*

11 (3) (A) *Each board under this code shall annually make*  
12 *available to the public through the board's Internet Web site and*  
13 *through a report submitted to the appropriate policy committees*  
14 *of the Legislature deidentified information collected pursuant to*  
15 *this subdivision. Each board shall ensure confidentiality of the*  
16 *individual applicants.*

17 (B) *A report pursuant to subparagraph (A) shall be submitted*  
18 *in compliance with Section 9795 of the Government Code.*

19 (h) *"Conviction" as used in this section shall have the same*  
20 *meaning as defined in Section 7.5.*

21 (i) *This section supersedes any contradictory provision in a*  
22 *licensing act under this code or initiative act referred to in Division*  
23 *2 (commencing with Section 500) that authorizes license denial*  
24 *based on a criminal conviction, arrest, or the acts underlying an*  
25 *arrest or conviction.*

26 *SEC. 3. Section 481 of the Business and Professions Code is*  
27 *amended to read:*

28 481. (a) ~~Each board under the provisions of this code shall~~  
29 ~~develop criteria to aid it, when considering the denial, suspension~~  
30 ~~suspension, or revocation of a license, to determine whether a~~  
31 ~~crime or act is substantially~~ *is directly and adversely related to the*  
32 *qualifications, functions, or duties of the business or profession it*  
33 *regulates.*

34 (b) *Criteria for determining whether a crime is directly and*  
35 *adversely related to the qualifications, functions, or duties of the*  
36 *business or profession a board regulates shall include all of the*  
37 *following:*

38 (1) *The nature and gravity of the offense.*

39 (2) *The number of years elapsed since the date of the offense.*

1 (3) *The nature and duties of the profession in which the*  
 2 *applicant seeks licensure or in which the licensee is licensed.*

3 (c) *A board shall not deny a license based in whole or in part*  
 4 *on a conviction without considering evidence of rehabilitation.*

5 (d) *Each board shall post on its Internet Web site a summary*  
 6 *of the criteria used to consider whether a crime is considered to*  
 7 *be directly and adversely related to the qualifications, functions,*  
 8 *or duties of the business or profession it regulates consistent with*  
 9 *this section.*

10 SEC. 4. *Section 481.5 is added to the Business and Professions*  
 11 *Code, to read:*

12 481.5. (a) *Probationary terms or restrictions placed on a*  
 13 *license by a board shall be limited to two years or less. Any*  
 14 *additional conditions may be imposed only if the board determines*  
 15 *that there is clear and convincing evidence that additional*  
 16 *conditions are necessary to address a risk shown by clear and*  
 17 *convincing evidence.*

18 (b) *Each board under this code shall develop criteria to aid it*  
 19 *when considering the imposition of probationary conditions or*  
 20 *restrictions to determine what conditions may be imposed to*  
 21 *address a risk shown by clear and convincing evidence.*

22 (c) (1) *A licensee or registrant whose license or registration*  
 23 *has been placed on probation may petition the board for a change*  
 24 *to the probation, including modification or termination of*  
 25 *probation, one year from the effective date of the decision. The*  
 26 *board shall issue its decision on the petition within 90 days of*  
 27 *submission of the petition. The petition shall be deemed granted*  
 28 *by operation of law if the board does not file a decision denying*  
 29 *the petition within 90 days of submission of the petition.*

30 (2) *The one-year time period to petition for modification or*  
 31 *termination of penalty shall control over longer time periods under*  
 32 *a licensing act under this code or initiative act referred to in*  
 33 *Division 2 (commencing with Section 500).*

34 SEC. 5. *Section 482 of the Business and Professions Code is*  
 35 *amended to read:*

36 482. (a) *Each board under ~~the provisions of~~ this code shall*  
 37 *develop criteria to evaluate the rehabilitation of a person ~~when:~~*  
 38 *when doing either of the following:*

39 (a)

1 (1) Considering the denial of a license by the board under  
2 Section ~~480~~, or 480.

3 ~~(b)~~

4 (2) Considering suspension or revocation of a license under  
5 Section 490.

6 ~~Each~~

7 (b) ~~Each board shall take into account all competent evidence~~  
8 ~~of rehabilitation furnished by the applicant or licensee. find that~~  
9 ~~an applicant or licensee has made a showing of rehabilitation if~~  
10 ~~any of the following are met:~~

11 (1) ~~The applicant or licensee has completed the criminal~~  
12 ~~sentence at issue without a violation of parole or probation.~~

13 (2) (A) ~~The applicant or licensee documents that he or she has~~  
14 ~~worked in a related field continuously for at least one year prior~~  
15 ~~to licensure or successfully completed a course of training in a~~  
16 ~~related field, unless the board finds a public record of an official~~  
17 ~~finding that the applicant committed professional misconduct in~~  
18 ~~the course of that work.~~

19 (B) ~~Work in a related field may include, but is not limited to,~~  
20 ~~work performed without compensation and work performed while~~  
21 ~~incarcerated.~~

22 (C) ~~“Related field,” for purposes of this paragraph, means a~~  
23 ~~field of employment whose duties are substantially similar to the~~  
24 ~~field regulated by the board.~~

25 (3) ~~The applicant or licensee has satisfied criteria for~~  
26 ~~rehabilitation developed by the board.~~

27 *SEC. 6. Section 488 of the Business and Professions Code is*  
28 *amended to read:*

29 488. Except as otherwise provided by law, following a hearing  
30 requested by an applicant pursuant to subdivision (b) of Section  
31 485, the board may take any of the following actions:

32 (a) Grant the license effective upon completion of all licensing  
33 requirements by the applicant.

34 (b) Grant the license effective upon completion of all licensing  
35 requirements by the applicant, *grant the license and immediately*  
36 *issue a public reproof pursuant to Section 495,* immediately  
37 revoke the license, stay the revocation, and impose probationary  
38 conditions on the license, which may include suspension.

39 (c) Deny the license.

1 (d) Take other action in relation to denying or granting the  
2 license as the board in its discretion may deem proper.

3 *SEC. 7. Section 490 of the Business and Professions Code is*  
4 *amended to read:*

5 490. (a) (1) In addition to any other action that a board is  
6 permitted to take against a licensee, a board may suspend or revoke  
7 a license on the ground that the licensee has been convicted of a  
8 crime, ~~if the crime is substantially related to the qualifications,~~  
9 ~~functions, or duties of the business or profession for which the~~  
10 ~~license was issued: crime for which the applicant is presently~~  
11 ~~incarcerated or for which the conviction occurred within the~~  
12 ~~preceding five years. However, the preceding five year limitation~~  
13 ~~shall not apply to a conviction for a violent felony, as defined in~~  
14 ~~Section 667.5 of the Penal Code.~~

15 (2) ~~The board may suspend or revoke a license pursuant to this~~  
16 ~~subdivision only if the crime is directly and adversely related to~~  
17 ~~the qualifications, functions, or duties of the business or profession~~  
18 ~~for which application is made.~~

19 (b) Notwithstanding any other provision of law, a board may  
20 exercise any authority to discipline a licensee for conviction of a  
21 crime that is independent of the authority granted under subdivision  
22 (a) only if ~~the both of the following are met:~~

23 (1) ~~The crime is substantially directly and adversely related to~~  
24 ~~the qualifications, functions, or duties of the business or profession~~  
25 ~~for which the licensee's license was issued.~~

26 (2) ~~The licensee was convicted of the crime within the preceding~~  
27 ~~five years or is presently incarcerated for the crime. However, the~~  
28 ~~preceding five year limitation shall not apply to a conviction for~~  
29 ~~a violent felony, as defined in Section 667.5 of the Penal Code.~~

30 (c) ~~A conviction within the meaning of this section means a~~  
31 ~~plea or verdict of guilty or a conviction following a plea of nolo~~  
32 ~~contendere. An action that a board is permitted to take following~~  
33 ~~the establishment of a conviction may be taken when the time for~~  
34 ~~appeal has elapsed, or the judgment of conviction has been affirmed~~  
35 ~~on appeal, or when an order granting probation is made suspending~~  
36 ~~the imposition of sentence, irrespective of a subsequent order under~~  
37 ~~Section 1203.4 of the Penal Code.~~

38 (d) ~~The Legislature hereby finds and declares that the application~~  
39 ~~of this section has been made unclear by the holding in Petropoulos~~  
40 ~~v. Department of Real Estate (2006) 142 Cal.App.4th 554, and~~

1 ~~that the holding in that case has placed a significant number of~~  
2 ~~statutes and regulations in question, resulting in potential harm to~~  
3 ~~the consumers of California from licensees who have been~~  
4 ~~convicted of crimes. Therefore, the Legislature finds and declares~~  
5 ~~that this section establishes an independent basis for a board to~~  
6 ~~impose discipline upon a licensee, and that the amendments to this~~  
7 ~~section made by Chapter 33 of the Statutes of 2008 do not~~  
8 ~~constitute a change to, but rather are declaratory of, existing law.~~

9 *(c) Notwithstanding any other provision of this code, a board*  
10 *shall not suspend or revoke a license on the basis of a conviction,*  
11 *or of the acts underlying a conviction, where that conviction has*  
12 *been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or*  
13 *1203.42 of the Penal Code or a comparable dismissal or*  
14 *expungement.*

15 *(d) Notwithstanding any other provision of this code, a board*  
16 *shall not suspend or revoke a license on the basis of an arrest that*  
17 *resulted in a disposition other than a conviction, including an*  
18 *arrest that resulted in an infraction, citation, or juvenile*  
19 *adjudication.*

20 *(e) The board shall use the following procedures in requesting*  
21 *or acting on a licensee's criminal history information:*

22 *(1) A board shall not require a licensee to disclose any*  
23 *information or documentation regarding the licensee's criminal*  
24 *history.*

25 *(2) If a board chooses to file an accusation against a licensee*  
26 *based solely or in part on the licensee's conviction history, the*  
27 *board shall notify the licensee in writing of the processes for the*  
28 *licensee to request a copy of the licensee's complete conviction*  
29 *history and question the accuracy or completeness of his or her*  
30 *criminal record pursuant to Sections 11122 to 11127, inclusive,*  
31 *of the Penal Code.*

32 *(f) (1) For a minimum of three years, each board under this*  
33 *code shall retain all documents submitted by a licensee, notices*  
34 *provided to a licensee, all other communications received from or*  
35 *provided to a licensee, and criminal history reports of a licensee.*

36 *(2) Each board under this code shall retain all of the following*  
37 *information:*

38 *(A) The number of licensees with a criminal record who received*  
39 *notice of potential revocation or suspension of their license or who*  
40 *had their license suspended or revoked.*

1 (B) *The number of licensees with a criminal record who*  
2 *provided evidence of mitigation or rehabilitation.*

3 (C) *The number of licensees with a criminal record who*  
4 *appealed any suspension or revocation of a license.*

5 (D) *The final disposition and demographic information,*  
6 *including, but not limited to, voluntarily provided information on*  
7 *race or gender, of any applicant described in subparagraph (A),*  
8 *(B), or (C).*

9 (3) (A) *Each board under this code shall annually make*  
10 *available to the public through the board’s Internet Web site and*  
11 *through a report submitted to the appropriate policy committees*  
12 *of the Legislature deidentified information collected pursuant to*  
13 *this subdivision. Each board shall ensure the confidentiality of the*  
14 *individual licensees.*

15 (B) *A report pursuant to subparagraph (A) shall be submitted*  
16 *in compliance with Section 9795 of the Government Code.*

17 (g) (1) *This section supersedes any contradictory provision in*  
18 *a licensing act under this code or initiative act referred to in*  
19 *Division 2 (commencing with Section 500) that authorizes action*  
20 *based on a criminal conviction, arrest, or the acts underlying an*  
21 *arrest or conviction.*

22 (2) *This section shall not prohibit any agency from taking*  
23 *disciplinary action against a licensee for professional misconduct*  
24 *in the course and scope of the licensee’s profession that is based*  
25 *on evidence that is independent of an arrest.*

26 SEC. 8. *Section 490.5 of the Business and Professions Code*  
27 *is repealed.*

28 ~~490.5. A board may suspend a license pursuant to Section~~  
29 ~~17520 of the Family Code if a licensee is not in compliance with~~  
30 ~~a child support order or judgment.~~

31 SEC. 9. *Section 492 of the Business and Professions Code is*  
32 *amended to read:*

33 492. (a) *Notwithstanding any other provision of law, successful*  
34 *completion of any diversion program under the Penal Code,*  
35 *successful completion by a licensee or applicant of any*  
36 *nonstatutory diversion program, deferred entry of judgment, or*  
37 *successful completion of an alcohol and drug problem assessment*  
38 *program under Article 5 (commencing with Section 23249.50) of*  
39 *Chapter 12 of Division 11 of the Vehicle Code, shall not prohibit*  
40 *any agency established under Division 2 (commencing with Section*

1 500) of this code, or any initiative act referred to in that division,  
2 board from taking disciplinary action against a licensee or from  
3 denying a license for professional misconduct, notwithstanding  
4 that evidence of that misconduct may be recorded in a record  
5 pertaining to an arrest. *misconduct.*

6 This section shall not be construed to apply to any drug diversion  
7 program operated by any agency established under Division 2  
8 (commencing with Section 500) of this code, or any initiative act  
9 referred to in that division.

10 (b) *This section shall not prohibit any agency established under*  
11 *Division 2 (commencing with Section 500) of this code, or any*  
12 *initiative act referred to in that division, from taking disciplinary*  
13 *action against a licensee for professional misconduct in the course*  
14 *and scope of the profession, which is based on evidence that is*  
15 *independent of an arrest.*

16 SEC. 10. *Section 493 of the Business and Professions Code is*  
17 *amended to read:*

18 493. (a) Notwithstanding any other provision of law, in a  
19 proceeding conducted by a board within the department pursuant  
20 to law to deny an application for a license or to suspend or revoke  
21 a license or otherwise take disciplinary action against a person  
22 who holds a license, upon the ground that the applicant or the  
23 licensee has been convicted of a crime ~~substantially~~ *directly and*  
24 *adversely* related to the qualifications, functions, and duties of the  
25 licensee in question, the record of conviction of the crime shall be  
26 conclusive evidence of the fact that the conviction occurred, but  
27 only of that fact, and the board may inquire into the circumstances  
28 surrounding the commission of the crime in order to fix the degree  
29 of discipline or to determine if the conviction is substantially  
30 related to the qualifications, functions, and duties of the licensee  
31 in question. *fact.*

32 (b) (1) *Criteria for determining whether a crime is directly and*  
33 *adversely related to the qualifications, functions, or duties of the*  
34 *business or profession the board regulates shall include all of the*  
35 *following:*

36 (A) *The nature and gravity of the offense.*

37 (B) *The number of years elapsed since the date of the offense.*

38 (C) *The nature and duties of the profession.*

1 (2) A board shall not categorically bar an applicant based solely  
2 on the type of conviction without considering evidence of  
3 rehabilitation.

4 As

5 (c) As used in this section, “license” includes “certificate,”  
6 “permit,” “authority,” and “registration.”

7 SEC. 11. Section 1005 of the Business and Professions Code  
8 is amended to read:

9 1005. The provisions of Sections 12.5, 23.9, 29.5, 30, 31, 35,  
10 104, 114, 115, 119, 121, 121.5, 125, 125.6, 136, 137, 140, 141,  
11 143, 163.5, 461, 462, 475, 480, 484, 485, 487, 489, 490, ~~490.5~~,  
12 491, 494, 495, 496, 498, 499, 510, 511, 512, 701, 702, 703, 704,  
13 710, 716, 730.5, 731, and 851 are applicable to persons licensed  
14 by the State Board of Chiropractic Examiners under the  
15 Chiropractic Act.

16 ~~SEC. 2.~~

17 SEC. 12. Section 11345.2 of the Business and Professions Code  
18 is amended to read:

19 11345.2. (a) An individual shall not act as a controlling person  
20 for a registrant if any of the following apply:

21 (1) The individual has entered a plea of guilty or no contest to,  
22 or been convicted of, a felony. If the individual’s felony conviction  
23 has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41  
24 of the Penal Code, the bureau may allow the individual to act as  
25 a controlling person.

26 (2) The individual has had a license or certificate to act as an  
27 appraiser or to engage in activities related to the transfer of real  
28 property refused, denied, canceled, or revoked in this state or any  
29 other state.

30 (b) Any individual who acts as a controlling person of an  
31 appraisal management company and who enters a plea of guilty  
32 or no contest to, or is convicted of, a felony, or who has a license  
33 or certificate as an appraiser refused, denied, canceled, or revoked  
34 in any other state shall report that fact or cause that fact to be  
35 reported to the office, in writing, within 10 days of the date he or  
36 she has knowledge of that fact.

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<b>Bill Number:</b>	<b>AB 2138</b>
<b>Current Version:</b>	<b>As amended April 2, 2018</b>
<b>Author:</b>	<b>Chiu/Low</b>
<b>Topic:</b>	<b>Licensing boards: denial of application: revocation or suspension of licensure: criminal conviction.</b>
<b>Staff Recommendation:</b>	<b>Oppose</b>

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**AFFECTED SECTIONS:** Amends Sections 7.5, 480, 481, 482, 490, 492, 493, 1005, 11345.2; adds Section 481.5 and repeals Section 490.5 to of the BPC.

**STATUS:** Assembly Business and Professions Committee hearing April 24, 2018

**SUMMARY:**

This bill would place significant limits on the Board's enforcement process including limits on when a board can deny, revoke or suspend a license based on a conviction or other act and limits on the length of probation. It also limits the Board's timeframe to decide on a petition to modify probation to 90 days.

**EXISTING LAW:**

- 1) Allows a board under the Department of Consumer Affairs (DCA) to deny a license on grounds the applicant has one of the following (Business and Professions Code (BPC) §480(a)):
  - a. A criminal conviction. A conviction means a plea or verdict of guilty or a conviction following a plea of nolo contendere.
  - b. Committed a dishonest, fraudulent, or deceitful act with intent to substantially benefit his/herself, or with the intent to substantially injure someone else.
  - c. Committed an act that, if committed by a licensee, would be grounds to suspend or revoke the license.
- 2) Only allows a board to deny a license if the crime or act is substantially related to the qualifications, functions, or duties of the profession. (BPC §480(a))
- 3) Prohibits a board from denying an applicant a license solely because he or she was convicted of a felony, if the applicant has obtained a certificate of rehabilitation. (BPC §480(b))
- 4) Prohibits a board from denying an applicant a license solely because he or she was convicted of a misdemeanor, if the applicant has met all of the rehabilitation requirements developed by the Board. (BPC §480(b))
- 5) Prohibits the denial of a license solely based on a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code. The applicant must provide proof of the dismissal. (BPC §480(c))
- 6) Permits a board to deny a license because the applicant knowingly made a false statement of a fact that is required to be revealed in the license application. (BPC §480(d))

- 7) Requires a board to develop criteria for use when considering a denial, suspension, or revocation, to determine whether a crime or act is substantially related to the qualifications, functions, or duties of the profession it regulates (BPC §481)
- 8) Requires the Board to develop criteria to evaluate a person's rehabilitation when considering the denial, suspension, or revocation of a license. (BPC §482)
- 9) Specifies that conviction of a crime (either drug related and/or substantially related) is unprofessional conduct (BPC §4301)
- 10) Requires the Board of Pharmacy to consider the following when evaluating the rehabilitation of an applicant and his or her present eligibility for a license or registration (16 CCR §1769):
  - a. The nature and severity of the act or crimes;
  - b. Evidence of committing any subsequent acts;
  - c. The time elapsed since the acts;
  - d. The applicant's compliance with his or her terms of probation, parole, restitution, or other sanctions; and
  - e. Any evidence of rehabilitation by the applicant.

**Law Related to Suspending or Revoking a License:**

- 1) Permits a board to suspend or revoke a license because the licensee has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the profession. (BPC §490)
- 2) Permits a board to suspend a license if a licensee is not in compliance with a child support order. (BPC §490.5) 3) Provides that successful completion of any Penal Code diversion program or successful completion of an alcohol and drug problem assessment program shall not prohibit a board from taking disciplinary action against a licensee or from denying a license for professional misconduct. (BPC §492)
- 3) Allows, in a board proceeding to deny, suspend, revoke, or discipline a license, the board to inquire about the circumstances surrounding a crime to determine the degree of discipline or to determine if the conviction is substantially related to the profession. (BPC §493)

**Law Related to Expungement:**

- 1) Allows a court to permit a defendant to withdraw a plea of guilty or nolo contendere and enter a not guilty plea, or allows a court to set aside a guilty verdict, if the defendant has fulfilled the conditions of probation, been discharged from probation, or otherwise been granted relief. The court must then dismiss the accusations and release the defendant from all penalties and disabilities. The defendant is still required to disclose the conviction in an application for state licensure. This provision of law does not apply to certain sex offenses. (Penal Code (PC) §1203.4) 2)
- 2) Allows a court to permit a defendant who was convicted of a misdemeanor or infraction and not granted probation to, after one year, withdraw a plea of guilty or nolo contendere and enter a not guilty plea, or allows a court to set aside a guilty verdict, if the defendant has fully complied with and completed the court's sentence, is not serving a sentence for another offense, and is obeying all laws. The court must then dismiss the accusations and release the defendant from all penalties and disabilities. (PC §1203.4a) +
- 3) Allows a court to permit defendants who were convicted of certain felonies punishable by imprisonment in county jail, to, after a specified period of time of time after completion of the sentence, withdraw a plea of guilty or nolo contendere and enter a not guilty plea, or

allows a court to set aside a guilty verdict, if the defendant is not under supervision or serving or charged for another offense. The court must then release the defendant from all penalties and disabilities. The defendant is still required to disclose the conviction in an application for state licensure. (PC §§1203.41, 1170)

**Other Law:**

- 1) Defines a “violent felony” to include several types of crimes. (PC §667.5(c)) (Attachment B)

**THIS BILL WOULD:**

1. Amend the definition of a “conviction” to mean a judgement following a plea or verdict of guilty or a plea of nolo contendere or finding of guilt. A board may act following the conviction when the time for appeal has elapsed, the conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence.
2. Only permit a board to deny a license (including denying an unrestricted license and then issuing a restricted or probationary license) on grounds the applicant has been convicted of a crime or subjected to formal discipline under the following circumstances (BPC §480):
  - a. The applicant is presently incarcerated for the conviction, or the conviction occurred within the past 5 years. (The 5-year limit does not apply to a violent felony as defined in PC §667.5 (Attachment B))
    - i. A board is permitted to suspend or revoke a license and discipline a licensee for (a) above
  - b. The applicant has been subject to formal discipline by a licensing board in the past 5 years based on professional misconduct that would have been cause for discipline by the board, and the misconduct is directly and adversely related to the qualifications, functions, or duties of the business or profession. However, disciplinary action within the past 5 years cannot be a basis for denial if the basis for the disciplinary action was a conviction that has been dismissed pursuant to PC §§1203.4, 1203.4a, or 1203.41.

A board may only deny, suspend, revoke or discipline for these reasons if the crime is directly and adversely related to the qualifications, functions, or duties of the business or profession.

3. Prohibit a board from denying a license based in the following circumstances
  - a. he or she was convicted of a crime, or on the basis of acts underlying a conviction of a crime if the applicant has obtained a certificate of rehabilitation under Chapter 3.5 of Title 6 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to BPC §482.
  - b. based on any conviction, or on the basis of acts underlying a conviction, that has been dismissed pursuant to PC §§1203.4, 1203.4a, or 1203.41, or a comparable dismissal or expungement.
  - c. an arrest that resulted in an outcome other than a conviction, such as an arrest that resulted in an infraction, citation, or juvenile adjudication.
    - i. A board is not permitted to suspend or revoke a license and discipline a licensee for (b) or (c) above
  - d. solely on the applicant’s failure to disclose a fact that would not have been cause for denial of the license.

4. Establish the following procedures when a board is requesting or acting on an applicant's criminal history:
  - a. Prohibits a board from requiring an applicant to disclose any information or documentation regarding criminal history.
  - b. In the case of application denial based or accusation based on an applicant's criminal conviction history, a board must notify the applicant of the denial, the procedure to challenge the decision or request reconsideration, the right to appeal, and the process for the applicant to request a copy of his or her complete conviction history and question the accuracy or completeness of the record.
  - c. A board may not require an applicant to disclose any information or documentation regarding criminal history.
5. Require a board to retain documents submitted by the applicant or licensee, notices provided to the applicant, all communications from and provided to the applicant, and criminal history reports, for at least 3 years.
6. Require a board to retain the following data and report it each year on its web site and to the Legislature:
  - a. Number of applications received for each license type;
  - b. Number of applications requiring criminal history inquiries;
  - c. Number of applicants with a criminal record who were denied or disqualified from licensure;
  - d. Number of applicants with a criminal record who provided evidence of rehabilitation
  - e. Number of applicants with a criminal record who appealed a denial or disqualification from licensure;
  - f. Final outcome and demographic information, including voluntarily provided information on race or gender, of any applicant described in items c, d, or e above.
7. Provide that the provisions described above override any contradictory provisions currently in any board's licensing act.
8. Require a board to develop criteria to determine whether a crime is directly and adversely related to the qualifications, functions, or duties of the profession it regulates. The board must post a summary of this criteria on its website. The criteria must include the following:
  - a. The nature and gravity of the offense;
  - b. Number of years since the offense;
  - c. The nature and duties of the profession;
9. Prohibit a board from denying a license based on a conviction without considering rehabilitation.
10. Limit the amount of time a license may be placed on probation to two years or less. Additional conditions may be imposed only if a board determines there is clear and convincing evidence that additional conditions are necessary to address a risk.
11. Require each board to develop criteria to use when considering probation conditions to determine what conditions may be imposed to address a risk shown by clear and convincing evidence.
12. Allow a probationer to petition the board for a modification or termination of probation after one year. The board would then have 90 days to make a decision. If the board does not deny the petition within 90 days, it is considered granted.

13. Require a board to find an applicant is rehabilitated if he or she meets any of the following:
  - a. Completion of the criminal sentence without violating parole or probation;
  - b. Can document that he or she has worked in a related field continuously for at least one year or successfully completed training in a related field, as long as there are no public or official findings of professional misconduct; or
  - c. Has satisfied criteria for rehabilitation developed by the board.
14. If, after a hearing requested by an applicant to appeal a denial, a board decides to grant the license, revoke it, stay the revocation and impose probationary conditions, requires the board to also issue a public reproof.
15. State that this section does not prohibit a board from disciplining a licensee for professional misconduct that is based on evidence independent of an arrest.
16. Repeal the provision in law allowing a board to suspend a license if the licensee is not in compliance with a child support order.
17. Prohibit a board from taking disciplinary action against a licensee or from denying a license for professional misconduct if any of the following are met:
  - a. Successful completion of a diversion program;
  - b. A deferred entry of judgement; or
  - c. Successful completion of a specified alcohol and drug assessment program prescribed under the Vehicle Code.
18. A board is permitted to take disciplinary action against a licensee for professional misconduct that falls within the scope of the profession, based on evidence that is independent of an arrest.
19. Provides that in a proceeding to deny, suspend, revoke, or discipline a license, the record of a conviction shall be conclusive evidence of the fact the conviction occurred. Removes the board's ability to inquire into the circumstances surrounding the commission of the crime to determine discipline or to determine the conviction is substantially related to the qualification, functions, or duties of the licensee.
20. Requires a board to use the following criteria to determine if a crime is directly and adversely related to the qualifications, functions, or duties of the business or profession:
  - a. The nature and gravity of the offense;
  - b. The years elapsed since the offense;
  - c. The nature and duties of the profession;
  - d. The board may not bar an applicant based solely on the type of conviction without considering evidence of rehabilitation.

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure. Board staff have significant policy concerns that this measure will negatively impact the board's ability to thoroughly review and consider criminal arrests and/or convictions of applicants and licensees. The policy being put forth in this measure runs contrary to the board's consumer protection mandate as well as efforts by the Legislature to strengthen the ability of programs within the DCA to more robustly protect consumers. Creating barriers or limiting information the board can consider when making a licensing decision and enforcement action will undo gains the board has made in this area and significantly undermine the board's consumer protection mandate.

Currently, board staff only deny applications for criminal conviction history when a nexus can be established between the crime and the qualifications, functions, or duties of the business or profession. This bill seeks to raise the burden of proof from a preponderance of the evidence (A requirement that more than 50% of the evidence points to something) to clear and convincing evidence (A medium level of burden of proof whereby, a party must prove that it is substantially more likely than not that it is true. This standard is employed in both civil and criminal trials).

According to the author, approximately 1 in 3 adults in California have arrest or conviction records. They note that California has one of the highest re-offense rates in the country, with many committing new crimes within a year of release. A root cause of this is the inability of these individuals to gain employment after release from jail. However, nearly 30% of California jobs require licensure, and qualified individuals are often denied a license, or their license is revoked or suspended based on prior arrests or convictions, many of which are old, unrelated to the job, or dismissed. Therefore, the author is seeking to remove barriers on these individuals' ability to gain employment. While this policy may be appropriate for some professionals it does not appear appropriate for individuals working in healthcare related fields.

From a practical standpoint if this bill were to become law, key changes to the Board's current enforcement process would be as follows:

In the case of dismissed or expunged convictions, the Board would be prohibited from acting based on the crime's underlying acts. At times staff must consider the details of the crimes to establish the nexus between the act and the qualifications, functions, and duties of the business or profession.

The Board would be unable to require a licensee or applicant to disclose or document information about his or her criminal history. This is a necessary step in determining the suitability of an individual for licensure.

The board would be limited to probation terms of two years or less, unless the Board can provide clear and convincing evidence that additional conditions are necessary. Clear and convincing evidence is a medium level of burden of proof whereby, a party must prove that it is substantially more likely than not that it is true. This requirement lessens the Board's oversight of particular licensees and could negatively impact the public.

Further, the board would be required to decide on a petition for modification or termination or probation within 90 days or it is automatically granted. There are times where it may take longer for the Board to decide on a particular case and automatically granting a petition when more information is necessary could be detrimental to the protection of the consumer. The board currently convenes one-day board meetings to hear petitions. Even with these regularly scheduled meetings, petitions are not heard within 90 days.

A conviction may be nonviolent and substantially related to the practice of the profession, and may be especially relevant if there are multiple convictions showing a pattern.

**FISCAL IMPACT ON THE BOARD:**

This measure would likely have significant impact on the Board as it shortens the timeframe for a probation petition and it requires extensive data collection on applicants and licensees.

Currently, a hearing must be held within 180 days, but under the bill, the Board must decide within 90 days. Therefore, the Board would need to meet more frequently to make these decisions. It would also likely need additional legal staff and enforcement staff to comply with the 90-day time limit.

The Board would need modifications to its Applicant Tracking system to track the required information, and potentially an additional staff position to collect and compile the information.

Conflict with Current Board Law. The provisions of this bill contradict and override several existing enforcement provisions in the Boards existing licensing laws. For example, the Board's unprofessional conduct sections state criteria for denying a license or registration, much of which would be overridden. If this bill passes, the Board will need to work with its legal counsel to determine which areas of its licensing laws are in conflict and need to be revised.

**SUPPORT / OPPOSITION:**SUPPORT:

All of Us or None  
 Anchor of Hope Ministries  
 Anti-Recidivism Coalition  
 Because Black is Still Beautiful  
 Californians for Prop 57  
 Californians for Safety and Justice  
 Center for Employment Opportunities (CEO)  
 Center for Living and Learning  
 Checkr  
 East Bay Community Law Center  
 Legal Services for Prisoners with Children  
 Los Angeles Regional Reentry Partnership (LARRP)  
 National Association of Social Workers  
 California Chapter  
 Prisoner Reentry Network  
 Project Rebound: Expanded  
 REDF (Roberts Enterprise Development Fund)  
 Rise Together Bay Area  
 Root & Rebound  
 San Jose State University Record Clearance Project  
 The Young Women's Freedom Center

OPPOSITION:**BILL HISTORY:**

04/03/18	Re-referred to Com. on B. & P.
04/02/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
02/26/18	Referred to Com. on B. & P.
02/13/18	From printer. May be heard in committee March 15.
02/12/18	Read first time. To print.

**ASSEMBLY BILL**

**No. 2256**

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**Introduced by Assembly Member Santiago**

February 13, 2018

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An act to add Section 4119.9 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2256, as introduced, Santiago. Law enforcement agencies: opioid antagonist.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and wholesalers by the California State Board of Pharmacy within the Department of Consumer Affairs. Existing law authorizes a pharmacy to furnish naloxone hydrochloride or other opioid antagonists to a school district, county office of education, or charter school if specified criteria are met.

This bill would authorize a pharmacy or wholesaler to furnish naloxone hydrochloride or other opioid antagonists to a law enforcement agency, as provided.

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 4119.9 is added to the Business and
- 2 Professions Code, to read:
- 3 4119.9. Notwithstanding any other law, a pharmacy or
- 4 wholesaler may furnish naloxone hydrochloride or another opioid

1 antagonist to a law enforcement agency if both of the following  
2 are met:

3 (a) The naloxone hydrochloride or another opioid antagonist is  
4 furnished exclusively for use by employees of the law enforcement  
5 agency who have completed training, provided by the law  
6 enforcement agency, in administering naloxone or another opioid  
7 antagonist.

8 (b) Records regarding the acquisition and disposition of  
9 naloxone hydrochloride or another opioid antagonist furnished  
10 pursuant to this section shall be maintained by the law enforcement  
11 agency for a period of three years from the date the records were  
12 created. The law enforcement agency shall be responsible for  
13 monitoring the supply of naloxone hydrochloride or another opioid  
14 antagonist and ensuring the destruction of expired naloxone  
15 hydrochloride or another opioid antagonist.



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<b>Bill Number:</b>	<b>AB 2256</b>
<b>Current Version:</b>	<b>As introduced February 13, 2018</b>
<b>Author:</b>	<b>Santiago</b>
<b>Topic:</b>	<b>Law enforcement agencies: opioid antagonist</b>
<b>Staff Recommendation:</b>	<b>Support</b>

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**AFFECTED SECTIONS:** Adds Section 4119.9 to the Business & Professions Code.

**STATUS:** Assembly Public Safety

**EXISTING LAW:**

Allows any person to purchase the opioid antagonist Naloxone for the purpose of reversing lethal opioid overdose. Additionally, a law enforcement agency may purchase Naloxone, but not without first acquiring a prescription from a physician. (BCP §4052.01)

**THIS BILL WOULD:**

Allow law enforcement agencies throughout the state to acquire Naloxone without a prescription if:

- The opioid antagonist is exclusively for use by employees of the agency who have completed training in administering an opioid antagonist
- Acquisition and disposition records shall be maintained by the law enforcement agency for three years

**STAFF COMMENTS:**

This bill is consistent with the board's policy to support the availability and use of naloxone as an important tool to reduce deaths caused by opioid overdose.

**FISCAL IMPACT ON THE BOARD:**

Minor and absorbable.

**SUPPORT / OPPOSITION:**

SUPPORT:

Los Angeles County Sheriff's Department (sponsor)  
California Academy of Family Physicians  
California Pharmacists Association  
California Police Chiefs Association

OPPOSITION:

**BILL HISTORY:**

04/10/18	From committee: Do pass and re-refer to Com. on PUB. S. (Ayes 15. Noes 0.) (April 10). Re-referred to Com. on PUB. S.
03/01/18	Referred to Coms. on B. & P. and PUB. S.
02/14/18	From printer. May be heard in committee March 16.
02/13/18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 16, 2018

AMENDED IN ASSEMBLY MARCH 23, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2409**

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**Introduced by Assembly Member Kiley**

February 14, 2018

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An act to add Section 37 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 2409, as amended, Kiley. Professions and vocations: occupational regulations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs and provides that those boards are established for the purpose of ensuring that those private businesses and professions deemed to engage in activities that have potential impact upon the public health, safety, and welfare are adequately regulated in order to protect the people of California. Existing law authorizes a board to deny a license if an applicant has been convicted of a crime, done any act involving dishonesty, fraud, or deceit with intent to substantially benefit himself or herself or another or substantially injure another, or does any act that, if done by a licentiate of the business or profession, would be grounds for suspension or revocation.

This bill would establish that a person has a right to engage in a lawful profession or vocation without being subject to an occupational regulation, as defined, that imposes a substantial burden on that right, and would require each occupational regulation to be limited to what

is demonstrably necessary and narrowly tailored to fulfill a legitimate public health, safety, or welfare objective. The bill would include within this the right of a person with a criminal record to ~~obtain a license and not to have a board use the person's criminal record~~ *used by a board* as an automatic or mandatory permanent bar to engaging in a lawful profession or ~~vocation. The bill would also include~~ *vocation, except as specified, and the right of a person who is behind on his or her taxes or student loans to petition a board not to use these factors against that person, as prescribed. loan payments to not have a board use that fact as an automatic or mandatory permanent bar to engaging in a lawful profession or vocation.*

The bill would authorize a person ~~who is denied a license to file a petition and appeal to the board. The bill would prescribe procedures and legal standards by which a board may determine that a person's criminal record disqualifies that person. The bill would also permit a person, following the response to an administrative petition, to file an appeal to a court for a declaratory judgment or injunctive or other equitable relief, in accordance with certain legal procedures and criteria.~~ *to petition a board to review an occupational regulation, as defined, within the board's jurisdiction for compliance with the above rights, as specified. The bill would authorize a person with a criminal record to petition a board at any time for a determination of whether the person's criminal record will automatically disqualify the person from obtaining a license from the board and would specify the criteria a board is allowed to use in making that determination.* The bill would include related definitions and declare the intent of the Legislature in this regard.

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. This act may be known as the "Occupational
- 2 Opportunity Act."
- 3 SEC. 2. The Legislature finds and declares all of the following:
- 4 (a) Each individual has the right to pursue a chosen profession
- 5 and vocation, free from arbitrary or excessive government
- 6 interference.
- 7 (b) The freedom to earn an honest living traditionally has
- 8 provided the surest means for economic mobility.

1 (c) In recent years, many regulations of entry into professions  
2 and vocations have exceeded legitimate public purposes and have  
3 had the effect of arbitrarily limiting entry and reducing competition.

4 (d) The burden of excessive regulation is borne most heavily  
5 by individuals outside the economic mainstream, for whom  
6 opportunities for economic advancement are curtailed.

7 (e) It is in the public interest to do all of the following:

8 (1) Ensure the right of all individuals to pursue legitimate  
9 entrepreneurial and professional opportunities to the limits of their  
10 talent and ambition.

11 (2) Provide the means for the vindication of this right.

12 (3) Ensure that regulations of entry into professions and  
13 vocations are demonstrably necessary and narrowly tailored to  
14 fulfill legitimate health, safety, and welfare objectives.

15 SEC. 3. Section 37 is added to the Business and Professions  
16 Code, to read:

17 37. (a) (1) Notwithstanding Section 480 or any other law, a  
18 person has a right to engage in a lawful profession or vocation  
19 without being subject to an occupational regulation that imposes  
20 a substantial burden on that right. To achieve this purpose, each  
21 occupational regulation shall be limited to what is demonstrably  
22 necessary and shall be narrowly tailored to fulfill a legitimate  
23 public health, safety, or welfare objective.

24 (2) Notwithstanding any other law, the right set forth in  
25 paragraph (1) includes the right of a person with a criminal record  
26 ~~to obtain a license to engage in a profession or vocation, and the~~  
27 ~~right to not have a board use the person's criminal record as an~~  
28 ~~automatic or mandatory permanent bar to engaging in a lawful~~  
29 ~~profession or vocation.~~ *to not have the person's criminal record*  
30 *be used by a board as an automatic or mandatory permanent bar*  
31 *to engaging in a lawful profession or vocation, unless for reasons*  
32 *specified in this section.*

33 (3) Notwithstanding any other law, the right set forth in  
34 paragraph (1) also includes the right of a person who is behind on  
35 his or her taxes or student ~~loans~~ *loan payments* to obtain a license  
36 to engage in a profession or vocation, and the right to not have the  
37 board use the person's status with respect to his or her taxes or  
38 student ~~loans~~ *loan payments* as an automatic or mandatory  
39 permanent bar to engaging in a lawful profession or vocation.

1 ~~(b) (1) (A) A person denied a license may file a petition and~~  
2 ~~appeal to the board.~~

3 ~~(B) If the person has a criminal record, the person shall include~~  
4 ~~in the petition a copy of his or her criminal record or shall authorize~~  
5 ~~the board to obtain a copy that record. The person may additionally~~  
6 ~~include information about his or her current circumstances,~~  
7 ~~including, but not limited to, the time passed since the offense,~~  
8 ~~completion of the criminal sentence, other evidence of~~  
9 ~~rehabilitation, testimonials, employment history, and employment~~  
10 ~~aspirations.~~

11 ~~(C) Notwithstanding any other law, the board may find that the~~  
12 ~~person's criminal record disqualifies that person from obtaining a~~  
13 ~~license only if the person's criminal record includes a conviction~~  
14 ~~for a felony or a violent misdemeanor and the board concludes~~  
15 ~~that the state has an important interest in protecting public safety~~  
16 ~~that is superior to the person's individual right. The board may~~  
17 ~~make this conclusion only if it determines, by clear and convincing~~  
18 ~~evidence at the time of the petition, all of the following:~~

19 ~~(i) The specific offense for which the person was convicted is~~  
20 ~~substantially related to the qualifications, functions, or duties of~~  
21 ~~the profession or vocation for which application was denied.~~

22 ~~(ii) The person, based on the nature of the specific offense for~~  
23 ~~which he or she was convicted and his or her current circumstances,~~  
24 ~~would be put in a position in which that person is more likely to~~  
25 ~~reoffend by having the license than if the person did not obtain~~  
26 ~~that license.~~

27 ~~(iii) A reoffense by the person would cause greater harm than~~  
28 ~~it would if the person did not have a license and was not put in a~~  
29 ~~position in which the person is more likely to reoffend.~~

30 ~~(2) Within 90 days of a petition filed pursuant to paragraph (1),~~  
31 ~~the board shall make a determination on the appeal, based on the~~  
32 ~~standards set forth in subdivision (a).~~

33 ~~(e) (1) Following the response to an administrative petition~~  
34 ~~pursuant to paragraph (2) of subdivision (b), a person may file an~~  
35 ~~appeal to a court of general jurisdiction for a declaratory judgment~~  
36 ~~or injunctive relief or other equitable relief for a violation of~~  
37 ~~subdivision (a).~~

38 ~~(2) In such an action, the board bears the burden of proving by~~  
39 ~~preponderance of the evidence that the challenged occupational~~

1 regulation meets the criteria set forth in paragraph (1) of  
2 subdivision (a):

3 ~~(3) If the board fails to meet the burden of proof and the court  
4 finds by a preponderance of evidence that the challenged  
5 occupational regulation fails to meet the criteria set forth in  
6 paragraph (1) of subdivision (a), the court shall enjoin further  
7 enforcement of the occupational regulation and shall award  
8 reasonable attorney's fees and costs to the plaintiff.~~

9 ~~(4) A court shall liberally construe this section to protect the  
10 rights established in paragraph (1) of subdivision (a).~~

11 *(b) (1) A person may petition a board to review an occupational  
12 regulation within the board's jurisdiction for compliance with  
13 subdivision (a). The board shall respond within 90 days after the  
14 petition is submitted, and shall, in writing, inform the petitioner  
15 of the board's decision to do one of the following depending on  
16 the circumstances:*

17 *(A) Subject to the Administrative Procedure Act (Chapter 3.5  
18 (commencing with Section 11340) of Part 1 of Division 3 of Title  
19 2 of the Government Code), repeal the occupational regulation.*

20 *(B) Subject to the Administrative Procedure Act (Chapter 3.5  
21 (commencing with Section 11340) of Part 1 of Division 3 of Title  
22 2 of the Government Code), amend the occupational regulation  
23 to bring it into compliance with subdivision (a).*

24 *(C) Recommend the enactment of legislation by the Legislature.*

25 *(D) State the basis on which the board concludes the  
26 occupational regulation complies with subdivision (a).*

27 *(2) A person may appeal the board's determination in paragraph  
28 (1) by filing an action in a court of general jurisdiction for  
29 declaratory judgment, injunctive relief, or other equitable relief.*

30 *(A) In such an action, the board bears the burden of proving  
31 by a preponderance of the evidence that the challenged  
32 occupational regulation is in compliance with subdivision (a).*

33 *(B) If the board fails to meet the burden of proof and the court  
34 finds by a preponderance of the evidence that the challenged  
35 occupational regulation does not comply with subdivision (a), the  
36 court shall enjoin further enforcement of the occupational  
37 regulation and shall award reasonable attorney's fees and costs  
38 to the petitioner.*

39 *(c) (1) Notwithstanding any other law, a person with a criminal  
40 record may petition a board at any time for a determination of*

1 *whether the person’s criminal record will automatically disqualify*  
2 *the person from obtaining a license from the board.*

3 (2) *The person shall include in the petition the person’s criminal*  
4 *record or authorize the board to obtain the person’s criminal*  
5 *record.*

6 (3) *Notwithstanding any other statute or rule, the board may*  
7 *find the individual’s criminal record disqualifies the individual*  
8 *from obtaining a license only if both of the following are met:*

9 (A) *The person’s criminal record includes a conviction for a*  
10 *felony or violent misdemeanor.*

11 (B) *The board concludes the state has an important interest in*  
12 *protecting public safety that is superior to the person’s right in*  
13 *subdivision (a). The board may make this conclusion only if it*  
14 *determines, by clear and convincing evidence at the time of the*  
15 *petition, that all of the following are met:*

16 (i) *The specific offense for which the person was convicted is*  
17 *substantially related to the state’s interest in protecting public*  
18 *safety.*

19 (ii) *The person, based on the nature of the specific offense for*  
20 *which he or she was convicted and the person’s current*  
21 *circumstances, will be put in a position where the person is more*  
22 *likely to reoffend by having the license than if the individual did*  
23 *not have the license.*

24 (iii) *A reoffense will cause greater harm than if the individual*  
25 *did not have a license and was not put in the position where the*  
26 *individual is more likely to reoffend.*

27 (4) *The board shall issue its determination within 90 days after*  
28 *the board receives the petition. The determination shall be in*  
29 *writing and include, but not be limited to, the person’s criminal*  
30 *record, findings of fact, and the board’s legal conclusions.*

31 (d) *For purposes of this section, the following terms apply:*

32 (1) *“Board” has the same meaning as set forth in Section 22.*

33 (2) *“License” has the same meaning as set forth in Section 23.7.*

34 (3) *“Occupational regulation” means a regulation, rule, policy,*  
35 *condition, test, permit, administrative practice, or other state*  
36 *government-prescribed requirement for a person to engage in a*  
37 *lawful profession or vocation.*

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<b>Bill Number:</b>	<b>AB 2409</b>
<b>Current Version:</b>	<b>As amended April 16, 2018</b>
<b>Author:</b>	<b>Kiley</b>
<b>Topic:</b>	<b>Professions and vocations: occupational regulations</b>
<b>Staff Recommendation:</b>	<b>Oppose Unless Amended</b>

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**AFFECTED SECTIONS:** Adds Section 37 to the Business & Professions Code.

**STATUS:** Assembly Judiciary

**EXISTING LAW:**

Provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs and provides that those boards are established for the purpose of ensuring that those private businesses and professions deemed to engage in activities that have potential impact upon the public health, safety, and welfare are adequately regulated in order to protect the people of California.

Authorizes a board to deny a license if an applicant has been convicted of a crime, done any act involving dishonesty, fraud, or deceit with intent to substantially benefit himself or herself or another or substantially injure another, or does any act that, if done by a licentiate of the business or profession, would be grounds for suspension or revocation.

**THIS BILL WOULD:**

- Establish a right to engage in a lawful profession or vocation without being subject to an occupational regulation, as defined, that imposes a substantial burden on that right
- Require each occupational regulation to be limited to what is demonstrably necessary and narrowly tailored to fulfill a legitimate public health, safety, or welfare objective.
- Include within this the right of a person with a criminal record to not have the person's criminal record used by a board as an automatic or mandatory permanent bar to licensure
- Include within this right a person who is behind on his or her taxes or student loan payments to not have a board use that fact as an automatic or mandatory permanent bar to licensure
- Authorize a person to petition a board to review an occupational regulation, as defined, within the board's jurisdiction for compliance with the above rights, as specified.

- Authorize a person with a criminal record to petition a board at any time for a determination of whether the person’s criminal record will automatically disqualify the person from obtaining a license from the board and would specify the criteria a board is allowed to use in making that determination.

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure. Board staff have concerns that establishing a statutory right to a license is counter to the Board’s consumer protection mandate. Additionally, allowing any applicant to challenge any of the Board’s regulations would impose a workload to respond to those petitions that would impact the productivity of the Board and staff.

Currently, staff will review an applicant’s criminal history as part of the approval process, if any crimes listed on the report substantially relate to the position for which they are seeking a license than that is considered grounds for denial. For example, if an applicant has committed a nonviolent crime involving drugs such information is considered and may be grounds for denial. Under the provisions of this measure, the board would be prohibited from such action.

Staff notes that last year the board was successful in negotiating an amendment to changes in the deferred entry of judgement program by excluding some of the provisions from applying to healing arts licensed professional. Board staff suggest that similar amendments be requested and if not accepted the board change its positions to an oppose position.

**FISCAL IMPACT ON THE BOARD:**

This measure could have a significant fiscal impact based upon the number of appeals that are filed including attorney and court costs as well as staff resources.

**SUPPORT / OPPOSITION:**

SUPPORT:

Goldwater Institute  
 Pacific Legal Foundation  
 R Street Institute

OPPOSITION:

California Nurses Association  
 Professional Beauty Federation of California

04/17/18	In committee: Set, first hearing. Failed passage. Reconsideration granted.
04/17/18	Re-referred to Com. on B. & P.
04/16/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/02/18	Re-referred to Com. on B. & P.

03/23/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/22/18	Referred to Coms. on B. & P. and JUD.
02/15/18	From printer. May be heard in committee March 17.
02/14/18	Read first time. To print.

**BILL HISTORY:**

**ASSEMBLY BILL**

**No. 2576**

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**Introduced by Assembly Member Aguiar-Curry**  
**(Coauthors: Assembly Members Levine and Wood)**  
(Coauthors: Senators Dodd and McGuire)

February 15, 2018

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An act to add Section 4062.5 to the Business and Professions Code, to add Section 8628.5 to the Government Code, and to add Section 14132.723 to the Welfare and Institutions Code, relating to emergencies.

LEGISLATIVE COUNSEL'S DIGEST

AB 2576, as introduced, Aguiar-Curry. Emergencies: healthcare.

(1) Existing law, the California Emergency Services Act, authorizes the Governor to proclaim a state of emergency, and local officials and local governments to proclaim a local emergency, when specified conditions of disaster or extreme peril to the safety of persons and property exist, and authorizes the Governor or the appropriate local government to exercise certain powers in response to that emergency. Existing law authorizes the Governor, during a state of emergency, to direct all state agencies to utilize and employ state personnel, equipment, and facilities to perform activities that are designed to prevent or alleviate actual and threatened damage due to that emergency. Existing law authorizes a state agency so directed to expend any of the moneys that have been appropriated to it in order to perform that activity.

This bill would authorize the Governor, during a state of emergency, to direct all state agencies to utilize, employ, and direct state personnel, equipment, and facilities for the performance of any and all activities that are designed to allow community clinics and health centers to provide and receive reimbursement for services provided during or

immediately following the emergency. The bill would authorize any agency directed by the Governor to perform those activities to expend any of the moneys that have been appropriated to it in order to perform those activities, irrespective of the particular purpose for which the money was originally appropriated.

(2) Existing law, the Pharmacy Law, the knowing violation of which is a crime, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. Existing law authorizes a pharmacy to furnish dangerous drugs only to specified persons or entities, and subjects certain pharmacies and persons who violate the provision to specified fines. Existing law authorizes a pharmacist to, in good faith, furnish a dangerous drug or device in reasonable quantities without a prescription during a federal, state, or local emergency, in order to further the health and safety of the public by complying with certain record keeping requirements, and authorizes the board to waive any application of the Pharmacy Law during an emergency if the board determines that the waiver will aid in the protection of the public health or the provision of patient care. Existing law requires the board, during a declared federal, state, or local emergency, to allow for the employment of a mobile pharmacy in impacted areas under specified conditions, and authorizes the board to allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged under specified conditions.

This bill would require the board, during or immediately following a proclaimed state of emergency described above, to issue, upon request, a temporary pharmacy clinic permit to further the health and safety of the public. The bill would require a pharmacy or clinic who receives such a permit to use best efforts to keep certain records, but would require the permit holder to maintain the name, strength, and quantity of any drug or device furnished. The bill would provide a temporary pharmacy or clinic permit issued under these provisions to remain valid until 90 calendar days after the termination of the emergency, except as provided. The bill would require the board, during the emergency, to allow for the employment of a mobile pharmacy clinic in impacted areas under specified conditions. The bill would require the board, during the emergency, to waive any application fees for a temporary or mobile pharmacy or clinic permit, and to waive any other requirement if either the board, or the Governor, the waiver will aid in the protection of public health or the provision of patient care.

(3) Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions.

Existing law provides that in-person contact between a health care provider and a patient is not required under the Medi-Cal program for services appropriately provided through telehealth, as defined, subject to reimbursement policies adopted by the department to compensate a licensed health care provider who provides health care services through telehealth that are otherwise reimbursed pursuant to the Medi-Cal program. Existing law, for purposes of payment for covered treatment or services provided through telehealth, prohibits the department from limiting the type of setting where services are provided for the patient or by the health care provider.

This bill would provide, only to the extent that federal financial participation is available, that neither face-to-face contact nor a patient's physical presence on the premises of an enrolled community clinic, is required for services provided by the clinic to a Medi-Cal beneficiary during or immediately following a state of emergency, as specified. The bill would require that telehealth services, telephonic services, and other specified services be reimbursable when provided by an enrolled community clinic during a state of emergency.

This bill would require the department to seek federal approval of any necessary state plan amendments or waivers to implement these provisions, and would authorize the department to implement the provisions by all-county letters, provider bulletins, or similar instructions.

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. The Legislature finds and declares all of the
- 2 following:
- 3 (a) The Legislature has previously granted broad authority to
- 4 the Governor to direct state agencies to take various actions in
- 5 order to facilitate the immediate provision of emergency necessities
- 6 and resources to the public throughout disruptions caused by
- 7 natural disasters and other declared emergencies.

1 (b) Ensuring that both institutional and individual healthcare  
2 providers can continue to provide care to patients both during and  
3 immediately following a declared emergency is essential for  
4 protecting the public health and safety.

5 (c) In the case of a natural disaster or other emergency situations,  
6 healthcare is often provided through innovative or extraordinary  
7 means, including providing care telephonically or in temporary  
8 shelters. However, given the complexities of healthcare regulation  
9 and reimbursement, often neither the state nor local jurisdictions  
10 are able to readily advise and support healthcare providers who  
11 are trying to help patients under these circumstances.

12 (d) Community clinics and health centers are crucial to  
13 emergency response and recovery efforts by doing all of the  
14 following: providing patients with necessary resources, such as  
15 how to apply for CalFresh, and information on local assistance  
16 centers; information on how to apply for assistance from the  
17 Federal Emergency Management Agency (FEMA) and other state  
18 and federal resources; information on how to obtain emergency  
19 refills for prescription drugs; and information on disaster services  
20 from the Employment Development Department for patients who  
21 have lost their jobs as a result of the fires. Community clinics and  
22 health centers are responsible to the most vulnerable in our state;  
23 those individuals who have been hit the hardest by these natural  
24 disasters.

25 (e) The purpose of this legislation is to clarify what state and  
26 local agencies can currently do under existing law to ensure  
27 continuity of care and access to the broadest array of healthcare  
28 services possible during and immediately following a state of  
29 emergency, and to require state agencies to seek any necessary  
30 federal approvals that may be required in order to provide care to  
31 as many people impacted by the emergency as possible.

32 SEC. 2. Section 4062.5 is added to the Business and Professions  
33 Code, to read:

34 4062.5. (a) (1) Notwithstanding any other law, during or  
35 immediately following a proclaimed state of emergency, a  
36 pharmacy or a clinic, as described in Section 4180, may request,  
37 and the board shall immediately issue, a temporary pharmacy or  
38 clinic permit to further the health and safety of the public.

1 (2) For purposes of this subdivision, “immediately following”  
2 shall mean within 30 calendar days after the conclusion of the  
3 proclaimed state of emergency.

4 (b) A pharmacy or clinic issued a temporary permit under this  
5 section shall use best efforts to keep a record containing the date,  
6 name, and address of each person to whom a drug or device is  
7 furnished during a proclaimed state of emergency. However, a  
8 pharmacy or clinic issued a temporary permit under this section  
9 shall maintain the name, strength, and quantity of any drug or  
10 device furnished during the emergency.

11 (c) A temporary pharmacy or clinic permit issued under this  
12 section shall be valid until 90 calendar days after the termination  
13 of the proclaimed state of emergency. In cases of extraordinary  
14 circumstances, such as the destruction of a permitted pharmacy or  
15 clinic, and at the discretion of the board or by the direction of the  
16 Governor, a temporary pharmacy or clinic permit issued under this  
17 section shall be valid for a period of time longer than 90 calendar  
18 days and as long as is necessary for the health and safety of the  
19 public.

20 (d) During a proclaimed state of emergency, the board shall  
21 allow for the employment of a mobile pharmacy or mobile clinic  
22 in impacted areas in order to ensure the continuity of patient care,  
23 if all of the following conditions are met:

24 (1) The mobile pharmacy or clinic shares common ownership  
25 with at least one currently licensed pharmacy or clinic in good  
26 standing.

27 (2) The mobile pharmacy or clinic retains records of dispensing,  
28 as required by subdivision (b).

29 (3) A licensed pharmacist or professional director is on the  
30 premises and the mobile pharmacy or clinic is under the control  
31 and management of a pharmacist or professional director while  
32 the drugs are being dispensed.

33 (4) Reasonable security measures are taken to safeguard the  
34 drug supply maintained in the mobile pharmacy.

35 (5) The mobile pharmacy or clinic is located within the declared  
36 emergency area or affected areas.

37 (6) The mobile pharmacy or clinic ceases the provision of  
38 services within 48 hours following the termination of the declared  
39 emergency.

1 (e) During a proclaimed state of emergency, the board shall  
 2 waive any application fees for a temporary or mobile pharmacy  
 3 or clinic permit that may apply. The board shall waive any other  
 4 provisions of this chapter or the regulations adopted pursuant to  
 5 it if, in the board’s opinion, or at the Governor’s direction, the  
 6 waiver will aid in the protection of public health or the provision  
 7 of patient care.

8 (f) For purposes of this section, “proclaimed state of emergency”  
 9 means a state of emergency described in Section 8628.5 of the  
 10 Government Code.

11 SEC. 3. Section 8628.5 is added to the Government Code, to  
 12 read:

13 8628.5. (a) During a state of emergency, the Governor may  
 14 direct all state agencies to utilize, employ, and direct state  
 15 personnel, equipment, and facilities for the performance of any  
 16 and all activities designed to allow community clinics and health  
 17 centers to provide and receive reimbursement for services provided  
 18 during or immediately following the emergency, including all of  
 19 the following:

- 20 (1) To issue permits.
- 21 (2) To expedite application processing timelines.
- 22 (3) To direct, to the extent necessary, the state Department of  
 23 Health Care Services, or any other state agency, to seek all  
 24 appropriate federal approvals to allow community clinics and  
 25 health centers to provide and be reimbursed for Medi-Cal or other  
 26 services that are provided either telephonically, or to patients at a  
 27 shelter or other location within the geographical boundaries of the  
 28 emergency as stated in the proclamation declaring the state of  
 29 emergency.
- 30 (4) To provide guidance, supplemental services, or whatever  
 31 resources may be necessary to political subdivisions to ensure the  
 32 provision of services by community clinics and health centers that  
 33 are necessary to provide for the health and safety of the citizens  
 34 of the affected area.
- 35 (b) Any agency directed by the Governor to perform activities  
 36 pursuant to subdivision (a) may expend any of the moneys that  
 37 have been appropriated to it in order to perform those activities,  
 38 irrespective of the particular purpose for which the moneys were  
 39 originally appropriated.

1 SEC. 4. Section 14132.723 is added to the Welfare and  
2 Institutions Code, to read:

3 14132.723. (a) Notwithstanding any other law, and only to  
4 the extent that federal financial participation is available, neither  
5 face-to-face contact nor a patient’s physical presence on the  
6 premises shall be required for services provided by an enrolled  
7 community clinic to a Medi-Cal beneficiary during or immediately  
8 following a state of emergency, as described in Section 8628.5 of  
9 the Government Code.

10 (b) For purposes of this section, the following terms shall have  
11 the following meanings:

12 (1) “Enrolled community clinic” shall mean a community clinic  
13 licensed under subdivision (a) of Section 1204 of the Health and  
14 Safety Code, an intermittent clinic exempt from licensure under  
15 subdivision (h) of Section 1206 of the Health Safety Code, a tribal  
16 clinic exempt from licensure under subdivision (c) of Section 1206  
17 of the Health and Safety Code, or an outpatient setting conducted,  
18 maintained, or operated by a federally recognized Indian Tribe,  
19 Tribal Organization, or Urban Indian Organization, as defined in  
20 Section 1603 of Title 25 of the United States Code, that is certified,  
21 as applicable, and enrolled in good standing as a Medi-Cal provider  
22 or, in the case of an intermittent site, is added to a parent clinic’s  
23 provider master file under Section 14043.15. An outpatient setting  
24 that operates as a federally qualified health center (FQHC) or a  
25 rural health center (RHC) shall also qualify as an enrolled  
26 community clinic, regardless of its license type or license-exempt  
27 status.

28 (2) “Immediately following” shall mean within 90 calendar days  
29 after the conclusion of the proclaimed state of emergency. Under  
30 extraordinary circumstances, including, but not limited to, the  
31 destruction of an enrolled community clinic site, the department  
32 may determine in its discretion or at the direction of the Governor  
33 that the period of time immediately following the conclusion of a  
34 state of emergency should be extended beyond 90 calendar days  
35 and for as long as is necessary for the health and safety of the  
36 public.

37 (3) “Premises” shall mean a site located within the four walls  
38 of the enrolled community clinic, at the address listed on the  
39 primary care clinic license or listed in the provider master file.

- 1 (4) “Telehealth” shall have the same meaning as that term is
- 2 defined in Section 2290.5 of the Business and Professions Code.
- 3 (c) The following services shall be reimbursable when provided
- 4 by an enrolled community clinic during a state of emergency:
- 5 (1) Telehealth services.
- 6 (2) Telephonic services.
- 7 (3) All covered benefit services that are otherwise reimbursable
- 8 to an enrolled community clinic but that are provided somewhere
- 9 other than on the enrolled community clinic’s premises, including,
- 10 but not limited to, services provided at a temporary shelter, a
- 11 patient’s home, or any location other than the location identified
- 12 on the primary care clinic license or in the provider master file, if
- 13 the services are provided somewhere located within the boundaries
- 14 of the emergency proclamation.
- 15 (d) Notwithstanding Chapter 3.5 (commencing with Section
- 16 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
- 17 the department may implement, interpret, and make specific this
- 18 section by means of all-county letters, provider bulletins, or similar
- 19 instructions.
- 20 (e) The department shall seek federal approval of any necessary
- 21 state plan amendments or waivers to implement this section.



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<b>Bill Number:</b>	<b>AB 2576</b>
<b>Current Version:</b>	<b>As amended April 25, 2018</b>
<b>Author:</b>	<b>Aguiar-Curry Levine, Wood Dodd, McGuire</b>
<b>Topic:</b>	<b>Emergencies: healthcare</b>
<b>Staff Recommendation:</b>	<b>Support</b>

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**AFFECTED SECTIONS:** Amends Section 4062, 4064, and 4126.5 to the Business & Professions Code. Adds Section 8628.5 to the Government Code. Adds Section 14132.723 to the Welfare & Institutions Code.

**STATUS:** Assembly Business & Professions

**EXISTING LAW:**

Allows for the following during a declared federal, state, or local emergency (BPC §4062);

- Allows a pharmacist to in good faith dispense a dangerous drug or device without a prescription
- Allows for the establishment of a mobile pharmacy in accordance with specific provisions.
- Allows for the board to issue a temporary license (BPC §4129.8)...

**THIS BILL WOULD:**

- Expand the emergency provision described above to authorize a clinic licensed by the Board to purchase drugs at wholesale for administration or dispensing to patients, to furnish dangerous drugs or devices in reasonable quantities without a prescription during a federal, state, or local emergency.
- Authorizes the Board to waive application of any provision if, in the Board's opinion, the waiver will aid in the protection of the public.
- Clarify existing law to ensure that the process for allowing telephonic visits during declared emergencies in the future is automatic and timely.
- Clarifies that health centers can bill for services that are provided outside of the clinic setting when the clinic is not available or accessible.
- Grants the ability to provide, and be reimbursed for, home visits.

**STAFF COMMENTS:**

The board currently has authority to issue temporary permits as well as a process to waive certain requirements in the event of a declared natural disaster. Many of these provisions currently only apply to a pharmacy. It appears that allowing greater flexibility for clinic licenses would be consistent with the board's policy of ensuring displaced patients have ready access to prescription medications.

Discussions with the author's office suggest that this measure is being sought to apply lessons learned from the wildfires last year. The intent of this measure is to allow additional flexibility to the board.

Board staff provided technical input to reconcile the provisions with current law.

**FISCAL IMPACT ON THE BOARD:**

The provision in this measure that explicitly prohibits the board from assessing fees for these services could cause the board to experience minor negative fiscal impact. Staff believe the workload could be absorbed within existing resources, but depending on the implementation of the provisions, a subsidy from other licenses may be necessary.

**SUPPORT / OPPOSITION:**

SUPPORT:

CaliforniaHealth+Advocates (cosponsor)  
Redwood Community Health Coalition (cosponsor)  
Alameda Health Consortium  
Borrego Community Health Foundation  
California School-Based Health Alliance  
Capitol Health Network  
Clinicas de Salud del Pueblo  
Coastal Health Alliance  
CommuniCare Health Centers  
Community Clinic Association of Los Angeles County  
Community Clinic Consortium  
Community Health Systems, Inc.  
Health Alliance of Northern California  
Health Center Partners of Southern California  
Imperial Beach Community Clinic  
Indian Health Center of Santa Clara Valley  
Indian Health Council, Inc.  
La Maestra Health Centers  
Lifelong Medical Care  
Marin Community Clinics  
Mountain Health and Community Services  
Neighborhood Healthcare  
North Coast Clinics Network  
North County Health Services  
Northeast Valley Health Corporation  
Operation Samahan  
Planned Parenthood of the Pacific Southwest  
San Diego American Indian Health Council  
San Diego Family Care  
San Francisco Community Clinic Consortium  
San Ysidro Health

San Ysidro Health Center  
 Santa Rosa Community Health  
 Sonoma Valley Community Health Center  
 Southern Indian Health Council  
 Sycuan Medical Dental Center  
 Vista Community Clinic  
 West County Health Centers, Inc.  
 Westside Family Health Center

OPPOSITION:

None on file

**BILL HISTORY:**

04/11/18	From committee: Do pass and re-refer to Com. on B. & P. (Ayes 15. Noes 0.) (April 10). Re-referred to Com. on B. & P.
03/08/18	Referred to Coms. on HEALTH and B. & P.
02/16/18	From printer. May be heard in committee March 18.
02/15/18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 12, 2018

AMENDED IN ASSEMBLY APRIL 2, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2859**

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**Introduced by Assembly Member Caballero  
(Coauthor: Assembly Member Rodriguez)**

February 16, 2018

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An act to add *and repeal* Section 4106.5-~~to~~ of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2859, as amended, Caballero. Pharmacy: safe storage products.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy, which is within the Department of Consumer Affairs, and provides that a violation of that law is punishable as a misdemeanor.

This bill would require a chain community pharmacy or an independent community pharmacy that dispenses Schedule II, III, or IV controlled substances to display safe storage products within the pharmacy department. The bill would require the board to assess a fine against a pharmacy for violation of these provisions, except that the bill would allow the board to choose not to take administrative action against a pharmacy if the board determines that compliance with the law would create a financial hardship on the pharmacy. The bill would specify that a violation of these provisions shall not be punishable as a misdemeanor. The bill would also define certain terms for these purposes. *The bill would repeal these provisions on January 1, 2023.*

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. This act shall be known, and may be cited, as the  
2 Protecting Our Children and Adolescents from Opioids Act of  
3 2018.

4 SEC. 2. (a) The Legislature finds and declares all of the  
5 following:

6 (1) Drug overdoses are now the leading cause of death by injury  
7 in the United States, outnumbering both traffic crashes and  
8 gun-related deaths.

9 (2) In 2015, there were 52,404 drug overdose deaths, with  
10 33,091 of those deaths involving the use of opioids.

11 (3) Every day, 3,000 children 12 to 17 years of age abuse a  
12 prescription painkiller for the first time.

13 (4) The federal Centers for Disease Control and Prevention  
14 estimates that the nonmedical use of prescription painkillers costs  
15 public and private health insurers \$72.8 billion annually.

16 (5) The National Institute on Drug Abuse has found 90 percent  
17 of all teens who abuse pharmaceutical drugs obtain their drugs  
18 from their home medicine cabinet or from a friend's medicine  
19 cabinet.

20 (6) Researchers at the Johns Hopkins Bloomberg School of  
21 Public Health found that nearly 70 percent of prescription opioid  
22 medications kept in homes with children are not stored safely.

23 (7) Only 18 percent of providers have been estimated to discuss  
24 safe storage and disposal of drugs with their patients.

25 (8) The Partnership for Drug-Free Kids has found that one of  
26 the key drivers for abusing prescription painkillers amongst teens  
27 is easy access, with more than 3 in 5 teens stating that pain relievers  
28 were easy to obtain from their parents' medicine cabinets.

29 (9) New reports have found that the number of emergency room  
30 visits for accidental poisoning amongst toddlers has tripled since  
31 1997.

32 (b) It is the intent of the Legislature that increasing safe storage  
33 practices among parents is an important component to protecting  
34 teens and children from the dangers of opioid abuse and that the  
35 state must do more to encourage parents to safeguard these

1 medications that are vital to managing certain chronic pain  
2 conditions among adults.

3 SEC. 3. Section 4106.5 is added to the Business and Professions  
4 Code, to read:

5 4106.5. (a) For purposes of this section, the following terms  
6 shall have the following meanings:

7 (1) “Chain community pharmacy” has the same meaning as in  
8 subdivision (c) of Section 4001.

9 (2) “Independent community pharmacy” has the same meaning  
10 as in subdivision (c) of Section 4001.

11 (3) “Pharmacy” means either a chain community pharmacy or  
12 an independent community pharmacy.

13 (4) “Safe storage products” means either:

14 (A) A ~~box~~ box, bag, or medicine cabinet made with the intent  
15 of storing medicine that includes a locking mechanism that cannot  
16 be tampered with or opened without extreme force.

17 (B) A medicine locking closure container accessible only by  
18 the designated patient with a passcode, an alphanumeric code, a  
19 key, or by another secure mechanism. A medicine locking closure  
20 container includes, but is not limited to, a prescription container  
21 combined with a resettable alphanumeric code.

22 (5) “Schedule II, III, or IV controlled substances” means any  
23 substance defined as a Schedule II, III, or IV controlled substance  
24 in Sections 11055, 11056, and 11057 of the Health and Safety  
25 Code.

26 (b) A pharmacy that dispenses Schedule II, III, or IV controlled  
27 substances shall display safe storage products within the pharmacy  
28 department.

29 (c) (1) The board shall assess a fine in an amount to be  
30 determined by the board for a violation of this section.

31 (2) Notwithstanding paragraph (1), the board may choose not  
32 to take administrative action against a pharmacy if it determines  
33 that compliance with this section would create a financial hardship  
34 on the pharmacy.

35 (d) Section 4321 shall not apply to a violation of this section.

36 (e) *This section shall remain in effect only until January 1, 2023,*  
37 *and as of that date is repealed.*

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**Bill Number:** AB 2859

**Current Version:** As amended April 12, 2018

**Author:** Caballero

**Topic:** Pharmacy: safe storage products

**Staff Recommendation:** None

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**AFFECTED SECTIONS:** Adds 4106.5 to the Business & Professions Code and subsequent repeal.

**STATUS:** Assembly appropriations

**EXISTING LAW:**

There is no law currently governing the display of safe storage products.

**THIS BILL WOULD:**

Require community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products within the pharmacy.

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure. This measure appears consistent with the board's policy to combat the opioid epidemic.

Board staff recommend offering amendments to remove (c)(1) and (2) as the Board already has the authority to cite and fine for noncompliance with regulations.

**FISCAL IMPACT ON THE BOARD:**

Minor and absorbable.

**SUPPORT / OPPOSITION:**

SUPPORT:

AIDS Healthcare Foundation  
California Coalition for Children Health and Safety  
CORE Medical Clinic  
Gatekeeper Innovation, Inc.  
Monterey County Prescribe Safe Initiative

OPPOSITION:

None on file

**BILL HISTORY:**

04/12/18	Read second time and amended.
04/11/18	From committee: Amend, and do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (April 10).
04/03/18	Re-referred to Com. on B. & P.
04/02/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/08/18	Referred to Com. on B. & P.
02/17/18	From printer. May be heard in committee March 19.
02/16/18	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 11, 2018

AMENDED IN ASSEMBLY MARCH 23, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2863**

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**Introduced by Assembly Member Nazarian**

February 16, 2018

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An act to add ~~Section 4445 to the Business and Professions Code, relating to pharmacy. Section 1367.47 to the Health and Safety Code, and to add Section 10123.65 to the Insurance Code, relating to health care coverage.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 2863, as amended, Nazarian. ~~Pharmacy: prescriptions: pharmacy benefit manager: cost. Health care coverage: prescriptions.~~

*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 the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or health insurer that covers outpatient prescription drug benefits to provide coverage for specified prescription drugs, and requires cost sharing for outpatient prescription drugs to be reasonable so as to allow access to medically necessary outpatient prescription drugs.*

*This bill would limit the amount a health care service plan, health insurer, or pharmacy benefit manager may require an enrollee or insured to pay at the point of sale for a covered prescription to the lesser of the applicable cost-sharing amount or the retail price. The*

*bill would prohibit a health care service plan, health insurer, or pharmacy benefit manager from requiring a pharmacy to charge or collect a copayment from an enrollee or insured that exceeds the total submitted charges by the network pharmacy. The bill would require the amount paid for a prescription to be applied to the enrollee's or insured's deductible and out-of-pocket maximum if the enrollee or insured pays the retail price.*

*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.*

~~The Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy within the Department of Consumer Affairs. Existing law establishes requirements for prescriptions, including specific requirements for the substitution of drugs on filling a prescription order.~~

~~Existing law requires a pharmacy benefit manager that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis to include information identifying any national drug pricing compendia or other data sources used to determine the maximum allowable cost for the drugs on a maximum allowable cost list and to provide for an appeal process for the contracting pharmacy in any contract entered into or renewed on or after January 1, 2016. Existing law requires a pharmacy benefit manager to make available to a contracting pharmacy, upon request, the most up-to-date maximum allowable cost list or lists used by the pharmacy benefit manager for patients served by the pharmacy.~~

~~This bill would prohibit a contract between a health carrier or a pharmacy benefit manager and a pharmacy from penalizing a pharmacy's disclosure of the cost of the prescription medication or the availability of alternative medications or less costly alternative methods of purchasing a medication to a health benefit plan beneficiary. The bill would limit the amount a health carrier or pharmacy benefit manager may require a health benefit plan beneficiary to pay at the point of sale for a covered prescription medication to the lesser of the applicable cost-sharing amount or the amount the beneficiary would pay without using a health benefit plan. The bill would prohibit a health carrier or pharmacy benefit manager from requiring a pharmacy to charge or~~

collect a copayment from a beneficiary that exceeds the total submitted charges by the network pharmacy. The bill would require the amount paid for a prescription to be applied to the beneficiary's deductible and out-of-pocket maximum if the beneficiary opts to pay the cash price.

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 1367.47 is added to the Health and Safety  
2 Code, to read:

3     1367.47. (a) The maximum amount a health care service plan  
4 or pharmacy benefit manager, as defined in Section 4430 of the  
5 Business and Professions Code, may require an enrollee to pay  
6 at the point of sale for a covered prescription medication is the  
7 lesser of the following:

8     (1) The applicable cost-sharing amount for the prescription  
9 medication.

10    (2) The retail price.

11    (b) A health care service plan or pharmacy benefit manager  
12 shall not require a pharmacist or pharmacy to charge or collect  
13 from an enrollee a copayment that exceeds the total submitted  
14 charges by the network pharmacy. If an enrollee pays the retail  
15 price instead of paying the cost-sharing amount for the prescription  
16 medication, that amount shall be applied to the enrollee's  
17 deductible and out-of-pocket maximum in the same manner as if  
18 the enrollee had purchased the prescription medication by paying  
19 the cost-sharing amount.

20    SEC. 2. Section 10123.65 is added to the Insurance Code, to  
21 read:

22    10123.65. (a) The maximum amount a health insurer or  
23 pharmacy benefit manager, as defined in Section 4430 of the  
24 Business and Professions Code, may require an insured to pay at  
25 the point of sale for a covered prescription medication is the lesser  
26 of the following:

27    (1) The applicable cost-sharing amount for the prescription  
28 medication.

29    (2) The retail price.

30    (b) A health insurer or pharmacy benefit manager shall not  
31 require a pharmacist or pharmacy to charge or collect from an

1 insured a copayment that exceeds the total submitted charges by  
 2 the network pharmacy. If an insured pays the retail price instead  
 3 of paying the cost-sharing amount for the prescription medication,  
 4 that amount shall be applied to the insured's deductible and  
 5 out-of-pocket maximum in the same manner as if the insured had  
 6 purchased the prescription medication by paying the cost-sharing  
 7 amount.

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

17 SECTION 1. ~~Section 4445 is added to the Business and~~  
 18 ~~Professions Code, to read:~~

19 4445. (a) ~~A contract entered into or renewed on or after January~~  
 20 ~~1, 2019, between a health carrier or a pharmacy benefit manager~~  
 21 ~~and a pharmacist or pharmacy may not penalize a pharmacist's or~~  
 22 ~~pharmacy's disclosure of any of the following information to a~~  
 23 ~~health benefit plan beneficiary purchasing prescription medication:~~

- 24 (1) ~~The cost of the prescription medication to the beneficiary.~~
- 25 (2) ~~The availability of any therapeutically equivalent alternative~~  
 26 ~~medications or alternative methods of purchasing the prescription~~  
 27 ~~medication that are less expensive than the cost of the prescription~~  
 28 ~~medication to the beneficiary, including, but not limited to, paying~~  
 29 ~~the cash price.~~

30 (b) ~~The maximum amount a health carrier or pharmacy benefit~~  
 31 ~~manager may require a health benefit plan beneficiary to pay at~~  
 32 ~~the point of sale for a covered prescription medication is the lesser~~  
 33 ~~of the following:~~

- 34 (1) ~~The applicable cost-sharing amount for the prescription~~  
 35 ~~medication.~~
- 36 (2) ~~The amount the beneficiary would pay for the prescription~~  
 37 ~~medication if the beneficiary purchased the prescription medication~~  
 38 ~~without using a health benefit plan or any other source of~~  
 39 ~~prescription medication benefits or discounts.~~

1 ~~(e) A health carrier or pharmacy benefit manager shall not~~  
2 ~~require a pharmacist or pharmacy to charge or collect from a~~  
3 ~~beneficiary a copayment that exceeds the total submitted charges~~  
4 ~~by the network pharmacy. If a beneficiary pays the amount~~  
5 ~~specified in paragraph (2) of subdivision (b) instead of paying the~~  
6 ~~cost-sharing amount for the prescription medication, that amount~~  
7 ~~shall be applied to the beneficiary's deductible and out-of-pocket~~  
8 ~~maximum in the same manner as if the beneficiary had purchased~~  
9 ~~the prescription medication by paying the cost-sharing amount.~~

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**Bill Number:** AB 2863

**Current Version:** As amended April 11, 2018

**Author:** Nazarian

**Topic:** Health Care Coverage: Prescriptions

**Staff Recommendation:** None

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**AFFECTED SECTIONS:** Adds Section 1367.47 is to the Health and Safety Code, Adds Section 10123.65 to the Insurance Code.

**STATUS:** Assembly Business and Professions

**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 the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or health insurer that covers outpatient prescription drug benefits to provide coverage for specified prescription drugs, and requires cost sharing for outpatient prescription drugs to be reasonable so as to allow access to medically necessary outpatient prescription drugs.

**THIS BILL WOULD:**

Limit the amount a health care service plan, health insurer, or pharmacy benefit manager may require an enrollee or insured to pay at the point of sale for a covered prescription to the lesser of either the applicable cost-sharing amount or the retail price. The bill would prohibit a health care service plan, health insurer, or pharmacy benefit manager from requiring a pharmacy to charge or collect a copayment from an enrollee or insured that exceeds the total submitted charges by the network pharmacy. The bill would require the amount paid for a prescription to be applied to the enrollee's or insured's deductible and out-of-pocket maximum if the enrollee or insured pays the retail price.

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure. This measure seems to be consistent with the Board's consumer protection mandate by requiring the consumer be charged the lesser amount for their prescriptions.

**FISCAL IMPACT ON THE BOARD:**

Minor and absorbable.

**SUPPORT / OPPOSITION:**

SUPPORT:

None known

**OPPOSITION:**

None known

**BILL HISTORY:**

04/12/18	Re-referred to Com. on HEALTH.
04/11/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
04/02/18	Re-referred to Com. on HEALTH.
03/23/18	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
03/22/18	Referred to Coms. on HEALTH and B. & P.
02/17/18	From printer. May be heard in committee March 19.
02/16/18	Read first time. To print.

AMENDED IN SENATE APRIL 16, 2018

**SENATE BILL**

**No. 1021**

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**Introduced by Senator Wiener  
(Principal coauthor: Senator Atkins)**

February 7, 2018

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An act to amend and repeal Section 1342.71 of the Health and Safety Code, and to amend and repeal Section 10123.193 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1021, as amended, Wiener. Prescription drugs.

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 the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance.

Existing law prohibits the formulary or formularies for outpatient prescription drugs maintained by a health care service plan or health insurer from discouraging the enrollment of individuals with health conditions and from reducing the generosity of the benefit for enrollees or insureds with a particular condition. Existing law, until January 1, 2020, provides that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed \$250 for a supply of up to 30 days, except as specified. Existing law, until January 1, 2020, requires a nongrandfathered individual or small group plan contract or policy to use specified definitions for each tier of a drug formulary.

This bill would extend those provisions indefinitely. The bill would prohibit a drug formulary maintained by a health care service plan or

health insurer from containing more than 4 tiers, and would permit a biologic with a therapeutic equivalent to be placed on a tier other than tier 4, as specified. The bill would require a prescription drug benefit to provide that an enrollee or an insured is not required to pay more than the retail price for a prescription drug if a pharmacy’s retail price is less than the applicable copayment or coinsurance ~~amount.~~ *amount, and the payment rendered by an enrollee or insured would constitute the applicable cost sharing, as specified.*

Existing law requires a plan contract or policy to cover a single-tablet prescription drug regimen for combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, as specified.

This bill would extend that coverage requirement to combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, as specified. Because a willful violation of the bill’s requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

- 1 SECTION 1. Section 1342.71 of the Health and Safety Code,
- 2 as amended by Section 175 of Chapter 86 of the Statutes of 2016,
- 3 is amended to read:
- 4 1342.71. (a) The Legislature hereby finds and declares all of
- 5 the following:
- 6 (1) The federal Patient Protection and Affordable Care Act, its
- 7 implementing regulations and guidance, and related state law
- 8 prohibit discrimination based on a person’s expected length of life,
- 9 present or predicted disability, degree of medical dependency,
- 10 quality of life, or other health conditions, including benefit designs
- 11 that have the effect of discouraging the enrollment of individuals
- 12 with significant health needs.
- 13 (2) The Legislature intends to build on existing state and federal
- 14 law to ensure that health coverage benefit designs do not have an

1 unreasonable discriminatory impact on chronically ill individuals,  
2 and to ensure affordability of outpatient prescription drugs.

3 (3) Assignment of all or most prescription medications that treat  
4 a specific medical condition to the highest cost tiers of a formulary  
5 may effectively discourage enrollment by chronically ill  
6 individuals, and may result in lower adherence to a prescription  
7 drug treatment regimen.

8 (b) A nongrandfathered health care service plan contract that is  
9 offered, amended, or renewed on or after January 1, 2017, shall  
10 comply with this section. The cost-sharing limits established by  
11 this section apply only to outpatient prescription drugs covered by  
12 the contract that constitute essential health benefits, as defined in  
13 Section 1367.005.

14 (c) A health care service plan contract that provides coverage  
15 for outpatient prescription drugs shall cover medically necessary  
16 prescription drugs, including nonformulary drugs determined to  
17 be medically necessary consistent with this chapter.

18 (d) (1) Consistent with federal law and guidance, the formulary  
19 or formularies for outpatient prescription drugs maintained by the  
20 health care service plan shall not discourage the enrollment of  
21 individuals with health conditions and shall not reduce the  
22 generosity of the benefit for enrollees with a particular condition  
23 in a manner that is not based on a clinical indication or reasonable  
24 medical management practices. Section 1342.7 and any regulations  
25 adopted pursuant to that section shall be interpreted in a manner  
26 that is consistent with this section.

27 (2) For combination antiretroviral drug treatments that are  
28 medically necessary for the treatment or prevention of AIDS/HIV,  
29 a health care service plan contract shall cover a single-tablet drug  
30 regimen that is as effective as a multitablet regimen unless,  
31 consistent with clinical guidelines and peer-reviewed scientific  
32 and medical literature, the multitablet regimen is clinically equally  
33 or more effective and more likely to result in adherence to a drug  
34 regimen.

35 (e) (1) With respect to an individual or group health care service  
36 plan contract subject to Section 1367.006, the copayment,  
37 coinsurance, or any other form of cost sharing for a covered  
38 outpatient prescription drug for an individual prescription for a  
39 supply of up to 30 days shall not exceed two hundred fifty dollars  
40 (\$250), except as provided in paragraphs (2) and (3).

1 (2) With respect to products with actuarial value at, or equivalent  
2 to, the bronze level, cost sharing for a covered outpatient  
3 prescription drug for an individual prescription for a supply of up  
4 to 30 days shall not exceed five hundred dollars (\$500), except as  
5 provided in paragraph (3).

6 (3) For a health care service plan contract that is a “high  
7 deductible health plan” under the definition set forth in Section  
8 223(c)(2) of Title 26 of the United States Code, paragraphs (1)  
9 and (2) of this subdivision shall apply only once an enrollee’s  
10 deductible has been satisfied for the year.

11 (4) For a nongrandfathered individual or small group health  
12 care service plan contract, the annual deductible for outpatient  
13 drugs, if any, shall not exceed twice the amount specified in  
14 paragraph (1) or (2), respectively.

15 (5) For purposes of paragraphs (1) and (2), “any other form of  
16 cost sharing” shall not include a deductible.

17 (f) (1) If a health care service plan contract for a  
18 nongrandfathered individual or small group product maintains a  
19 drug formulary grouped into tiers that includes a fourth tier, a  
20 health care service plan contract shall use the following definitions  
21 for each tier of the drug formulary:

22 (A) Tier one shall consist of most generic drugs and low-cost  
23 preferred brand name drugs.

24 (B) Tier two shall consist of nonpreferred generic drugs,  
25 preferred brand name drugs, and any other drugs recommended  
26 by the health care service plan’s pharmacy and therapeutics  
27 committee based on safety, efficacy, and cost.

28 (C) Tier three shall consist of nonpreferred brand name drugs  
29 or drugs that are recommended by the health care service plan’s  
30 pharmacy and therapeutics committee based on safety, efficacy,  
31 and cost, or that generally have a preferred and often less costly  
32 therapeutic alternative at a lower tier.

33 (D) Tier four shall consist of drugs that are biologics, drugs that  
34 the FDA or the manufacturer requires to be distributed through a  
35 specialty pharmacy, drugs that require the enrollee to have special  
36 training or clinical monitoring for self-administration, or drugs  
37 that cost the health plan more than six hundred dollars (\$600) net  
38 of rebates for a one-month supply.

39 (2) In placing specific drugs on specific tiers, or choosing to  
40 place a drug on the formulary, the health care service plan shall

1 take into account the other provisions of this section and this  
2 chapter.

3 (3) A health care service plan contract may maintain a drug  
4 formulary with fewer than four tiers. A health care service plan  
5 contract shall not maintain a drug formulary with more than four  
6 tiers.

7 (4) This section shall not be construed to limit a health care  
8 service plan from placing any drug in a lower tier. If a biologic  
9 has a therapeutic equivalent, consistent with state law, it may be  
10 placed on a tier other than tier four.

11 (g) A health care service plan contract shall ensure that the  
12 placement of prescription drugs on formulary tiers is based on  
13 clinically indicated, reasonable medical management practices.

14 (h) (1) This section shall not be construed to require a health  
15 care service plan to impose cost sharing.

16 (2) This section shall not be construed to require cost sharing  
17 for prescription drugs that state or federal law otherwise requires  
18 to be provided without cost sharing.

19 (3) A plan's prescription drug benefit shall provide that if the  
20 pharmacy's retail price for a prescription drug is less than the  
21 applicable copayment or coinsurance amount, the enrollee shall  
22 not be required to pay more than the retail price. *The payment*  
23 *rendered shall constitute the applicable cost sharing and shall*  
24 *apply to the deductible, if any, and also to maximum out of pocket*  
25 *limit.*

26 (i) In the provision of outpatient prescription drug coverage, a  
27 health care service plan may utilize formulary, prior authorization,  
28 step therapy, or other reasonable medical management practices  
29 consistent with this chapter.

30 (j) This section does not apply to a health care service plan that  
31 contracts with the State Department of Health Care Services.

32 SEC. 2. Section 1342.71 of the Health and Safety Code, as  
33 added by Section 2 of Chapter 619 of the Statutes of 2015, is  
34 repealed.

35 SEC. 3. Section 10123.193 of the Insurance Code, as amended  
36 by Section 204 of Chapter 86 of the Statutes of 2016, is amended  
37 to read:

38 10123.193. (a) The Legislature hereby finds and declares all  
39 of the following:

- 1 (1) The federal Patient Protection and Affordable Care Act, its  
2 implementing regulations and guidance, and related state law  
3 prohibit discrimination based on a person’s expected length of life,  
4 present or predicted disability, degree of medical dependency,  
5 quality of life, or other health conditions, including benefit designs  
6 that have the effect of discouraging the enrollment of individuals  
7 with significant health needs.
- 8 (2) The Legislature intends to build on existing state and federal  
9 law to ensure that health coverage benefit designs do not have an  
10 unreasonable discriminatory impact on chronically ill individuals,  
11 and to ensure affordability of outpatient prescription drugs.
- 12 (3) Assignment of all or most prescription medications that treat  
13 a specific medical condition to the highest cost tiers of a formulary  
14 may effectively discourage enrollment by chronically ill  
15 individuals, and may result in lower adherence to a prescription  
16 drug treatment regimen.
- 17 (b) A nongrandfathered policy of health insurance that is offered,  
18 amended, or renewed on or after January 1, 2017, shall comply  
19 with this section. The cost-sharing limits established by this section  
20 apply only to outpatient prescription drugs covered by the policy  
21 that constitute essential health benefits, as defined by Section  
22 10112.27.
- 23 (c) A policy of health insurance that provides coverage for  
24 outpatient prescription drugs shall cover medically necessary  
25 prescription drugs, including nonformulary drugs determined to  
26 be medically necessary consistent with this part.
- 27 (d) Copayments, coinsurance, and other cost sharing for  
28 outpatient prescription drugs shall be reasonable so as to allow  
29 access to medically necessary outpatient prescription drugs.
- 30 (e) (1) Consistent with federal law and guidance, the formulary  
31 or formularies for outpatient prescription drugs maintained by the  
32 health insurer shall not discourage the enrollment of individuals  
33 with health conditions and shall not reduce the generosity of the  
34 benefit for insureds with a particular condition in a manner that is  
35 not based on a clinical indication or reasonable medical  
36 management practices. Section 1342.7 of the Health and Safety  
37 Code and any regulations adopted pursuant to that section shall  
38 be interpreted in a manner that is consistent with this section.
- 39 (2) For combination antiretroviral drug treatments that are  
40 medically necessary for the treatment or prevention of AIDS/HIV,

1 a policy of health insurance shall cover a single-tablet drug regimen  
2 that is as effective as a multitablet regimen unless, consistent with  
3 clinical guidelines and peer-reviewed scientific and medical  
4 literature, the multitablet regimen is clinically equally or more  
5 effective and more likely to result in adherence to a drug regimen.

6 (3) Any limitation or utilization management shall be consistent  
7 with and based on clinical guidelines and peer-reviewed scientific  
8 and medical literature.

9 (f) (1) With respect to an individual or group policy of health  
10 insurance subject to Section 10112.28, the copayment, coinsurance,  
11 or any other form of cost sharing for a covered outpatient  
12 prescription drug for an individual prescription for a supply of up  
13 to 30 days shall not exceed two hundred fifty dollars (\$250), except  
14 as provided in paragraphs (2) and (3).

15 (2) With respect to products with actuarial value at or equivalent  
16 to the bronze level, cost sharing for a covered outpatient  
17 prescription drug for an individual prescription for a supply of up  
18 to 30 days shall not exceed five hundred dollars (\$500), except as  
19 provided in paragraph (3).

20 (3) For a policy of health insurance that is a “high deductible  
21 health plan” under the definition set forth in Section 223(c)(2) of  
22 Title 26 of the United States Code, paragraphs (1) and (2) of this  
23 subdivision applies only once an insured’s deductible has been  
24 satisfied for the year.

25 (4) For a nongrandfathered individual or small group policy of  
26 health insurance, the annual deductible for outpatient drugs, if any,  
27 shall not exceed twice the amount specified in paragraph (1) or  
28 (2), respectively.

29 (5) For purposes of paragraphs (1) and (2), “any other form of  
30 cost sharing” shall not include a deductible.

31 (g) (1) If a policy of health insurance offered, sold, or renewed  
32 in the nongrandfathered individual or small group market maintains  
33 a drug formulary grouped into tiers that includes a fourth tier, a  
34 policy of health insurance shall use the following definitions for  
35 each tier of the drug formulary:

36 (A) Tier one shall consist of most generic drugs and low-cost  
37 preferred brand name drugs.

38 (B) Tier two shall consist of nonpreferred generic drugs,  
39 preferred brand name drugs, and any other drugs recommended

1 by the health insurer's pharmacy and therapeutics committee based  
2 on safety, efficacy, and cost.

3 (C) Tier three shall consist of nonpreferred brand name drugs  
4 or drugs that are recommended by the health insurer's pharmacy  
5 and therapeutics committee based on safety, efficacy, and cost, or  
6 that generally have a preferred and often less costly therapeutic  
7 alternative at a lower tier.

8 (D) Tier four shall consist of drugs that are biologics, drugs that  
9 the FDA or the manufacturer requires to be distributed through a  
10 specialty pharmacy, drugs that require the insured to have special  
11 training or clinical monitoring for self-administration, or drugs  
12 that cost the health insurer more than six hundred dollars (\$600)  
13 net of rebates for a one-month supply.

14 (2) In placing specific drugs on specific tiers, or choosing to  
15 place a drug on the formulary, the insurer shall take into account  
16 the other provisions of this section and this part.

17 (3) A policy of health insurance may maintain a drug formulary  
18 with fewer than four tiers. A policy of health insurance shall not  
19 maintain a drug formulary with more than four tiers.

20 (4) This section shall not be construed to limit a health insurer  
21 from placing any drug in a lower tier. If a biologic has a therapeutic  
22 equivalent, consistent with state law, it may be placed on a tier  
23 other than tier four.

24 (h) (1) This section shall not be construed to require a health  
25 insurer to impose cost sharing.

26 (2) This section shall not be construed to require cost sharing  
27 for prescription drugs that state or federal law otherwise requires  
28 to be provided without cost sharing.

29 (3) A prescription drug benefit shall provide that if the  
30 pharmacy's retail price for a prescription drug is less than the  
31 applicable copayment or coinsurance amount, the insured shall  
32 not be required to pay more than the retail price. *The payment*  
33 *rendered shall constitute the applicable cost sharing and shall*  
34 *apply to the deductible, if any, and also to maximum out of pocket*  
35 *limit.*

36 (i) A policy of health insurance shall ensure that the placement  
37 of prescription drugs on formulary tiers is based on clinically  
38 indicated, reasonable medical management practices.

39 (j) In the provision of outpatient prescription drug coverage, a  
40 health insurer may utilize formulary, prior authorization, step

1 therapy, or other reasonable medical management practices  
2 consistent with this part.

3 SEC. 4. Section 10123.193 of the Insurance Code, as added  
4 by Section 8 of Chapter 619 of the Statutes of 2015, is repealed.

5 SEC. 5. No reimbursement is required by this act pursuant to  
6 Section 6 of Article XIII B of the California Constitution because  
7 the only costs that may be incurred by a local agency or school  
8 district will be incurred because this act creates a new crime or  
9 infraction, eliminates a crime or infraction, or changes the penalty  
10 for a crime or infraction, within the meaning of Section 17556 of  
11 the Government Code, or changes the definition of a crime within  
12 the meaning of Section 6 of Article XIII B of the California  
13 Constitution.

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**Bill Number:** SB 1021

**Current Version:** As amended April 16, 2018

**Author:** Wiener  
Atkins

**Topic:** Prescription drugs

**Staff Recommendation:**

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**AFFECTED SECTIONS:** Amends Section 1342.71 of the Health & Safety Code and Section 10123.193 of the Insurance Code.

**STATUS:** Senate Health

**EXISTING LAW:**

AB 339 (Gordon 2015), added Section 1342.71 to the Health & Safety Code, which capped monthly copays at \$250 total per patient; prevented discrimination against patients with specific conditions, by ensuring that all of the drugs for a given disease could not be placed in the most expensive tier; and extended all protections to plans in the large employer market as well as the individual and small employer coverage markets, will expire on January 1, 2020.

This legislation also required placement of drugs in health plan's formulary to be based on clinical guidelines as well as safety and efficacy standards, as opposed to just cost. Following implementation of these provisions, patients of all income levels have become better able to purchase the drugs they rely on without facing exorbitant costs.

**THIS BILL WOULD:**

Eliminate the sunset date on provisions of AB 339 (Gordon, 2015).

Additionally, this legislation will add preventive treatments to the definition of the AIDS drug cocktail, codify an existing regulation capping copays at the drug's retail price, and limit drug formularies (lists of drugs offered) to four pricing tiers.

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure. Amendments made in Senate Health Committee added language similar to AB 2863 capping the co pay amount at the retail price if it is lower than the co pay. This measure seems to be consistent with the Board's consumer protection mandate.

**FISCAL IMPACT ON THE BOARD:**

Minor and absorbable.

**SUPPORT / OPPOSITION:**

SUPPORT:

None on file.

OPPOSITION:

None on file

**BILL HISTORY:**

03/12/18	Set for hearing April 25.
02/14/18	Referred to Com. on HEALTH.
02/08/18	From printer. May be acted upon on or after March 10.
02/07/18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 18, 2018

AMENDED IN SENATE APRIL 4, 2018

**SENATE BILL**

**No. 1109**

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**Introduced by Senator Bates**

**(Coauthors: Senators Nguyen and Stone)**

(Coauthors: Assembly Members ~~Brough, Choi, Brough~~ and Mathis)

February 13, 2018

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An act to amend Sections 1645, 2190.5, 2191, 2196.2, 2454.5, 2746.51, 2836.1, 3059, and 3502.1 of, and to add Section ~~4079~~ 4076.7 to, the Business and Professions Code, to add Section 49476 to the Education Code, and to add Sections 11158.1 and 124236 to the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 1109, as amended, Bates. Controlled substances: Schedule II drugs: opioids.

(1) The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Under that act, the board is required to adopt and administer standards for the continuing education of physicians and surgeons. Existing law requires a physician and surgeon to complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. That act requires the board to give its highest priority to considering a course in pain management among its continuing education requirements for licensees, and requires the board to periodically develop and disseminate information and educational material on pain management techniques and procedures to licensees and general acute care hospitals.

This bill would require, for physicians and surgeons licensed on or after January 1, 2019, the mandatory continuing education course to also include the subject of the risks of addiction associated with the use of Schedule II drugs. The bill would require the board to give its highest priority to considering a course in the risks of addiction associated with the use of Schedule II drugs among its continuing education requirements for physicians and surgeons and would require the board to periodically develop and disseminate information and educational material on the risks of addiction associated with the use of Schedule II drugs to physicians and surgeons and general acute care hospitals.

(2) The Nursing Practice Act provides for the licensure and regulation of the practice of nursing by the Board of Registered Nursing and makes a violation of its provisions a crime. Existing law authorizes a certified nurse-midwife to furnish or order drugs or devices under specified circumstances, including board certification that the certified nurse-midwife has completed a course in pharmacology, as specified.

This bill would require the pharmacology course to include the risks of addiction and neonatal abstinence syndrome associated with the use of opioids.

Existing law also authorizes a nurse practitioner to furnish or order drugs or devices under specified circumstances, including board certification that the nurse practitioner has completed a course in pharmacology, as specified. Existing law requires nurse practitioners who are authorized to furnish Schedule II controlled substances to complete a mandatory continuing education course in Schedule II controlled substances.

This bill would require the mandatory continuing education course to include the risks of addiction associated with their use.

By expanding the scope of a crime under the Nursing Practice Act, the bill would impose a state-mandated local program.

(3) The Physician Assistant Practice Act provides for licensure and regulation of physician assistants by the Physician Assistant Board and authorizes a physician assistant to perform medical services as set forth by regulations when those services are rendered under the supervision of a licensed physician and surgeon, as specified. The act prohibits a physician assistant from administering, providing, or issuing a drug order to a patient for Schedule II through Schedule V controlled substances without advance approval by a supervising physician and surgeon for that particular patient unless the physician assistant has completed an education course that meets specific standards.

This bill would require that course to include the risks of addiction associated with the use of Schedule II controlled substances.

(4) The Pharmacy Law provides for the licensure and regulation of pharmacists, pharmacy technicians, and pharmacies by the California State Board of Pharmacy. Existing law requires the board to promulgate regulations that require a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. The act makes a violation of its provisions a crime.

~~This bill would require the board to adopt an emergency regulation requiring a warning label on all Schedule II controlled substance vials or prescription bottles that addresses the risk of addiction and overdose when using opioids: a pharmacy or practitioner dispensing an opioid to a patient for outpatient use to prominently display on the label or container a notice that warns of the risk of overdose and addiction, as specified. To the extent that this provision would expand the scope of a crime under the Pharmacy Law, Because a violation of that requirement would be a crime, the bill would impose a state-mandated local program.~~

(5) *The Dental Practice Act provides for the licensure and regulation of persons engaged in the practice of dentistry by the Dental Board of California, which is within the Department of Consumer Affairs. The act authorizes the board, as a condition of license renewal, to require licentiates to successfully complete a portion of required continuing education hours in specific areas, including patient care, health and safety, and law and ethics.*

*This bill would include the risks of addiction associated with the use of Schedule II drugs in those specific areas of continuing education.*

(6) *Existing law, the Osteopathic Act, establishes the Osteopathic Medical Board of California, which issues certificates to, and regulates, osteopathic physicians and surgeons. Existing law requires the board to require each licensed osteopathic physician and surgeon to complete a minimum of 100 hours of American Osteopathic Association continuing education hours during each 2-year cycle, of which 40 hours must be completed in American Osteopathic Association Category I continuing education hours as a condition for renewal of an active license.*

*This bill would additionally require licensed osteopathic physician and surgeons to complete a course on the risks of addiction associated with the use of Schedule II drugs.*

(7) *The Optometry Practice Act provides for the licensure and regulation of the practice of optometry by the State Board of Optometry. The act requires an optometrist certified to use therapeutic pharmaceutical agents to complete a total of 50 hours of continuing education every 2 years in order to renew his or her certificate. Existing law requires 35 of the 50 hours of continuing education to be on the diagnosis, treatment, and management of ocular disease in any combination of specified areas, including pain medication.*

*This bill would expand the areas of continuing education to include risks of addiction associated with the use of Schedule II drugs.*

(5)

(8) The California Uniform Controlled Substances Act classifies opioids as Schedule II controlled substances and places restrictions on the prescription of those drugs, including prohibiting refills and specifying the requirements of a prescription for these drugs. The act makes a violation of its provisions a crime.

This bill would require a prescriber to discuss specified information with and obtain the consent of the minor, the minor's parent or guardian, or other adult authorized to consent to the minor's medical treatment before directly dispensing or issuing for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid. This bill would provide that a violation of these requirements is not a criminal offense, but would subject the prescriber to disciplinary action for unprofessional conduct under the prescriber's respective licensing act.

(6)

(9) Existing law requires a school district, charter school, or private school that elects to offer an athletic program to take specified actions if an athlete is suspected to have sustained a concussion and to obtain a signed concussion and head injury information sheet from the athlete and athlete's parent or guardian before the athlete initiates practice or competition.

This bill would require a school district, charter school, or private school that elects to offer an athletic program to annually give ~~an information sheet about the risks of opioid addiction to a specified~~ *Opioid Factsheet for Patients* to each athlete, and would require ~~that sheet to be signed, each athlete and his or her parent to sign a document verifying receipt of that factsheet,~~ as specified.

(7)

(10) Existing law requires a youth sports organization, as defined, that elects to offer an athletic program to, among other things, annually give a concussion and head injury information sheet to each athlete and requires that the sheet be signed, as specified.

This bill would also require a youth sports organization that elects to offer an athletic program to annually ~~give an information sheet about the risk of opioid addiction~~ *a specified Opioid Factsheet for Patients* to each athlete, and would require that ~~sheet to be signed~~, *each athlete and his or her parent to sign a document verifying receipt of that factsheet*, as specified.

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:*

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

3 (a) Addiction, misuse, and overdose of prescription opioids is  
4 a public health crisis affecting both adults and children.

5 (b) Urgent measures are needed to better inform the public of  
6 the risks associated with both the long-term and short-term use of  
7 opioids in an effort to address this problem.

8 (c) Both short-term and long-term prescriptions of opioids to  
9 minors fall within situations that require counseling and written  
10 consent under the Guidelines for Prescribing Controlled Substances  
11 for Pain issued by the Medical Board of California.

12 (d) It is the intent of the Legislature to codify the Medical Board  
13 of California’s Guidelines for Prescribing Controlled Substances  
14 for Pain, as it relates to patient counseling, consent, and pain  
15 management agreements, and to ensure that health care providers  
16 and young athletes receive necessary education on this topic.

17 *SEC. 2. Section 1645 of the Business and Professions Code is*  
18 *amended to read:*

19 1645. (a) Effective with the 1974 license renewal period, if  
20 the board determines that the public health and safety would be

1 served by requiring all holders of licenses under this chapter to  
2 continue their education after receiving a license, it may require,  
3 as a condition to the renewal thereof, that they submit assurances  
4 satisfactory to the board that they will, during the succeeding  
5 two-year period, inform themselves of the developments in the  
6 practice of dentistry occurring since the original issuance of their  
7 licenses by pursuing one or more courses of study satisfactory to  
8 the board or by other means deemed equivalent by the board.

9 The board shall adopt regulations providing for the suspension  
10 of the licenses at the end of the two-year period until compliance  
11 with the assurances provided for in this section is accomplished.

12 (b) The board may also, as a condition of license renewal,  
13 require licentiates to successfully complete a portion of the required  
14 continuing education hours in specific areas adopted in regulations  
15 by the board. The board may prescribe this mandatory coursework  
16 within the general areas of patient care, health and safety, ~~and law~~  
17 ~~and ethics: ethics, and the risks of addiction associated with the~~  
18 ~~use of Schedule II drugs.~~ The mandatory coursework prescribed  
19 by the board shall not exceed fifteen hours per renewal period for  
20 dentists, and seven and one-half hours per renewal period for dental  
21 auxiliaries. Any mandatory coursework required by the board shall  
22 be credited toward the continuing education requirements  
23 established by the board pursuant to subdivision (a).

24 (c) For a retired dentist who provides only uncompensated care,  
25 the board shall not require more than 60 percent of the hours of  
26 continuing education that are required of other licensed dentists.  
27 Notwithstanding subdivision (b), all of the hours of continuing  
28 education as described in this subdivision shall be gained through  
29 courses related to the actual delivery of dental services to the  
30 patient or the community, as determined by the board. Nothing in  
31 this subdivision shall be construed to reduce any requirements  
32 imposed by the board pursuant to subdivision (b).

33 (d) The board shall report on the outcome of subdivision (c)  
34 pursuant to, and at the time of, its regular sunset review process,  
35 as provided in Section 1601.1.

36 ~~SEC. 2.~~

37 *SEC. 3.* Section 2190.5 of the Business and Professions Code  
38 is amended to read:

39 2190.5. (a) (1) All physicians and surgeons shall complete a  
40 mandatory continuing education course in the subjects of pain

1 management and the treatment of terminally ill and dying patients.  
2 For the purposes of this section, this course shall be a one-time  
3 requirement of 12 credit hours within the required minimum  
4 established by regulation, to be completed by December 31, 2006.  
5 All physicians and surgeons licensed on and after January 1, 2002,  
6 shall complete this requirement within four years of their initial  
7 license or by their second renewal date, whichever occurs first.  
8 The board may verify completion of this requirement on the  
9 renewal application form.

10 (2) For physicians and surgeons licensed on or after January 1,  
11 2019, the course described in paragraph (1) shall also include the  
12 subject of the risks of addiction associated with the use of Schedule  
13 II drugs.

14 (b) By regulatory action, the board may exempt physicians and  
15 surgeons by practice status category from the requirement in  
16 subdivision (a) if the physician and surgeon does not engage in  
17 direct patient care, does not provide patient consultations, or does  
18 not reside in the State of California.

19 (c) This section shall not apply to physicians and surgeons  
20 practicing in pathology or radiology specialty areas.

21 ~~SEC. 3.~~

22 *SEC. 4.* Section 2191 of the Business and Professions Code is  
23 amended to read:

24 2191. (a) In determining its continuing education requirements,  
25 the board shall consider including a course in human sexuality,  
26 defined as the study of a human being as a sexual being and how  
27 he or she functions with respect thereto, and nutrition to be taken  
28 by those licensees whose practices may require knowledge in those  
29 areas.

30 (b) The board shall consider including a course in child abuse  
31 detection and treatment to be taken by those licensees whose  
32 practices are of a nature that there is a likelihood of contact with  
33 abused or neglected children.

34 (c) The board shall consider including a course in acupuncture  
35 to be taken by those licensees whose practices may require  
36 knowledge in the area of acupuncture and whose education has  
37 not included instruction in acupuncture.

38 (d) The board shall encourage every physician and surgeon to  
39 take nutrition as part of his or her continuing education, particularly  
40 a physician and surgeon involved in primary care.

1 (e) The board shall consider including a course in elder abuse  
2 detection and treatment to be taken by those licensees whose  
3 practices are of a nature that there is a likelihood of contact with  
4 abused or neglected persons 65 years of age and older.

5 (f) In determining its continuing education requirements, the  
6 board shall consider including a course in the early detection and  
7 treatment of substance abusing pregnant women to be taken by  
8 those licensees whose practices are of a nature that there is a  
9 likelihood of contact with these women.

10 (g) In determining its continuing education requirements, the  
11 board shall consider including a course in the special care needs  
12 of drug addicted infants to be taken by those licensees whose  
13 practices are of a nature that there is a likelihood of contact with  
14 these infants.

15 (h) In determining its continuing education requirements, the  
16 board shall consider including a course providing training and  
17 guidelines on how to routinely screen for signs exhibited by abused  
18 women, particularly for physicians and surgeons in emergency,  
19 surgical, primary care, pediatric, prenatal, and mental health  
20 settings. In the event the board establishes a requirement for  
21 continuing education coursework in spousal or partner abuse  
22 detection or treatment, that requirement shall be met by each  
23 licensee within no more than four years from the date the  
24 requirement is imposed.

25 (i) In determining its continuing education requirements, the  
26 board shall consider including a course in the special care needs  
27 of individuals and their families facing end-of-life issues, including,  
28 but not limited to, all of the following:

- 29 (1) Pain and symptom management.
- 30 (2) The psycho-social dynamics of death.
- 31 (3) Dying and bereavement.
- 32 (4) Hospice care.

33 (j) In determining its continuing education requirements, the  
34 board shall give its highest priority to considering a course on pain  
35 management and the risks of addiction associated with the use of  
36 Schedule II drugs.

37 (k) In determining its continuing education requirements, the  
38 board shall consider including a course in geriatric care for  
39 emergency room physicians and surgeons.

1 ~~SEC. 4.~~

2 *SEC. 5.* Section 2196.2 of the Business and Professions Code  
3 is amended to read:

4 2196.2. The board shall periodically develop and disseminate  
5 information and educational material regarding pain management  
6 techniques and procedures, including the risks of addiction  
7 associated with the use of Schedule II drugs, to each licensed  
8 physician and surgeon and to each general acute care hospital in  
9 this state. The board shall consult with the State Department of  
10 Public Health in developing the materials to be distributed pursuant  
11 to this section.

12 *SEC. 6. Section 2454.5 of the Business and Professions Code*  
13 *is amended to read:*

14 2454.5. In order to ensure the continuing competence of  
15 licensed osteopathic physicians and surgeons, the board shall adopt  
16 and administer standards for the continuing education of those  
17 licensees. The board shall require each licensed osteopathic  
18 physician and surgeon to demonstrate satisfaction of the continuing  
19 education requirements as a condition for the renewal of a license  
20 at intervals of not less than one year nor more than two years.  
21 Commencing January 1, 2018, the board shall require each licensed  
22 osteopathic physician and surgeon to complete a minimum of 100  
23 hours of American Osteopathic Association continuing education  
24 hours during each two-year cycle, of which 40 hours shall be  
25 completed in American Osteopathic Association Category 1  
26 continuing education hours and the remaining 60 hours shall be  
27 either American Osteopathic Association or American Medical  
28 Association accredited as a condition for renewal of an active  
29 license. *Licensed osteopathic physicians and surgeons shall*  
30 *complete a course on the risks of addiction associated with the*  
31 *use of Schedule II drugs.*

32 For purposes of this section, “American Osteopathic Association  
33 Category 1” means continuing education activities and programs  
34 approved for Category 1 credit by the Committee on Continuing  
35 Medical Education of the American Osteopathic Association.

36 ~~SEC. 5.~~

37 *SEC. 7.* Section 2746.51 of the Business and Professions Code  
38 is amended to read:

39 2746.51. (a) Neither this chapter nor any other provision of  
40 law shall be construed to prohibit a certified nurse-midwife from

1 furnishing or ordering drugs or devices, including controlled  
2 substances classified in Schedule II, III, IV, or V under the  
3 California Uniform Controlled Substances Act (Division 10  
4 (commencing with Section 11000) of the Health and Safety Code),  
5 when all of the following apply:

6 (1) The drugs or devices are furnished or ordered incidentally  
7 to the provision of any of the following:

8 (A) Family planning services, as defined in Section 14503 of  
9 the Welfare and Institutions Code.

10 (B) Routine health care or perinatal care, as defined in  
11 subdivision (d) of Section 123485 of the Health and Safety Code.

12 (C) Care rendered, consistent with the certified nurse-midwife's  
13 educational preparation or for which clinical competency has been  
14 established and maintained, to persons within a facility specified  
15 in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the  
16 Health and Safety Code, a clinic as specified in Section 1204 of  
17 the Health and Safety Code, a general acute care hospital as defined  
18 in subdivision (a) of Section 1250 of the Health and Safety Code,  
19 a licensed birth center as defined in Section 1204.3 of the Health  
20 and Safety Code, or a special hospital specified as a maternity  
21 hospital in subdivision (f) of Section 1250 of the Health and Safety  
22 Code.

23 (2) The drugs or devices are furnished or ordered by a certified  
24 nurse-midwife in accordance with standardized procedures or  
25 protocols. For purposes of this section, standardized procedure  
26 means a document, including protocols, developed and approved  
27 by the supervising physician and surgeon, the certified  
28 nurse-midwife, and the facility administrator or his or her designee.  
29 The standardized procedure covering the furnishing or ordering  
30 of drugs or devices shall specify all of the following:

31 (A) Which certified nurse-midwife may furnish or order drugs  
32 or devices.

33 (B) Which drugs or devices may be furnished or ordered and  
34 under what circumstances.

35 (C) The extent of physician and surgeon supervision.

36 (D) The method of periodic review of the certified  
37 nurse-midwife's competence, including peer review, and review  
38 of the provisions of the standardized procedure.

39 (3) If Schedule II or III controlled substances, as defined in  
40 Sections 11055 and 11056 of the Health and Safety Code, are

1 furnished or ordered by a certified nurse-midwife, the controlled  
2 substances shall be furnished or ordered in accordance with a  
3 patient-specific protocol approved by the treating or supervising  
4 physician and surgeon. For Schedule II controlled substance  
5 protocols, the provision for furnishing the Schedule II controlled  
6 substance shall address the diagnosis of the illness, injury, or  
7 condition for which the Schedule II controlled substance is to be  
8 furnished.

9 (4) The furnishing or ordering of drugs or devices by a certified  
10 nurse-midwife occurs under physician and surgeon supervision.  
11 For purposes of this section, no physician and surgeon shall  
12 supervise more than four certified nurse-midwives at one time.  
13 Physician and surgeon supervision shall not be construed to require  
14 the physical presence of the physician, but does include all of the  
15 following:

16 (A) Collaboration on the development of the standardized  
17 procedure or protocol.

18 (B) Approval of the standardized procedure or protocol.

19 (C) Availability by telephonic contact at the time of patient  
20 examination by the certified nurse-midwife.

21 (b) (1) The furnishing or ordering of drugs or devices by a  
22 certified nurse-midwife is conditional on the issuance by the board  
23 of a number to the applicant who has successfully completed the  
24 requirements of paragraph (2). The number shall be included on  
25 all transmittals of orders for drugs or devices by the certified  
26 nurse-midwife. The board shall maintain a list of the certified  
27 nurse-midwives that it has certified pursuant to this paragraph and  
28 the number it has issued to each one. The board shall make the list  
29 available to the California State Board of Pharmacy upon its  
30 request. Every certified nurse-midwife who is authorized pursuant  
31 to this section to furnish or issue a drug order for a controlled  
32 substance shall register with the United States Drug Enforcement  
33 Administration.

34 (2) The board has certified in accordance with paragraph (1)  
35 that the certified nurse-midwife has satisfactorily completed a  
36 course in pharmacology covering the drugs or devices to be  
37 furnished or ordered under this section, including the risks of  
38 addiction and neonatal abstinence syndrome associated with the  
39 use of opioids. The board shall establish the requirements for  
40 satisfactory completion of this paragraph.

1 (3) A physician and surgeon may determine the extent of  
2 supervision necessary pursuant to this section in the furnishing or  
3 ordering of drugs and devices.

4 (4) A copy of the standardized procedure or protocol relating  
5 to the furnishing or ordering of controlled substances by a certified  
6 nurse-midwife shall be provided upon request to any licensed  
7 pharmacist who is uncertain of the authority of the certified  
8 nurse-midwife to perform these functions.

9 (5) Certified nurse-midwives who are certified by the board and  
10 hold an active furnishing number, who are currently authorized  
11 through standardized procedures or protocols to furnish Schedule  
12 II controlled substances, and who are registered with the United  
13 States Drug Enforcement Administration shall provide  
14 documentation of continuing education specific to the use of  
15 Schedule II controlled substances in settings other than a hospital  
16 based on standards developed by the board.

17 (c) Drugs or devices furnished or ordered by a certified  
18 nurse-midwife may include Schedule II controlled substances  
19 under the California Uniform Controlled Substances Act (Division  
20 10 (commencing with Section 11000) of the Health and Safety  
21 Code) under the following conditions:

22 (1) The drugs and devices are furnished or ordered in accordance  
23 with requirements referenced in paragraphs (2) to (4), inclusive,  
24 of subdivision (a) and in paragraphs (1) to (3), inclusive, of  
25 subdivision (b).

26 (2) When Schedule II controlled substances, as defined in  
27 Section 11055 of the Health and Safety Code, are furnished or  
28 ordered by a certified nurse-midwife, the controlled substances  
29 shall be furnished or ordered in accordance with a patient-specific  
30 protocol approved by the treating or supervising physician and  
31 surgeon.

32 (d) Furnishing of drugs or devices by a certified nurse-midwife  
33 means the act of making a pharmaceutical agent or agents available  
34 to the patient in strict accordance with a standardized procedure  
35 or protocol. Use of the term “furnishing” in this section shall  
36 include the following:

37 (1) The ordering of a drug or device in accordance with the  
38 standardized procedure or protocol.

39 (2) Transmitting an order of a supervising physician and  
40 surgeon.

1 (e) “Drug order” or “order” for purposes of this section means  
2 an order for medication or for a drug or device that is dispensed  
3 to or for an ultimate user, issued by a certified nurse-midwife as  
4 an individual practitioner, within the meaning of Section 1306.03  
5 of Title 21 of the Code of Federal Regulations. Notwithstanding  
6 any other provision of law, (1) a drug order issued pursuant to this  
7 section shall be treated in the same manner as a prescription of the  
8 supervising physician; (2) all references to “prescription” in this  
9 code and the Health and Safety Code shall include drug orders  
10 issued by certified nurse-midwives; and (3) the signature of a  
11 certified nurse-midwife on a drug order issued in accordance with  
12 this section shall be deemed to be the signature of a prescriber for  
13 purposes of this code and the Health and Safety Code.

14 ~~SEC. 6.~~

15 *SEC. 8.* Section 2836.1 of the Business and Professions Code  
16 is amended to read:

17 2836.1. Neither this chapter nor any other provision of law  
18 shall be construed to prohibit a nurse practitioner from furnishing  
19 or ordering drugs or devices when all of the following apply:

20 (a) The drugs or devices are furnished or ordered by a nurse  
21 practitioner in accordance with standardized procedures or  
22 protocols developed by the nurse practitioner and the supervising  
23 physician and surgeon when the drugs or devices furnished or  
24 ordered are consistent with the practitioner’s educational  
25 preparation or for which clinical competency has been established  
26 and maintained.

27 (b) The nurse practitioner is functioning pursuant to standardized  
28 procedure, as defined by Section 2725, or protocol. The  
29 standardized procedure or protocol shall be developed and  
30 approved by the supervising physician and surgeon, the nurse  
31 practitioner, and the facility administrator or the designee.

32 (c) (1) The standardized procedure or protocol covering the  
33 furnishing of drugs or devices shall specify which nurse  
34 practitioners may furnish or order drugs or devices, which drugs  
35 or devices may be furnished or ordered, under what circumstances,  
36 the extent of physician and surgeon supervision, the method of  
37 periodic review of the nurse practitioner’s competence, including  
38 peer review, and review of the provisions of the standardized  
39 procedure.

1 (2) In addition to the requirements in paragraph (1), for Schedule  
2 II controlled substance protocols, the provision for furnishing  
3 Schedule II controlled substances shall address the diagnosis of  
4 the illness, injury, or condition for which the Schedule II controlled  
5 substance is to be furnished.

6 (d) The furnishing or ordering of drugs or devices by a nurse  
7 practitioner occurs under physician and surgeon supervision.  
8 Physician and surgeon supervision shall not be construed to require  
9 the physical presence of the physician, but does include (1)  
10 collaboration on the development of the standardized procedure,  
11 (2) approval of the standardized procedure, and (3) availability by  
12 telephonic contact at the time of patient examination by the nurse  
13 practitioner.

14 (e) For purposes of this section, no physician and surgeon shall  
15 supervise more than four nurse practitioners at one time.

16 (f) (1) Drugs or devices furnished or ordered by a nurse  
17 practitioner may include Schedule II through Schedule V controlled  
18 substances under the California Uniform Controlled Substances  
19 Act (Division 10 (commencing with Section 11000) of the Health  
20 and Safety Code) and shall be further limited to those drugs agreed  
21 upon by the nurse practitioner and physician and surgeon and  
22 specified in the standardized procedure.

23 (2) When Schedule II or III controlled substances, as defined  
24 in Sections 11055 and 11056, respectively, of the Health and Safety  
25 Code, are furnished or ordered by a nurse practitioner, the  
26 controlled substances shall be furnished or ordered in accordance  
27 with a patient-specific protocol approved by the treating or  
28 supervising physician. A copy of the section of the nurse  
29 practitioner's standardized procedure relating to controlled  
30 substances shall be provided, upon request, to any licensed  
31 pharmacist who dispenses drugs or devices, when there is  
32 uncertainty about the nurse practitioner furnishing the order.

33 (g) (1) The board has certified in accordance with Section  
34 2836.3 that the nurse practitioner has satisfactorily completed a  
35 course in pharmacology covering the drugs or devices to be  
36 furnished or ordered under this section.

37 (2) A physician and surgeon may determine the extent of  
38 supervision necessary pursuant to this section in the furnishing or  
39 ordering of drugs and devices.

1 (3) Nurse practitioners who are certified by the board and hold  
2 an active furnishing number, who are authorized through  
3 standardized procedures or protocols to furnish Schedule II  
4 controlled substances, and who are registered with the United  
5 States Drug Enforcement Administration, shall complete, as part  
6 of their continuing education requirements, a course including  
7 Schedule II controlled substances, and the risks of addiction  
8 associated with their use, based on the standards developed by the  
9 board. The board shall establish the requirements for satisfactory  
10 completion of this subdivision.

11 (h) Use of the term “furnishing” in this section, in health  
12 facilities defined in Section 1250 of the Health and Safety Code,  
13 shall include (1) the ordering of a drug or device in accordance  
14 with the standardized procedure and (2) transmitting an order of  
15 a supervising physician and surgeon.

16 (i) “Drug order” or “order” for purposes of this section means  
17 an order for medication which is dispensed to or for an ultimate  
18 user, issued by a nurse practitioner as an individual practitioner,  
19 within the meaning of Section 1306.02 of Title 21 of the Code of  
20 Federal Regulations. Notwithstanding any other provision of law,  
21 (1) a drug order issued pursuant to this section shall be treated in  
22 the same manner as a prescription of the supervising physician;  
23 (2) all references to “prescription” in this code and the Health and  
24 Safety Code shall include drug orders issued by nurse practitioners;  
25 and (3) the signature of a nurse practitioner on a drug order issued  
26 in accordance with this section shall be deemed to be the signature  
27 of a prescriber for purposes of this code and the Health and Safety  
28 Code.

29 *SEC. 9. Section 3059 of the Business and Professions Code is*  
30 *amended to read:*

31 3059. (a) It is the intent of the Legislature that the public health  
32 and safety would be served by requiring all holders of licenses to  
33 practice optometry granted under this chapter to continue their  
34 education after receiving their licenses. The board shall adopt  
35 regulations that require, as a condition to the renewal thereof, that  
36 all holders of licenses submit proof satisfactory to the board that  
37 they have informed themselves of the developments in the practice  
38 of optometry occurring since the original issuance of their licenses  
39 by pursuing one or more courses of study satisfactory to the board  
40 or by other means deemed equivalent by the board.

1 (b) The board may, in accordance with the intent of this section,  
2 make exceptions from continuing education requirements for  
3 reasons of health, military service, or other good cause.

4 (c) If for good cause compliance cannot be met for the current  
5 year, the board may grant exemption of compliance for that year,  
6 provided that a plan of future compliance that includes current  
7 requirements as well as makeup of previous requirements is  
8 approved by the board.

9 (d) The board may require that proof of compliance with this  
10 section be submitted on an annual or biennial basis as determined  
11 by the board.

12 (e) An optometrist certified to use therapeutic pharmaceutical  
13 agents pursuant to Section 3041.3 shall complete a total of 50 hours  
14 of continuing education every two years in order to renew his or  
15 her certificate. Thirty-five of the required 50 hours of continuing  
16 education shall be on the diagnosis, treatment, and management  
17 of ocular disease in any combination of the following areas:

18 (1) Glaucoma.

19 (2) Ocular infection.

20 (3) Ocular inflammation.

21 (4) Topical steroids.

22 (5) Systemic medication.

23 (6) ~~Pain medication.~~ *medication, including the risks of addiction*  
24 *associated with the use of Schedule II drugs.*

25 (f) The board shall encourage every optometrist to take a course  
26 or courses in pharmacology and pharmaceuticals as part of his or  
27 her continuing education.

28 (g) The board shall consider requiring courses in child abuse  
29 detection to be taken by those licensees whose practices are such  
30 that there is a likelihood of contact with abused or neglected  
31 children.

32 (h) The board shall consider requiring courses in elder abuse  
33 detection to be taken by those licensees whose practices are such  
34 that there is a likelihood of contact with abused or neglected elder  
35 persons.

36 ~~SEC. 7.~~

37 *SEC. 10.* Section 3502.1 of the Business and Professions Code  
38 is amended to read:

39 3502.1. (a) In addition to the services authorized in the  
40 regulations adopted by the Medical Board of California, and except

1 as prohibited by Section 3502, while under the supervision of a  
2 licensed physician and surgeon or physicians and surgeons  
3 authorized by law to supervise a physician assistant, a physician  
4 assistant may administer or provide medication to a patient, or  
5 transmit orally, or in writing on a patient's record or in a drug  
6 order, an order to a person who may lawfully furnish the  
7 medication or medical device pursuant to subdivisions (c) and (d).

8 (1) A supervising physician and surgeon who delegates authority  
9 to issue a drug order to a physician assistant may limit this authority  
10 by specifying the manner in which the physician assistant may  
11 issue delegated prescriptions.

12 (2) Each supervising physician and surgeon who delegates the  
13 authority to issue a drug order to a physician assistant shall first  
14 prepare and adopt, or adopt, a written, practice specific, formulary  
15 and protocols that specify all criteria for the use of a particular  
16 drug or device, and any contraindications for the selection.  
17 Protocols for Schedule II controlled substances shall address the  
18 diagnosis of illness, injury, or condition for which the Schedule II  
19 controlled substance is being administered, provided, or issued.  
20 The drugs listed in the protocols shall constitute the formulary and  
21 shall include only drugs that are appropriate for use in the type of  
22 practice engaged in by the supervising physician and surgeon.  
23 When issuing a drug order, the physician assistant is acting on  
24 behalf of and as an agent for a supervising physician and surgeon.

25 (b) "Drug order," for purposes of this section, means an order  
26 for medication that is dispensed to or for a patient, issued and  
27 signed by a physician assistant acting as an individual practitioner  
28 within the meaning of Section 1306.02 of Title 21 of the Code of  
29 Federal Regulations. Notwithstanding any other provision of law,  
30 (1) a drug order issued pursuant to this section shall be treated in  
31 the same manner as a prescription or order of the supervising  
32 physician, (2) all references to "prescription" in this code and the  
33 Health and Safety Code shall include drug orders issued by  
34 physician assistants pursuant to authority granted by their  
35 supervising physicians and surgeons, and (3) the signature of a  
36 physician assistant on a drug order shall be deemed to be the  
37 signature of a prescriber for purposes of this code and the Health  
38 and Safety Code.

39 (c) A drug order for any patient cared for by the physician  
40 assistant that is issued by the physician assistant shall either be

1 based on the protocols described in subdivision (a) or shall be  
2 approved by the supervising physician and surgeon before it is  
3 filled or carried out.

4 (1) A physician assistant shall not administer or provide a drug  
5 or issue a drug order for a drug other than for a drug listed in the  
6 formulary without advance approval from a supervising physician  
7 and surgeon for the particular patient. At the direction and under  
8 the supervision of a physician and surgeon, a physician assistant  
9 may hand to a patient of the supervising physician and surgeon a  
10 properly labeled prescription drug prepackaged by a physician and  
11 surgeon, manufacturer as defined in the Pharmacy Law, or a  
12 pharmacist.

13 (2) A physician assistant shall not administer, provide, or issue  
14 a drug order to a patient for Schedule II through Schedule V  
15 controlled substances without advance approval by a supervising  
16 physician and surgeon for that particular patient unless the  
17 physician assistant has completed an education course that covers  
18 controlled substances and that meets standards, including  
19 pharmacological content, approved by the board. The education  
20 course shall be provided either by an accredited continuing  
21 education provider or by an approved physician assistant training  
22 program. If the physician assistant will administer, provide, or  
23 issue a drug order for Schedule II controlled substances, the course  
24 shall contain a minimum of three hours exclusively on Schedule  
25 II controlled substances, including the risks of addiction associated  
26 with their use. Completion of the requirements set forth in this  
27 paragraph shall be verified and documented in the manner  
28 established by the board prior to the physician assistant's use of a  
29 registration number issued by the United States Drug Enforcement  
30 Administration to the physician assistant to administer, provide,  
31 or issue a drug order to a patient for a controlled substance without  
32 advance approval by a supervising physician and surgeon for that  
33 particular patient.

34 (3) Any drug order issued by a physician assistant shall be  
35 subject to a reasonable quantitative limitation consistent with  
36 customary medical practice in the supervising physician and  
37 surgeon's practice.

38 (d) A written drug order issued pursuant to subdivision (a),  
39 except a written drug order in a patient's medical record in a health  
40 facility or medical practice, shall contain the printed name, address,

1 and telephone number of the supervising physician and surgeon,  
2 the printed or stamped name and license number of the physician  
3 assistant, and the signature of the physician assistant. Further, a  
4 written drug order for a controlled substance, except a written drug  
5 order in a patient's medical record in a health facility or a medical  
6 practice, shall include the federal controlled substances registration  
7 number of the physician assistant and shall otherwise comply with  
8 Section 11162.1 of the Health and Safety Code. Except as  
9 otherwise required for written drug orders for controlled substances  
10 under Section 11162.1 of the Health and Safety Code, the  
11 requirements of this subdivision may be met through stamping or  
12 otherwise imprinting on the supervising physician and surgeon's  
13 prescription blank to show the name, license number, and if  
14 applicable, the federal controlled substances registration number  
15 of the physician assistant, and shall be signed by the physician  
16 assistant. When using a drug order, the physician assistant is acting  
17 on behalf of and as the agent of a supervising physician and  
18 surgeon.

19 (e) The supervising physician and surgeon shall use either of  
20 the following mechanisms to ensure adequate supervision of the  
21 administration, provision, or issuance by a physician assistant of  
22 a drug order to a patient for Schedule II controlled substances:

23 (1) The medical record of any patient cared for by a physician  
24 assistant for whom the physician assistant's Schedule II drug order  
25 has been issued or carried out shall be reviewed, countersigned,  
26 and dated by a supervising physician and surgeon within seven  
27 days.

28 (2) If the physician assistant has documentation evidencing the  
29 successful completion of an education course that covers controlled  
30 substances, and that controlled substance education course (A)  
31 meets the standards, including pharmacological content, established  
32 in Sections 1399.610 and 1399.612 of Title 16 of the California  
33 Code of Regulations, and (B) is provided either by an accredited  
34 continuing education provider or by an approved physician assistant  
35 training program, the supervising physician and surgeon shall  
36 review, countersign, and date, within seven days, a sample  
37 consisting of the medical records of at least 20 percent of the  
38 patients cared for by the physician assistant for whom the physician  
39 assistant's Schedule II drug order has been issued or carried out.  
40 Completion of the requirements set forth in this paragraph shall

1 be verified and documented in the manner established in Section  
2 1399.612 of Title 16 of the California Code of Regulations.  
3 Physician assistants who have a certificate of completion of the  
4 course described in paragraph (2) of subdivision (c) shall be  
5 deemed to have met the education course requirement of this  
6 subdivision.

7 (f) All physician assistants who are authorized by their  
8 supervising physicians to issue drug orders for controlled  
9 substances shall register with the United States Drug Enforcement  
10 Administration (DEA).

11 (g) The board shall consult with the Medical Board of California  
12 and report during its sunset review required by Article 7.5  
13 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of  
14 Division 2 of Title 2 of the Government Code the impacts of  
15 exempting Schedule III and Schedule IV drug orders from the  
16 requirement for a physician and surgeon to review and countersign  
17 the affected medical record of a patient.

18 ~~SEC. 8. Section 4079 is added to the Business and Professions~~  
19 ~~Code, to read:~~

20 ~~4079. The board shall adopt an emergency regulation that~~  
21 ~~requires a warning label on all Schedule II controlled substance~~  
22 ~~vials or prescription bottles that addresses the risks of addiction~~  
23 ~~and overdose when using opioids.~~

24 *SEC. 11. Section 4076.7 is added to the Business and*  
25 *Professions Code, to read:*

26 *4076.7. In addition to the requirements of Sections 4076 and*  
27 *4076.5, whenever a prescription drug containing an opioid is*  
28 *dispensed to a patient for outpatient use, the pharmacy or*  
29 *practitioner dispensing the drug shall prominently display on the*  
30 *label or container a notice that states "Caution: Opioid. Risk of*  
31 *overdose and addiction."*

32 ~~SEC. 9:~~

33 *SEC. 12. Section 49476 is added to the Education Code, to*  
34 *read:*

35 *49476. (a) If a school district, charter school, or private school*  
36 *elects to offer an athletic program, the school district, charter*  
37 *school, or private school shall annually give an information sheet*  
38 *about the risk of opioid addiction the Opioid Factsheet for Patients*  
39 *published by the Centers for Disease Control and Prevention to*  
40 *each athlete. The information sheet shall be signed and returned*

1 ~~by the~~ *The* athlete ~~before the athlete initiates practice or~~  
2 ~~competition. If~~ *and, if* the athlete is 17 years of age or younger,  
3 ~~the information sheet the athlete's parent or guardian shall also~~  
4 ~~be signed by the athlete's parent or guardian~~ *sign a document*  
5 *acknowledging receipt of the Opioid Factsheet for Patients and*  
6 *return that document to the school district, charter school, or*  
7 *private school before the athlete initiates practice or competition.*  
8 ~~The information sheet~~ *Opioid Factsheet for Patients* may be sent  
9 and returned through an electronic medium, including, but not  
10 limited to, fax or email.

11 (b) This section does not apply to an athlete engaging in an  
12 athletic activity during the regular schoolday or as part of a physical  
13 education course required pursuant to subdivision (d) of Section  
14 51220.

15 ~~SEC. 10.~~

16 *SEC. 13.* Section 11158.1 is added to the Health and Safety  
17 Code, to read:

18 11158.1. (a) Except when a patient is being treated as set forth  
19 in Sections 11159, 11159.2, and 11167.5, and Article 2  
20 (commencing with Section 11215) of Chapter 5, pertaining to the  
21 treatment of addicts, or for a diagnosis of chronic intractable pain  
22 as used in Section 124960 of this code and Section 2241.5 of the  
23 Business and Professions Code, a prescriber shall do all of the  
24 following before directly dispensing or issuing for a minor the first  
25 prescription in a single course of treatment for a controlled  
26 substance containing an opioid:

27 (1) Discuss all of the following with the minor, with the minor's  
28 parent or guardian, or with another adult authorized to consent to  
29 the minor's medical treatment:

30 (A) The risks of addiction and overdose associated with the use  
31 of opioids.

32 (B) The increased risk of addiction to an opioid to an individual  
33 who is suffering from both mental and substance abuse disorders.

34 (C) The danger of taking an opioid with a benzodiazepine,  
35 alcohol, or another central nervous system depressant.

36 (D) Any other information required by law.

37 (2) Obtain the signature of the minor, and the minor's parent or  
38 guardian or other adult authorized to consent to the minor's medical  
39 treatment. The prescriber shall include the signed consent form in  
40 the minor's medical record.

1 (b) Paragraph (1) of subdivision (a) does not apply in any of  
2 the following circumstances:

3 (1) If the minor’s treatment is associated with or incident to a  
4 medical emergency.

5 (2) If the minor’s treatment is associated with or incident to an  
6 emergency surgery, regardless of whether the surgery is performed  
7 on an inpatient or outpatient basis.

8 (3) If, in the prescriber’s professional judgment, fulfilling the  
9 requirements of paragraph (1) of subdivision (a) would be  
10 detrimental to the minor’s health or safety.

11 (c) The consent described in paragraph (2) of subdivision (a)  
12 shall be obtained in a form that is separate from any other document  
13 that a prescriber uses to obtain the informed consent for the  
14 treatment of a minor and shall contain all of the following:

15 (1) The name and quantity of the controlled substance being  
16 prescribed for the minor and the amount of the initial dose.

17 (2) A statement indicating that a controlled substance is a drug  
18 or other substance that has been identified as having a potential  
19 for abuse.

20 (3) A statement certifying that the prescriber discussed with the  
21 minor, and with the minor’s parent or guardian or with another  
22 adult authorized to consent to the minor’s medical treatment, the  
23 topics described in paragraph (1) of subdivision (a), unless the  
24 exemption in subdivision (b) applies.

25 (4) A space for the signature of the minor’s parent or guardian  
26 or other adult authorized to consent to the minor’s medical  
27 treatment, and a space to indicate the date that the minor’s parent  
28 or guardian or other adult authorized to consent to the minor’s  
29 medical treatment signed the form.

30 (d) Notwithstanding any other law, including Section 11374,  
31 failure to comply with this section shall not constitute a criminal  
32 offense, but may subject the prescriber to disciplinary action for  
33 unprofessional conduct under the prescriber’s respective licensing  
34 act under Division 2 (commencing with Section 500) of the  
35 Business and Professions Code.

36 ~~SEC. 11.~~

37 *SEC. 14.* Section 124236 is added to the Health and Safety  
38 Code, to read:

39 124236. (a) A youth sports organization, as defined in  
40 paragraph (3) of subdivision (b) of Section 124235, that elects to

1 offer an athletic program shall annually give an information sheet  
 2 ~~about the risk of opioid addiction~~ *the Opioid Factsheet for Patients*  
 3 *published by the Centers for Disease Control and Prevention* to  
 4 each athlete. The information sheet shall be signed and returned  
 5 by the athlete before the athlete initiates practice or competition.  
 6 ~~If and, if~~ the athlete is 17 years of age or younger, *the athlete's*  
 7 *parent or guardian* the information sheet shall also be signed by  
 8 ~~the athlete's parent or guardian~~ *sign a document acknowledging*  
 9 *receipt of the Opioid Factsheet for Patients and return that*  
 10 *document to the school district, charter school, or private school*  
 11 before the athlete initiates practice or competition. The information  
 12 ~~sheet~~ *Opioid Factsheet for Patients* may be sent and returned  
 13 through an electronic medium, including, but not limited to, fax  
 14 or email.

15 (b) This section shall apply to all athletes participating in the  
 16 activities of a youth sports organization, irrespective of their ages.  
 17 This section shall not be construed to prohibit a youth sports  
 18 organization, or any other appropriate entity, from adopting and  
 19 enforcing rules intended to provide a higher standard of safety for  
 20 athletes than the standard established under this section.

21 ~~SEC. 12.~~

22 *SEC. 15.* No reimbursement is required by this act pursuant to  
 23 Section 6 of Article XIII B of the California Constitution because  
 24 the only costs that may be incurred by a local agency or school  
 25 district will be incurred because this act creates a new crime or  
 26 infraction, eliminates a crime or infraction, or changes the penalty  
 27 for a crime or infraction, within the meaning of Section 17556 of  
 28 the Government Code, or changes the definition of a crime within  
 29 the meaning of Section 6 of Article XIII B of the California  
 30 Constitution.



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**Bill Number:** SB 1109

**Current Version:** As amended April 18, 2018

**Author:** Bates  
Nguyen, Stone  
Brough, Mathis

**Topic:** Controlled substances: Schedule II drugs: opioids.

**Staff Recommendation:** None

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**AFFECTED SECTIONS:** Amends Sections 2190.5, 2191, 2196.2, 2746.51, 2836.1, and 3502.1 of, and adds Section 4079 to, the Business and Professions Code, adds Section 49476 to the Education Code, and adds Sections 11158.1 and 124236 to the Health and Safety Code.

**STATUS:** Senate Health

**EXISTING LAW:**

The California Uniform Controlled Substances Act classifies opioids as Schedule II controlled substances and places restrictions on the prescription of those drugs, including prohibiting refills and specifying the requirements of a prescription for these drugs. Additionally, the business and professions code requires the Board of Pharmacy to promulgate regulations that require a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

Existing business and professions code requires physician and surgeons to complete a continuing education course on pain management. Although nurse practitioners, certified nurse-midwives and physicians assistants have limitations as to their authority to prescribe Schedule II drugs, those that do are subject to continuing education requirements on Schedule II drugs.

Current health and safety code statute requires a school district, charter school, or private school as well as youth sports organizations that elects to offer an athletic program to take specified actions if an athlete is suspected to have sustained a concussion and to obtain a signed concussion and head injury information sheet from the athlete and the parent or guardian before the athlete initiates practice or competition.

**THIS BILL WOULD:**

- 1) Require existing continuing education courses for all prescribers to include the risks of addiction and overdose associated with the use of Schedule II controlled substances
- 2) Require a warning label on all Schedule II controlled substances prescription bottles on the associated addiction and overdose risks

- 3) Require a prescriber to discuss with a minor's parent's and/or guardian's after a required consultation with a prescriber for any minor receiving an initial opioid prescription
- 4) Require an information sheet on the risks of opioids to be signed by a minor athlete and the minor athlete's parent or guardian before participation in organized team sports

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure. Specifically, the opioid epidemic in California; has reached a death toll of: 1,925 deaths in 2016. Additionally, 3,630 infants born in California were addicted to drugs in 2015. California spends 19.5% of its budget on addiction, substance use and abuse<sup>1</sup>.

Board staff have worked with the author's office on the details of the prescription label and more information will be forthcoming.

**FISCAL IMPACT ON THE BOARD:**

The board's cost will include all work (policy, research etc) necessary for promulgation of both the emergency regulation as well as the standard regulation that must be done to make the changes permanent.

**SUPPORT / OPPOSITION:**SUPPORT:

Office of the San Diego County District Attorney

OPPOSITION:

California Pharmacists Association  
American Academy Pediatrics

04/18/18	From committee with author's amendments. Read second time and amended. Re-referred to Com. on HEALTH.
04/18/18	Set for hearing April 25.
04/17/18	From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 8. Noes 0.) (April 16). Re-referred to Com. on HEALTH.
04/04/18	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/28/18	April 9 set for first hearing canceled at the request of author.
03/20/18	Set for hearing April 9.

<sup>1</sup>CASA Columbia. (2009). Shoveling Up II: The Impact of Substance Abuse on Federal, State and Local Budgets.

02/22/18	Referred to Coms. on B., P. & E.D. and HEALTH.
02/14/18	From printer. May be acted upon on or after March 16.
02/13/18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

**BILL HISTORY:**

AMENDED IN SENATE APRIL 9, 2018

AMENDED IN SENATE MARCH 19, 2018

**SENATE BILL**

**No. 1229**

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**Introduced by Senator Stone**

February 15, 2018

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An act to add Section 4079 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1229, as amended, Stone. Pharmacists: opioid medications: consultation.

Existing law, the Pharmacy Law, ~~a knowing violation of which is a misdemeanor~~, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. ~~Existing~~ *A knowing violation of that law is a misdemeanor. That* law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription under specified circumstances, and requires a pharmacist to use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions. Existing regulatory law requires a pharmacist to provide oral consultation to a patient upon the patient's request or whenever the pharmacist, in his or her professional judgment, deems it warranted.

~~This bill~~ *bill, except as specified*, would require a ~~pharmacist~~ *pharmacist, on dispensing any opioid medication to a patient or the patient's agent for the first time*, to provide oral consultation ~~to a patient or the patient's agent~~ before dispensing ~~any opioid medication the medication~~, in accordance with regulations ~~to be adopted by the board, except as specified.~~ *board. The bill would prohibit the pharmacist from dispensing the medication if the patient or the patient's agent declines*

*the consultation.* Because a knowing violation of the bill’s 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.

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

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

1 SECTION 1. Section 4079 is added to the Business and  
2 Professions Code, to read:

3 4079. (a) A ~~pharmacist shall provide oral consultation~~  
4 *pharmacist, on dispensing any opioid medication* to a patient or  
5 the patient’s agent *for the first time, shall provide oral consultation*  
6 before dispensing ~~any opioid~~ *the medication.* The *initial*  
7 *consultation pursuant to this subdivision* shall be a condition of  
8 obtaining the opioid medication and the *pharmacist shall not*  
9 *dispense the medication if the patient or the patient’s agent* ~~may~~  
10 ~~not decline declines~~ the consultation.

11 (b) Notwithstanding subdivision (a), a pharmacist at a hospital  
12 pharmacy is not required to provide oral consultation before  
13 dispensing an opioid medication to a patient who has been admitted  
14 to the hospital. For purposes of this subdivision, “hospital  
15 pharmacy” has the same meaning as that term is defined in Section  
16 4029.

17 (c) Subject to Section 4001.1, the board shall adopt regulations  
18 to implement this section that include, but are not limited to,  
19 establishing matters required to be discussed in the consultation.

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

1 the meaning of Section 6 of Article XIII B of the California  
2 Constitution.

O



**Bill Number:** SB 1229

**Current Version:** As amended April 9, 2018

**Author:** Stone

**Topic:** Pharmacists: opioid medications: consultation

**Staff Recommendation:**

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**AFFECTED SECTIONS:** Adds Section 4079 to the Business & Professions Code.

**STATUS:** Senate Business, Professions and Economic Development

**EXISTING LAW:**

Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription under specified circumstances, and requires a pharmacist to use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions. Existing regulations require a pharmacist to provide oral consultation to a patient upon the patient's request or whenever the pharmacist, in his or her professional judgment, deems it warranted.

Further, the board has the authority to issue a citation with or without a fine for violations of pharmacy law.

**THIS BILL WOULD:**

Require, except as specified, a pharmacist to provide oral consultation before dispensing any opioid medication to a patient or the patient's agent for the first time.

Prohibit a pharmacist from dispensing the medication if the patient or patient's agent declines the consultation

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure. Currently, consultations may be declined by the patient or patient's agent when dispensed an opioid medication. The board has expressed concern with low patient consultation rates. The policy being offered in this measure appears to address the board's concern as it relates to patient consultation for opioids.

As part of its consideration it may be appropriate to consider if the current elements for patient consultation should be more specific for opioid prescriptions and if the current fine is appropriate for such violations.

**FISCAL IMPACT ON THE BOARD:**

Board staff have identified IT costs in the amount of \$2,500.00.

**SUPPORT / OPPOSITION:**SUPPORT:

None on file.

OPPOSITION:

None on file.

**BILL HISTORY:**

04/11/18	Set for hearing April 23.
04/10/18	April 16 hearing postponed by committee.
04/09/18	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/20/18	Set for hearing April 16.
03/19/18	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/01/18	Referred to Com. on B., P. & E.D.
02/16/18	From printer. May be acted upon on or after March 18.
02/15/18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 18, 2018

AMENDED IN SENATE APRIL 2, 2018

**SENATE BILL**

**No. 1254**

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**Introduced by Senator Stone**

February 15, 2018

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An act to add Section 4118.5 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1254, as amended, Stone. Hospital pharmacies: medication profiles or lists for high-risk patients.

Existing law, the Pharmacy Law, a willful violation of which is a misdemeanor, provides for the licensure and regulation of pharmacists, intern pharmacists, pharmacy technicians, and pharmacies by the California State Board of Pharmacy. Existing regulatory law requires a pharmacy to maintain medication profiles on all patients who have prescriptions filled at that pharmacy, except under specified circumstances.

This bill would require a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission ~~and discharge of the patient.~~ *patient under specified circumstances*. The bill would authorize an intern pharmacist or a pharmacy technician to perform the task of obtaining an accurate medication profile or list for a high-risk patient if certain conditions are satisfied. The bill would require the hospital to determine what constitutes a high-risk patient for purposes of the bill's provisions based on the populations served by the hospital.

By placing new requirements on a pharmacist, this bill would expand the scope of an existing crime and would, therefore, impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 4118.5 is added to the Business and  
 2 Professions Code, to read:  
 3 4118.5. (a) ~~At a hospital pharmacy, a~~ A pharmacist *at a*  
 4 *hospital pharmacy* shall obtain an accurate medication profile or  
 5 list for each high-risk patient upon admission ~~and discharge~~ of the  
 6 ~~high-risk patient.~~ *patient under the following conditions:*  
 7 (1) *The hospital has more than 100 beds.*  
 8 (2) *The accurate medication profile or list may be acquired by*  
 9 *the pharmacist during the hospital pharmacy's hours of operation.*  
 10 (b) Notwithstanding any other law, a pharmacy technician or a  
 11 pharmacy intern may perform the task of obtaining an accurate  
 12 medication profile or list for a high-risk patient if ~~both~~ *all* of the  
 13 following conditions are satisfied:  
 14 (1) The hospital pharmacy has a quality assurance program,  
 15 which is under the direction of the pharmacist-in-charge, to monitor  
 16 competency.  
 17 (2) The hospital has established policies and procedures for  
 18 training and proctoring pharmacy technicians or pharmacy interns  
 19 *by the hospital pharmacy department* and the pharmacy technician  
 20 or pharmacy intern has completed that training and proctoring.  
 21 (3) *If a pharmacy technician's only function is to obtain accurate*  
 22 *medication profiles or lists pursuant to this section, the hospital*  
 23 *does not include the pharmacy technician for purposes of*  
 24 *calculating the hospital's pharmacist-to-technician ratio.*  
 25 (c) The hospital shall establish criteria regarding who is a  
 26 high-risk patient for purposes of this section based on the patient  
 27 populations served by the hospital.

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

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**Bill Number:** SB 1254

**Current Version:** As amended April 2, 2018

**Author:** Stone

**Topic:** Hospital pharmacies: medication profiles or lists for high-risk patients.

**Staff Recommendation:**

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**AFFECTED SECTIONS:** Adds Section 4118.5 to the Business & professions Code.

**STATUS:** Senate Business, Professions and Economic Development

**EXISTING LAW:**

Existing law provides for the licensure and regulation of pharmacists, intern pharmacists, pharmacy technicians, and pharmacies by the Board. Existing regulations requires a pharmacy to maintain medication profiles on all patients who have prescriptions filled at that pharmacy, except under specified circumstances.

**THIS BILL WOULD:**

Require a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge of the patient.

The criteria for determining whether a patient is high risk will be established by each hospital.

Additionally, this measure allows for this duty to be performed by a pharmacy technician or a pharmacy intern, if they have successfully completed training and proctoring by a pharmacist and where a quality assurance program is used to monitor competency.

**STAFF COMMENTS:**

This measure is being brought to the committee to seek input on the policy of the measure.

**FISCAL IMPACT ON THE BOARD:**

**SUPPORT / OPPOSITION:**

SUPPORT:

University of California at San Francisco  
Numerous Individuals

OPPOSITION:

None on file.

**BILL HISTORY:**

04/11/18	Set for hearing April 23.
04/09/18	April 9 hearing: Testimony taken. Hearing postponed by committee.
04/02/18	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/28/18	April 16 hearing postponed by committee.
03/20/18	Set for hearing April 16.
03/01/18	Referred to Com. on B., P. & E.D.
02/16/18	From printer. May be acted upon on or after March 18.
02/15/18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 2, 2018

**SENATE BILL**

**No. 1442**

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**Introduced by Senator ~~Newman~~ Wiener**

February 16, 2018

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An act to add Section 4113.5 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1442, as amended, ~~Newman~~ Wiener. Pharmacies: staffing.

Under the Pharmacy Law, the California State Board of Pharmacy licenses and regulates the practice of pharmacy and the conduct of a pharmacy in this state. A knowing violation of that law is a crime.

This bill would prohibit a pharmacy from requiring a pharmacist to engage in the practice of pharmacy unless the pharmacist is assisted at all times by either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located. By imposing a new requirement on pharmacies, the knowing violation of which would be a crime, this bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. The Legislature finds and declares as follows:

2 (a) Licensed pharmacists are health care professionals whose  
3 training and experience play a vital role in protecting public health.

4 (b) Pharmacists are legally and ethically bound to advise their  
5 patients, physicians, and other health practitioners on the selection,  
6 dosages, interactions, and side effects of ~~medications~~, *medications*  
7 as well as monitor the health and progress of those patients to  
8 ensure that they are using their medications safely and effectively.

9 (c) Pursuant to Section 4001.1 of the Business and Professions  
10 Code, the highest priority for the regulation of pharmacists is  
11 protection of the public.

12 (d) The duties of a pharmacist include preventing the abuse of  
13 prescription opioids. In August 2013, the California State Board  
14 of Pharmacy revoked the licenses of both a pharmacy and its  
15 pharmacist because the pharmacist failed to comply with  
16 corresponding responsibility requirements in the distribution of  
17 opioid drugs. Four patients died as a result of the pharmacist's  
18 actions.

19 (e) The California State Board of Pharmacy's decision and order  
20 in that case identifies "red flags" that pharmacists are legally  
21 obligated to watch for before filling such a prescription. These  
22 "red flags" include:

23 (1) Irregularities on the face of the prescription itself.

24 (2) Nervous patient demeanor.

25 (3) The age or presentation of patient (e.g., youthful patients  
26 seeking chronic pain medications).

27 (4) Multiple patients all with the same address.

28 (5) Multiple prescriptions for the same patient for duplicate  
29 therapy.

30 (6) Requests for early refills of prescriptions.

31 (7) Prescriptions written for an unusually large quantity of drugs.

32 (8) Prescriptions written for duplicative drug therapy.

33 (9) Initial prescriptions written for strong opiates.

34 (10) Long distances traveled from the patient's home to the  
35 prescriber's office or to the pharmacy.

36 (11) Irregularities in the prescriber's qualifications in relation  
37 to the type of medications prescribed.

1 (12) Prescriptions that are written outside of the prescriber's  
2 medical specialty.

3 (13) Prescriptions for medications with no logical connection  
4 to an illness or condition.

5 (f) In 2013, the Governor signed legislation that significantly  
6 expanded the scope of practice of pharmacists. Pharmacists are  
7 now, without a prescription from a physician, permitted to  
8 vaccinate their patients, aid them in the administration of  
9 self-administered hormonal contraception, and provide nicotine  
10 replacement products. The California State Board of Pharmacy  
11 has by regulation promulgated extensive protocols governing each  
12 of these new duties.

13 (g) For self-administered hormonal contraception, the California  
14 Code of Regulations requires a pharmacist to complete the  
15 following steps:

16 (1) Ask the patient to use and complete the self-screening tool.

17 (2) Review the self-screening answers and clarify responses if  
18 needed.

19 (3) Measure and record the patient's seated blood pressure if  
20 combined hormonal contraceptives are requested or recommended.

21 (4) Before furnishing self-administered hormonal contraception,  
22 ensure that the patient is appropriately trained in administration  
23 of the requested or recommended contraceptive medication.

24 (5) When a self-administered hormonal contraceptive is  
25 furnished, provide the patient with appropriate counseling and  
26 information on the product furnished, including:

27 (A) Dosage.

28 (B) Effectiveness.

29 (C) Potential side effects.

30 (D) Safety.

31 (E) The importance of receiving recommended preventative  
32 health screenings.

33 (F) That self-administered hormonal contraception does not  
34 protect against sexually transmitted infections.

35 (h) For nicotine replacement products, the California Code of  
36 Regulations requires a pharmacist to complete the following steps:

37 ~~(a)~~

38 (I) Review the patient's current tobacco use and past quit  
39 attempts.

40 ~~(b)~~

1 (2) Ask the patient screening questions related to pregnancy,  
2 heart attacks, history of heart ailments, chest pain, or nasal  
3 allergies.

4 (e)

5 (3) Review the instructions for use with every patient using a  
6 nicotine replacement product.

7 (i) For vaccines, Section 1746.4 of Title 16 of the California  
8 Code of Regulations requires a pharmacist to notify each patient's  
9 primary care provider of any vaccine administered to the patient,  
10 or enter the appropriate information in a patient record system  
11 shared with the primary care provider, as permitted by the primary  
12 care provider.

13 (j) Notwithstanding the number, complexity, and importance  
14 of a pharmacist's duties, including those new obligations described  
15 above, the Legislature has heard uncontradicted testimony that  
16 licensed pharmacists are left alone for indeterminate periods of  
17 time in the pharmacy and are, simultaneously, required by such  
18 establishments to perform nonpharmacist functions such as staffing  
19 cash registers and assisting consumers in purchasing prescriptions,  
20 groceries, and other nonpharmacy goods. Survey information of  
21 pharmacists working in pharmacies reinforces the testimony.

22 (k) Staffing inadequacies like these interfere with the  
23 professional responsibilities of licensed pharmacists, including  
24 those requiring time and professional judgment listed above, and  
25 pose a risk to the public health because it leaves licensed  
26 pharmacists an insufficient amount of time to perform their licensed  
27 functions safely and lawfully, exercise their professional discretion,  
28 and comply with their legal and ethical obligations to protect the  
29 health and well-being of patients.

30 SEC. 2. Section 4113.5 is added to the Business and Professions  
31 Code, to read:

32 4113.5. A pharmacy shall not require a pharmacist employee  
33 to engage in the practice of pharmacy unless the pharmacist is  
34 assisted at all times by either another employee of the pharmacy  
35 or, if the pharmacy is located within another establishment, an  
36 employee of the establishment within which the pharmacy is  
37 located. This section shall not be construed to permit an employee  
38 who is not licensed under this chapter to engage in any act for  
39 which a license is required under this chapter.

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

O



**Bill Number:** SB 1442  
**Current Version:** As Amended April 2, 2018  
**Author:** Weiner  
**Topic:** Pharmacies: staffing  
**Staff Recommendation:** None

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**AFFECTED SECTIONS:** Add BPC section 4113.5.

**STATUS:** Referred to Senate Appropriations Committee

**CURRENT LAW:**

- Establishes the board and states that the top priority of the board shall be protection of the public.
- Establishes the authority for a pharmacist to provide various patient care services (e.g. furnishing hormonal contraception, furnishing naloxone, etc) in addition to traditional pharmacy services.

**THIS BILL WOULD:**

Specify that a pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy unless the pharmacist is assisted at all times by another employee as specified.

**STAFF COMMENTS:**

This measure recently passed out of the Senate Business, Professions, and Economic Development committee. As part of the committee's discussion, concern was raised about independent pharmacy business.

**FISCAL IMPACT ON THE BOARD:**

Board staff believe the fiscal impact would be minor and absorbable.

**SUPPORT / OPPOSITION:**

SUPPORT:

United Food & Commercial Workers Western States Council (UFCW), Sponsor  
California State Council of the Service Employees International Union

OPPOSITION:

None on file as of April 10, 2018

**BILL HISTORY:**

<b>Date</b>	<b>Action</b>
04/10/2018	Set for hearing April 23.
04/09/2018	April 16 set for first hearing canceled at the request of author.
03/20/2018	Set for hearing April 16.
03/08/2018	Referred to Com. on B., P. & E.D.
02/20/2018	From printer. May be acted upon on or after March 22.
02/16/2018	Introduced. Read first time. To Com. on RLS. for assignment. To print

# **Attachment 3**

1. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors

**Timeline:**

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: February 9, 2017

Returned to the board on: February 28, 2017

Re-submitted to DCA for Pre-Notice Review: October 25, 2017

Returned to the board on: March 26, 2018

Board staff is currently amending the rulemaking file to incorporate the changes requested by DCA Legal on March 26<sup>th</sup>.

**Summary of Regulation:**

This regulation establishes the regulatory framework for third-party logistics providers.

2. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

**Timeline:**

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 23, 2017

Returned to the board: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: August 21, 2017

Returned to the board: February 24, 2018

Modified language approved by board: March 27, 2018

Board staff is currently amending the rulemaking file to incorporate the changes to the language approved by the board on March 27<sup>th</sup>.

**Summary of Regulation:**

This regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

3. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

**Timeline:**

Approved by Board: January 24, 2017

Submitted to DCA for Pre-Notice Review: April 27, 2017

Returned to the board: January 18, 2018

Board staff is currently amending the rulemaking file to incorporate the changes requested by DCA Legal on January 18<sup>th</sup>.

**Summary of Regulation:**

This regulation amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

4. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

**Timeline:**

Approved by Board: May 4, 2017

Submitted to DCA for Pre-Notice Review: May 31, 2017

Returned to the board: January 18, 2018

Modified language approved by board: March 27, 2018

Board staff is currently amending the rulemaking file to incorporate the changes to the language approved by the board on March 27<sup>th</sup>.

**Summary of Regulation:**

This regulation amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

**Timeline:**

Approved by Board: October 27, 2016

Submitted to DCA for Pre-Notice Review: January 26, 2017

Returned to the Board on: March 28, 2017

Board staff is currently reviewing the changes requested by DCA Legal to determine the next course of action for this rulemaking.

**Summary of Regulation:**

This regulation amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

6. Proposed Regulations to Add Title 16 CCR section 1717.5 Related to Automatic Refill Programs

**Timeline:**

Approved by Board: May 3, 2017

Submitted to DCA for Pre-Notice Review: November 7, 2017

Returned to the Board on: March 26, 2018

Board staff is currently amending the rulemaking file to incorporate the changes requested by DCA Legal on March 26<sup>th</sup>.

**Summary of Regulation:**

This regulation establishes regulatory requirements for automated refill programs.

7. Proposed Regulations to Amend Title 16 CCR sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 Related to Compounding

**Timeline:**

Approved by Board: July 25, 2017

Submitted to DCA for Pre-Notice Review: November 20, 2017

**Summary of Regulation:**

This regulation formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system.

8. Proposed Regulations to Amend Title 16 CCR section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

**Timeline:**

Approved by Board: November 8, 2017

Submitted to DCA for Pre-Notice Review: February 2, 2018

**Summary of Regulation:**

This regulation updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

**Third-Party Logistics  
Providers and  
Dangerous Drug  
Distributors  
§§ 1780-1783**

## Title 16. Board of Pharmacy

### Proposed Language

To Amend Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

#### **Article 10. ~~Wholesalers~~ Dangerous Drug Distributors**

To Amend Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

##### **1780. Minimum Standards for ~~Wholesalers~~.**

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision) official compendium.
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
  - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
  - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
  - (3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.
- (d) All materials must be examined upon receipt and/or before shipment.
  - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
  - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
  - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
  - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
  - (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
  - (1) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security,

storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

- (2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
  - (3) ~~Each~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
  - (4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.
- (g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, ~~4045~~, 4051, 4053, ~~4053.1~~, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code; Section 321 of Title 21, U.S. Code; and Section 205.05 of Title 21, Code of Federal Regulations.

**To Amend** Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1781. ~~Exemption Certificate~~ Designated Representative.**

A registered pharmacist, ~~or an~~ designated representative ~~or designated representative –3PL~~ certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's, ~~or~~ wholesaler's ~~or a third-party logistics provider's~~ licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

**To Amend** Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1782. Reporting Sales of Drugs Subject to Abuse.**

~~All~~ Each ~~manufacturers, and~~ wholesalers and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Sections 4005 and 4164, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~ Reference: Sections 4053.1, 4081, 4164, and 4332, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~

To Amend Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1783. Manufacturer, ~~or Wholesaler or Third-Party Logistics Provider~~ Furnishing Drugs and Devices.**

- (a) A manufacturer, ~~or wholesaler or third-party logistics provider~~ shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or wholesaler, or third-party logistics provider~~ shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
- (b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or wholesaler or third-party logistics provider~~ furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
- (c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler or third-party logistics provider~~ shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler or third-party logistics provider~~ may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler or third-party logistics provider~~ if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler or third-party logistics provider~~ by the next business day after the delivery to the pharmacy receiving area.
- (d) A manufacturer, ~~or wholesaler or third-party logistics provider~~ shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.
- (e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler or third-party logistics provider~~ to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or wholesaler or third-party logistics provider~~ shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4053.1, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

# **Pharmacy Technician**

**16 CCR § 1793.5,  
1793.6, and 1793.65**

**Title 16. Board of Pharmacy  
Proposed Regulation Text**

**Proposal to amend** §1793.5 of 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. ~~10/15~~ 3/2018)), 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 (NPDB) 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.

Note: Authority cited: Sections ~~163.5, 4005, 4007, 4038, 4115, and 4202, 4207 and 4400~~, Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

**Proposal to amend** §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§ 1793.6. Training Courses Specified by the Board.**

A course of training that meets the requirements of Business and Professions Code section 4202

(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(± A) Knowledge and understanding of different pharmacy practice settings.

(2 B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3 C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4 D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5 E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6 F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7 G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(B) Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115~~, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

**Proposal to add §1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1793.65 Pharmacy Technician Certification Programs Approved by the Board.**

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:

(1) The Pharmacy Technician Certification Board, and

(2) The National Healthcareer Association.

(b) Approval of these programs is valid through December 31, 2021.

Note: Authority cited: Business and Professions Code Sections 4005 and 4202. Reference: Business and Professions Code Sections 4038 and 4202.

# **Offsite Storage**

## **16 CCR § 1707**

Proposal to Amend 16 CCR § 1707

**§ 1707. Waiver Requirements for Off-Site Storage of Records.**

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.~~

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

# **Naloxone Fact Sheet**

## **16 CCR § 1746.3**

## BOARD OF PHARMACY

**Proposal to amend** § 1746.3 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read:

### **§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.**

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

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

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

(1) Screen the potential recipient by asking the following questions:

(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);

(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);

(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

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

(3) When naloxone hydrochloride is furnished:

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

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

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

(4) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

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

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that is contained in the current board-approved fact sheet. ~~This~~ The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.

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

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

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

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

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

Note: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.

**Pharmacy Ownership,  
Management, and  
Control, Including  
Through Trusts  
16 CCR § 1709**

**Title 16. Board of Pharmacy  
Proposed Text**

**To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

§1709. Names of Owners and Pharmacist In Charge Disclosure and Notification Requirements

- (a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership (~~individual, partnership or corporation~~) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.
- (b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.
- (c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a transfer of ~~permit~~ license and require application for a change of ownership: any transfer of a of the beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.
- (d) The board may issue, or renew, a license to an entity that is controlled by a revocable or irrevocable trust that meets the requirements of this subsection.
- (1) In addition to the requirements in (a), as part of its application and during its annual renewal, the entity shall also report the name of any other person in any position with management or control of the pharmacy.

- (2) An applicant shall disclose the full name of the trust, and shall provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.
- (3) An applicant shall disclose as part of its application and during its annual renewal the name, address and contact information for each grantor, settlor, trustee, trust protector, as applicable. In addition, the applicant shall disclose the name, address and contact information for each beneficiary named in the trust that is age 18 or greater.
- (4) The licensee, or any person with management or control of the pharmacy, shall notify the board in writing within 30 days of all the following:
- (A) A change in the trustee, protector or any other person with management or control of the pharmacy.
  - (B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.
  - (C) The revocation of the trust.
  - (D) The dissolution of the trust.
  - (E) Any amendment(s) to the trust since the original application.
- (e) An applicant or licensee may be denied, suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4058, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4133, 4144, 4149, 4160, 4161, 4196, 4201, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

# **Automatic Refill Programs**

**16 CCR § 1717.5**

**Title 16. Board of Pharmacy  
Proposed Text**

**Add section 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1717.5 Automatic Refill Programs**

- a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.
- 1) Written notice regarding the program shall be given to the patient or patient's agent. Such notice shall include instructions about how to withdraw a prescription medication from the program.
  - 2) The patient or patient's agent shall enroll by written, online or electronic consent to participate in the program.
  - 3) The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.
  - 4) The pharmacy shall have written policies and procedures in place that outline specifics of the program. The policies and procedures shall specify the medications that may be refilled through the program.
  - 5) The patient or patient's agent shall have the option to withdraw from the program at any time.
  - 6) The pharmacy shall complete a drug regimen review for each prescription refilled through the program.
  - 7) Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.
  - 8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy had been notified of withdrawal or disenrollment from the program.
  - 9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.
- b) A health care facility licensed pursuant to Health and Safety Code section 1250 that automatically refills prescription medications for its patients need not comply with the provisions of this section.

Authority cited: Section 4001.1 and 4005, Business and Professions Code. Reference: Sections 4063 and 4076.6 Business and Professions Code and 1250, Health and Safety Code.

# **Compounding**

## **16 CCR §§ 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4**

## Title 16. Board of Pharmacy

Changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language. Additionally, [Brackets] indicate language that is not being amended.

**Amend section 1735.1(c) and (f) in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### 1735.1. Compounding Definitions.

[.....]

- (c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ~~ventilation~~ exhausting. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI.
- (d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.
- (e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.
- (1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.
- (2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.
- (f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ~~ventilation~~ exhaust. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

[.....]

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

**Amend section 1735.2(i) in Article 4.5 of Division 17 of Title 16 California Code of Regulations to read as follows:**

**1735.2. Compounding Limitations and Requirements; Self-Assessment.**

[.....]

- (i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.
  - (1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:
    - (A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
    - (B) the chemical stability of any one ingredient in the compounded drug preparation;
    - (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
    - (D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
    - (E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
    - (F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
    - (G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:
      - (i) the nature of the drug and its degradation mechanism,
      - (ii) the dosage form and its components,
      - (iii) the potential for microbial proliferation in the preparation,
      - (iv) the container in which it is packaged,
      - (v) the expected storage conditions, and
      - (vi) the intended duration of therapy.
  - Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.
- (2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
  - (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

- (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
  - (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
  - (D) The beyond use date assigned for sterility in section 1751.8.
- (3) For sterile compounded drug preparations, E extension of a beyond use date is only allowable when supported by the following:
- (A) Method Suitability Test,
  - (B) Container Closure Integrity Test, and
  - (C) Stability Studies
- (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.
- (5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

[.....]

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

**Amend section 1735.6(e) in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.6. Compounding Facilities and Equipment.**

[.....]

- (e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:
  - (1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and
  - (2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and
  - (3) Each ~~PEG~~ BSC in the room shall also be externally vented except that a BSC used only for nonsterile compounding may also use a redundant-HEPA filter in series; and
  - (4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.
- (f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

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

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

**Amend section 1751.1(a)(5) in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.1. Sterile Compounding Recordkeeping Requirements.**

- (a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:
- (1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
  - (2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
  - (3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
  - (4) Results of viable air and surface sampling.
  - (5) ~~Biannual~~ ~~video~~ of smoke studies in all ISO Class 5 certified spaces.
  - (6) Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
    - (A) Controlled room temperature.
    - (B) Controlled cold temperature.
    - (C) Controlled freezer temperature.

[.....]

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

**Amend section 1751.4(k) in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.4. Facility and Equipment Standards for Sterile Compounding.**

[.....]

- (k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of ~~20-24~~ degrees Celsius (~~68-75~~ degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.
- (l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

# **Self-Assessment Forms**

**§ 1715**

**17M – 13**

**17M – 14**

**Title 16. Board of Pharmacy  
Proposed Regulation**

**Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 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) A pharmacist-in-charge of a community pharmacy shall use the the components of this assessment shall be on Form 17M-13 (Rev. 10/14 16) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment and on Form 17M-14 (Rev. 10/14 16) entitled "Hospital Pharmacy Self-Assessment." ~~which are Both forms are~~ hereby incorporated by reference ~~to evaluate compliance with federal and state laws and regulations.~~

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name and license number of the pharmacy

(B) Address, phone number, and website address, if applicable, of the pharmacy

(C) DEA registration number, expiration date and date of most recent DEA inventory

(D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person's license type and number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond "yes", "no" or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that pharmacy setting.

(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

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

(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

# **Attachment 4**

1. Proposed Regulations to Amend Title 16 CCR section 1735.2 Related to Compounding Self-Assessment Form 17M-39

**Timeline:**

Approved by Board: November 8, 2017

**Summary of Regulation:**

This regulation updates the Self-Assessment form 17M-39 (rev. 12/16) as incorporated by reference in Title 16 CCR section 1735.2. Additionally, this regulation updates section 1735.2 with clarifying language as to the completion and certification requirements of the self-assessment form.

2. Proposed Regulations to Add Title 16 CCR section 1793.9 Related to Remote Dispensing Technicians

**Timeline:**

Approved by Board: February 6, 2018

**Summary of Regulation:**

This regulation establishes regulatory requirements for pharmacy technicians working in a remote dispensing site pharmacy.

3. Proposed Regulations to Amend Title 16 CCR section 1706.2 Related to the Abandonment of Applications

**Timeline:**

Approved by Board: February 6, 2018

**Summary of Regulation:**

This regulation updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

4. Proposed Regulations to Amend Title 16 CCR section 1784 to Update the Self-Assessment Form 17M-26

**Timeline:**

Approved by Board: November 8, 2017

**Summary of Regulation:**

This regulation updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

**Compounding  
Self-Assessment  
§ 1735.2**

## Proposal to Amend Section 1735.2(k)

...

(k) Prior to allowing any drug product preparation 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~~ 12/2016.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. 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 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 date of a new pharmacist-in-charge or change of location, 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.

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name of the pharmacy and the license number of the pharmacy as well as the license numbers for any specialty licenses issued by the board including sterile compounding license number and centralized hospital packaging license number, if applicable.

(B) Address, phone number, fax number, and website address, if applicable, of the pharmacy

(C) Hours of operation of the pharmacy

(D) Name of Accreditation Agency and dates, if applicable

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person’s license number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond “Yea”, “no” or “not applicable” (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that setting.

(4) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficient identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct.

(7) The pharmacy owner or hospital administrator shall provide certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in revocation of the pharmacy’s license issued by the board. This certification shall be made under penalty of perjury of the State of California.

(8) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(9) Any identified areas of noncompliance shall be corrected as specified in the certification.

(l) ...

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

**Remote Dispensing  
Technicians  
§ 1793.9**

**Add section 1793.9 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

1793.9 Pharmacy Technician in a Remote Dispensing Site Pharmacy

A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:

- (a) Possess a pharmacy technician license that is in good standing.
- (b) Possess and maintain a certification issued by an approved pharmacy technician certifying program.
- (c) (1) Possess a minimum of an associate's degree in pharmacy technology or a bachelor's degree in any subject, or (2) complete a board approved training program.
- (d) Complete 1,000 hours of experience working as a pharmacy technician within the three years prior to first working in the remote dispensing site pharmacy.

Authority: Section 4005 and 4132, Business and Professions Code

Reference: 4005, 4026.5, 4044.3, 4052.1, 4115, 4132, and 4202, Business and Professions Code

**Abandonment of  
Applications  
§ 1706.2**

Proposal to Amend Title 16, California Code of Regulations as follows:

## § 1706.2. Abandonment of Application

(a) An applicant for a premises license ~~to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food animal drug retailer, or to furnish hypodermic needles and syringes~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

~~(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

~~(be)~~ An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

~~(cd)~~ An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

~~(de)~~ An applicant for an intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

~~(e) An applicant for an individual license not included in subdivision (b), (c), or (d), who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4034, 4034.5, 4037, 4041, 4042, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.5, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, and 4208, and 4210, Business and Professions Code.

**Self-Assessment  
Forms  
§ 1784  
17M – 26**

## Proposal to Amend 16 CCR Amend § 1784

§ 1784. Self-Assessment of a Wholesaler/Third Party Logistics Provider by the Designated Representative-In- Charge or Responsible Manager.

(a) ~~The designated representative-in-charge of~~ Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, 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 or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new ~~wholesaler permit~~ license is issued, ~~or~~

(2) There is a change in the designated representative-in-charge or responsible manager.

The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) ~~The components of this assessment shall be on Form 17M-26 (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.~~ Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name and license number of the premises;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) DEA registration number and expiration date and date of most recent DEA;  
inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date,  
if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of  
each Board-licensed staff person currently employed by the licensee in the facility at the  
time the self-assessment is completed, the person's license type and number, and the  
expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes",  
"no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the  
self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible  
manager shall provide a corrective action or action plan to come into compliance with the  
law.

(5) The designated representative-in-charge or responsible manager shall initial each page  
of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under  
penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he  
or she is responsible;

(B) Any deficiency identified within the self-assessment will be corrected and the  
timeframe for correction;

(C) He or she understands that all responses are subject to verification by the Board of  
Pharmacy; and

(D) The information provided in the self-assessment form is true and correct.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page  
of the self-assessment that he or she has read and reviewed the completed self-assessment  
and understands that failure to correct any deficiency identified in the self-assessment

could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

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

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.