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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Governor Edmund G. Brown Jr.

ENFORCEMENT COMMITTEE REPORT
December 20, 2018

Allen Schaad, Licensee Member, Chair
Albert Wong, Licensee Member, Vice Chair
Victor Law, Licensee Member
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Ricardo Sanchez, Public Member

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

2. **Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings**
Note: The board 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)]

3. **Discussion and Consideration of Implementation Strategies for Chaptered Legislation**

Background
At the October Board and September Enforcement Committee meetings members of the public suggested that the legislation passed in this year's legislative session be brought to the committee for discussion.

a. AB 2086 (Gallagher) (Chapter 274, Statutes of 2018) Controlled Substances: CURES Database

Attachment 1

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

Questions regarding this measure
1. Can a pharmacist working under a collaboration practice agreement similarly obtain a list of patients where he/she is listed as the prescriber?
2. Can CURES accommodate this modification?

b. AB 2783 (O'Donnell) (Chapter 589, Statutes of 2018) Controlled Substances: Hydrocodone Combination Products: Schedules

Attachment 2

This measure reclassifies specific hydrocodone combination products as Schedule II controlled substances, making California law consistent with federal law.

This bill is straightforward because it makes state law consistent with federal law for these products. Staff is unaware of any implementation issues.

c. AB 2789 (Wood) (Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission

Attachment 3

This law requires that by January 1, 2022, all written prescriptions, issued by licensed prescribers in California, be issued as an electronic transmission prescription (e-prescription). Also, by January 1, 2022, all pharmacies, pharmacists, or other practitioners authorized to dispense or furnish a medication must have the capability to receive an e-prescription.

There are multiple exemptions which include:

- Any medication prescribed under Health & Safety Code §11159.2 (for use by hospice or terminally ill patients)
- Technological/electrical failure making transmission problematic
- Prescription that will be dispensed outside of California
- Issued by hospital emergency department or urgent care clinic AND
- the patient resides outside of California, or outside the geographical area of the hospital
- the patient is indigent or homeless
- the prescription is issued when a patient's pharmacy is closed
- Prescription issued by veterinarians
- The prescription is for eyeglasses or contact lenses
- The prescriber and dispenser are the same entity
- Any time e-prescribing would cause a delay in therapy
- Prescription is not covered by National Council for Prescription Drug Programs' SCRIPT standard

Questions regarding this measure

a. When or if the DEA will amend the electronic prescribing provisions, e.g., addressing the current prohibition for transferring an e-prescription to another pharmacy, if it has not been filled.
b. Who is responsible for ensuring that prescribers provide e-prescriptions, e.g., prescribers who never acquire the technology?

d. SB 1447 (Hernandez) (Chapter 666, Statutes of 2018) Pharmacy: Automated Drug Delivery Systems and AB 2037 (Bonta) (Chapter 647, Statutes of 2018) Pharmacy: Automated Patient Dispensing Systems

Attachment 4

As enacted, these measures establish requirements for automated drug delivery system (ADDS) registration requirements with a licensing program that recognizes the different uses for such a device. The measure establishes definitions for the two different functions of ADDS one for administration to patients and one used for dispensing directly to the patients.

Specifically, effective July 1, 2019, this measure prohibits an ADDS from being installed, leased, owned or operated in California unless specific requirements are met. One requirement specifies an ADDS license will only be issued to the holder of a valid and active California pharmacy license. The bill expands the locations for placement and operation of an ADDS to specific locations, including the licensed pharmacy issued the ADDS license, a licensed health facility, a licensed clinic, or a specific medical office. Further, this measure requires the pharmacy issued the ADDS license to own or lease the ADDS machine and own the drugs and devices located within it. The measure requires the pharmacy to supervise the operation of the ADDS. This measure details specific stocking and transfer requirements for the ADDS, requires the pharmacy issued the ADDS license to provide training on the operation and use of that ADDS to specific individuals, and requires the pharmacy to complete periodic self-assessments. The bill requires additional conditions for ADDS used to dispense medication to patients. The bill authorizes 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. Lastly, this measure requires the board to report to the legislature regarding the regulations of ADDS machines on or before January 1, 2024, as part of the board's sunset evaluation process.

Questions regarding this measure

a. Under the provisions of the law, drugs can be stored for a period of up to 48 hours in a secured room within the ADDS location (BPC§4427.4(f)). Regarding where the pharmacy elects to store medications ultimately to be stocked, should the committee/board consider providing more specific storage and recordkeeping requirements, e.g. specified minimal security requirements, access issues, records requirements, etc.?
b. Under the provisions of the law, an incident involving an APDS where a complaint, error, or omissions has occurred shall be reviewed as part of the pharmacy's quality assurance program (BPC§4427.6(i)). Should the committee/board consider requiring such reviews to be separately reported to the board?

Note: The Licensing Committee is developing a self-assessment process for ADDS that must be conducted annually.

e. AB 1753 (Low) (Chapter 479, Statutes of 2018) Controlled Substances: CURES Database

Attachment 5

This law reduces the number of authorized security printers approved by the Department of Justice (DOJ). Further, this measure requires security prescription forms to contain a unique serialized number that must be reported to CURES and establishes reporting requirements to the DOJ on the delivery of security prescription forms to a prescriber.

Questions regarding this measure

1. As written, this measure does not provide for a transition period to the new security forms. Should the committee/board offer recommendations to the DOJ on the need

for a specific implementation date for the new requirements?

f. AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction

Attachment 6

This law, effective July 1, 2020, places restrictions on the convictions, crimes, and other acts the board may consider to deny, revoke or suspend a license. The law requires reporting on the board's website of denial summaries as well as a list of crimes that will be considered for denial and how they substantially relate to the qualifications, functions, or duties of the practice of pharmacy.

Note: Staff recommends that it begin working with the Office of the Attorney General and DCA counsel to identify next steps including possible statutory changes that could minimize the impacts of this measure as enacted. Further, it is recommended that staff, in concert with counsel, perform a GAP analysis as the first step towards implementation.

It is our understanding that DCA is also working on implementation strategies for the department. An update will be provided at the next committee meeting if information is available.

g. AB 2859 (Caballero) (Chapter 240, Statutes of 2018) Pharmacy: Safe Storage Products

Attachment 7

This law requires community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products on the premises and close to the pharmacy. Pharmacies, where a licensed pharmacist is the majority owner and manager of no more than four pharmacies, are exempt from this requirement. These provisions will remain in effect until January 1, 2023.

Questions regarding this measure

1. The language in the bill states that pharmacies are required to *display* safe storage products but does not specifically state that the pharmacy must offer them for sale. Should the board/committee discuss whether to require pharmacies to stock and sell these products or simply display them for informational purposes?
2. Under the measure, the board is required to assess a fine in an amount to be determined by the board for a violation of this section. Should the board/committee wish to establish a specific fine for such violations, a regulation is necessary.
3. Typically, when new requirements take effect the board focuses on educational compliance for the first six months to a year. Due to the specific requirement for a fine to be assessed, the board/committee needs to determine its implementation guidance.

h. SB 212 (Jackson) (Chapter 1004, Statutes of 2018) Solid Waste: Pharmaceutical and Sharps Waste Stewardship

Attachment 8

This law establishes a statewide program to fund drug takeback and sharps disposal programs throughout California. The provisions take effect on or before January 1, 2021. Under the provisions, the funding will be provided by covered entities (typically manufacturers) of drugs sold in California. CalRecycle is required to develop regulations governing this stewardship program by January 1, 2021.

Under this chapter, the board is required to develop and maintain a list of all covered drugs sold in California, as defined in the measure. Further, the board is required to review each stewardship plan for compliance with applicable federal and state laws governing drug take back programs. Board staff will collaborate with CalRecycle beginning the end of this year.

Questions regarding this measure

1. As enacted, the board is required to review a list of covered and not covered products for sale in California. Should the board/committee develop reporting requirements to ensure consistency in the receipt of such data, such an approach could require regulations.
2. As enacted, the board is provided the authority to adopt regulations for administration of provisions for which it is responsible. Should the board/committee discuss consequences for noncompliance of provisions?

i. SB 1109 (Bates) (Chapter 693, Statutes of 2018) Controlled Substances: Schedule II Drugs: Opioids

Attachment 9

This law requires completion of continuing education for prescribers on the hazards of opioid use. Further, this law requires a specified warning notice shall be prominently displayed on the label or container for an opioid dispensed to a patient for outpatient use.

Questions regarding this measure

1. As enacted, the continuing education requirements does not apply to pharmacists who prescribe under a collaborative practice agreement. Should the board/committee consider developing a similar requirement for pharmacists performing in such a capacity?

j. SB 1254 (Stone) (Chapter 697, Statutes of 2018) Hospital Pharmacies: Medication Profiles or Lists for High-Risk Patients

Attachment 10

This law requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge. The criteria for determining whether a patient is high-risk will be established by each hospital. Additionally, this law allows for this function to be performed by a pharmacy technician

or intern pharmacist, if they have successfully completed training and proctoring by the pharmacy department or another healing arts licensee issued a license pursuant Division 2. Under the provisions, the board has the authority to adopt regulations.

Questions regarding this measure

1. Does the board/committee wish to have staff identify hospitals that have chosen to implement medication reconciliation under the purview of the pharmacy?

The California Hospital Association developed an FAQ for dissemination to its members. A copy is provided as part of **Attachment 10**.

k. SB 1442 (Wiener) (Chapter 569, Statutes of 2018) Community Pharmacies: Staffing

Attachment 11

This law prohibits a community pharmacy from requiring a pharmacist to work alone. It requires either another employee of the pharmacy or the establishment be made available to assist the pharmacy at all times.

The law provides some exceptions including:

- Hospital pharmacies and hospital outpatient services
- Government owned pharmacies
- Pharmacies owned by individuals who own up to four pharmacies in California
- Pharmacies owned and operated by a health care service plan that exclusively contracts with no more than two medical groups
- Pharmacies with a drive-through window service
  - when only the drive-through is open
  - and the employer does not require the pharmacist to retrieve items outside the pharmacy for sale
- Pharmacies that do not sell, furnish, or dispense controlled substances, dangerous drugs or dangerous devices at retail

Questions regarding this measure

a. In such cases where the secondary staff person is not a licensee of the board, should the board/committee establish recommendations for background checks of such individuals?

l. Chaptered Bills Relating to Health Care Coverage: Prescription Drugs

Attachment 12

The following three chaptered bills relate to Health Care Coverage: Prescription Drugs

- **AB 2863 (Nazarian) (Chapter 770, Statutes of 2018) Health Care Coverage: Prescriptions**
  This law requires a pharmacy to inform the consumer of the lower price of a covered medication, whether that is the retail price or the cost sharing amount unless, the pharmacy automatically charges the lower amount. The pharmacy must submit the

retail cost to the health care plan in the same manner as if the customer had paid the co-pay.

- **AB 315 (Wood) (Chapter 905, Statutes of 2018) Pharmacy Benefit Management**
  This law similarly requires a pharmacy to inform the customer at the point of sale of a covered prescription drug whether the retail price is lower than the co-pay amount, unless the pharmacy automatically charges the lower amount. The pharmacy must submit the retail cost to the health care plan in the same manner as if the customer had paid the co-pay.

- **SB 1021 (Wiener) (Chapter 787, Statutes of 2018) Prescription Drugs**
  This law extends provisions regarding drug formulary coverage. Most related to board operations, it similarly requires a drug benefit plan to provide that if the pharmacy's retail price for a prescription drug is less than the applicable copay, the consumer shall not be required to pay more than the retail price.

All three bills are intended to ensure that patients do not pay more for a drug if they have health insurance, than if they had paid the cash price directly.

Questions regarding the measure

1. The California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) indicate that there are no national standards or computer fields available within existing software that allows them to submit a claim based on cash payments. They request a delay in enforcement of this provision until cleanup legislation can be enacted.
2. Prior public comment on this measure indicated that these provisions may conflict with state law that enables Medicare recipients in some cases to obtain medications at a cost that is no higher than the Medi-Cal reimbursement rate for those drugs. Those provisions, however, only apply when the prescription medication is not covered by insurance. As such, we believe no conflict exists.

Provided in **Attachment 12** are the bills, the letter from CRA/NACDS, a recent newsletter article regarding a Medicare patient's ability to obtain some prescription medications at Medi-Cal rates and a fact sheet on the issue.

4. Discussion and Consideration of Amendments to California Code of Regulations, Title 16, Section 1713 Related to Automated Drug Delivery Systems

Attachment 13

As discussed earlier in this report, recently enacted legislation regarding ADDS alters the condition under which a pharmacy can operate such a device. With the enactment of SB 1447 and AB 2037, the board/committee should consider amending existing regulations for ADDS that dispense medications to patients to reflect current law in this area.

Provided in **Attachment 13** is a statement from Asteres Director of Regulatory Affairs, Sara Lake, detailing proposed regulatory changes pursuant to the enactment of SB 1447. Also included are a broader set of amendments developed by staff to remove duplication

between the regulation and the new law as well as conflicts created by enactment of the new statute.

Should the committee choose to recommend such action, the following motion could be used to accomplish this:

Committee Recommendation: Recommend to the board initiation of a rulemaking to amend Title 16, California Code of Regulations section 1713 and delegate to the Executive Officer the authority to make technical or non-substantive changes consistent with the board's policy.

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5. Discussion and Consideration of Possible Statutory Amendment to Clarify CURES Reporting Requirement Related to the Dispensing Date

Attachment 14

Background

Currently, all Schedule II – IV controlled substance prescriptions dispensed in California must be reported to the Prescription Drug Monitoring Program (PDMP) known as CURES.

Records of dispensing must be sent to CURES within seven days of the dispensing of the controlled substance, but there is currently no requirement to send a void/cancel message for prescriptions that were filled in the pharmacy but never picked up.

Committee Consideration and Discussion

While the CURES reporting system is administered by the California Department of Justice, actual submissions by pharmacies are transmitted to a third party, Atlantic Associates (AAI). AAI is tasked with data integrity, formatting checks, identifying duplicate entries, and reconciling "near matches." AAI then transmits the data for insertion into the CURES database.

While some pharmacy systems hold a prescription's transmission to CURES until the patient actually receives the filled prescription, most systems do not. Thus, CURES reports may contain medication that, in fact, were never actually dispensed to the patient.

As the reliance on CURES grows, it is important that a patient's record is accurate.

During the meeting the committee will hear a brief presentation on this issue by Profession Robert Stein, PharmD, JD. For this discussion, also present will be a representative of the CURES program

Attachment 14 includes a copy of the issue statement prepared by Dr. Stein.

6. Discussion and Consideration of Board's Enforcement Statistics

Attachment 15

Enforcement statistics for the first five months of FY 2018/19 have been provided as **Attachment 15**.

As reflected in the attachment, the board received 1156 complaints and closed 1180 investigations. As of November 30, the board had 1,853 investigations pending.

Of the investigations closed, 595 compliants were closed without a substantiated violation, including 140 complaints that were determined non-jurisdictional.

The board issued 625 citations, 94 of which the board offered abatement to either reduce or eliminate the fine. The board referred 108 investigations to the Office of the Attorney General.

The board resolved 120 administrative cases that resulted in 96 revocations or surrenders of a license, 45 licenses being placed on probation, and issued 20 public reprovals.

7. Future Committee Meeting Dates

Enforcement Committee dates for 2019:
March 14, 2019
July 2, 2019
September 25, 2019

Attachment 1
AB 2086

AB-2086 Controlled substances: CURES database. (2017-2018)

SECTION 1. *Section 11165.6 is added to the Health and Safety Code, to read:*

11165.6. *A prescriber shall be allowed to access the CURES database for a list of patients for whom that prescriber is listed as a prescriber in the CURES database.*

Attachment 2
AB 2783

AB-2783 Controlled substances: hydrocodone combination products: schedules. (2017-2018)

SECTION 1. Section 11055 of the Health and Safety Code is amended to read:

11055. (a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

(A) Raw opium.

(B) Opium extracts.

(C) Opium fluid extracts.

(D) Powdered opium.

(E) Granulated opium.

(F) Tincture of opium.

(G) Codeine.

(H) Ethylmorphine.

(I) *(i)* Hydrocodone.

(ii) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(iii) Oral liquid preparations of dihydrocodeinone containing the above specified amounts that contain, as its nonnarcotic ingredients, two or more antihistamines in combination with each other.

(iv) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(J) Hydromorphone.

(K) Metopon.

(L) Morphine.

(M) Oxycodone.

(N) Oxymorphone.

(O) Thebaine.

(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(6) Cocaine, except as specified in Section 11054.

(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.

(c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanyl.

(2) Alphaprodine.

(3) Anileridine.

(4) Bezitramide.

(5) Bulk dextropropoxyphene (nondosage forms).

(6) Dihydrocodeine.

(7) Diphenoxylate.

(8) Fentanyl.

(9) Isomethadone.

(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).

(11) Levomethorphan.

(12) Levorphanol.

(13) Metazocine.

(14) Methadone.

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,
4-diphenyl butane.

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1,
1-diphenylpropane-carboxylic acid.

(17) Pethidine (meperidine).

(18) Pethidine-Intermediate-A,
4-cyano-1-methyl-4-phenylpiperidine.

(19) Pethidine-Intermediate-B,
ethyl-4-phenylpiperidine-4-carboxylate.

(20) Pethidine-Intermediate-C,
1-methyl-4-phenylpiperidine-4-carboxylic acid.

(21) Phenazocine.

(22) Piminodine.

(23) Racemethorphan.

(24) Racemorphan.

(25) Sufentanyl.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Methamphetamine, its salts, isomers, and salts of its isomers.

(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.

(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.

(5) Phenmetrazine and its salts.

(6) Methylphenidate.

(7) Khat, which includes all parts of the plant classified botanically as Catha Edulis, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

(8) Cathinone (also known as alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone).

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital.

(2) Pentobarbital.

(3) Phencyclidines, including the following:

(A) 1-(1-phenylcyclohexyl) piperidine (PCP).

(B) 1-(1-phenylcyclohexyl) morpholine (PCM).

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

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

(4) Secobarbital.

(5) Glutethimide.

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

(1) Immediate precursor to amphetamine and methamphetamine:

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

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine.

(B) 1-piperidinocyclohexane carbonitrile (PCC).

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

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

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

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

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

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

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

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital
or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

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

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital
or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.

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

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

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

(d) Nalorphine.

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

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

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

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

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

~~(5)~~ *(3)* Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

~~(6)~~ *(4)* Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(7)~~ *(5)* Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(8)~~ *(6)* Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

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

(1) Androisoxazole.

(2) Androstenediol.

(3) Bolandiol.

(4) Bolasterone.

(5) Boldenone.

(6) Chlormethandienone.

(7) Clostebol.

(8) Dihydromesterone.

(9) Ethylestrenol.

(10) Fluoxymesterone.

(11) Formyldienolone.

(12) 4-Hydroxy-19-nortestosterone.

(13) Mesterolone.

(14) Methandriol.

(15) Methandrostenolone.

(16) Methenolone.

(17) 17-Methyltestosterone.

(18) Methyltrienolone.

(19) Nandrolone.

(20) Norbolethone.

(21) Norethandrolone.

(22) Normethandrolone.

(23) Oxandrolone.

(24) Oxymestrone.

(25) Oxymetholone.

(26) Quinbolone.

(27) Stanolone.

(28) Stanozolol.

(29) Stenbolone.

(30) Testosterone.

(31) Trenbolone.

(32) Chorionic Gonadotropin (HGC).

(g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.

(h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

SEC. 2.5. Section 11056 of the Health and Safety Code is amended to read:

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

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

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

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

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

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

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital
or any salt thereof and one or more other active medicinal ingredients ~~which~~ *that* are not listed in any schedule.

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

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital
or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.

(3) Any substance ~~which~~ *that* contains any quantity of a derivative of barbituric acid or any salt thereof.

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

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

(d) Nalorphine.

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

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

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

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

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

~~(5)~~ *(3)* Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

~~(6)~~ *(4)* Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(7)~~ *(5)* Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(8)~~ *(6)* Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt

Anabolic Steroid Products" (Section 1308.34 of Title 21 of the Code of Federal Regulations), as exempt from the federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to, the following:

(1) Androisoxazole.

(2) Androstenediol.

(3) Bolandiol.

(4) Bolasterone.

(5) Boldenone.

(6) Chlormethandienone.

(7) Clostebol.

(8) Dihydromesterone.

(9) Ethylestrenol.

(10) Fluoxymesterone.

(11) Formyldienolone.

(12) 4-Hydroxy-19-nortestosterone.

(13) Mesterolone.

(14) Methandriol.

(15) Methandrostenolone.

(16) Methenolone.

(17) 17-Methyltestosterone.

(18) Methyltrienolone.

(19) Nandrolone.

(20) Norbolethone.

(21) Norethandrolone.

(22) Normethandrolone.

(23) Oxandrolone.

(24) Oxymestrone.

(25) Oxymetholone.

(26) Quinbolone.

(27) Stanolone.

(28) Stanozolol.

(29) Stenbolone.

(30) Testosterone.

(31) Trenbolone.

(32) *Human* ~~Chorionic Gonadotropin (HGC).~~ *clorionic gonadotropin (hCG), except when possessed by, sold to, purchased by, transferred to, or administered by a licensed veterinarian, or a licensed veterinarian's designated agent, exclusively for veterinary use.*

(g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.

(h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

SEC. 3. *Section 2.5 of this bill incorporates amendments to Section 11056 of the Health and Safety Code proposed by both this bill and Assembly Bill 2589. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2019, (2) each bill amends Section 11056 of the Health and Safety Code, and (3) this bill is enacted after Assembly Bill 2589, in which case Section 2 of this bill shall not become operative.*

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

Attachment 3
AB 2789

AB-2789 Health care practitioners: prescriptions: electronic data transmission. (2017-2018)

SECTION 1. *Section 688 is added to the Business and Professions Code, to read:*

688. *(a) On and after January 1, 2022, a health care practitioner authorized to issue a prescription pursuant to Section 4040 shall have the capability to issue an electronic data transmission prescription, as defined under Section 4040, on behalf of a patient and to transmit that electronic data transmission prescription to a pharmacy selected by the patient.*

(b) On and after January 1, 2022, a pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 shall have the capability to receive an electronic data transmission prescription on behalf of a patient.

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

(d) On and after January 1, 2022, a prescription prescribed by a health care practitioner shall be issued as an electronic data transmission prescription. This subdivision shall not apply to prescriptions issued pursuant to subdivision (e).

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

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

(2) An electronic data transmission prescription is not available due to a temporary technological or electrical failure. For purposes of this paragraph, "temporary technological or electrical failure" means failure of a computer system, application, or device, or the loss of electrical power to that system, application, or device, or any other service interruption affecting the certified electronic data transmission prescription application used to transmit the prescription.

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

(4) (A) The prescription is issued in a hospital emergency department or urgent care clinic and one or more of the following conditions are present:

(i) The patient resides outside California.

(ii) The patient resides outside the geographic area of the hospital.

(iii) The patient is homeless or indigent and does not have a preferred pharmacy.

(iv) The prescription is issued at a time when a patient's regular or preferred pharmacy is likely to be closed.

(B) Under any of the conditions described in subparagraph (A), a prescription shall be electronically issued but does not require electronic transmission and may be provided directly to the patient.

(5) The prescription is issued by a veterinarian.

(6) The prescription is for eyeglasses or contact lenses.

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

(8) The prescription is issued by a prescribing health care practitioner under circumstances whereby the practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by

an electronic data transmission prescription in a timely manner, and the delay would adversely impact the patient's medical condition.

(9) The prescription that is issued includes elements not covered by the latest version of the National Council for Prescription Drug Programs' SCRIPT standard, as amended from time to time.

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

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

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

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

(j) A health care practitioner, pharmacist, or pharmacy who fails to meet the applicable requirements of this section shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board. This section does not create a private right of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(k) This section shall not apply to a health care practitioner, pharmacist, or pharmacy when providing health care services to an inmate, individual on parole, or youth under the jurisdiction of the Department of Corrections and Rehabilitation.

Attachment 4
SB 1447

SB-1447 Pharmacy: automated drug delivery systems. (2017-2018)

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

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

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

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

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

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

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

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

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

(g) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 2. *Section 4008 is added to the Business and Professions Code, to read:*

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

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

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable

cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

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

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

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

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

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

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

(h) This section shall become operative on July 1, 2019.

SEC. 3. *Section 4017.3 is added to the Business and Professions Code, to read:*

4017.3. *(a) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.*

(b) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(d) This section shall become operative on July 1, 2019.

SEC. 4. Section 4105.5 of the Business and Professions Code is amended to read:

4105.5. (a) For purposes of this section, an "automated drug delivery system" has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.

(b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:

(1) Use of the automated drug delivery system is consistent with legal requirements.

(2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.

(4) The pharmacy license is unexpired and not subject to disciplinary conditions.

(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license under Section 1250.8 of the Health and Safety Code shall be exempt from the requirements of subdivision (b).

(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 5. Section 4119.1 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 6. Section 4186 of the Business and Professions Code is amended to read:

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

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

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

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

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

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

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

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

(i) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 7. *Section 4186 is added to the Business and Professions Code, to read:*

4186. *(a) Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.*

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

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

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

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

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

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(h) This section shall become operative on July 1, 2019.

SEC. 8. Section 4400 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

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

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

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

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

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

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

(z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars ($325) and may be increased to three hundred sixty dollars ($360).

(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250). The fee for the annual renewal of the license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250).

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

Article 25. Automated Drug Delivery System

4427. *As used in this article, "drugs" or "dangerous drugs" shall have the same meaning as "dangerous drug" as provided in Section 4022 and "devices" or "dangerous devices" shall have the same meaning as "dangerous device" as provided in Section 4022.*

4427.1. *An ADDS shall not be installed or operated in California unless it meets the requirements of this article.*

4427.2. *(a) An ADDS installed, leased, owned, or operated in California shall be licensed by the board.*

(b) An ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

(c) A separate application and license shall be required for each ADDS.

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

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

(2) The proposed location for installation of the ADDS meets the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

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

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

(e) Prior to issuance of the license, the board shall conduct a prelicensure inspection, within 30 days of a completed application for an ADDS license, at the proposed location of the ADDS. Relocation of the ADDS shall require a new application for licensure. Replacement of an ADDS shall require notification to the board within 30 days.

(f) The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license may be submitted to the board.

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

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

(i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in this article. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request.

(j) An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices.

4427.3. *(a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.*

(b) An ADDS shall be placed and operated in one of the following locations:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

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

(4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

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

4427.4. *(a) The ADDS shall be owned or leased by the pharmacy holding the license for the ADDS.*

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

(c) An ADDS shall be considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and shall be subject to inspection pursuant to Section 4008.

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

(e) (1) The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

(2) Access to the ADDS shall be controlled and tracked using an identification or password system or biosensor.

(3) The ADDS shall make a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system.

(f) If drugs or devices are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs and devices shall be stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3. Upon retrieval of these drugs and devices from secured storage, an inventory shall be taken to detect any losses or overages.

4427.5. *Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to subdivision (b) of Section 4427.3.*

4427.6. *In addition to any other requirements imposed by this article, an APDS shall additionally meet the following requirements:*

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

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

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

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

(4) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of Section 4427.3, regarding maintenance and filing procedures for the APDS.

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

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

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

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

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

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

(f) All prescribed drugs and devices dispensed to a patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(g) The APDS shall include a notice, prominently posted on the APDS, providing the name, address, and phone number of the pharmacy that holds the ADDS license for that APDS.

(h) The labels on all drugs and devices dispensed by the APDS shall comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

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

(j) An APDS may be located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice.

(k) The board shall not issue a pharmacy more than 15 ADDS licenses for APDS units. Consistent with Section 4001.1, the board, by regulation, may reduce the number of ADDS licenses a pharmacy may be issued for APDS units.

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

4427.7. *(a) A pharmacy holding an ADDS license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.*

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

4427.8. *(a) This article shall become operative on July 1, 2019.*

(b) On or before January 1, 2024, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5 of the Government Code, the board shall report to the appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following:

(1) The use and dispersion of ADDS throughout the health care system.

(2) The number of ADDS inspections conducted by the board each year and the findings from the inspections.

(3) Public safety concerns relating to the use of ADDS as identified by the board.

SEC. 10. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or ~~(k),~~ *(k)* of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

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

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

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

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

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

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

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

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

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

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 11. *Section 1261.6 is added to the Health and Safety Code, to read:*

1261.6. *(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.*

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

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

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

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

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug delivery system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system

to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

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

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

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

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

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

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become operative on July 1, 2019.

***SEC. 12.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

Attachment 4
AB 2037

AB-2037 Pharmacy: automated patient dispensing systems. (2017-2018)

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

4119.11. *(a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:*

(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.

(2) The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3) Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6) The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7) The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.

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

(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10) The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.

(11) A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.

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

(1) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(3) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) (1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

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

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient if all of the following requirements are met:

(1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.

(B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

(C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.

(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

(E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.

(F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system in the event the automated patient dispensing system is disabled or malfunctions.

(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).

(3) The automated patient dispensing system shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.

(4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.

(8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.

(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.

(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

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

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

(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) A pharmacy holding an automated patient dispensing system license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.

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

SEC. 3. *This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:*

(a) Approximately 115 communities in 47 California counties do not have a pharmacist within 10 miles, creating a barrier to necessary health care. Many of these communities are susceptible to wild fires, enhancing the need for immediate access to medications and to the advice and care of pharmacists.

(b) Rural and isolated communities desperately lack comprehensive pharmacy services. Automated dispensing, remotely performed by a pharmacist, brings a high level of pharmacy care and medication availability to these communities.

(c) Through the use of automated patient dispensing systems, pharmacists can immediately provide medication to underserved patients, and improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.

(d) In less-isolated communities, the pharmacist is on the front line of health care as the medical professional that the patient sees most often. It is necessary to bring that level of care to millions of people in the state.

(e) Therefore, in order to provide pharmacy services through the use of an automated patient dispensing system as soon as possible, it is necessary that this act take effect immediately.

Attachment 5
AB 1753

AB-1753 Controlled substances: CURES database. (2017-2018)

SECTION 1. *The Legislature finds and declares the following:*

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

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

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

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

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

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

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

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

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

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

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; all managing general partners, if any; and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms.

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

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

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

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the

department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (l) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

(D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints, and related information to the department.

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

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

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

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

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

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

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

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

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

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

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

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

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

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

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

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

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

(l) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

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

(4) A feature printed in thermochromic ink.

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

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

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

1–24

25–49

50–74

75–100

101–150

151 and over.

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

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

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

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

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(15) A uniquely serialized number, in a manner prescribed by the Department of Justice.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

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

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

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

(d) ~~This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.~~ *Within the next working day following delivery, a security printer shall submit via Web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:*

(1) Serial numbers of all prescription forms delivered.

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

(3) The delivery shipment recipient names.

(4) The date of delivery.

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

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

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

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

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

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

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

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

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

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

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

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

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

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

SEC. 4.5. Section 11165 of the Health and Safety Code is amended to read:

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

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

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

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

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

(3) The Department of Justice shall, no later than July 1, 2020, adopt regulations regarding the access and use of the information within CURES. The Department of Justice shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

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

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

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

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

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

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

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

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

(h) (1) The Department of Justice may enter into an agreement with any entity operating an interstate data sharing hub, or any agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the Department of Justice pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the Department of Justice for interstate data sharing of prescription drug monitoring program information.

(3) Any agreement entered into by the Department of Justice for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if he or she is registered and in good standing with that state's prescription drug monitoring program.

(5) The Department of Justice shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

SEC. 5. *Section 4.5 of this bill incorporates amendments to Section 11165 of the Health and Safety Code proposed by both this bill and Assembly Bill 1751. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2019, (2) each bill amends Section 11165 of the Health and Safety Code, and (3) this bill is enacted after Assembly Bill 1751, in which case Section 4 of this bill shall not become operative.*

Attachment 6
AB 2138

AB-2138 Licensing boards: denial of application: revocation or suspension of licensure: criminal conviction. (2017-2018)

SECTION 1. Section 7.5 of the Business and Professions Code is amended to read:

7.5. *(a)* A conviction within the meaning of this code means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code. However, a board may not deny a license to an applicant who is otherwise qualified pursuant to subdivision (b) of Section 480.

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

(b) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 2. *Section 7.5 is added to the Business and Professions Code, to read:*

7.5. *(a) A conviction within the meaning of this code means a judgment following a plea or verdict of guilty or a plea of nolo contendere or finding of guilt. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence. However, a board may not deny a license to an applicant who is otherwise qualified pursuant to subdivision (b) or (c) of Section 480.*

(b) (1) Nothing in this section shall apply to the licensure of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3.

(2) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(A) The State Athletic Commission.

(B) The Bureau for Private Postsecondary Education.

(C) The California Horse Racing Board.

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

(d) This section shall become operative on July 1, 2020.

SEC. 3. Section 480 of the Business and Professions Code is amended to read:

480. (a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

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

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

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

(B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that he or she has been convicted of a misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation developed by the board to evaluate the rehabilitation of a person when considering the denial of a license under subdivision (a) of Section 482.

(c) Notwithstanding any other provisions of this code, a person shall not be denied a license solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.

(d) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.

(e) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 4. *Section 480 is added to the Business and Professions Code, to read:*

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

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.

(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

(i) Chapter 1 (commencing with Section 5000) of Division 3.

(ii) Chapter 6 (commencing with Section 6500) of Division 3.

(iii) Chapter 9 (commencing with Section 7000) of Division 3.

(iv) Chapter 11.3 (commencing with Section 7512) of Division 3.

(v) Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.

(vi) Division 4 (commencing with Section 10000).

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that he or she has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 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 Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

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

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny 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 it been disclosed.

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

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

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

(A) The denial or disqualification of licensure.

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

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

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

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

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

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

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

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

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

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

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

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

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

***SEC. 5.** Section 480.2 is added to the Business and Professions Code, to read:*

***480.2.** (a) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license regulated by it on the grounds that the applicant has one of the following:*

(1) Been convicted of a crime.

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

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

(B) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that he or she has been convicted of a misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation developed by the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board to evaluate the rehabilitation of a person when considering the denial of a license under paragraph (1) of subdivision (f).

(c) Notwithstanding any other provisions of this code, a person shall not be denied a license by the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.

(d) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license regulated by it on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.

(e) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall develop criteria to aid it, when considering the denial, suspension or revocation of a license, to determine whether a crime or act is substantially related to the qualifications, functions, or duties of the business or profession it regulates.

(f) (1) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall develop criteria to evaluate the rehabilitation of a person either when:

(A) Considering the denial of a license under this section.

(B) Considering suspension or revocation of a license under Section 490.

(2) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall take into account all competent evidence of rehabilitation furnished by the applicant or licensee.

(g) Except as otherwise provided by law, following a hearing requested by an applicant pursuant to subdivision (b) of Section 485, the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may take any of the following actions:

(1) Grant the license effective upon completion of all licensing requirements by the applicant.

(2) Grant the license effective upon completion of all licensing requirements by the applicant, immediately revoke the license, stay the revocation, and impose probationary conditions on the license, which may include suspension.

(3) Deny the license.

(4) Take other action in relation to denying or granting the license as the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board, in its discretion, may deem proper.

(h) Notwithstanding any other law, in a proceeding conducted by the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the ground that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, and the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, and duties of the licensee in question.

(i) Notwithstanding Section 7.5, a conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action that the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4, 1203.4a, or 1203.41 of the Penal Code.

(j) This section shall become operative on July 1, 2020.

SEC. 6. Section 481 of the Business and Professions Code is amended to read:

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

(b) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 7. *Section 481 is added to the Business and Professions Code, to read:*

481. *(a) Each board under this code shall 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 it regulates.*

(b) Criteria for determining whether a crime is substantially related to the qualifications, functions, or duties of the business or profession a board regulates shall include all of the following:

(1) The nature and gravity of the offense.

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

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

(c) A board shall not deny a license based in whole or in part on a conviction without considering evidence of rehabilitation submitted by an applicant pursuant to any process established in the practice act or regulations of the particular board and as directed by Section 482.

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

(e) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(f) This section shall become operative on July 1, 2020.

SEC. 8. Section 482 of the Business and Professions Code is amended to read:

482. *(a)* Each board under the provisions of this code shall develop criteria to evaluate the rehabilitation of a person when:

~~(a)~~ *(1)* Considering the denial of a license by the board under Section 480; or

~~(b)~~ *(2)* Considering suspension or revocation of a license under Section 490.

(b) Each board shall take into account all competent evidence of rehabilitation furnished by the applicant or licensee.

(c) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 9. *Section 482 is added to the Business and Professions Code, to read:*

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

(1) Considering the denial of a license by the board under Section 480.

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

(b) Each board shall consider whether an applicant or licensee has made a showing of rehabilitation if either of the following are met:

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

(2) The board, applying its criteria for rehabilitation, finds that the applicant is rehabilitated.

(c) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(d) This section shall become operative on July 1, 2020.

SEC. 10. Section 488 of the Business and Professions Code is amended to read:

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

~~(a)~~ *(1)* Grant the license effective upon completion of all licensing requirements by the applicant.

~~(b)~~ *(2)* Grant the license effective upon completion of all licensing requirements by the applicant, immediately revoke the license, stay the revocation, and impose probationary conditions on the license, which may include suspension.

~~(c)~~ *(3)* Deny the license.

~~(d)~~ *(4)* Take other action in relation to denying or granting the license as the board in its discretion may deem proper.

(b) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 11. *Section 488 is added to the Business and Professions Code, to read:*

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

(1) Grant the license effective upon completion of all licensing requirements by the applicant.

(2) Grant the license effective upon completion of all licensing requirements by the applicant, immediately revoke the license, stay the revocation, and impose probationary conditions on the license, which may include suspension.

(3) Deny the license.

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

(b) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(c) This section shall become operative on July 1, 2020.

SEC. 12. Section 493 of the Business and Professions Code is amended to read:

493. *(a)* Notwithstanding any other provision of law, in a proceeding conducted by a board within the department pursuant to law to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the ground that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, and the board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, and duties of the licensee in question.

(b) As used in this section, "license" includes "certificate," "permit," "authority," and "registration."

(c) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 13. *Section 493 is added to the Business and Professions Code, to read:*

493. *(a) Notwithstanding any other law, in a proceeding conducted by a board within the department pursuant to law to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the ground that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact.*

(b) (1) Criteria for determining whether a crime is substantially related to the qualifications, functions, or duties of the business or profession the board regulates shall include all of the following:

(A) The nature and gravity of the offense.

(B) The number of years elapsed since the date of the offense.

(C) The nature and duties of the profession.

(2) A board shall not categorically bar an applicant based solely on the type of conviction without considering evidence of rehabilitation.

(c) As used in this section, "license" includes "certificate," "permit," "authority," and "registration."

(d) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(e) This section shall become operative on July 1, 2020.

SEC. 14. Section 11345.2 of the Business and Professions Code is amended to read:

11345.2. (a) An individual shall not act as a controlling person for a registrant if any of the following apply:

(1) The individual has entered a plea of guilty or no contest to, or been convicted of, a felony. Notwithstanding subdivision (c) of Section 480, if the individual's felony conviction has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code, the bureau may allow the individual to act as a controlling person.

(2) The individual has had a license or certificate to act as an appraiser or to engage in activities related to the transfer of real property refused, denied, canceled, or revoked in this state or any other state.

(b) Any individual who acts as a controlling person of an appraisal management company and who enters a plea of guilty or no contest to, or is convicted of, a felony, or who has a license or certificate as an appraiser refused, denied, canceled, or revoked in any other state shall report that fact or cause that fact to be reported to the office, in writing, within 10 days of the date he or she has knowledge of that fact.

(c) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 15. *Section 11345.2 is added to the Business and Professions Code, to read:*

11345.2. *(a) An individual shall not act as a controlling person for a registrant if any of the following apply:*

(1) The individual has entered a plea of guilty or no contest to, or been convicted of, a felony. If the individual's felony conviction has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code, the bureau may allow the individual to act as a controlling person.

(2) The individual has had a license or certificate to act as an appraiser or to engage in activities related to the transfer of real property refused, denied, canceled, or revoked in this state or any other state.

(b) Any individual who acts as a controlling person of an appraisal management company and who enters a plea of guilty or no contest to, or is convicted of, a felony, or who has a license or certificate as an appraiser refused, denied, canceled, or revoked in any other state shall report that fact or cause that fact to be reported to the office, in writing, within 10 days of the date he or she has knowledge of that fact.

(c) This section shall become operative on July 1, 2020.

Attachment 7
AB 2859

AB-2859 Pharmacy: safe storage products. (2017-2018)

SECTION 1. *This act shall be known, and may be cited, as the Protecting Our Children and Adolescents from Opioids Act of 2018.*

SEC. 2. *(a) The Legislature finds and declares all of the following:*

(1) Drug overdoses are now the leading cause of death by injury in the United States, outnumbering both traffic crashes and gun-related deaths.

(2) In 2015, there were 52,404 drug overdose deaths, with 33,091 of those deaths involving the use of opioids.

(3) Every day, 3,000 children 12 to 17 years of age abuse a prescription painkiller for the first time.

(4) The federal Centers for Disease Control and Prevention estimates that the nonmedical use of prescription painkillers costs public and private health insurers $72.8 billion annually.

(5) The National Institute on Drug Abuse has found 90 percent of all teens who abuse pharmaceutical drugs obtain their drugs from their home medicine cabinet or from a friend's medicine cabinet.

(6) Researchers at the Johns Hopkins Bloomberg School of Public Health found that nearly 70 percent of prescription opioid medications kept in homes with children are not stored safely.

(7) Only 18 percent of providers have been estimated to discuss safe storage and disposal of drugs with their patients.

(8) The Partnership for Drug-Free Kids has found that one of the key drivers for abusing prescription painkillers amongst teens is easy access, with more than 3 in 5 teens stating that pain relievers were easy to obtain from their parents' medicine cabinets.

(9) New reports have found that the number of emergency room visits for accidental poisoning amongst toddlers has tripled since 1997.

(b) It is the intent of the Legislature that increasing safe storage practices among parents is an important component to protecting teens and children from the dangers of opioid abuse and that the state must do more to encourage parents to safeguard these medications that are vital to managing certain chronic pain conditions among adults.

SEC. 3. *Section 4106.5 is added to the Business and Professions Code, to read:*

4106.5. *(a) For purposes of this section, the following terms shall have the following meanings:*

(1) "Pharmacy" does not include a pharmacy that meets both of the following requirements:

(A) It is owned and operated by a person or persons in which the majority of the beneficial interest, as well as management and control, resides with at least one board-licensed pharmacist, as that term is defined in Section 4036, that exclusively oversees the operations of the pharmacy.

(B) The owner and operator with the beneficial interest, management, and control described in subparagraph (A) owns, operates, and has management and control of no more than four pharmacies.

(2) "Safe storage products" means a device or product made with the purpose of storing prescription medications that includes a locking mechanism that is accessible only by the designated patient with a passcode, alphanumeric code, key, or by another secure mechanism. A safe storage product includes, but is not limited to, medicine lock boxes, locking medicine cabinets, locking medication bags, and prescription locking vials.

(3) "Schedule II, III, or IV controlled substances" means any substance defined as a Schedule II, III, or IV controlled substance in Sections 11055, 11056, and 11057 of the Health and Safety Code.

(b) A pharmacy that dispenses Schedule II, III, or IV controlled substances shall display safe storage products in a place on the building premises that is located close to the pharmacy.

(c) (1) The board shall assess a fine in an amount to be determined by the board for a violation of this section.

(2) Notwithstanding paragraph (1), the board may choose not to take administrative action against a pharmacy if it determines that compliance with this section would create a financial hardship on the pharmacy or that the pharmacy is temporarily out of stock of safe storage products.

(d) Section 4321 shall not apply to a violation of this section.

(e) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

Attachment 8
SB 212

SB-212 Solid waste: pharmaceutical and sharps waste stewardship. (2017-2018)

SECTION 1. *Chapter 2 (commencing with Section 42030) is added to Part 3 of Division 30 of the Public Resources Code, to read:*

CHAPTER 2. Pharmaceutical and Sharps Waste Stewardship
Article 1. Definitions
42030. *For purposes of this chapter, the following terms have the following meanings:*

(a) "Authorized collection site" means a location where an authorized collector operates a secure collection receptacle for collecting covered products.

(b) "Authorized collector" means a person or entity that has entered into an agreement with a program operator to collect covered drugs, including, but not limited to, any of the following:

(1) A person or entity that is registered with the United States Drug Enforcement Administration and that qualifies under federal law to modify that registration to collect controlled substances for the purpose of destruction.

(2) A law enforcement agency.

(3) A retail pharmacy that offers drug take-back services in compliance with Article 9.1 (commencing with Section 1776) of Title 16 of the California Code of Regulations.

(c) "Controlled substance" means a substance listed under Sections 11053 to 11058, inclusive, of the Health and Safety Code or Section 812 or 813 of Title 21 of the United States Code, or any successor section.

(d) "Cosmetic" means an article, or a component of an article, intended to be rubbed, poured, sprinkled, sprayed, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. "Cosmetic" includes articles with or without expiration dates.

(e) (1) "Covered drug" means a drug, including a brand name or generic drug, sold, offered for sale, or dispensed in the State of California in any form, including, but not limited to, any of the following:

(A) Prescription and nonprescription drugs approved by the United States Food and Drug Administration pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or Section 351 of the federal Public Health Service Act (42 U.S.C. 262).

(B) A drug marketed pursuant to an over-the-counter drug monograph.

(C) A drug in a medical device, or a combination product containing a drug and a medical device.

(2) "Covered drug" does not include any of the following:

(A) Vitamins or supplements.

(B) Herbal-based remedies and homeopathic drugs, products, or remedies.

(C) Cosmetics, soap, with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or any other personal care product that is regulated as both a cosmetic and a nonprescription drug under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(D) A drug for which a pharmaceutical product stewardship program or drug takeback program is provided in the state as part of a United States Food and Drug Administration managed risk evaluation and mitigation strategy under 21 U.S.C. Sec. 355-1.

(E) Biological drug products, as defined by 42 U.S.C. 262(i)(1), including those products currently approved in the state under a new drug application that will be deemed to be licensed under section 351 of the Public Health

Service Act (42 U.S.C. 262) pursuant to Section 7002(e) of the federal Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148).

(F) A medical device, or a component part or accessory of a medical device, if it does not contain a covered drug.

(G) Drugs that are used for animal medicines, including, but not limited to, parasiticide products for animals.

(H) Dialysate drugs or other saline solutions required to perform kidney dialysis.

(f) (1) (A) "Covered entity" means the manufacturer of covered products that are sold in or into the state.

(B) If no entity that meets the definition in subparagraph (A) is in the state, "covered entity" means the distributor of covered products that are sold in or into the state that is licensed as a wholesaler, as defined in Section 4043 of the Business and Professions Code, but does not include a warehouse of a retail pharmacy chain that is licensed as a wholesaler if it engages only in intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

(C) If no entity that meets the definition in subparagraph (A) or (B) is in the state, "covered entity" means a repackager, as defined in Section 4044 of the Business and Professions Code, of covered products that are sold in or into the state.

(D) If no entity that meets the definition in subparagraph (A), (B), or (C) is in the state, "covered entity" means the owner or licensee of a trademark or brand under which covered products are sold in or into the state, regardless of whether the trademark is registered.

(E) If no entity that meets the definition in subparagraph (A), (B), (C), or (D) is in the state, "covered entity" means the importer of the covered products that are sold in or into the state.

(2) The department shall adopt regulations on the process for determining what entity is a covered entity following the priority order set forth in paragraph (1).

(g) "Covered product" means a covered drug or home-generated sharps waste.

(h) "Department" means the Department of Resources Recycling and Recovery, and any successor agency.

(i) "Distributor" means a wholesaler, as that term is defined in Section 4043 of the Business and Professions Code.

(j) "Drug" means any of the following:

(1) An article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) A substance, other than food, intended to affect the structure or any function of the body of humans or other animals.

(4) A substance intended for use as a component of any substance specified in this subdivision.

(k) "Generic drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strengths, route of administration, quality, performance, characteristics, and intended use, though inactive ingredients may vary.

(l) (1) "Home-generated sharps waste" has the same meaning as defined in Section 117671 of the Health and Safety Code.

(2) "Home-generated sharps waste" does not include either of the following:

(A) Components manufactured for use with external ambulatory insulin pump therapy systems or continuous glucose monitoring systems, including, but not limited to, insulin infusion sets, glucose sensors that are sterile goods indicated for single subcutaneous use, sterile drug delivery channels indicated for single subcutaneous use, and injection ports.

(B) A biological product, as defined in Section 262(i)(1) of Title 42 of the United States Code, including a combination product, as defined in Section 3.2(e) of Title 21 of the Code of Federal Regulations.

(m) "Mail-back program" means a method of collecting covered products from ultimate users by using prepaid, preaddressed mailing envelopes as described in Section 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations.

(n) "Nonprescription drug" means any drug that may be lawfully sold without a prescription.

(o) "Pharmacy" has the same meaning as defined in Section 4037 of the Business and Professions Code.

(p) "Prescription drug" means a drug, including, but not limited to, a controlled substance, that is required under federal or state law to be dispensed with a prescription, or is restricted to use by practitioners only.

(q) "Program operator" means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program in accordance with this chapter.

(r) "Proprietary information" means information that is all of the following:

(1) Submitted pursuant to this chapter.

(2) A trade secret, or commercial or financial information, that is privileged or confidential, and is identified as such by the entity providing the information to the department.

(3) Not required to be disclosed under any other law or any regulation affecting a covered product or covered entity.

(s) "Retail pharmacy" means an independent pharmacy, a supermarket pharmacy, a chain pharmacy, or a mass merchandiser pharmacy possessing a license from the state board to operate a pharmacy.

(t) "Retail pharmacy chain" means a retail pharmacy with five or more stores in the state.

(u) "Sharps" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.

(v) "State board" means the California State Board of Pharmacy.

(w) "Stewardship organization" means an organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3)) that is established by a group of covered entities in accordance with this chapter to develop, implement, and administer a stewardship program established pursuant to this chapter.

(x) "Stewardship plan," or "plan" means the plan for collecting and properly managing covered products that is developed by a covered entity or stewardship organization pursuant to this chapter.

(y) "Stewardship program" means a stewardship program for the collection, transportation, and disposal of covered products.

(z) "Ultimate user" means a state resident or other nonbusiness entity and includes a person who has lawfully obtained, and who possesses, a covered product, including a controlled substance, for his or her own use or for the use of a member of his or her household. "Ultimate user" does not include a needle exchange program established under Section 121349 of the Health and Safety Code, or a medical waste generator, as defined in Section 117705 of the Health and Safety Code.

Article 2. Covered Entities and Stewardship Organizations

42031. *(a) (1) No later than 90 days after the effective date of this section, a covered entity shall provide a list of covered products, and a list and description of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the state board.*

(2) A covered entity, or a stewardship organization on behalf of a group of covered entities, shall update the lists described in paragraph (1) and provide the updated lists to the state board on or before January 15 of each year or upon request of the department.

(b) No later than 90 days after the effective date of this section, a retail pharmacy that sells a covered product under its own label shall provide written notification to the state board identifying the covered entity from which the retail pharmacy obtains a covered product that the retail pharmacy sells under its store label.

(c) The state board shall verify the information received pursuant to subdivisions (a) and (b) and make it available to the department upon request.

(d) The state board may issue a letter of inquiry to any entity listed in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (f) of Section 42030. requesting a list of all drugs and sharps it distributes in California, regardless of whether the drugs or sharps are covered under this chapter, the name of the manufacturer of such products, and any additional information necessary to carry out this chapter. An entity that is issued a letter of inquiry pursuant to this subdivision shall respond in writing no later than 60 days after receipt of the letter. Responses to those inquiries may be shared with the department, but are otherwise deemed proprietary and exempt from disclosure. If the entity does not believe it is a covered entity for purposes of this chapter, it shall submit all of the following to the state board in response to the letter of inquiry:

(1) The basis for the claim that it is not a covered entity.

(2) A list of any drugs and sharps it sells, distributes, repackages, or otherwise offers for sale within the state.

(3) If applicable, the name and contact information of the person or entity from which it obtains a drug or sharp identified pursuant to paragraph (2).

(e) The state board shall obtain and verify and, within 30 days of receipt or upon request by the department, submit to the department a list of drugs and sharps sold or offered for sale in the state excluded from the definition of "covered drugs" pursuant to paragraph (2) of subdivision (e) of Section 42030 or excluded from the definition of "home-generated sharps waste" in subdivision (l) of Section 42030.

(f) Notwithstanding Section 42036.4, information submitted by the state board to the department under this chapter may include proprietary information.

(g) The state board shall notify the department if any covered entity or stewardship organization is in violation of this section for purposes of enforcement by the department.

42031.2. *(a) The department shall adopt regulations for the implementation of this chapter with an effective date of no later than January 1, 2021.*

(b) The state board may adopt regulations for the administration of the portions of this chapter for which it has been given responsibilities.

42031.4. *(a) Except as specified in subdivision (d) of Section 42035, a covered entity is not in compliance with this chapter and is subject to penalties pursuant to Article 6 (commencing with Section 42035) if, commencing one year from the adoption of regulations pursuant to Section 42031.2, a covered product sold or offered for sale by the covered entity is not subject to an approved stewardship plan, which is submitted by the covered entity or by a stewardship organization that includes the covered entity, that has been approved by the department pursuant to Section 42032.*

(b) In order to comply with the requirements of this chapter, a covered entity may establish and implement a stewardship program independently, or as part of a group of covered entities through membership in a stewardship organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3)).

42031.6. *(a) A program operator shall conduct a comprehensive education and outreach program intended to promote participation in the stewardship program. At a minimum, the education and outreach program shall do all of the following:*

(1) Promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary.

(2) Provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.

(3) Establish an Internet Web site that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program.

(4) Prepare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs and home-generated sharps waste.

(5) Encourage ultimate users to separate products that are not covered products from covered products, when appropriate, before submitting the covered products to an authorized collection site or mail-back program.

(b) A program operator shall not, as part of the education and outreach program, promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program.

Article 3. Stewardship Plans

42032. *(a) (1) Within six months of the adoption date of regulations by the department pursuant to Section 42031.2, a program operator shall submit to the department for approval a complete stewardship plan that meets the requirements of Section 42032.2 for the establishment and implementation of a stewardship program, in a format determined by the department.*

(2) The department shall approve a proposed stewardship program if the program operator submits a completed plan that meets the requirements of this section.

(b) (1) Before submitting a stewardship plan to the department pursuant to this section, a program operator shall submit its proposed stewardship plan to the state board for review, and to any other applicable state agencies with areas of authority relative to the stewardship plan. The duration of time that the state board takes to review a stewardship plan pursuant to this paragraph shall not count toward the time limit specified in paragraph (1) of subdivision (a).

(2) An agency that receives a plan shall review the plan for compliance with state and federal laws and regulations related to the agency's respective authority. The agency shall determine compliance or noncompliance with those laws and regulations, and provide to the program operator that determination and an explanation for any finding of noncompliance, within 90 days of receipt of the plan.

(3) A program operator may submit an updated proposed plan to an agency that issued a determination of noncompliance to attempt to obtain a determination of compliance. A program operator shall submit any determination received from an agency when it submits its stewardship plan to the department.

(4) If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations.

(c) (1) The department shall determine if a stewardship plan is complete, including the determinations required pursuant to subdivision (b), and notify the submitting program operator within 30 days of receipt.

(2) If the department finds that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan set forth in subdivision (d) shall commence upon the original date of receipt.

(3) If the department determines the stewardship plan is incomplete, the department shall identify for the program operator the required additional information, and the program operator shall resubmit the plan within 30 days.

(4) If the department determines upon resubmission that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan shall commence upon the date of receipt of the resubmitted plan.

(d) (1) The department shall review a complete submitted stewardship plan and shall approve, disapprove, or conditionally approve the plan within 90 days of receipt of the complete plan.

(2) The department may consult with, or submit a stewardship plan for review to, the state board or another state agency it determines is necessary to determine the completeness of the stewardship plan or for making a determination on the approval of the stewardship plan or an amendment to the stewardship plan. The duration of time that the department takes to review a stewardship plan pursuant to this paragraph shall not count toward the 90-day time limit specified in paragraph (1).

(e) A program operator shall submit any significant changes to a stewardship plan in writing for approval by the department, and shall not implement the changes prior to that approval.

(f) (1) If the department disapproves a submitted stewardship plan pursuant to subdivision (d), the department shall explain, in writing within 30 days, how the plan does not comply with this chapter, and the program operator shall resubmit a revised plan to the department.

(2) If the department finds that the revised stewardship plan submitted by the program operator does not comply with the requirements of this chapter and disapproves the plan, the covered entity operating its own stewardship program, or the stewardship organization and the covered entities that are members of the stewardship organization, are not in compliance with this chapter until the program operator submits a plan that the department approves.

(g) A program operator shall fully implement operation of an approved stewardship program no later than 270 days after approval by the department of the stewardship plan that establishes the stewardship program.

(h) If a stewardship plan is revoked pursuant to subdivision (a) of Section 42035.4 or terminated by the program operator that submitted the plan, a covered entity no longer subject to that plan may, without being subject to penalties pursuant to Article 6 (commencing with Section 42035), sell or offer for sale covered products in the state for a period of up to one year after the plan terminated or was revoked if the covered entity continues to operate under the most recent approved stewardship plan to which the covered entity was subject.

(i) The department shall make all stewardship plans submitted pursuant to this section available to the public, except proprietary information in the plans protected pursuant to Section 42036.4.

***42032.2.** (a) (1) To be complete, a stewardship plan for covered drugs shall do all of the following:*

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered drug sold or offered for sale by each participating covered entity.

(B) Identify and provide contact information for the authorized collectors for the stewardship program, as well as the reasons for excluding any potential authorized collectors from participation in the program.

(C) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(D) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(E) Provide for a handling, transport, and disposal system that complies with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

(F) Provide for a collection system that complies with the requirements of this chapter and meets all of the following requirements for authorized collection sites in each county in which the plan will be implemented:

(i) Provides for a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater.

(ii) Provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread.

(iii) Provides for a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.

(G) Require a program operator to do all of the following:

(i) Permit an ultimate user who is a homeless, homebound, or disabled individual to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (2) of subdivision (c), that would render the covered drug inert. A program operator shall accept that request through an Internet Web site and toll-free telephone number that it shall maintain to comply with the requests.

(ii) Provide alternative methods of collection from ultimate users for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program, to the extent technically feasible and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(iii) (I) Provide a service schedule that meets the needs of each authorized collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner. Additionally, a receipt or collection manifest shall be left with the authorized collection site to support verification of the service. The authorized collection site shall maintain and make available to the department this documentation.

(II) An authorized collector shall comply with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations.

(H) Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug, describe how and where records will be maintained and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and to improve safety and security.

(2) Paragraph (1) shall apply only with regard to covered drugs.

(b) (1) At least 120 days before submitting a stewardship plan to the department, the operator of a stewardship program for covered drugs shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. If a potential authorized collector expresses interest in participating in a stewardship program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days.

(2) A retail pharmacy shall make a reasonable effort to serve as an authorized collector as part of a stewardship program in the county in which it is located. If the minimum threshold described in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in a stewardship program.

(3) A program operator shall include as an authorized collector under its stewardship program any entity listed in subdivision (b) of Section 42030 that offers to participate in the stewardship program, in writing and without compensation, even if the minimum convenience standards set in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) have been achieved. The program operator shall include the offering entity as an authorized collector in the program within 90 days of receiving the written offer to participate. A program operator shall not be required to respond to offers pursuant to this paragraph until the program operator's stewardship plan has been approved by the department.

(c) After a stewardship plan for covered drugs has been approved, the program operator may supplement service, if approved by the department, for a county in which it operates that does not have the minimum number of authorized collection sites due to circumstances beyond the program operator's control, by establishing one or both of the following:

(1) A mail-back program. The mail-back program may include providing information on where and how to receive mail-back materials or providing the locations at which it distributes prepaid, preaddressed mailing envelopes. The program operator shall propose the locations of those envelope distribution locations as part of the stewardship plan. Prepaid mailing envelopes may be mailed to an ultimate user upon request.

(2) An alternative form of collection and disposal of covered drugs that complies with applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(d) (1) To be complete, a stewardship plan for home-generated sharps waste shall do all of the following:

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered product sold or offered for sale by each participating covered entity.

(B) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(C) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(D) Provide for a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable state and federal laws.

(E) Maintain an Internet Web site and toll-free telephone number for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users.

(F) Provide that a stewardship program for home-generated sharps waste shall be a mail-back program for home-generated sharps waste that complies with this chapter and that meets all the following requirements:

(i) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period.

(I) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include information on proper sharps waste disposal.

(II) All sharps waste containers shall include on a label affixed to the container or packaging, or on a separate insert included in the container or packaging, the program operator's Internet Web site and toll-free telephone number.

(III) All sharps waste containers shall include prepaid postage affixed to the container or to the mail-back packaging.

(ii) Upon request, the program provides for reimbursement to local agencies for disposal costs related to home-generated sharps waste, unless the program operator provides for the removal of the home-generated sharps waste from the local household hazardous waste facility.

(I) A local agency shall not knowingly request reimbursement for disposal expenses pursuant to this subparagraph for disposal costs resulting from a municipal needle exchange program or a medical waste generator.

(II) Reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.

(III) A request for reimbursement pursuant to this clause shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.

(IV) A cost is eligible for reimbursement pursuant to this clause if the cost is incurred 270 days or more after the approval of a stewardship plan for home-generated sharps waste.

(2) Paragraph (1) shall apply only with regard to home-generated sharps waste.

(e) A stewardship plan shall include provisions to expand into jurisdictions not included in the stewardship plan pursuant to Section 42036.2, in the event a jurisdiction repeals its local stewardship program ordinance.

(f) A stewardship plan shall include educational and outreach provisions to meet the requirements of Section 42031.6.

Article 4. Reports, Budgets, and Records

42033. *With the submission of a stewardship plan, a program operator shall submit to the department an initial stewardship program budget for the first five calendar years of operation of its stewardship program that includes both of the following:*

(a) Total anticipated revenues and costs of implementing the stewardship program.

(b) A total recommended funding level sufficient to cover the plan's budgeted costs and to operate the stewardship program over a multiyear period.

42033.2. *(a) On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the department both of the following:*

(1) A written report describing the stewardship program activities during the previous reporting period of one year.

(2) A written program budget for stewardship program implementation for the upcoming calendar year.

(b) An annual report submitted pursuant to paragraph (1) of subdivision (a) shall include, at a minimum, all of the following for the prior year:

(1) A list of covered entities participating in the stewardship organization.

(2) The updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.

(3) The amount, by weight, of covered products collected from ultimate users at each authorized collection site that is part of the stewardship program.

(4) For a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected.

(5) For a stewardship plan for home-generated sharps waste, information on the mail-back program.

(6) Whether policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan, were followed during the reporting period and a description of each instance of noncompliance, if any occurred.

(7) Whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.

(8) How the program operator complied with all elements in its stewardship plan.

(9) Any other information the department reasonably requires.

(c) An annual program budget submitted pursuant to paragraph (2) of subdivision (a) shall include, at a minimum, both of the following for the upcoming calendar year:

(1) An independent financial audit of the stewardship program, as required by subdivision (b) of Section 42033.4, funded by the stewardship organization from the charge paid from its member covered entities pursuant to Section 42034 or by a covered entity if it operates its own stewardship program.

(2) Anticipated costs and the recommended funding level necessary to implement the stewardship program, including, but not limited to, costs to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multiyear period in a prudent and responsible manner.

(d) (1) The department shall determine if a submitted annual report and program budget are complete and notify the submitting stewardship organization or covered entity within 30 days.

(2) If the department finds that an annual report and program budget are complete, the department's 90-day review period for consideration of approval of the annual report and program budget, set forth in subdivision (e), shall commence upon the original date of receipt.

(3) If the department determines either an annual report or a program budget is incomplete, the department shall identify for the program operator within 30 days the required additional information, and the program operator shall submit a revised annual report or program budget, as applicable, within 30 days.

(4) If the department determines upon resubmission that the annual report or program budget is complete, the department's 90-day review period for consideration of approval of the annual report or program budget shall commence upon the date of receipt of the resubmitted report or program budget.

(e) (1) The department shall review the annual report and program budget required pursuant to this section and within 90 days of receipt shall approve, disapprove, or conditionally approve the annual report and program budget.

(2) (A) If the department conditionally approves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall comply with the conditions of the conditional approval within 60 days of the notice date, unless the Director of Resources Recycling and Recovery determines that additional time is needed.

(B) If the department conditionally approves an annual report or program budget and the conditions are not met within 60 days of the notice date, unless additional time is granted pursuant to subparagraph (A), the department shall disapprove the annual report or program budget.

(3) If the department disapproves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall submit a revised annual report or program budget and provide any supplemental information requested within 60 days of the notice date.

42033.4. *(a) A program operator shall keep minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship program.*

(b) (1) The minutes, books, and records of a program operator shall be audited at the program operator's expense by an independent certified public accountant retained by the program operator at least once each calendar year.

(2) A program operator shall arrange for the independent certified public accountant audit to be delivered to the department, along with the annual report and program budget submitted pursuant to subdivision (a) of Section 42033.2.

(3) The department may conduct its own audit of a program operator. The department shall review the independent certified public accountant audit for compliance with this chapter and consistency with the program operator's stewardship plan, annual report, and program budget submitted pursuant to this chapter. The department shall notify the program operator of any conduct or practice that does not comply with this chapter or of any inconsistencies identified in the department's audit. The program operator may obtain copies of the department's audit, including proprietary information contained in the department's audit, upon request. The department shall not disclose any confidential proprietary information protected pursuant to Section 42036.4 that is included in the department's audit.

42033.5. *For a local jurisdiction that requests removal of home-generated sharps waste or cost recovery or reimbursement for removal pursuant to Section 42032.2, the local jurisdiction shall provide information on home-generated sharps waste to the covered entity or program operator, within a reasonable time upon request by the covered entity or program operator.*

42033.6. *As part of the administration of this chapter, within 12 months of a program operator's submission of three consecutive complete annual reports submitted pursuant to Section 42033.2, the department shall develop, and post on its Internet Web site, a report analyzing whether the program operator's stewardship program provides adequate access to safe disposal of home-generated sharps waste or covered drugs, as applicable, to the ultimate user.*

Article 5. Financial Provisions

42034. *In order to further the objective that covered entities establish and implement stewardship programs that comply with the requirements of this chapter, each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.*

42034.2. *(a) (1) On or before the end of the 2022–23 fiscal year, and once every three months thereafter, a program operator shall pay to the department an administrative fee. The department shall set the fee at an amount that, when paid by every covered entity, is adequate to cover the department's and any other state agency's full costs of administering and enforcing this chapter. The total amount of fees collected shall not exceed the state's actual and reasonable regulatory costs to implement and enforce this chapter. These costs may include the actual and reasonable costs associated with regulatory activities pursuant to this chapter before submission of stewardship plans pursuant to Section 42032.*

(2) For a stewardship organization, the administrative fee paid pursuant to paragraph (1) shall be funded by the covered entities that make up the stewardship organization. This administrative fee shall be in addition to the charge paid pursuant to Section 42034. A stewardship organization may require its participating covered entities to pay the administrative fee and the charge paid pursuant to Section 42034 at the same time.

(b) The department shall deposit administrative fees paid by a program operator pursuant to subdivision (a) into the Pharmaceutical and Sharps Stewardship Fund, which is hereby established. Upon appropriation by the Legislature, moneys in the fund may be expended by the department, the state board, and any other agency that assists in the regulatory activities of administering and enforcing this chapter. Upon appropriation by the Legislature, moneys in the fund may be used for those regulatory activities and to reimburse any outstanding loans made from other funds used to finance the startup costs of the department's activities pursuant to this chapter. Moneys in the fund shall not be expended for any purpose not enumerated in this chapter.

42034.4. *(a) (1) A stewardship organization may conduct an audit of covered entities that are required to remit a charge or administrative fee to the stewardship organization pursuant to Sections 42034 and 42034.2 to verify that the administrative fees and charges paid are proper and accurate. In addition, a stewardship organization may conduct an audit of authorized collectors to verify the charges submitted are proper and accurate.*

(2) The purpose of the audits described in paragraph (1) is to ensure parties required by this chapter to pay or collect an administrative fee or charge are paying or collecting the proper amount to implement the program.

(b) If a stewardship organization conducts an audit pursuant to subdivision (a), it shall do all of the following:

(1) Conduct the audit in accordance with generally accepted auditing practices.

(2) Limit the scope of the audit of covered entities to confirming whether a charge or administrative fee has been properly paid by the covered entities.

(3) Hire an independent third-party auditor to conduct the audit.

(4) Provide a copy of the audit to the department.

Article 6. Enforcement

42035. *(a) (1) On or before June 30, 2022, and at least annually thereafter, the department shall post on its Internet Web site a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter.*

(2) The state board shall coordinate with the department to verify that the list posted pursuant to paragraph (1) is consistent with the information submitted to each agency pursuant to Section 42031.

(b) A covered entity or stewardship organization that is not listed on the department's Internet Web site pursuant to subdivision (a), but demonstrates compliance with this chapter before the department is required to post the following year's list pursuant to subdivision (a), may request a certification letter from the department stating that the covered entity or stewardship organization is in compliance with this chapter. A covered entity or stewardship organization that receives a certification letter shall be deemed to be in compliance with this chapter.

(c) A distributor or wholesaler of covered products, and a pharmacy or other retailer that sells or offers for sale a covered product, shall monitor the department's Internet Web site to determine which covered entities and stewardship organizations are in compliance with this chapter. The distributor or wholesaler and the pharmacy or other retailer shall notify the department if it determines that a covered product that it sells or offers for sale is from a covered entity that is not listed on the department's Internet Web site.

(d) The sale, distribution, or offering for sale of any inventory that was in stock before the commencement of a stewardship program is exempt from this chapter and not required to be subject to a stewardship plan.

(e) If the department determines a covered entity or stewardship organization is not in compliance with this chapter, the department shall remove the entity from the list maintained on the department's Internet Web site pursuant to subdivision (a).

***42035.2.** (a) (1) The department may impose an administrative penalty on any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this chapter.*

(2) The amount of the administrative penalty imposed pursuant to this subdivision shall not exceed ten thousand dollars ($10,000) per day unless the violation is intentional, knowing, or reckless, in which case the administrative penalty shall not exceed fifty thousand dollars ($50,000) per day.

(b) The department shall not impose a penalty on a program operator pursuant to this section for failure to comply with this chapter if the program operator demonstrates it received false or misleading information that contributed to its failure to comply, including, for a stewardship organization, from a participating covered entity.

(c) The department shall deposit all penalties collected pursuant to this section in the Pharmaceutical and Sharps Stewardship Penalty Account, which is hereby created in the Pharmaceutical and Sharps Stewardship Fund established in Section 42034.2. Upon appropriation by the Legislature, moneys in the Pharmaceutical and Sharps Stewardship Penalty Account may be expended by the department on activities including, but not limited to, the promotion of safe handling and disposal of covered products, grants for related purposes, and the administration and enforcement this chapter.

***42035.4.** Upon a written finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement of this chapter, in addition to any other penalties authorized under this chapter, the department may take one or both of the following actions to ensure compliance with the requirements of this chapter, after affording the covered entity, stewardship organization, or authorized collector a reasonable opportunity to respond to, or rebut, the finding:*

(a) Revoke the program operator's stewardship plan approval or require the program operator to resubmit the plan.

(b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met.

***42035.6.** (a) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall do both of the following:*

(1) Upon request, provide the department with reasonable andep accessible all records required to be kept or submitted pursuant to this chapter for a minimum of three years.

(c) All reports and records provided to the department pursuant to this chapter shall be provided under penalty of perjury.

(d) The department may take disciplinary action against a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain that fails to provide the department with the access to information required pursuant to this section, including one or both of the following:

(1) Imposing an administrative penalty pursuant to Section 42035.2.

(2) Posting a notice on the department's Internet Web site, in association with the list that the department maintains pursuant to paragraph (1) of subdivision (a) of Section 42035, that the covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain is no longer in compliance with this chapter.

(e) The department shall not prohibit as a disciplinary action a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain from selling a covered product.

42035.8. *All handling, transport, and disposal undertaken as part of a stewardship program under this chapter shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.*

Article 7. Miscellaneous Provisions

42036. *(a) Except as provided in subdivision (c), an action specified in subdivision (b) that is taken by a stewardship organization or a covered entity pursuant to this chapter is not a violation of the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the Unfair Competition Law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code).*

(b) Subdivision (a) shall apply to all of the following actions taken by a stewardship organization or covered entity:

(1) The creation, implementation, or management of a stewardship plan approved by the department pursuant to Article 3 (commencing with Section 42032) and the determination of the types or quantities of covered products collected or otherwise managed pursuant to a stewardship plan.

(2) The determination of the cost and structure of an approved stewardship plan.

(3) The establishment, administration, collection, or disbursement of the charge or administrative fee imposed pursuant to Section 42034 or 42034.2, respectively.

(c) Subdivision (a) shall not apply to an agreement that does any of the following:

(1) Fixes a price of or for covered products, except for an agreement related to costs, charges, or administrative fees associated with participation in a stewardship plan approved by the department and otherwise in accordance with this chapter.

(2) Fixes the output of production of covered products.

(3) Restricts the geographic area in which, or customers to whom, covered products are sold.

42036.2. *(a) This chapter does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. If that ordinance is repealed in the jurisdiction or, if more than one ordinance is applicable, those ordinances are repealed in the jurisdiction, the drug or sharp shall be subject to this chapter in that jurisdiction within 270 days after the date on which the ordinance is, or ordinances are, repealed.*

(b) This chapter shall preempt a local stewardship program for drugs or sharps enacted by an ordinance or ordinances with an effective date on or after April 18, 2018.

(c) A local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, may continue in operation, but the program and its participants shall not receive or benefit from moneys from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account, including, but not limited to, for administrative or enforcement costs. Participants of a local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, shall be eligible to participate in a stewardship program under this chapter and thereby become eligible to receive funds from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account only if the local stewardship program is dissolved.

42036.4. *Proprietary information submitted to the department under this chapter shall be protected by all parties as confidential and shall be exempt from public disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). The department and other parties may only disclose proprietary information in an aggregated form that does not directly or indirectly identify financial, production, or sales data of an individual covered entity or stewardship organization. Proprietary information may be disclosed to the party that submitted the proprietary information.*

SEC. 2. *The Legislature finds and declares that Section 1 of this act, which adds Section 42036.4 to the Public Resources Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:*

In order to ensure that the competitive market in the state for the manufacture and sale of drugs and sharps is not compromised, it is necessary that proprietary information collected for the purpose of administering a stewardship program be confidential.

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

Attachment 9
SB 1109

SB-1109 Controlled substances: Schedule II drugs: opioids. (2017-2018)

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

(a) Addiction, misuse, and overdose of prescription opioids is a public health crisis affecting both adults and children.

(b) Urgent measures are needed to better inform the public of the risks associated with both the long-term and short-term use of opioids in an effort to address this problem.

(c) Both short-term and long-term prescriptions of opioids to minors fall within situations that require counseling of patients and their parents or guardians by their prescribers.

(d) It is the intent of the Legislature to ensure that health care providers and young athletes receive necessary education on this topic.

SEC. 2. Section 1645 of the Business and Professions Code is amended to read:

1645. (a) Effective with the 1974 license renewal period, if the board determines that the public health and safety would be served by requiring all holders of licenses under this chapter to continue their education after receiving a license, it may require, as a condition to the renewal thereof, that they submit assurances satisfactory to the board that they will, during the succeeding two-year period, inform themselves of the developments in the practice of dentistry occurring since the original issuance of their licenses by pursuing one or more courses of study satisfactory to the board or by other means deemed equivalent by the board.

The board shall adopt regulations providing for the suspension of the licenses at the end of the two-year period until compliance with the assurances provided for in this section is accomplished.

(b) The board may also, as a condition of license renewal, require licentiates to successfully complete a portion of the required continuing education hours in specific areas adopted in regulations by the board. The board may prescribe this mandatory coursework within the general areas of patient care, health and safety, ~~and law and ethics.~~ *law and ethics, and the risks of addiction associated with the use of Schedule II drugs.* The mandatory coursework prescribed by the board shall not exceed ~~fifteen~~ *15* hours per renewal period for dentists, and ~~seven and one-half~~ *7.5* hours per renewal period for dental auxiliaries. Any mandatory coursework required by the board shall be credited toward the continuing education requirements established by the board pursuant to subdivision (a).

(c) For a retired dentist who provides only uncompensated care, the board shall not require more than 60 percent of the hours of continuing education that are required of other licensed dentists. Notwithstanding subdivision (b), all of the hours of continuing education as described in this subdivision shall be gained through courses related to the actual delivery of dental services to the patient or the community, as determined by the board. Nothing in this subdivision shall be construed to reduce any requirements imposed by the board pursuant to subdivision (b).

(d) The board shall report on the outcome of subdivision (c) pursuant to, and at the time of, its regular sunset review process, as provided in Section 1601.1.

SEC. 2.5. Section 1645 of the Business and Professions Code is amended to read:

1645. (a) ~~Effective~~ *(1)* ~~with the 1974 license renewal period, if the board determines that the public health and safety would be served by requiring all~~ *All* holders of licenses under this chapter ~~to~~ *shall* continue their education after receiving a ~~license, it may require,~~ *license* as a condition to the renewal thereof, ~~that they submit assurances~~ *and shall obtain evidence* satisfactory to the board that they ~~will,~~ *have,* during the ~~succeeding~~ *preceding* two-year period, ~~inform themselves of the~~ *obtained continuing education relevant to* developments in the practice of dentistry ~~occurring since the original issuance of their licenses by pursuing one~~

~~or more courses of study satisfactory to the board or by other means deemed equivalent by the~~ *and dental assisting consistent with the regulations of the* board.

The board shall adopt regulations providing for the suspension of the licenses at the end of the two-year period until compliance with ~~the assurances provided for in~~ this section is accomplished.

(b) The board may also, as a condition of license renewal, require licentiates to successfully complete a portion of the required continuing education hours in specific areas adopted in regulations by the board. The board may prescribe this mandatory coursework within the general areas of patient care, health and safety, ~~and law and ethics.~~ *law and ethics, and the risks of addiction associated with the use of Schedule II drugs.* The mandatory coursework prescribed by the board shall not exceed ~~fifteen~~ *15* hours per renewal period for dentists, and ~~seven and one-half~~ *7.5* hours per renewal period for dental auxiliaries. Any mandatory coursework required by the board shall be credited toward the continuing education requirements established by the board pursuant to subdivision (a).

(c) For a retired dentist who provides only uncompensated care, the board shall not require more than 60 percent of the hours of continuing education that are required of other licensed dentists. Notwithstanding subdivision (b), all of the hours of continuing education as described in this subdivision shall be gained through courses related to the actual delivery of dental services to the patient or the community, as determined by the board. Nothing in this subdivision shall be construed to reduce any requirements imposed by the board pursuant to subdivision (b).

(d) The board shall report on the outcome of subdivision (c) pursuant to, and at the time of, its regular sunset review process, as provided in Section 1601.1.

SEC. 3. Section 2190.5 of the Business and Professions Code is amended to read:

2190.5. (a)*(1)* All physicians and surgeons shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. For the purposes of this section, this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, to be completed by December 31, 2006. All physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. The board may verify completion of this requirement on the renewal application form.

(2) For physicians and surgeons licensed on or after January 1, 2019, the course described in paragraph (1) shall also include the subject of the risks of addiction associated with the use of Schedule II drugs.

(b) By regulatory action, the board may exempt physicians and surgeons by practice status category from the requirement in subdivision (a) if the physician and surgeon does not engage in direct patient care, does not provide patient consultations, or does not reside in the State of California.

(c) This section shall not apply to physicians and surgeons practicing in pathology or radiology specialty areas.

SEC. 4. Section 2191 of the Business and Professions Code is amended to read:

2191. (a) In determining its continuing education requirements, the board shall consider including a course in human sexuality, defined as the study of a human being as a sexual being and how he or she functions with respect thereto, and nutrition to be taken by those licensees whose practices may require knowledge in those areas.

(b) The board shall consider including a course in child abuse detection and treatment to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with abused or neglected children.

(c) The board shall consider including a course in acupuncture to be taken by those licensees whose practices may require knowledge in the area of acupuncture and whose education has not included instruction in acupuncture.

(d) The board shall encourage every physician and surgeon to take nutrition as part of his or her continuing education, particularly a physician and surgeon involved in primary care.

(e) The board shall consider including a course in elder abuse detection and treatment to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with abused or neglected persons 65 years of age and older.

(f) In determining its continuing education requirements, the board shall consider including a course in the early detection and treatment of substance abusing pregnant women to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with these women.

(g) In determining its continuing education requirements, the board shall consider including a course in the special care needs of drug addicted infants to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with these infants.

(h) In determining its continuing education requirements, the board shall consider including a course providing training and guidelines on how to routinely screen for signs exhibited by abused women, particularly for physicians and surgeons in emergency, surgical, primary care, pediatric, prenatal, and mental health settings. In the event the board establishes a requirement for continuing education coursework in spousal or partner abuse detection or treatment, that requirement shall be met by each licensee within no more than four years from the date the requirement is imposed.

(i) In determining its continuing education requirements, the board shall consider including a course in the special care needs of individuals and their families facing end-of-life issues, including, but not limited to, all of the following:

(1) Pain and symptom management.

(2) The psycho-social dynamics of death.

(3) Dying and bereavement.

(4) Hospice care.

(j) In determining its continuing education requirements, the board shall give its highest priority to considering a course on pain ~~management.~~ *management and the risks of addiction associated with the use of Schedule II drugs.*

(k) In determining its continuing education requirements, the board shall consider including a course in geriatric care for emergency room physicians and surgeons.

SEC. 5. Section 2196.2 of the Business and Professions Code is amended to read:

2196.2. The board shall periodically develop and disseminate information and educational material regarding pain management techniques and ~~procedures~~ *procedures, including the risks of addiction associated with the use of Schedule II drugs,* to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of *Public* Health ~~Services~~ in developing the materials to be distributed pursuant to this section.

SEC. 6. Section 2454.5 of the Business and Professions Code is amended to read:

2454.5. In order to ensure the continuing competence of licensed osteopathic physicians and surgeons, the board shall adopt and administer standards for the continuing education of those licensees. The board shall require each licensed osteopathic physician and surgeon to demonstrate satisfaction of the continuing education requirements as a condition for the renewal of a license at intervals of not less than one year nor more than two years. Commencing January 1, 2018, the board shall require each licensed osteopathic physician and surgeon to complete a minimum of 100 hours of American Osteopathic Association continuing education hours during each two-year cycle, of which 40 hours shall be completed in American Osteopathic Association Category 1 continuing education hours and the remaining 60 hours shall be either American Osteopathic Association or American Medical Association accredited as a condition for renewal of an active license. *Licensed osteopathic physicians and surgeons shall complete a course on the risks of addiction associated with the use of Schedule II drugs.*

For purposes of this section, "American Osteopathic Association Category 1" means continuing education activities and programs approved for Category 1 credit by the Committee on Continuing Medical Education of the American Osteopathic Association.

SEC. 7. Section 2746.51 of the Business and Professions Code is amended to read:

2746.51. (a) Neither this chapter nor any other provision of law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when all of the following apply:

(1) The drugs or devices are furnished or ordered incidentally to the provision of any of the following:

(A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.

(B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.

(C) Care rendered, consistent with the certified nurse-midwife's educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

(2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section, standardized procedure means a document, including protocols, developed and approved by the supervising physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:

(A) Which certified nurse-midwife may furnish or order drugs or devices.

(B) Which drugs or devices may be furnished or ordered and under what circumstances.

(C) The extent of physician and surgeon supervision.

(D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.

(3) If Schedule II or III controlled substances, as defined in Sections 11055 and 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon. For Schedule II controlled substance protocols, the provision for furnishing the Schedule II controlled substance shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(A) Collaboration on the development of the standardized procedure or protocol.

(B) Approval of the standardized procedure or protocol.

(C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.

(b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this ~~section.~~ *section, including the risks of addiction and neonatal abstinence syndrome associated with the use of opioids.* The board shall establish the requirements for satisfactory completion of this paragraph.

(3) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.

(4) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.

(5) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized through standardized procedures or protocols to furnish Schedule II controlled substances,

and who are registered with the United States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.

(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:

(1) The drugs and devices are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).

(2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.

(d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term "furnishing" in this section shall include the following:

(1) The ordering of a drug or device in accordance with the standardized procedure or protocol.

(2) Transmitting an order of a supervising physician and surgeon.

(e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 8. Section 2836.1 of the Business and Professions Code is amended to read:

2836.1. Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c) (1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(f) (1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.

(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

(g) (1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(2) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.

(3) Nurse practitioners who are certified by the board and hold an active furnishing number, who are authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration, shall complete, as part of their continuing education requirements, a course including Schedule II controlled ~~substances~~ *substances, and the risks of addiction associated with their use,* based on the standards developed by the board. The board shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term "furnishing" in this section, in health facilities defined in Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

(i) "Drug order" or "order" for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 9. Section 3059 of the Business and Professions Code is amended to read:

3059. (a) It is the intent of the Legislature that the public health and safety would be served by requiring all holders of licenses to practice optometry granted under this chapter to continue their education after receiving their licenses. The board shall adopt regulations that require, as a condition to the renewal thereof, that all holders of licenses submit proof satisfactory to the board that they have informed themselves of the developments in the practice of optometry occurring since the original issuance of their licenses by pursuing one or more courses of study satisfactory to the board or by other means deemed equivalent by the board.

(b) The board may, in accordance with the intent of this section, make exceptions from continuing education requirements for reasons of health, military service, or other good cause.

(c) If for good cause compliance cannot be met for the current year, the board may grant exemption of compliance for that year, provided that a plan of future compliance that includes current requirements as well as makeup of previous requirements is approved by the board.

(d) The board may require that proof of compliance with this section be submitted on an annual or biennial basis as determined by the board.

(e) An optometrist certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 shall complete a total of 50 hours of continuing education every two years in order to renew his or her certificate. Thirty-five of the required 50 hours of continuing education shall be on the diagnosis, treatment, and management of ocular disease in any combination of the following areas:

(1) Glaucoma.

(2) Ocular infection.

(3) Ocular inflammation.

(4) Topical steroids.

(5) Systemic medication.

(6) Pain ~~medication.~~ *medication, including the risks of addiction associated with the use of Schedule II drugs.*

(f) The board shall encourage every optometrist to take a course or courses in pharmacology and pharmaceuticals as part of his or her continuing education.

(g) The board shall consider requiring courses in child abuse detection to be taken by those licensees whose practices are such that there is a likelihood of contact with abused or neglected children.

(h) The board shall consider requiring courses in elder abuse detection to be taken by those licensees whose practices are such that there is a likelihood of contact with abused or neglected elder persons.

SEC. 10. Section 3502.1 of the Business and Professions Code is amended to read:

3502.1. (a) In addition to the services authorized in the regulations adopted by the Medical Board of California, and except as prohibited by Section 3502, while under the supervision of a licensed physician and surgeon or physicians and surgeons authorized by law to supervise a physician assistant, a physician assistant may administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device pursuant to subdivisions (c) and (d).

(1) A supervising physician and surgeon who delegates authority to issue a drug order to a physician assistant may limit this authority by specifying the manner in which the physician assistant may issue delegated prescriptions.

(2) Each supervising physician and surgeon who delegates the authority to issue a drug order to a physician assistant shall first prepare and adopt, or adopt, a written, practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or condition for which the Schedule II controlled substance is being administered, provided, or issued. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the physician assistant is acting on behalf of and as an agent for a supervising physician and surgeon.

(b) "Drug order," for purposes of this section, means an order for medication that is dispensed to or for a patient, issued and signed by a physician assistant acting as an individual practitioner within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription or order of the supervising physician, (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by physician assistants pursuant to authority granted by their supervising physicians and surgeons, and (3) the signature of a physician assistant on a drug order shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(c) A drug order for any patient cared for by the physician assistant that is issued by the physician assistant shall either be based on the protocols described in subdivision (a) or shall be approved by the supervising physician and surgeon before it is filled or carried out.

(1) A physician assistant shall not administer or provide a drug or issue a drug order for a drug other than for a drug listed in the formulary without advance approval from a supervising physician and surgeon for the particular patient. At the direction and under the supervision of a physician and surgeon, a physician assistant may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, manufacturer as defined in the Pharmacy Law, or a pharmacist.

(2) A physician assistant shall not administer, provide, or issue 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 covers controlled substances and that meets standards, including pharmacological content, approved by the board. The education course shall be provided either by an accredited continuing education provider or by an approved physician assistant training program. If the physician assistant will administer, provide, or issue a drug order for Schedule II controlled substances, the course shall contain a minimum of three hours exclusively on Schedule II controlled

~~substances.~~ *substances, including the risks of addiction associated with their use.* Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established by the board prior to the physician assistant's use of a registration number issued by the United States Drug Enforcement Administration to the physician assistant to administer, provide, or issue a drug order to a patient for a controlled substance without advance approval by a supervising physician and surgeon for that particular patient.

(3) Any drug order issued by a physician assistant shall be subject to a reasonable quantitative limitation consistent with customary medical practice in the supervising physician and surgeon's practice.

(d) A written drug order issued pursuant to subdivision (a), except a written drug order in a patient's medical record in a health facility or medical practice, shall contain the printed name, address, and telephone number of the supervising physician and surgeon, the printed or stamped name and license number of the physician assistant, and the signature of the physician assistant. Further, a written drug order for a controlled substance, except a written drug order in a patient's medical record in a health facility or a medical practice, shall include the federal controlled substances registration number of the physician assistant and shall otherwise comply with Section 11162.1 of the Health and Safety Code. Except as otherwise required for written drug orders for controlled substances under Section 11162.1 of the Health and Safety Code, the requirements of this subdivision may be met through stamping or otherwise imprinting on the supervising physician and surgeon's prescription blank to show the name, license number, and if applicable, the federal controlled substances registration number of the physician assistant, and shall be signed by the physician assistant. When using a drug order, the physician assistant is acting on behalf of and as the agent of a supervising physician and surgeon.

(e) The supervising physician and surgeon shall use either of the following mechanisms to ensure adequate supervision of the administration, provision, or issuance by a physician assistant of a drug order to a patient for Schedule II controlled substances:

(1) The medical record of any patient cared for by a physician assistant for whom the physician assistant's Schedule II drug order has been issued or carried out shall be reviewed, countersigned, and dated by a supervising physician and surgeon within seven days.

(2) If the physician assistant has documentation evidencing the successful completion of an education course that covers controlled substances, and that controlled substance education course (A) meets the standards, including pharmacological content, established in Sections 1399.610 and 1399.612 of Title 16 of the California Code of Regulations, and (B) is provided either by an accredited continuing education provider or by an approved physician assistant training program, the supervising physician and surgeon shall review, countersign, and date, within seven days, a sample consisting of the medical records of at least 20 percent of the patients cared for by the physician assistant for whom the physician assistant's Schedule II drug order has been issued or carried out. Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established in Section 1399.612 of Title 16 of the California Code of Regulations. Physician assistants who have a certificate of completion of the course described in paragraph (2) of subdivision (c) shall be deemed to have met the education course requirement of this subdivision.

(f) All physician assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration (DEA).

(g) The board shall consult with the Medical Board of California and report during its sunset review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code the impacts of exempting Schedule III and Schedule IV drug orders from the requirement for a physician and surgeon to review and countersign the affected medical record of a patient.

SEC. 11. *Section 4076.7 is added to the Business and Professions Code, to read:*

4076.7. *In addition to the requirements of Sections 4076 and 4076.5, whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug shall prominently display on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states "Caution: Opioid. Risk of overdose and addiction."*

SEC. 12. *Section 49476 is added to the Education Code, to read:*

49476. *(a) If a school district, charter school, or private school elects to offer an athletic program, the school district, charter school, or private school shall annually give the Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention to each athlete. The athlete and, if the athlete is 17 years of age or younger, the athlete's parent or guardian shall sign a document acknowledging receipt of the Opioid Factsheet for Patients and return that document to the school district, charter school, or private school before the athlete*

initiates practice or competition. The Opioid Factsheet for Patients may be sent and returned through an electronic medium, including, but not limited to, fax or email.

(b) This section does not apply to an athlete engaging in an athletic activity during the regular schoolday or as part of a physical education course required pursuant to subdivision (d) of Section 51220.

SEC. 13. *Section 11158.1 is added to the Health and Safety Code, to read:*

11158.1. *(a) Except when a patient is being treated as set forth in Sections 11159, 11159.2, and 11167.5, and Article 2 (commencing with Section 11215) of Chapter 5, pertaining to the treatment of addicts, or for a diagnosis of chronic intractable pain as used in Section 124960 of this code and Section 2241.5 of the Business and Professions Code, a prescriber shall discuss all of the following with the minor, the minor's parent or guardian, or another 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:*

(1) The risks of addiction and overdose associated with the use of opioids.

(2) The increased risk of addiction to an opioid to an individual who is suffering from both mental and substance abuse disorders.

(3) The danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.

(4) Any other information required by law.

(b) This section does not apply in any of the following circumstances:

(1) If the minor's treatment includes emergency services and care as defined in Section 1317.1.

(2) If the minor's treatment is associated with or incident to an emergency surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.

(3) If, in the prescriber's professional judgment, fulfilling the requirements of subdivision (a) would be detrimental to the minor's health or safety, or in violation of the minor's legal rights regarding confidentiality.

(c) Notwithstanding any other law, including Section 11374, failure to comply with this section shall not constitute a criminal offense.

SEC. 14. *Section 124236 is added to the Health and Safety Code, to read:*

124236. *(a) A youth sports organization, as defined in paragraph (3) of subdivision (b) of Section 124235, that elects to offer an athletic program shall annually give the Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention to each athlete. The athlete and, if the athlete is 17 years of age or younger, the athlete's parent or guardian shall sign a document acknowledging receipt of the Opioid Factsheet for Patients and return that document to the youth sports organization before the athlete initiates practice or competition. The Opioid Factsheet for Patients may be sent and returned through an electronic medium, including, but not limited to, fax or email.*

(b) This section shall apply to all athletes participating in the activities of a youth sports organization, irrespective of their ages. This section shall not be construed to prohibit a youth sports organization, or any other appropriate entity, from adopting and enforcing rules intended to provide a higher standard of safety for athletes than the standard established under this section.

SEC. 15. *Section 2.5 of this bill incorporates amendments to Section 1645 of the Business and Professions Code proposed by both this bill and Senate Bill 1491. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2019, (2) each bill amends Section 1645 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1491, in which case Section 2 of this bill shall not become operative.*

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

Attachment 10
SB 1254

SB-1254 Hospital pharmacies: medication profiles or lists for high-risk patients. (2017-2018)

SECTION 1. *Section 4118.5 is added to the Business and Professions Code, to read:*

4118.5. *(a) A pharmacist at a hospital pharmacy shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patient under the following conditions:*

(1) The hospital has more than 100 beds.

(2) The accurate medication profile or list may be acquired by the pharmacist during the hospital pharmacy's hours of operation.

(b) Notwithstanding any other law, a pharmacy technician or an intern pharmacist may perform the task of obtaining an accurate medication profile or list for a high-risk patient if both of the following conditions are satisfied:

(1) The hospital pharmacy has a quality assurance program to monitor competency.

(2) The hospital has established policies and procedures for training and proctoring pharmacy technicians or intern pharmacists by the hospital pharmacy department and the pharmacy technician or intern pharmacist has completed that training and proctoring.

(c) The hospital shall establish criteria regarding who is a high-risk patient for purposes of this section, and shall determine the timeframe for completion of the medication profile or list, based on the patient populations served by the hospital.

(d) The board may adopt rules and regulations to carry out the purposes and objectives of this section.

(e) This section shall not apply to the State Department of State Hospitals.

(f) Nothing in this section shall be construed to prohibit a healing arts licensee licensed pursuant to this division from obtaining an accurate medication profile or list.

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

1. **What is the definition of a high-risk patient?**
    a. Patient populations vary amongst hospitals; therefore, it is the intent to allow each hospital to develop criteria for high-risk patients analogous to the requirements for determining which drugs are high-alert.
    b. Criteria for high-risk patients shall be developed by pharmacists in collaboration with physicians, nurses, and executive management.
    c. Hospitals may consider 30-day readmission data, current literature, key diagnoses (e.g. CHF, Transplant, COPD), number of prescriptions, and categories of prescription medications (e.g. anticoagulants, immunosuppression) when identifying high-risk patient populations.
    d. It is highly recommended that the criteria developed by each institution be approved by the Pharmacy and Therapeutics Committee and/or Medication Safety Committee.
    e. Preliminary criteria of high-risk patients may start with limited populations based on current hospital data and the addition of further criteria may be considered in the future based on their experience.

2. **What is the timeframe for obtaining a list relative to the admission?**
    a. Each hospital shall determine a reasonable timeframe in which a medication history must be obtained.
    b. Hospitals may define circumstances in which additional time is allotted to obtain the list. For example, for patients who are medically unstable, have cognitive impairment and where family and/or caregivers are not available or unable to provide the patient's medication history, up to 72 hours may be needed to obtain the list.
    c. In situations when the medication list cannot be obtained due to the patient's condition, cognitive impairment, lack of medication information or patient refusal, the PTA medication list may be documented as "unable to assess."

3. **What is meant by obtaining an accurate medication list?**
    a. Obtaining an accurate medication list is determining what medications (prescription and non-prescription) the patient is currently taking including dose, frequency and route if the patient/caregiver is able to provide this information.
    b. Additional sources of information that can be used, if available, include a medication list brought in by the patient/family/caregiver, the medication list from the last patient encounter in the electronic medical record, the patient's physician's office, electronic prescription data or the patient's pharmacy.
    c. A best possible medication list obtained using this approach would be considered an accurate medication list since it is based on the information available at the time.
    d. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the Elements of Performance for NPSG.03.06.01.

4. **What happens if a medication error and/or discrepancy results from the medication list?**
If an error or discrepancy results from the medication list, the existing hospital policy on how to manage medication errors would be followed. This situation would be no different than the current situation since each physician or allied health professional and pharmacist is responsible for determining if medications listed are appropriate for ordering during the inpatient admission based on patient-specific conditions, diseases, concomitant drugs, etc.

5. **How are technicians trained?**
    a. An established procedure for training and proctoring pharmacy technicians and/or intern pharmacists will be implemented by the hospital pharmacy department.

b. A standard process to train staff and evaluate competency may include the following elements:
   i. Training manual
   ii. Competency examination
   iii. Proctoring and observation of technicians obtaining medication lists

6. **How often should quality assurance be performed?**
   Each hospital will develop a routine quality assurance program to ensure ongoing competency of staff.

7. **Are medication histories obtained by technician signed by pharmacists?**
   Medication histories or profiles may be transcribed by technicians into the medical record. Note that these lists are not orders until such time that the physician orders the medication. If the medications are ordered during the inpatient admissions, the pharmacist is responsible for reviewing and verifying the orders.

8. **How are interns (pharmacy students) trained?**
   Intern pharmacists are trained to obtain medication histories under the supervision of a pharmacist.

9. **B&P code 4118.5(a) indicates the medication profile or list be obtained for high high-risk patients under certain conditions, one of them being "the hospital has more than 100 beds". Since "hospital" is not defined or referenced in B&P code 4118.5(a), is the definition subject to interpretation and if so, what is the regulatory stance? For the purposes of B&P code 4118.5(a), would it be acceptable for organizations to use the definition of "hospital" as defined in California H&S code 1250(a)?**
   California H&S 1250(a) code to define "hospital". See link for legislative language.
   https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1250.&lawCode=HSC

10. **B&P code 4118.5(a) uses the word "admission" but does not define "admission". Seeking regulatory stance or interpretation for the word "admission" in the context of B&P code 4118.5(a). Per the code, would a medication profile or list for high-risk patients be required for patients in Observation Status?**
    The intended definition of admission is for high-risk patients who are admitted as inpatients; therefore, observation patient should be excluded.

Attachment 11
SB 1442

SB-1442 Community pharmacies: staffing. (2017-2018)

SECTION 1. *The Legislature finds and declares as follows:*

(a) Licensed pharmacists are health care professionals whose training and experience play a vital role in protecting public health.

(b) Pharmacists are legally and ethically bound to advise their patients, physicians, and other health practitioners on the selection, dosages, interactions, and side effects of medications as well as monitor the health and progress of those patients to ensure that they are using their medications safely and effectively.

(c) Pursuant to Section 4001.1 of the Business and Professions Code, the highest priority for the regulation of pharmacists is protection of the public.

(d) The duties of a pharmacist include preventing the abuse of prescription opioids. In August 2013, the California State Board of Pharmacy revoked the licenses of both a pharmacy and its pharmacist because the pharmacist failed to comply with corresponding responsibility requirements in the distribution of opioid drugs. Four patients died as a result of the pharmacist's actions.

(e) The California State Board of Pharmacy's decision and order in that case identifies "red flags" that pharmacists are legally obligated to watch for before filling such a prescription. These "red flags" include:

(1) Irregularities on the face of the prescription itself.

(2) Nervous patient demeanor.

(3) The age or presentation of patient (e.g., youthful patients seeking chronic pain medications).

(4) Multiple patients all with the same address.

(5) Multiple prescriptions for the same patient for duplicate therapy.

(6) Requests for early refills of prescriptions.

(7) Prescriptions written for an unusually large quantity of drugs.

(8) Prescriptions written for duplicative drug therapy.

(9) Initial prescriptions written for strong opiates.

(10) Long distances traveled from the patient's home to the prescriber's office or to the pharmacy.

(11) Irregularities in the prescriber's qualifications in relation to the type of medications prescribed.

(12) Prescriptions that are written outside of the prescriber's medical specialty.

(13) Prescriptions for medications with no logical connection to an illness or condition.

(f) In 2013, the Governor signed legislation that significantly expanded the scope of practice of pharmacists. Pharmacists are now, without a prescription from a physician, permitted to vaccinate their patients, aid them in the administration of self-administered hormonal contraception, and provide nicotine replacement products. The California State Board of Pharmacy has by regulation promulgated extensive protocols governing each of these new duties.

(g) For self-administered hormonal contraception, the California Code of Regulations requires a pharmacist to complete the following steps:

(1) Ask the patient to use and complete the self-screening tool.

(2) Review the self-screening answers and clarify responses if needed.

(3) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.

(4) Before furnishing self-administered hormonal contraception, ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.

(5) When a self-administered hormonal contraceptive is furnished, provide the patient with appropriate counseling and information on the product furnished, including:

(A) Dosage.

(B) Effectiveness.

(C) Potential side effects.

(D) Safety.

(E) The importance of receiving recommended preventative health screenings.

(F) That self-administered hormonal contraception does not protect against sexually transmitted infections.

(h) For nicotine replacement products, the California Code of Regulations requires a pharmacist to complete the following steps:

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

(2) Ask the patient screening questions related to pregnancy, heart attacks, history of heart ailments, chest pain, or nasal allergies.

(3) Review the instructions for use with every patient using a nicotine replacement product.

(i) For vaccines, Section 1746.4 of Title 16 of the California Code of Regulations requires a pharmacist to notify each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider.

(j) Notwithstanding the number, complexity, and importance of a pharmacist's duties, including those new obligations described above, the Legislature has heard uncontradicted testimony that licensed pharmacists are left alone for indeterminate periods of time in the pharmacy and are, simultaneously, required by such establishments to perform nonpharmacist functions such as staffing cash registers and assisting consumers in purchasing prescriptions, groceries, and other nonpharmacy goods. Survey information of pharmacists working in pharmacies reinforces the testimony.

(k) Staffing inadequacies like these interfere with the professional responsibilities of licensed pharmacists, including those requiring time and professional judgment listed above, and pose a risk to the public health because it leaves licensed pharmacists an insufficient amount of time to perform their licensed functions safely and lawfully, exercise their professional discretion, and comply with their legal and ethical obligations to protect the health and well-being of patients.

SEC. 2. *Section 4113.5 is added to the Business and Professions Code, to read:*

4113.5. *(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless 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, is made available to assist the pharmacist at all times.*

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Attachment 12
AB 2863

AB-2863 Health care coverage: prescriptions. (2017-2018)

SECTION 1. *Section 4079 is added to the Business and Professions Code, immediately following Section 4078, to read:*

4079. *(a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.*

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is inconsistent with this section is void and unenforceable.

(e) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

SEC. 2. *Section 1367.47 is added to the Health and Safety Code, to read:*

1367.47. *(a) The maximum amount a health care service plan may require an enrollee to pay at the point of sale for a covered prescription drug is the lesser of the following:*

(1) The applicable cost-sharing amount for the prescription drug.

(2) The retail price.

(b) A health care service plan shall not require a pharmacist or pharmacy to charge or collect from an enrollee a cost-sharing amount that exceeds the total retail price for the prescription drug.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

SEC. 3. *Section 10123.65 is added to the Insurance Code, to read:*

10123.65. *(a) The maximum amount a health insurer may require an insured to pay at the point of sale for a covered prescription drug is the lesser of the following:*

(1) The applicable cost-sharing amount for the prescription drug.

(2) The retail price.

(b) A health insurer shall not require a pharmacist or pharmacy to charge or collect from an insured a cost-sharing amount that exceeds the total retail price for the prescription drug.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the insured had purchased the prescription drug by paying the cost-sharing amount.

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

Attachment 12
AB 315

AB-315 Pharmacy benefit management. (2017-2018)

SECTION 1. *Section 4079.5 is added to the Business and Professions Code, to read:*

4079.5. *(a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.*

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is entered into on or after January 1, 2019, that is inconsistent with this section is void and unenforceable.

(e) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

SEC. 2. *Section 4441 is added to the Business and Professions Code, to read:*

4441. *(a) For purposes of this section, the following definitions shall apply:*

(1) "Labeler" means a person or entity that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Part 207 of Title 21 of the Code of Federal Regulations.

(2) "Proprietary information" means information on pricing, costs, revenue, taxes, market share, negotiating strategies, customers, and personnel that is held by a pharmacy benefit manager and used for its business purposes.

(3) "Purchaser" means a health benefit plan sponsor or other third-party payer with whom a pharmacy benefit manager contracts to provide the administration and management of prescription drug benefits, except for a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(b) This section shall apply to pharmacy benefit manager contracts that are entered into, amended, or renewed on or after January 1, 2019.

(c) A pharmacy benefit manager shall exercise good faith and fair dealing.

(d) A pharmacy benefit manager shall notify a purchaser in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the purchaser to exercise good faith and fair dealing pursuant to subdivision (c).

(e) The pharmacy benefit manager shall, on a quarterly basis, disclose, upon the request of the purchaser, the following information with respect to prescription product benefits specific to the purchaser:

(1) The aggregate wholesale acquisition costs from a pharmaceutical manufacturer or labeler for each therapeutic category of drugs containing three or more drugs, as outlined in the state's essential health benefits benchmark plan pursuant to Section 1367.005 of the Health and Safety Code.

(2) The aggregate amount of rebates received by the pharmacy benefit manager by therapeutic category of drugs containing three or more drugs, as outlined in the state's essential health benefits benchmark plan pursuant to Section 1367.005 of the Health and Safety Code. The aggregate amount of rebates shall include any utilization discounts the pharmacy benefit manager receives from a pharmaceutical manufacturer or labeler.

(3) Any administrative fees received from the pharmaceutical manufacturer or labeler.

(4) Whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a pharmaceutical manufacturer to exclusively dispense or provide a drug to a purchaser's employees, insureds, or enrollees, and the application of all consideration or economic benefits collected or received pursuant to that arrangement.

(5) Prescription drug utilization information for the purchaser's enrollees or insureds that is not specific to any individual enrollee or insured.

(6) The aggregate of payments, or the equivalent economic benefit, made by the pharmacy benefit manager to pharmacies owned or controlled by the pharmacy benefit manager.

(7) The aggregate of payments made by the pharmacy benefit manager to pharmacies not owned or collected by the pharmacy benefit manager.

(8) The aggregate amount of the fees imposed on, or collected from, network pharmacies or other assessments against network pharmacies, and the application of those amounts collected pursuant to the contract with the purchaser.

(f) The information disclosed pursuant to subdivision (e) shall apply to all retail, mail order, specialty, and compounded prescription products.

(g) Except for utilization information specified in paragraph (5) of subdivision (e), a pharmacy benefit manager is not required to make the disclosures required by subdivision (e) unless and until the purchaser agrees, in writing, to maintain as confidential any proprietary information.

(h) A pharmacy benefit manager shall not impose a penalty or offer an inducement to a purchaser for the purpose of deterring the purchaser from requesting the information set forth in subdivision (e).

(i) A pharmacy benefit manager shall disclose to a pharmacy network provider or its contracting agent any material change to a contract provision that affects the terms of reimbursement, the process for verifying benefits and eligibility, dispute resolution, procedures for verifying drugs included on the formulary, and contract termination at least 30 days before the date of the change to the provision.

(j) A pharmacy benefit manager shall not notify an individual receiving benefits through the pharmacy benefit manager that a pharmacy has been terminated from the pharmacy benefit manager's network until the notification of termination has been provided to that pharmacy pursuant to subdivision (i).

(k) A pharmacy benefit manager shall not include in a contract with a pharmacy network provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

(l) This section shall not apply to the following:

(1) A health care service plan or health insurer, if the health care service plan or health insurer offers, provides, or administers pharmacy benefit management services and if those services are offered, provided, or administered only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered, provided, or administered by that health care service plan or health insurer.

(2) An affiliate, subsidiary, related entity, or contracted medical group of a health care service plan or health insurer that would otherwise qualify as a pharmacy benefit manager, but offers, provides, or administers services only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered, provided, or administered by the health care service plan or health insurer.

(3) A contract authorized by Section 4600.2 of the Labor Code.

(m) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

SEC. 3. *Section 1368.6 is added to the Health and Safety Code, to read:*

1368.6. *(a) Effective January 1, 2020, there is established a pilot project to assess the impact of health care service plan and pharmacy benefit manager prohibitions on the dispensing of certain amounts of prescription drugs by network retail pharmacies. The provisions of subdivision (b) shall apply to pharmacy providers located in the Counties of Riverside and Sonoma.*

(b) Pursuant to the pilot project, a health care service plan shall not prohibit, or permit any delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing a particular amount of a prescribed medication if the plan or pharmacy benefit manager allows that amount to be dispensed through a pharmacy owned or controlled by the plan or pharmacy benefit manager, unless the prescription drug is subject to restricted distribution by the federal Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(c) This section shall not be construed to prohibit a health care service plan or pharmacy benefit manager from requiring the same reimbursement and terms and conditions for a pharmacy network provider as for a pharmacy owned or controlled by the health care service plan or pharmacy benefit manager.

(d) This section shall not be construed to prohibit differential cost sharing designed to encourage or discourage the use of mail-order pharmacy services or preferred pharmacies.

(e) On or before July 1, 2020, health care service plans subject to this section shall report annually to the Department of Managed Health Care information and data relating to changes, if any, to costs and utilization of prescription drugs attributable to the prohibition of contract terms in subdivision (b). The department shall solicit and receive any additional information relevant to changes in costs or utilization attributable to the pilot project from other interested stakeholders. The department shall summarize data received pursuant to this subdivision and provide the summary to the Governor and health policy committees of the Legislature on or before December 31, 2022.

(f) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

SEC. 4. *Article 6.1 (commencing with Section 1385.001) is added to Chapter 2.2 of Division 2 of the Health and Safety Code, to read:*

Article 6.1. Pharmacy Benefit Management Services

1385.001. *For the purposes of this article, "pharmacy benefit manager" means a person, business, or other entity that, pursuant to a contract with a health care service plan, manages the prescription drug coverage provided by the health care service plan, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs. This definition shall not include a health care service plan licensed under this chapter or any individual employee of a health care service plan or its contracted provider, as defined in subdivision (i) of Section 1345, performing the services described in this section.*

1385.002. *(a) Except as specified in Section 1385.007, the requirements of this article shall become operative on January 1, 2020.*

(b) Notwithstanding subdivision (a), the department has the authority to enforce the provisions of this article, including the authority to adopt, amend, or repeal any rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public and to implement this article, including, but not limited to, the director's enforcement authority under this chapter.

(c) Notwithstanding subdivision (a) and Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this article by means of all-plan letters or similar instructions to plans and pharmacy benefit managers, without taking regulatory action, until such time as regulations are adopted.

(d) The department may contract with a consultant or consultants with expertise in this subject area to assist the department in developing guidance or instructions described in subdivision (c), or the report required pursuant to Section 1385.007. The department's contract with a consultant shall include conflict-of-interest provisions to prohibit a person from participating in any report in which the person knows or has reason to know he or she has

a material financial interest, including, but not limited to, a person who has a consulting or other agreement with a person or organization that would be affected by the results of the report.

(e) Contracts entered into pursuant to the authority in this article shall be exempt from Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code, Section 19130 of the Government Code, and Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, and shall be exempt from the review or approval of any division of the Department of General Services.

1385.003. *(a) A health care service plan shall disclose to a contracted pharmacy provider or its contracting agent the prescription drug information contained in subdivision (a) of Section 1363.03, including, but not limited to, the telephone number pharmacy providers may call for assistance and information necessary to process a pharmacy claim.*

(b) A health care service plan shall not include in a contract with a pharmacy provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

1385.004. *(a) A health care service plan that contracts with a pharmacy benefit manager for management of any or all of its prescription drug coverage shall require the pharmacy benefit manager to do all of the following:*

(1) Comply with the provisions of Section 1385.003.

(2) Register with the department pursuant to the requirements of this article.

(3) Exercise good faith and fair dealing in the performance of its contractual duties to a health care service plan.

(4) Comply with the requirements of Chapter 9.5 (commencing with Section 4430) of Division 2 of the Business and Professions Code, as applicable.

(5) Inform all pharmacists under contract with or subject to contracts with the pharmacy benefit manager of the pharmacist's rights to submit complaints to the department under Section 1371.39 and of the pharmacist's rights as a provider under Section 1375.7.

(b) A pharmacy benefit manager shall notify a health care service plan in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the health care service plan to exercise good faith and fair dealing in the performance of its contractual duties pursuant to subdivision (a).

1385.005. *(a) A pharmacy benefit manager required to register with the department pursuant to Section 1385.004 shall complete an application for registration with the department that shall include, but not be limited to, all of the information required by subdivision (c).*

(b) A pharmacy benefit manager registration obtained pursuant to this section is not transferable.

(c) The department shall develop an application form for pharmacy benefit manager registration. The application form for a pharmacy benefit manager registration shall require the pharmacy benefit manager to submit the following information to the department:

(1) The name of the pharmacy benefit manager.

(2) The address and contact telephone number for the pharmacy benefit manager.

(3) The name and address of the pharmacy benefit manager's agent for service of process in the state.

(4) The name and address of each person beneficially interested in the pharmacy benefit manager.

(5) The name and address of each person with management or control over the pharmacy benefit manager.

(d) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the name, address, usual occupation, and professional qualifications of each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the department, the applicant shall furnish the department with the name, address, usual occupation, and professional qualifications of partners, members, or stockholders not named in the application, or shall refer the department to an appropriate source for that information.

(e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this article. If the applicant cannot make this statement, the

application shall contain a statement of the violation, if any, or shall describe the reasons that prevent the applicant from being able to comply with the requirements with respect to the statement.

(f) The department may set a fee for a registration required by this article. The application fee shall not exceed the reasonable costs of the department in carrying out its duties under this article.

(g) Within 30 days of a change in any of the information disclosed to the department on an application for a registration, the pharmacy benefit manager shall notify the department of that change in writing.

(h) For purposes of this section, "person beneficially interested" with respect to a pharmacy benefit manager means and includes the following:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

1385.006. *The failure by a health care service plan to comply with the contractual requirements pursuant to this article shall constitute grounds for disciplinary action. The director shall, as appropriate, investigate and take enforcement action against a health care service plan that fails to comply with these requirements and shall periodically evaluate contracts between health care service plans and pharmacy benefit managers to determine if any audit, evaluation, or enforcement actions should be undertaken by the department.*

1385.007. *(a) By July 1, 2019, the department, in collaboration with other agencies, departments, advocates, experts, health care service plan representatives, and other entities and stakeholders that it deems appropriate, shall convene a Task Force on Pharmacy Benefit Management Reporting to determine what information related to pharmaceutical costs, if any, the department should require to be reported by health care service plans or their contracted pharmacy benefit managers, in addition to reporting required by Section 1367.243. The task force shall consider inclusion of information including, but not limited to, the following:*

(1) Wholesale acquisition costs of pharmaceuticals.

(2) Rebates obtained by the health care service plan or the pharmacy benefit manager from pharmaceutical manufacturers.

(3) Payments to network pharmacies.

(4) Exclusivity arrangements between health care service plans or contracted pharmacy benefit managers with pharmaceutical manufacturers.

(b) The task force shall consider the results of information reporting pursuant to Section 1367.243 and Chapter 9 (commencing with Section 127675) of Part 2 of Division 107 in determining what information should be reported pursuant to subdivision (a).

(c) The department shall submit a report of the Task Force on Pharmacy Benefit Management Reporting to the President pro Tempore of the Senate, the Speaker of the Assembly, and the Senate and Assembly Committees on Health, with the recommendations of the task force no later than February 1, 2020, on which date the task force shall cease to exist.

(d) This section shall become inoperative on February 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 5. *The Legislature finds and declares that a special statute is necessary and that a general statute cannot be made applicable within the meaning of Section 16 of Article IV of the California Constitution for purposes of implementing Section 3 in different geographic regions for data comparison purposes.*

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

Attachment 12
SB 1021

SB-1021 Prescription drugs. (2017-2018)

SECTION 1. Section 1342.71 of the Health and Safety Code, as amended by Section 175 of Chapter 86 of the Statutes of 2016, is amended to read:

1342.71. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on *the* existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the contract that constitute essential health benefits, as defined in Section 1367.005.

(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.

(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

~~(e) (1) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).~~

~~(2) With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).~~

~~(3) For a health care service plan contract that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an enrollee's deductible has been satisfied for the year.~~

~~(4) For a nongrandfathered individual or small group health care service plan contract, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.~~

~~(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.~~

~~(f) (1) If a health care service plan contract for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:~~

~~(A) Tier one shall consist of most generic drugs and low cost preferred brand name drugs.~~

~~(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost.~~

~~(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.~~

~~(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars ($600) net of rebates for a one-month supply.~~

~~(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the health care service plan shall take into account the other provisions of this section and this chapter.~~

~~(3) A health care service plan contract may maintain a drug formulary with fewer than four tiers.~~

~~(4) This section shall not be construed to limit a health care service plan from placing any drug in a lower tier.~~

~~(g)~~ *(e)* A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(f) (1) This section shall not be construed to require a health care service plan to impose cost sharing.

~~(h)~~ *(2)* This section shall not be construed to require ~~a health care service plan to impose cost sharing. This section shall not be construed to require cost~~ *cost* sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

~~(i)~~ *(3)* ~~This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.~~ *A plan's prescription drug benefit shall provide that if the pharmacy's retail price for a prescription drug is less than the applicable copayment or coinsurance amount, the enrollee shall not be required to pay more than the retail price. The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription medication by paying the cost-sharing amount.*

~~(j)~~ *(g)* In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

~~(k)~~ *(h)* This section does not apply to a health care service plan ~~that contracts~~ *contract* with the State Department of Health Care Services.

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

SEC. 2. Section 1342.71 of the Health and Safety Code, as added by Section 2 of Chapter 619 of the Statutes of 2015, is repealed.

~~**1342.71.** (a) The Legislature hereby finds and declares all of the following:~~

~~(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability,~~

~~degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.~~

~~(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.~~

~~(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.~~

~~(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.~~

~~(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.~~

~~(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.~~

~~(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.~~

~~(e) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.~~

~~(f) This section shall not be construed to require a health care service plan to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.~~

~~(g) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.~~

~~(h) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.~~

~~(i) This section shall not apply to a health care service plan that contracts with the State Department of Health Care Services.~~

~~(j) This section shall become operative on January 1, 2020.~~

SEC. 3. *Section 1342.72 is added to the Health and Safety Code, to read:*

1342.72. *(a) For combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, a health care service plan shall not have utilization management policies or procedures, including a standard of care, which rely on a multitablet drug regimen instead of a single-tablet drug regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and equally or more likely to result in adherence to a drug regimen.*

(b) This section does not apply to a health care service plan contract with the State Department of Health Care Services.

(c) This section shall remain in effect only until January 1, 2023, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2023, deletes or extends that date.

SEC. 4. *Section 1342.73 is added to the Health and Safety Code, to read:*

__1342.73.__ (a) (1) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).

(3) For a health care service plan contract that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an enrollee's deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group health care service plan contract, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.

(b) (1) If a health care service plan contract for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the Food and Drug Administration of the United States Department of Health and Human Services or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars ($600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the health care service plan shall take into account the other provisions of this section and this chapter.

(3) A health care service plan contract may maintain a drug formulary with fewer than four tiers. A health care service plan contract shall not maintain a drug formulary with more than four tiers.

(4) This section shall not be construed to limit a health care service plan from placing any drug in a lower tier.

(c) This section does not apply to a health care service plan contract with the State Department of Health Care Services.

(d) This section shall remain in effect only until January 1, 2024, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2024, deletes or extends that date.

SEC. 5. Section 10123.193 of the Insurance Code, as amended by Section 204 of Chapter 86 of the Statutes of 2016, is amended to read:

10123.193. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on *the* existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the policy that constitute essential health benefits, as defined by Section 10112.27.

(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.

(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.

(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

~~(f) (1) With respect to an individual or group policy of health insurance subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).~~

~~(2) With respect to products with actuarial value at or equivalent to the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).~~

~~(3) For a policy of health insurance that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision applies only once an insured's deductible has been satisfied for the year.~~

~~(4) For a nongrandfathered individual or small group policy of health insurance, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.~~

~~(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.~~

~~(g) (1) If a policy of health insurance offered, sold, or renewed in the nongrandfathered individual or small group market maintains a drug formulary grouped into tiers that includes a fourth tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:~~

~~(A) Tier one shall consist of most generic drugs and low cost preferred brand name drugs.~~

~~(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost.~~

~~(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.~~

~~(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the insured to have special training or clinical monitoring for self-administration, or drugs that cost the health insurer more than six hundred dollars ($600) net of rebates for a one-month supply.~~

~~(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the insurer shall take into account the other provisions of this section and this part.~~

~~(3) A policy of health insurance may maintain a drug formulary with fewer than four tiers.~~

~~(4)~~ *(f) (1)* This section shall not be construed to ~~limit~~ *require* a health insurer ~~from placing any drug in a lower tier.~~ *to impose cost sharing.*

~~(h)~~ *(2)* This section shall not be construed to require ~~a health insurer to impose cost sharing. This section shall not be construed to require cost~~ *cost* sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(3) A prescription drug benefit shall provide that if the pharmacy's retail price for a prescription drug is less than the applicable copayment or coinsurance amount, the insured shall not be required to pay more than the retail price. The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription medication by paying the cost-sharing amount.

~~(i)~~ *(g)* A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

~~(j)~~ *(h)* In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.

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

SEC. 6. Section 10123.193 of the Insurance Code, as added by Section 8 of Chapter 619 of the Statutes of 2015, is repealed.

~~**10123.193.** (a) The Legislature hereby finds and declares all of the following:~~

~~(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.~~

~~(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.~~

~~(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.~~

~~(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.~~

~~(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.~~

~~(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.~~

~~(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.~~

~~(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.~~

~~(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.~~

~~(f) This section shall not be construed to require a health insurer to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.~~

~~(g) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.~~

~~(h) In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.~~

~~(i) This section shall become operative on January 1, 2020.~~

SEC. 7. *Section 10123.1931 is added to the Insurance Code, immediately following Section 10123.193, to read:*

10123.1931. *(a) For combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, a health insurer shall not have utilization management policies or procedures, including a standard of care, which rely on a multitablet drug regimen instead of a single-tablet drug regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and equally or more likely to result in adherence to a drug regimen.*

(b) This section shall remain in effect only until January 1, 2023, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2023, deletes or extends that date.

SEC. 8. *Section 10123.1932 is added to the Insurance Code, immediately following Section 10123.1931, to read:*

10123.1932. *(a) (1) With respect to an individual or group policy of health insurance subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).*

(2) With respect to products with actuarial value at or equivalent to the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).

(3) For a policy of health insurance that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision applies only once an insured's deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group policy of health insurance, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.

(b) (1) If a policy of health insurance offered, sold, or renewed in the nongrandfathered individual or small group market maintains a drug formulary grouped into tiers that includes a fourth tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the Food and Drug Administration of the United States Department of Health and Human Services or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the insured to have special training or clinical monitoring for self-administration, or drugs that cost the health insurer more than six hundred dollars ($600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the insurer shall take into account the other provisions of this section and this part.

(3) A policy of health insurance may maintain a drug formulary with fewer than four tiers. A policy of health insurance shall not maintain a drug formulary with more than four tiers.

(4) This section shall not be construed to limit a health insurer from placing any drug in a lower tier.

(c) This section shall remain in effect only until January 1, 2024, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2024, deletes or extends that date.

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

CALIFORNIA RETAILERS ASSOCIATION
980 Ninth Street, Suite 2100 · Sacramento, CA 95814
(916) 443-1975 Fax (916) 441-4218

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 24, 2018

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

Re: Assistance with Implementation AB 315 (Wood) and AB 2863 (Nazarian)

Dear Ms. Herold,

The California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) are writing to ask for the Board of Pharmacy's assistance in addressing a problem with the implementation of legislation passed by the Legislature and signed by the Governor this year. AB 315 (Chapter #905, 2018) and AB 2863 (Chapter #770, 2018) both contain identical language mandating new requirements on pharmacies as follows:

> **4079.5.**
> (a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.
> (b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

Pharmacies are supportive of providing customers with information regarding the retail price of a drug if and when it is lower than their cost-sharing amount. Pharmacies are also supportive of the authors' intent to ensure that a patient who chooses to pay retail price for the drug because it is cheaper still has the opportunity to have that amount deducted from their health plan's required deductible.

Unfortunately, pharmacies are not able to comply with the requirement in Section 4079.5(b) which requires them to submit a patient's retail price to the health care service plan. Pharmacies cannot comply with this requirement for two reasons:

1. There are no computer fields available within the pharmacy benefit manager's (PBM) or health care service plan's system that allows them to submit a claim based on a patient paying cash for a drug.
2. Even if a computer field was developed by a PBM or health plan, a pharmacy is prohibited from submitting this information until a "transaction standard" is developed by the National

Council for Prescription Drug Programs (NCPDP) and approved by the Centers for Medicaid & Medicare Services (CMS). Without this standard in place, the pharmacy would be violating HIPAA requirements that protect patient privacy.

NACDS and CRA retail pharmacy members are very supportive of the ability of patients to submit their cash price information directly to the health plan to be applied to their deductible, and are willing to work with the Board to ensure that patients have their receipt showing their cash payment. However, at this time pharmacies do not have the capability to submit the claim for the patient.

It is our understanding that the authors of the legislation are considering a clean-up measure with an urgency in 2019 that will modify language in AB 315 and AB 2863 and better align it with SB 1021 (Chapter #787, 2018) – at least until such time as new transaction standards can be authorized at the federal level. The language in SB 1021 authorizes the applicability of a cash price to a patient's deductible but does not require the pharmacy to submit the claim. It is CRA & NACDS's intent to work with authors, the payers and the pharmacy benefit managers to develop language that works for everyone while still insuring the patient can claim their cash price against their deductible.

In the meantime, NACDS & CRA would ask that the Board delay enforcement of the provisions in AB 315 and AB 2863 related to a pharmacy's submittal of cash claim information to a health plan until the Legislature can modify the statute to address the implementation concerns highlighted in this letter.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, fast food restaurants, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware and home stores. CRA works on behalf of California's retail industry, which currently operates over 164,200 stores with sales in excess of $571 billion annually and employing 2,776,000 people—nearly one fifth of California's total employment.

The National Association of Chain Drug Stores advances a pro-patient and pro-pharmacy agenda. For the ultimate benefit of the consumers served by NACDS members, the mission of NACDS is to advance the interests and objectives of the chain community pharmacy industry, by fostering its growth and promoting its role as a provider of healthcare services and consumer products.

Please let us know if we can provide you with any additional information. We look forward to working with the Board on a resolution.

Sincerely,

B. Dombrowski

Mary Staples

Bill Dombrowski
President
California Retailers Association

Mary Staples
Director, State Government Affairs
National Association of Chain Drug Stores

cc: The Honorable Jim Wood, California State Assembly
The Honorable Adrin Nazarian, California State Assembly

State law allows Medicare patients to obtain some prescription medications at Medi-Cal rates

State law enables Medicare recipients in some cases to obtain prescription medications at a cost that is no higher than the Medi-Cal reimbursement rate for those drugs.

Business and Professions Code (BPC) section 4425 establishes a drug discount program for Medicare recipients who get their prescriptions filled at pharmacies enrolled in Medi-Cal. The statute was initially adopted by SB 393 (Chapter 946, Statutes of 1999), and the current version has been effective since 2003 with amendments in 2010.

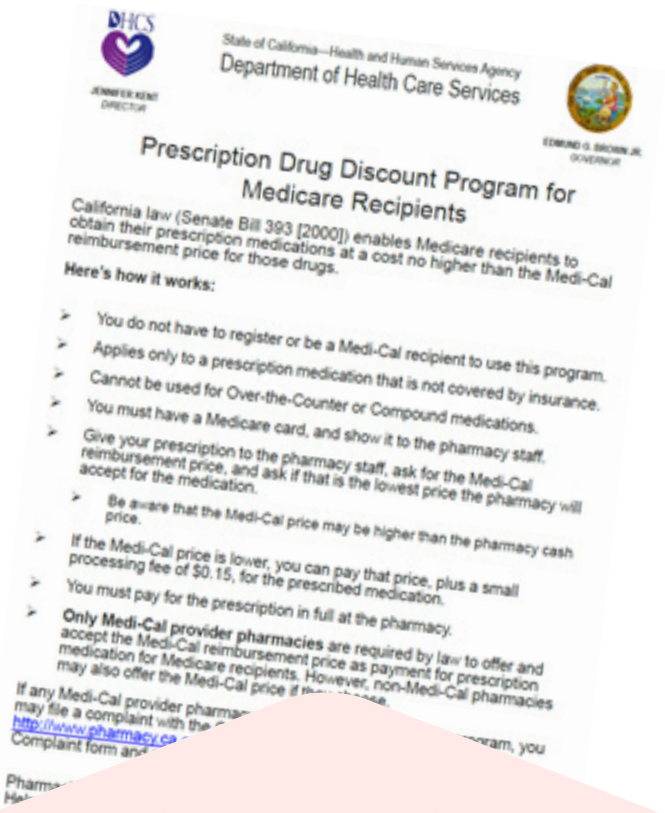
Consumers do not have to register or receive Medi-Cal to participate. The discount program applies only to prescription medications that are not covered by insurance, and it cannot be used for over-the-counter or compounded medications. Consumers must present their Medicare card to pharmacy staff to receive the Medi-Cal price.

The California Department of Health Care Services (DHCS) has an online search tool for SB 393 drug prices. Consumers can use the tool to find out how much Medi-Cal reimburses for 200 brand drugs.

Only Medi-Cal enrolled pharmacy providers are required to offer and accept the Medi-Cal reimbursement price as payment for prescription medications for Medicare patients, plus a processing fee of 15 cents. A consumer may file a Board of Pharmacy complaint form against a Medi-Cal enrolled pharmacy that refuses to offer the discount program.

The DHCS website also offers a flyer about the drug discount program that pharmacies can download, post and make available to consumers. The flyer explains how the program works and provides contact information for pharmacies and consumers who have questions:

- Phone: Medi-Cal Help Line, (800) 541-5555.
- Email: sb393inquiry@dhcs.ca.gov.



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

Prescription Drug Discount Program for Medicare Recipients

California law (Senate Bill 393 [2000]) enables Medicare recipients to obtain their prescription medications at a cost no higher than the Medi-Cal reimbursement price for those drugs.

Here's how it works:

- You do not have to register or be a Medi-Cal recipient to use this program.
- Applies only to a prescription medication that is not covered by insurance.
- Cannot be used for Over-the-Counter or Compound medications.
- You must have a Medicare card, and show it to the pharmacy staff.
- Give your prescription to the pharmacy staff, ask for the Medi-Cal reimbursement price, and ask if that is the lowest price the pharmacy will accept for the medication.
- Be aware that the Medi-Cal price may be higher than the pharmacy cash price.
- If the Medi-Cal price is lower, you can pay that price, plus a small processing fee of $0.15, for the prescribed medication.
- You must pay for the prescription in full at the pharmacy.
- **Only Medi-Cal provider pharmacies** are required by law to offer and accept the Medi-Cal reimbursement price as payment for prescription medication for Medicare recipients. However, non-Medi-Cal pharmacies may also offer the Medi-Cal price if

If any Medi-Cal provider pharma... may file a complaint with the ... http://www.pharmacy.ca... Complaint form and... ...ram, you

Pharma...

The California Department of Health Care Services offers a flyer about the Prescription Drug Discount Program for Medicare Recipients. The flyer can be downloaded for pharmacists and consumers.

Board establishes new e-mail address for processing pharmacy technician licenses

The email address for processing pharmacy technician licenses has changed. For questions regarding the status of a pending pharmacy technician application or licensing requirements, contact the Board of Pharmacy at the new address, TCHstatus@dca.ca.gov.

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

JENNIFER KENT
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

Prescription Drug Discount Program for Medicare Recipients

California law (Senate Bill 393 [2000]) enables Medicare recipients to obtain their prescription medications at a cost no higher than the Medi-Cal reimbursement price for those drugs.

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- Cannot be used for Over-the-Counter or Compound medications.
- You must have a Medicare card, and show it to the pharmacy staff.
- Give your prescription to the pharmacy staff, ask for the Medi-Cal reimbursement price, and ask if that is the lowest price the pharmacy will accept for the medication.
    - Be aware that the Medi-Cal price may be higher than the pharmacy cash price.
- If the Medi-Cal price is lower, you can pay that price, plus a small processing fee of $0.15, for the prescribed medication.
- You must pay for the prescription in full at the pharmacy.
- **Only Medi-Cal provider pharmacies** are required by law to offer and accept the Medi-Cal reimbursement price as payment for prescription medication for Medicare recipients. However, non-Medi-Cal pharmacies may also offer the Medi-Cal price if they choose.

If any Medi-Cal provider pharmacy refuses to participate in this program, you may file a complaint with the CA Board of Pharmacy electronically at http://www.pharmacy.ca.gov or by downloading the Board's Consumer Complaint form and mailing it to the Board.

Pharmacies or Medicare recipients with questions may contact the Medi-Cal Help Line at 1-800-541-5555 or by email at sb393inquiry@dhcs.ca.gov.

Attachment 13

Proposed Modifications

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver ~~previously dispensed~~ prescription medications to patients as authorized provided:

(1) ~~Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.~~

~~(2)~~ A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

~~(3)~~ (2)The device has a means to identify each patient and only release that patient's prescription medications.

(4) ~~The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).~~

~~(5)~~ (3)The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

~~(6) The device is located adjacent to the secure pharmacy area.~~

~~(7) The device is secure from access and removal by unauthorized individuals.~~

~~(8) The pharmacy is responsible for the prescription medications stored in the device.~~

~~(9)~~ (4)Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

~~(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).~~

(e) Any pharmacy making use of an automated delivery device ~~as permitted by subdivision (d)~~ shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device**,** notifying patients when expected prescription medications are not available in the device**,** and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

~~(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.~~

Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code.

Reference: Sections 4005, 4017.3, 4052, 4116, ~~and~~ 4117, 4417, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6 4427.7, and 4427.8, Business and Professions Code

Ms. Virgina Herold, Executive Director
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Automated Drug Delivery Systems

October 22, 2018

Dear Ms. Herold,

Following the enactment of *SB1447: Pharmacy: automated drug delivery systems*, it is our understanding that the California Board of Pharmacy will need to update *CA ADC § 1713 - Receipt and Delivery of Prescriptions and Prescription Medications* to comply with the statute. Please find proposed changes below.

CA ADC § 1713 - Receipt and Delivery of Prescriptions and Prescription Medications

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver ~~previously dispensed~~ prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to the patient.

(3) The device has a means to identify each patient <u>or patient's representative</u> and only release that patient's prescription medications.

4110 Sorrento Valley Blvd | San Diego, CA 92121
Tel 858-777-8600 | Fax 858-866-0669 | www.asteres.com

Thank you for your support throughout this legislative process.

Sincerely,

Sara Lake

Sara Lake
Director of Regulatory Affairs

4110 Sorrento Valley Blvd | San Diego, CA 92121
Tel 858-777-8600 | Fax 858-866-0669 | www.asteres.com

Attachment 14

STATEMENT OF ISSUE AND PROPOSED METHODS OF RESOLUTION FOR CURES SUBMISSIONS FROM PHARMACIES

Robert L. Stein, PharmD, JD, Professor of Practice for Pharmacy Law & Ethics and Health Information Technology
Keck Graduate Institute School of Pharmacy and Health Sciences

Background

Currently, all Schedule II – IV controlled substance prescriptions dispensed in California must be reported to the Prescription Drug Monitoring Program (PDMP) known as the "Controlled Substance Utilization Review and Evaluation System" (CURES).

While the CURES reporting system is administered by the California Department of Justice, actual submissions by pharmacies are transmitted to a third party, Atlantic Associates (AAI). AAI is tasked with data integrity and formatting checks, identifying duplicate entries and reconciling "near matches." AAI then transmits the data for insertion into the CURES database.

The CURES submission elements are defined in Health and Safety Code Section 11165(d):

> (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
> (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
> (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
> (4) National Drug Code (NDC) number of the controlled substance dispensed.
> (5) Quantity of the controlled substance **dispensed**.
> (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
> (7) Number of refills ordered.
> (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
> (9) Date of origin of the prescription.
> (10) Date of **dispensing** of the prescription.

Records of dispensing must be sent to CURES **within seven days of the dispensing** of the controlled substance.

Issue #1 – Transactions cannot be easily reversed/cancelled once transmitted to AAI

The ASAP v4.1 transmission specification used by CURES has a "reporting status" segment (DSP01), of which code "02", described in the specification as "02 Void (message to the PMP to remove the original prescription transaction from its data, or to mark the record as invalid or to be ignored). AAI has stated that they can accept the "02" code in DSP01, and as of today, CURES can accept and process these to remove them from the database. (We are awaiting information as to how long that process to remove cancelled/voided prescriptions will take.) Failure to use this automated method results in a laborious workflow to reverse a prescription returned to stock and not physically conveyed to the patient. *See Figures 1, 2 and 4.*

Issue #2 – Confusion of terms between Board of Pharmacy, DOJ, and AAI

AAI's instructions illustrate the conflation of the terms "dispense" and "fill":

> Users must enter all the required (*) Prescription fields. In the date fields, users must follow the proper format

(CCYYMMDD). Do not use special characters, e.g. no backlash (\) or dash in between numbers. Refill codes must be
two digits, e.g. 00, 01.

- Reporting Status
- Prescription Number
- Date Written (CCYYMMDD)
- Refills Authorized (If no refills enter 00)
- **Date Filled** (CCYYMMDD)
- Refill Number (One single fill or first fill code is 00.)
- Product ID Qualifier, select NDC or Compound.
- NDC -eleven digits required Enter eleven 9's if compound is selected
- Quantity **Dispensed**
- Days' Supply
- Drug Dosage Unit Codes – Unit of measure for the quantity dispensed (gm, ml or ea)
- Transmission Form of Rx (How Rx was received: written, phone, fax, electronic, etc.)
- Partial Fill Indicator

https://www.aaicures.com/Atlantic_Associates_CACures_Instructions.pdf (*Emphasis added.*)

Even in the scenario where the pharmacy system includes a Point of Sale (POS) or a "closed loop" dispensing system that records the actual dispensing of the prescription to the patient as in Figure 3 (allowing a CURES transmission to include a "date of sale" element), under the current specifications and law, *if the transmission were held until the time of sale* (obviating the need for a "reverse/cancel" transaction), *a pharmacy could potentially submit prescriptions that CURES and DOJ would consider "late," based on the date filled.* This is due to the fact that many pharmacy systems treat the "date of dispensing" as the date of fill. So, a prescription filled by a pharmacy on September 1 but not picked up by the patient until September 7 would not be sent to CURES until sometime after September 7, resulting in the transmission being more than seven days after the date of fill and potentially a violation of current law.

AB 1752 (2017-2018 session, died) attempted to partially address this situation by adding "date of sale" to the data elements required to be transmitted by the pharmacy. But even had AB 1752 passed, the law requiring transmission to CURES within seven days of the "dispense date"[1] still requires clarification as to when the transmission to CURES would be due. (Is it based on the *fill date* or the *sale date?*).

This illustrates some of the issues whereby "date filled," "dispense date," and "sale date" (when the patient actually receives the medication) need harmonization and concurrence between the Board of Pharmacy and Department of Justice, and pharmacy system vendors must update their systems to send the "02" void/cancel for any prescription filled but not subsequently picked up by a patient.

Conclusions and recommendations

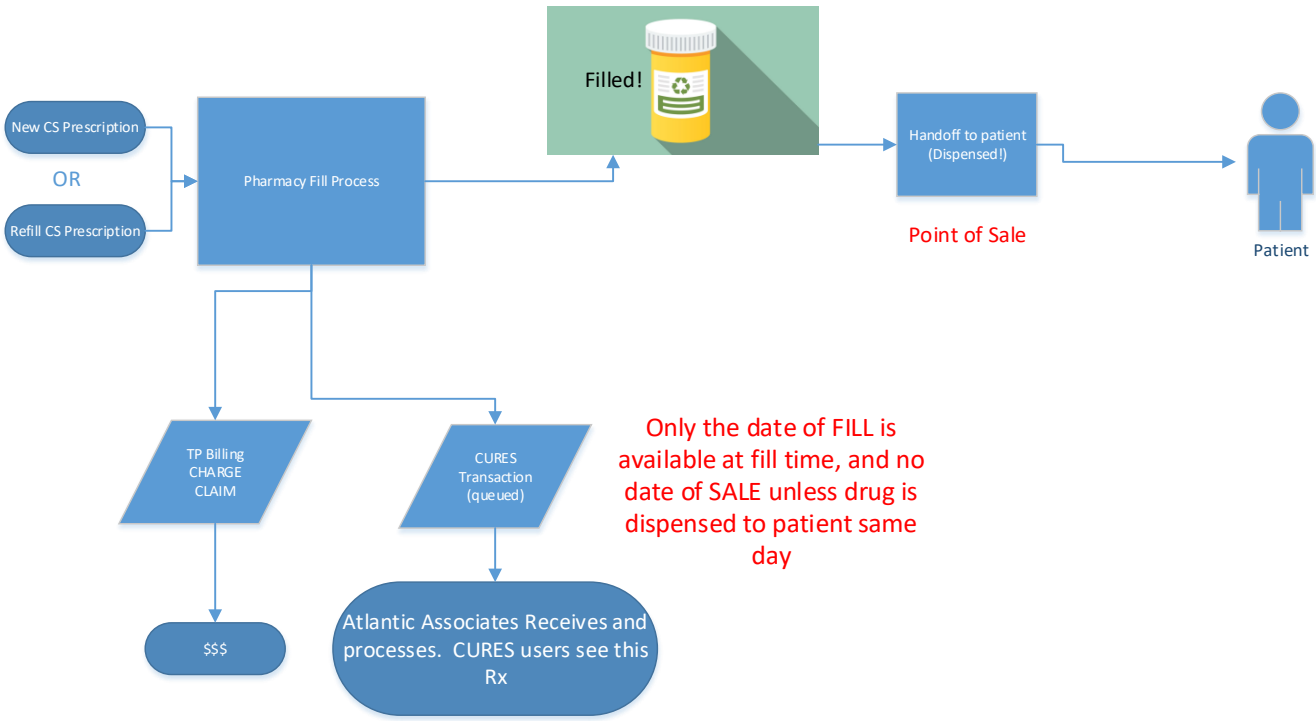
1. **A reverse/cancel (e.g., ASAP v4.1 Reporting Status element with code "02") transaction obviates the manual processes needed to remove a prescription not in fact conveyed to a patient from CURES.**

2. Pharmacies with computer systems that include integrated Point of Sale (POS) or "closed loop dispensing" may not require the reverse/cancel functionality if the date of sale (i.e., physical dispensing to the patient) becomes the "trigger event" to send a prescription record to CURES; however, if the "date of dispensing" is considered to be the date of fill in the pharmacy computer system, some prescriptions may be reported to CURES later than the statutory requirement. A statutory amendment to clarify that the time limit to submit the transaction to

[1] "AB 1752 also contained a proposal to amend the submission to CURES from seven days to "one working day."

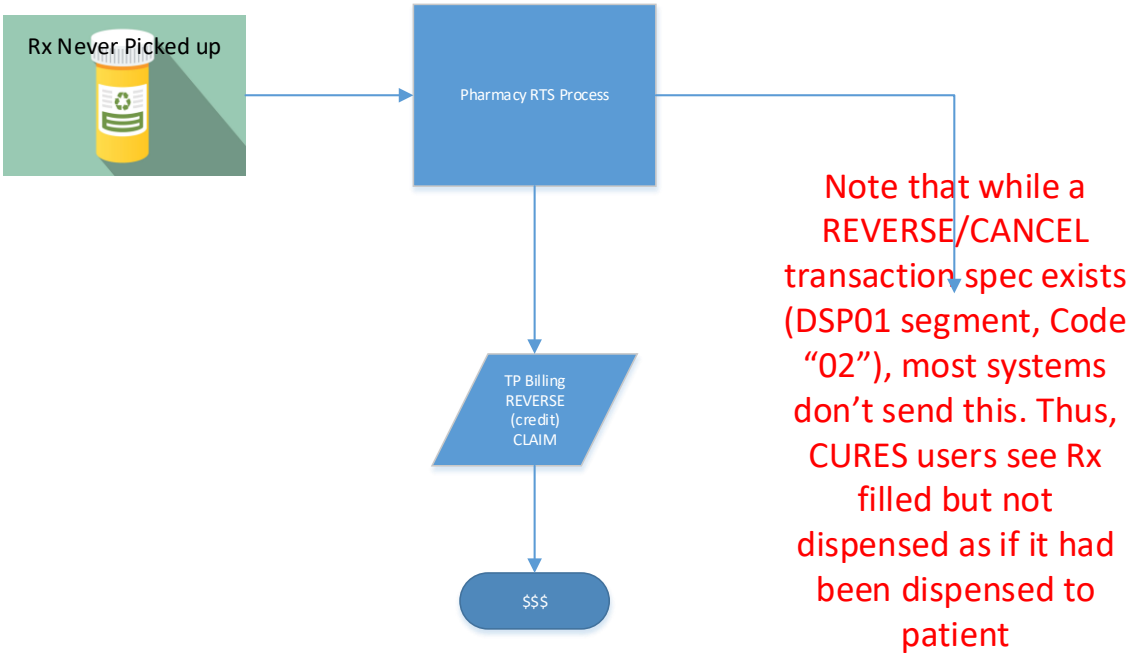
CURES begins at either the date of prescription processing or the date of actual dispense to the patient, whichever if later.

3. Pharmacy system vendors should be notified that to comply with California reporting requirements, they must modify their systems to send a “02” code (void/cancel) in the DSP01 segment to AAI.
4. Clarifying language in statutes and regulations that harmonizes definitions of “fill,” “dispense,” and “sale” dates.



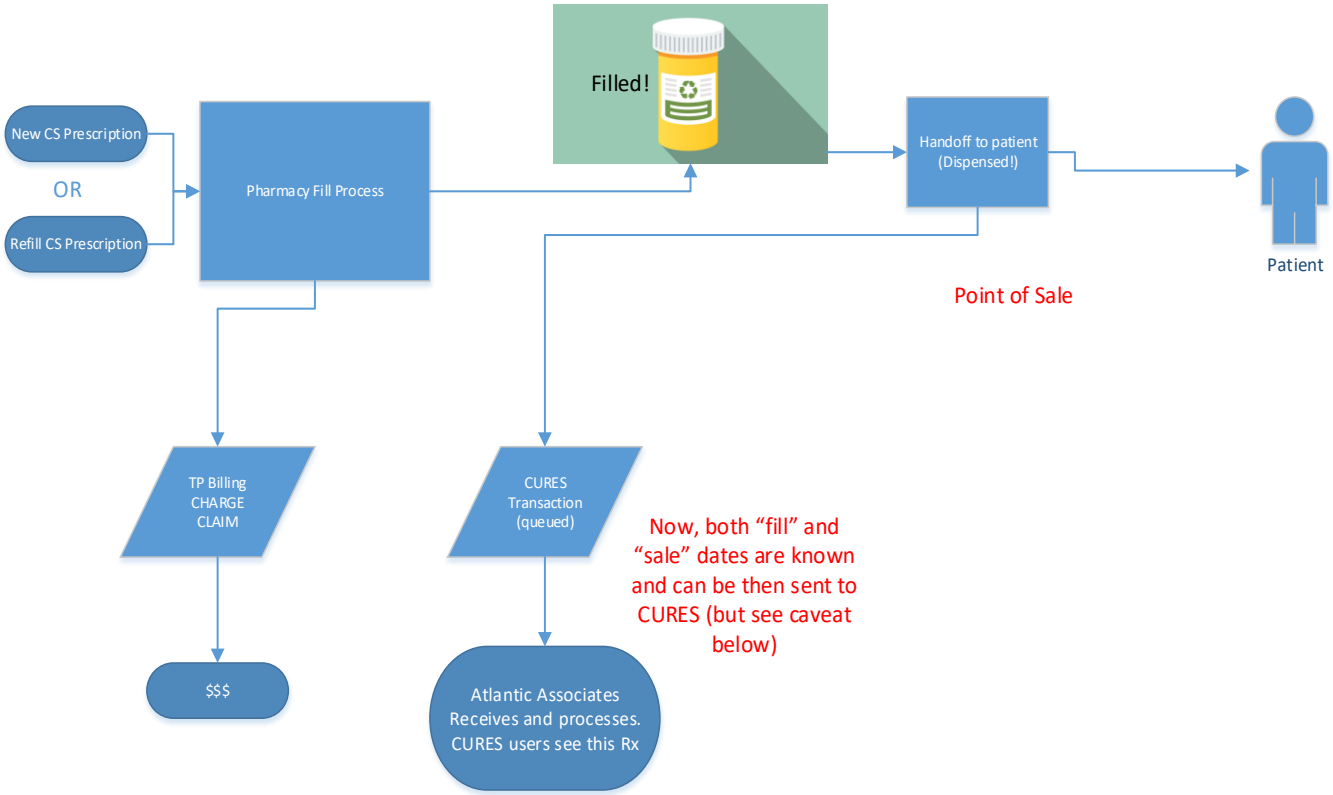
CS Rx Fill Typical Current Flow (pharmacies that do not have "closed loop" dispensing or a POS system)

Figure 1



Typical Current CS Rx Return to Stock Flow

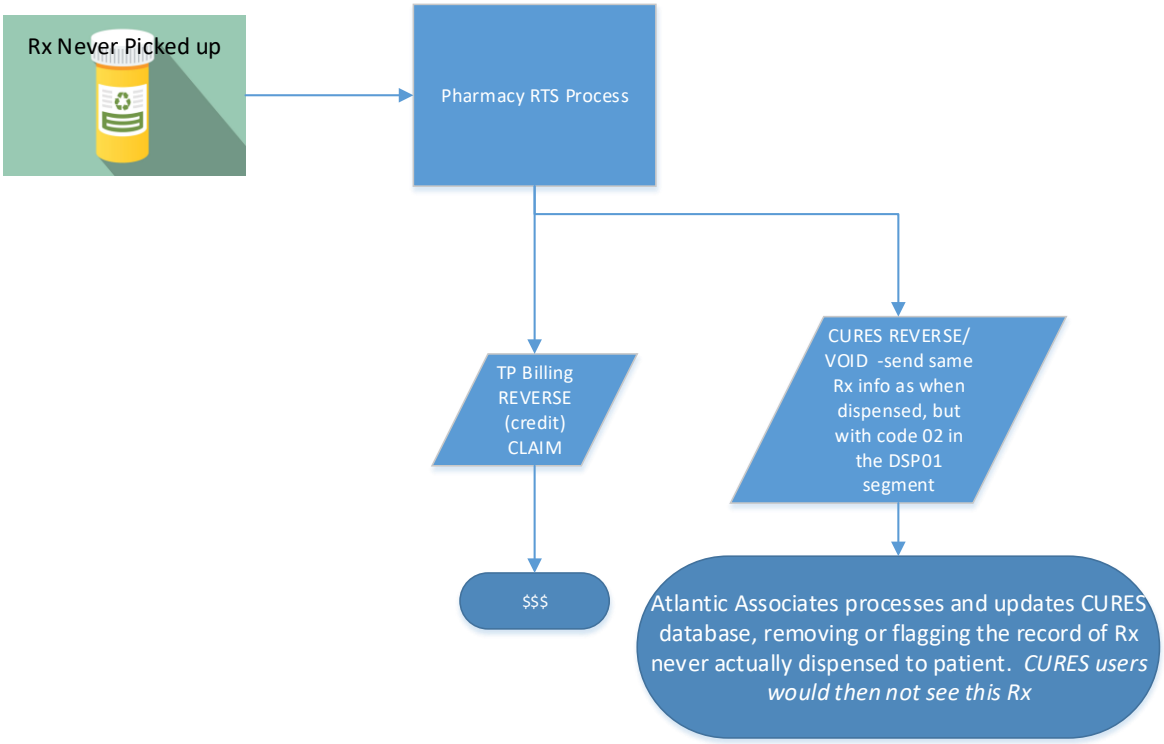
Figure 2



CS Rx Fill Ideal Flow (Integrated POS/Closed Loop Dispensing)

This obviates the need for a reverse/cancel transaction to CURES, as nothing sent to CURES unless/until patient actually receives Rx. *But not all pharmacies have an integrated POS (or closed loop dispensing) and thus the need for an alternative. Further, there is a potential for the prescription to be transmitted to CURES more than seven days passed "fill." Statutory fixes are required to harmonize which date (sale or fill) starts the clock ticking for the seven day window.*

Figure 3



Proposed CS Rx Return to Stock Flow with CURES reverse/cancel fill transaction

Figure 4