

Date of Hearing: March 29, 2022

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Marc Berman, Chair

AB 2265 (Arambula) – As Introduced February 16, 2022

NOTE: This bill is double-referred and if passed by this Committee will be referred to the Assembly Committee on Judiciary.

SUBJECT: Pharmacy: dispensing controlled substances: lockable vials.

SUMMARY: Requires a pharmacist who dispenses a Schedule II or Schedule IIN controlled substance to dispense the drug in a lockable vial paid for by the drug's manufacturer, include the code for the lockable vial in any patient notes, and provide the patient with an educational pamphlet on the risks associated with opioids.

EXISTING LAW:

- 1) Allows only a physician, dentist, podiatrist, veterinarian, naturopathic doctor, registered nurse, certified nurse-midwife, optometrist, or out-of-state prescriber to write or issue a prescription. (Health and Safety Code (HSC) § 11150)
- 2) States that a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice, and that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. (HSC § 11153)
- 3) Prohibits medical professionals from prescribing, administering, or dispensing a controlled substance to an addict, as defined. (HSC § 11156)
- 4) Lists a number of required features that must be included for all prescription forms for controlled substances, including fraud-prevention identifiers, printing information, and information relating to the prescribing practitioner. (HSC § 11162.1)
- 5) Requires all prescriptions and dispensations of controlled substances to meet a series of requirements including use of a controlled substance prescription form, presence of a signature and date in ink, and the address of the patient. (HSC § 11164)
- 6) Requires a prescriber to discuss with a minor, or the minor's representative, prior to dispensing or issuing a prescription of opioids for the first time, the risks of addiction and overdose associated with the use of opioids and the increased risk of opioid addiction to an individual suffering from mental and substance abuse disorders. (HSC § 11158.1)
- 7) Establishes the Controlled Substance Utilization Review and Evaluation System (CURES), a database maintained by the California Department of Justice for the purposes of collecting records of dispensed controlled substances for review by licensed prescribers and dispensers, regulatory investigators, law enforcement, and statistical researchers. (HSC § 11165)
- 8) Requires schools and youth sports organizations to annually provide athletes of all ages, as well as the parents or guardians of athletes 17 years of age or younger, with a copy of the

Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention, and requires that a signed document acknowledging receipt of the factsheet be returned prior to the athlete's participation in the sport. (HSC § 124236)

- 9) Requires a prescriber to provide information regarding, and offer a prescription for, naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression to a patient certain conditions are present. (Business and Professions Code (BPC) § 471)
- 10) Establishes the California State Board of Pharmacy (Board) to administer and regulate the Pharmacy Law. (BPC § 4001)
- 11) Requires labeling of all containers of prescription drugs stating information about the drug, directions for use, the names of the patient and the prescriber, and other information. (BPC § 4076)
- 12) Requires a pharmacy or practitioner to prominently display on the label or container for any opioid that is dispensed to a patient for outpatient use a notice that states "Caution: Opioid. Risk of overdose and addiction." (BPC § 4076.7)
- 13) Requires most pharmacies that dispense Schedule II, III, or IV controlled substances to display safe storage products, as defined, in a place on the building premises that is located close to the pharmacy. (BPC 4106.5)

THIS BILL:

- 1) Establishes the California Safe Dispensing Act, to become operative on June 30, 2023.
- 2) Defines "lockable vial" as a prescription locking vial that qualifies as a "safe storage product" that is made of materials classified as "generally recognized as safe" under federal regulations.
- 3) Requires a pharmacist who dispenses in solid oral dosage form a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act to dispense the controlled substance in a lockable vial.
- 4) If the lockable vial uses an alphanumeric passcode or other code, requires the pharmacist to include the code in any patient notes in the database or other system used by the pharmacy in the dispensing of prescription drugs.
- 5) Requires that the patient to choose the code, or the patient's parent or legal guardian if the patient is a minor or otherwise unable to authorize medical care, or the conservator of the patient if the conservator has been given the power to make health care decisions for the patient.
- 6) Provides that a pharmacist shall not dispense a Schedule II controlled substance in a lockable vial directly to a patient who, because of a physical or mental condition, would have difficulty opening the lockable vial.
- 7) Exempts from the requirement that a pharmacist dispense a Schedule II or Schedule IIN drug in a lockable vial if one or more of the following applies:

- a) The prescription, dispensation, and administration of the controlled substance occurs in a hospital or other inpatient care facility.
 - b) The patient or the patient's representative who is authorized to choose the code for the lockable vial requests to their prescriber or the pharmacist that the patient's medication not be dispensed in a lockable vial.
 - c) The prescriber indicated on the prescription that the patient requested not to receive their medication in a lockable vial.
- 8) Provides that the manufacturer of a controlled substance shall compensate the pharmacy for the cost of each lockable vial, as well as dispensing costs and services, within 30 days of receiving a claim.
 - 9) Requires the Board to establish a reasonable rate of compensation that is not less than \$2.50 per lockable vial.
 - 10) Subjects a manufacturer who fails to reimburse a pharmacy within the time period and for the amount specified to a civil penalty of \$1,000 per day for each day the manufacturer is delinquent in reimbursing the pharmacy, assessed and recovered in a civil action brought by the Board in the name of the people of the State of California.
 - 11) Authorizes a pharmacy technician or other pharmacy staff to complete all tasks in the bill that are not otherwise prohibited by law.
 - 12) Requires that any vendor that contracts with a pharmacy to provide a lockable vial shall make available at all times assistance online or through a toll-free number for patient use.
 - 13) Requires a pharmacist who dispenses a Schedule II or Schedule IIN drug to additionally provide a copy of the Opioid Factsheet for Patients published by the federal Centers for Disease Control and Prevention.
 - 14) Provides that a practitioner who prescribes a controlled substance dispensed in a lockable vial shall not be liable for any adverse consequences that result from either the failure of any lockable vial to prevent unauthorized access or a patient not being able to access medication in a lockable vial, without affecting a person's liability for existing product defect damages.
 - 15) Authorizes the Board to not take administrative action against a pharmacy if it determines that compliance would create a financial hardship on the pharmacy or that the pharmacy was temporarily out of stock of lockable vials after taking reasonable steps to ensure an adequate supply for all dispensations of Schedule II or Schedule IIN controlled substances.
 - 16) Exempts correctional pharmacies, correctional clinics, or patients of the Department of Corrections and Rehabilitation from the bill.
 - 17) Makes various findings and declarations.

FISCAL EFFECT: Unknown; this bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. According to the author:

“We should all welcome common-sense solutions when it comes safeguarding our prescribed medications, especially since some people don’t suspect that their friends and family may be accessing dangerous pharmaceuticals in their own medicine cabinets. By requiring that these highly addictive medications be dispensed in tamper-proof containers, AB 2265 will help reduce unauthorized access to potentially harmful medications and educate consumers on what to do when pilfering has been discovered in their household.”

Background.

Overview of the Opioid Crisis. In October of 2017, the White House declared the opioid crisis a public health emergency, formally recognizing what had long been understood to be a growing epidemic responsible for devastation in communities across the country. According to the Centers for Disease Control and Prevention, as many as 50,000 Americans died of an opioid overdose in 2016, representing a 28 percent increase over the previous year. Additionally, the number of Americans who died of an overdose of fentanyl and other opioids more than doubled during that time with nearly 20,000 deaths. These death rates compare to, and potentially exceed, those at the height of the AIDS epidemic.

Opioids are a class of drugs prescribed and administered by health professionals to manage pain. Modern use of the term “opioid” typically describes both naturally occurring opiates derived from the opium poppy as well as their manufactured synthetics. Common examples of prescription opioids include oxycodone (OxyContin, Percocet); hydrocodone (Vicodin, Norco, Lorcet); codeine; morphine; and fentanyl. Heroin is also an opioid.

In addition to providing pain relief, opioids can be used as a cough suppressant, an antidiarrheal, a method of sedation, and a treatment for shortness of breath. The majority of pharmaceutical opioids are Schedule II drugs under the federal Controlled Substances Act, considered by the federal Drug Enforcement Agency (DEA) to have a high potential for abuse that may lead to severe psychological or physical dependence. However, combination drugs containing lower doses of opioids combined with other active ingredients are typically less restricted; for example, cough syrups containing low doses of codeine are frequently classified Schedule V medications.

The abuse of prescription drugs was historically viewed as a criminal concern analogous to street narcotics cases regularly investigated by law enforcement. In recent years, however, an expert consensus has evolved around the opinion that the opioid crisis must be addressed through the lens of public health policy. This belief is supported by research demonstrating how health professionals may have inadvertently contributed to the origins of the crisis. It is widely accepted that health professionals will play a necessarily critical role in any meaningful solutions.

In the opioid crisis’s broader national context, there has been a persistent perception that California represents a relatively minor segment of an epidemic more typically identified with states like New Hampshire and West Virginia. However, there is substantial evidence that communities in California have been much harder hit than may be generally believed. For example, in 2015, several rural counties in California saw as many or more drug overdose deaths per 100,000 residents than some Midwestern states. It has been reported than some small

counties had more opioid prescriptions than residents. In total, the California Department of Public Health estimates that nearly 2,000 Californians died of an opioid overdose in 2016.

Safe Storage Products. Among the many solutions to preventing prescription drug abuse and overdose, patient safety advocates have championed the use of safe storage products designed to ensure that children and adolescents, as well as adults with diminished cognitive function, cannot access dangerous medications kept within the home. Reports of accidental poisonings resulting from child access to their parents' medicine cabinets are common anecdotes used to support policies to promote better storage practices.

According to the National Center on Addiction and Substance Abuse, 90 percent of individuals with substance use disorder began using substances before the age of 18, while 70 percent of prescription drugs obtained for non-medical use (12 years and older) came from a household. A study by the Partnership for Drug-Free Kids found that more than three in five teens said pain relievers were easy to obtain from their parents' medicine cabinets.

In response to both public policy imperative and financial incentive as awareness of the opioid crisis grows, a number of manufacturers have begun to market products aimed at providing safe storage options within the home. Current law requires that these products be carried and displayed at the majority of larger pharmacy chains. This bill would go a step further and require that every Schedule II or Schedule IIN drug be dispensed with one of these products, which would then be subsequently paid for by the manufacturer of the drug.

Prior Related Legislation. AB 1430 (Arambula) from 2021 was substantially similar to this measure. *This bill died on the Assembly Committee on Appropriations suspense file.*

SB 1084 (Umberg) from 2020 was substantially similar to this measure. *This bill died in the Senate Committee on Business, Professions, and Economic Development.*

AB 2859 (Caballero, Chapter 240, Statutes of 2018) Requires certain pharmacies that dispense Schedule II, III, or IV controlled substances to display safe storage products, as defined, for sale in a place on the building premises that is located close to the pharmacy.

SB 1109 (Bates, Chapter 693, Statutes of 2018) requires a prescriber to discuss the following with a minor, or the minor's parent, guardian, or other adult authorized to consent to the minor's medical treatment, information relating to the risks associated with opioids prior to dispensing or issuing a prescription of opioids to a minor for the first time.

AB 2592 (Cooper) from 2016 would have required all pharmacies in receipt of opioid abuse prevention grant dollars to offer all patients who are prescribed an opioid a medicine locking closure package. *This bill died on the Assembly Appropriations suspense file.*

ARGUMENTS IN SUPPORT:

None on file.

ARGUMENTS IN OPPOSITION:

The **California Retailers Association (CRA)** and **National Association of Chain Drug Stores (NACDS)** oppose this bill. The CRA and NACDS argue that "requiring pharmacies to dispense

Schedule II prescription drugs in lockable vials will do little to prevent theft and abuse of these controlled substances, all the while creating unwarranted and significant pharmacy workflow challenges.” They point out that “patients who are concerned about prescription drug pilfering already have the ability to purchase lockable vials where available” and state that they would remove their opposition “if the lockable vial mandate is made voluntary and if the requirement for pharmacies to maintain patients’ combination codes is removed.”

POLICY ISSUES:

Retention of Passcodes. Under the requirements of this bill, once a patient or their representative has selected a code for their lockable vial, the pharmacy would be responsible for including that code in any patient notes in their database or other system. Presumably this would be to ensure that the pharmacy is in a position to assist a patient with accessing their medication in the event that they forget their code. However, this could result in unknown but potentially significant costs to pharmacies in informational technology updates and workforce associated with confirming patient identities and providing code reminders, and pharmacies may not be best positioned to provide immediate customer service to patients in urgent need of their code. Meanwhile, more cost effective or convenient solutions may already be available – for example, Safe RX, a major manufacturer of safe storage products that would be covered under this bill, provides its own free registration program for vial codes.

IMPLEMENTATION ISSUES:

Compensation Rate Establishment. This bill would require the California State Board of Pharmacy to establish a reasonable rate of compensation for pharmacy services associated with dispensing controlled substances under the provisions of the bill, not to exceed \$2.50 per lockable vial. This requirement is outside the scope of the Board’s regular activities as a licensing entity and it is unclear what methodology it should use in that calculation. The author may wish to reconsider whether the Board is the appropriate entity to carry out this responsibility.

AMENDMENTS:

Strike the contents of paragraph (3) of subdivision (b) in Section 2 of the bill and insert:

(3) Provide the patient with information regarding the online assistance or toll-free number made available by the vendor providing the lockable vial pursuant to subdivision (e).

REGISTERED SUPPORT:

None on file.

REGISTERED OPPOSITION:

California Chamber of Commerce
California Retailers Association
Mallinckrodt, LLC.
National Association of Chain Drug Stores

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