

Date of Hearing: April 27, 2022

ASSEMBLY COMMITTEE ON APPROPRIATIONS

Chris Holden, Chair

AB 2265 (Arambula) – As Amended April 6, 2022

Policy Committee:	Business and Professions	Vote:	11 - 0
	Judiciary		7 - 1

Urgency: No                      State Mandated Local Program: No                      Reimbursable: No

**SUMMARY:**

This bill requires a pharmacist to dispense specified drugs in lockable vials. Specifically, this bill:

- 1) Requires a pharmacist who dispenses any drug listed on Schedule II or Schedule IIN of the federal Controlled Substances Act to dispense the product in a lockable vial and to provide a copy of the Opioid Factsheet for Patients published by the federal Centers for Disease Control and Prevention and information regarding online assistance or toll-free telephone number for the vendor of the lockable vial. (Schedule II and Schedule IIN drugs have a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Schedule II drugs are generally narcotics and Schedule IIN drugs are generally non-narcotic stimulants.)
- 2) Requires the patient or patient's parent, guardian or conservator to choose the code for the lockable vial.
- 3) Prohibits a pharmacist from dispensing a prescription in a lockable vial directly to a patient who, to the pharmacist's knowledge, would have difficulty opening the lockable vial.
- 4) Requires, by October 1, 2023, the Board of Pharmacy (Board) to establish reasonable minimum and maximum amounts of reimbursement that include the cost of the vial and services rendered and dispensing costs.
- 5) Defines "lockable vial," by reference, as 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, and requires the product to meet federal standards for poison control packaging.
- 6) Requires the manufacturer of a controlled substance to reimburse the pharmacy within 30 days of receiving a claim for the cost of lockable vials used by the pharmacy to dispense controlled substances, and requires the Board to assess a civil penalty of \$1,000 per day for each day the manufacturer is delinquent in reimbursing the pharmacy.
- 7) Provides a prescriber immunity from liability for any adverse consequences resulting from the failure of any lockable vial to prevent unauthorized access or a patient not being able to access medication in a lockable vial.

- 8) Exempts pharmacies and pharmacists in specified circumstances, such as for a patient who would have difficulty opening the lockable vial or who requests that a lockable vial not be used, or inpatient or correctional settings.

#### **FISCAL EFFECT:**

- 1) Administrative and enforcement costs to the Board of Pharmacy of \$177,000 per year in fiscal years (FYs) 2023-24 and 2024-25, and \$101,000 in FY 2025-26 and ongoing to fully support this bill (Pharmacy Board Contingent Fund).
- 2) Unknown, potentially significant cost pressure to Medi-Cal managed care or Medi-Cal fee-for-service to increase reimbursement for pharmaceuticals (General Fund and federal funds). This bill requires pharmaceutical manufacturers to reimburse pharmacies, but in the highly competitive generic market where actual drug costs may be less than the cost of a locking vial, this increased cost will likely be passed on to payers, including Medi-Cal, which insures one-third of the California population. If this increased cost makes the market less attractive to generic manufacturers, reduced competition could also increase costs.

#### **COMMENTS:**

- 1) **Purpose.** The author states:

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.

- 2) **Background.** Federal law classifies drugs into five schedules depending on each drug's medical use and potential for abuse or dependency. Schedule I drugs are considered the most dangerous and have no accepted medical use, while Schedule V are the least dangerous. According to the Drug Enforcement Agency, Schedule II or IIN drugs have a high potential for abuse that may lead to severe psychological or physical dependence.
- 3) **Prescription Opioid Misuse.** According to the California Department of Public Health, prescription opioid misuse is a public health problem that can lead to long-term health consequences, including limitations in daily activity, impaired driving, mental health problems, trouble breathing, overdose and death. Overdose deaths, in particular, have increased dramatically in recent years.
- 4) **Lockable Vials.** Safe storage devices can protect from accidental ingestion or pilfering. A number of methods for safe storage are available, including small safes with a combination locks, and devices that attach combination locks to medication bottles themselves, as well as locking vials that fit a single pill bottle.
- 5) **Related Legislation.**

SB 1109 (Bates), Chapter 693, Statutes of 2018, requires a prescriber to discuss 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 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.

AB 1430 (Arambula), of the current Legislative Session, was nearly identical to this bill and was held on the Suspense File of this committee.

AB 2592 (Cooper), of the 2015-16 Legislative Session, 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. AB 2592 was held on the Suspense File of this committee.

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