Date of Hearing: April 5, 2022

ASSEMBLY COMMITTEE ON JUDICIARY
Mark Stone, Chair
AB 2265 (Arambula) – As Amended March 30, 2022

As Proposed to be Amended

SUBJECT: PHARMACY: DISPENSING CONTROLLED SUBSTANCES: LOCKABLE VIALS

KEY ISSUE: IN ORDER TO PROTECT THE PUBLIC FROM THE RISK THAT POTENTIALLY DANGEROUS PRESCRIPTION MEDICATIONS, INCLUDNG OPIOIDS, ARE STOLEN AND INGESTED BY CHILDREN AND OTHER UNAUTHORIZED USERS, SHOULD ALL CONTROLLED SUBSTANCES LISTED IN SCHEDULE II OR SCHEDULE IIN OF THE FEDERAL CONTROLLED SUBSTANCES ACT BE REQUIRED, EXCEPT IN SPECIFIED CIRCUMSTANCES, TO BE DISPENSED IN LOCKABLE VIALS?

SYNOPSIS

Millions of Americans suffer from pain and are often prescribed opioids to treat their conditions. In 2017, more than 17% of Americans had at least one opioid prescription filled. The proliferation of opioid prescriptions has resulted in record numbers of opiate overdoses, including among children and adolescents.

Advocates have argued that one driver of opiate addiction is the stealing of prescription opiates from a friend or parent. To prevent prescription drug abuse, the FDA, CDC, and safety advocates recommend securing prescribed narcotics, such as Schedule II or Schedule IIN substances, in a locked container. This bill requires that pharmacies dispense certain Schedule II or Schedule IIN prescriptions in a lockable vial, as defined by the bill, and provides qualified immunity from liability to pharmacists if the lockable vial does not prevent unauthorized access or a patient is not able to access their medication due to the lockable vial. Manufacturers of substances covered in this bill would be required to reimburse pharmacies for the cost of the vials and services rendered to comply with these requirements. It establishes civil penalties for failure to reimburse within 30 days of receiving a claim. Amendments to this bill require the Board of Pharmacy to establish a reasonable maximum and minimum amount of reimbursement. Author's amendments are incorporated into the summary of the bill and explained in the analysis.

In support of the bill, co-sponsored by the California Consortium of Addiction Programs and Shatterproof, advocacy groups point out that, though opioids are strictly controlled before being dispensed, there is very little security to prevent unauthorized access once a patient takes them home. The groups argue that this bill has the potential to curb the practice of "pill pilfering" in which individuals develop an addiction to opioids by stealing prescription medications from an individual with a prescription. Arguments opposed have stressed the burden that this bill would have on pharmacies due to the additional workload. Opponents also argue that the cost imposed on pharmaceutical manufacturers makes producing generic prescriptions much less profitable, which may result in fewer manufacturers producing generics and ultimately driving up the price of medications.

SUMMARY: Requires that certain prescription medications be dispensed in a lockable vial; makes failure to do so subject to a civil penalty; and provides qualified immunity to prescribers for adverse consequences that result from the lockable vial either failing to prevent access, or a patient not being able to access medication in a lockable vial. Specifically, **this bill**:

1) Declares that it shall be known as the California Safe Dispensing Act and shall become operative on June 30, 2023.

2) Declares that it is the intent of the Legislature to enact legislation that would do all of the following:

    a) Expand safety precautions for the administration of Schedule II and Schedule IIN pharmaceuticals.

    b) Require a pharmacist who dispenses in a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act (21 U.S.C. Sec. 801 *et seq*.) to dispense the substance in a lockable vial, except as specified.

    c) Require the manufacturer of a controlled substance to reimburse a pharmacy for the cost of the vial, services rendered, and dispensing costs.

    d) Require the State Board of Pharmacy to establish a reasonable amount of reimbursement to a pharmacy for the cost of the vial, services rendered, and dispensing costs.

    e) Ensure that the cost of administering controlled substances in lockable vials does not increase costs to patients and insurers.

3) Defines "lockable vial" to mean a prescription locking vial that qualifies as a "safe storage product" as defined in existing law that is made of materials classified as "generally recognized as safe" as defined in specified federal regulations and meets the standards specified in federal regulations.

4) Requires, except as specified by the bill, a pharmacist who dispenses in solid oral dosage form a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act (21 U.S.C. Sec. 801 *et seq*.) to do all of the following:

    a) Dispense the controlled substance in a lockable vial.

    b) Provide a copy of the Opioid Factsheet for Patients published by the federal Centers for Disease Control and Prevention.

    c) Provide the patient with information about the online assistance or toll-free telephone number made available by the vendor who provides the lockable vial through a contract with the pharmacy.

5) Specifies that, except as provided below, a patient, 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 conservatee who has been given the power to make health care decisions for the patient conservatee, shall choose the code.

6) Provides that in the case of medications prescribed to a minor who may consent to specified services, the minor shall choose the code.

7) Prohibits a pharmacist from dispensing a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act in a lockable vial directly to a patient who, to the best of the pharmacist's knowledge, would have difficulty opening the lockable vial.

8) Provides that a pharmacist is not required to dispense a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act in a lockable vial in any of the following circumstances:

    a) The prescription, dispensation, and administration of the controlled substance occurs in a hospital or other inpatient care facility.

    b) The patient or patient's representative who is authorized to choose the code for the lockable vial as specified above requests to the prescriber or 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.

9) Requires the manufacturer of a controlled substance to reimburse the pharmacy each month for the cost of lockable vials used by the pharmacy to dispense controlled substances in that month.

10) Requires the manufacturer of a controlled substance to reimburse the pharmacy within 30 days of receiving the claim and pay a reasonable rate for the net acquisition cost of the lockable vials, dispensing costs, and services rendered, including any patient consultation and instruction. Allows for a pharmacy technician or other pharmacy staff to complete all tasks specified in this bill that are not otherwise prohibited by law.

11) Provides that a manufacturer of a controlled substance that fails to reimburse a pharmacy within the time period and for the amount specified in this subdivision is liable for a civil penalty of one thousand dollars ($1,000) per day for each day the manufacturer is delinquent in reimbursing the pharmacy, and clarifies the following about the civil penalty:

    a) It shall be assessed and recovered in a civil action brought by the State Board of Pharmacy in the name of the people of the State of California.

    b) It may be reviewed on appeal and the penalty may be reduced or waived for good cause.

12) Requires the State Board of Pharmacy to, by October 1, 2023, establish a reasonable maximum and minimum amount of the specified reimbursement that includes the cost of the vial, services rendered, and dispensing costs.

13) Requires any vendor that contracts with a pharmacy to provide a lockable vial to make available at all times assistance online or through a toll-free telephone number for patient use.

14) Provides that a prescriber, or the prescriber's professional corporation or other business entity, who prescribes or dispenses a controlled substance in a lockable vial shall not be liable for any adverse consequences that result from either of the following:

    a) The failure of any lockable vial to prevent unauthorized access.

    b) A patient not being able to access medication in a lockable vial.

15) Clarifies that 14), above, does not affect a person's liability under existing law for damages caused by defective products, or as a result of willful or wanton misconduct, recklessness, or gross negligence.

16) Allows the Board of Pharmacy to adopt regulations to carry out the provisions in this bill and requires the board to assess a fine in an amount to be determined by the board for a violation of the provisions in this bill by a pharmacist.

17) Authorizes the board to choose not to take administrative action against a pharmacy if it determines that compliance with this bill 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.

18) Provides that Section 4321 of the Business & Professions Code (which provides for penalties for violations of any provision of the law governing pharmacists, when no other penalty is provided) shall not apply to a violation of this bill.

19) Provides that the provisions in this bill do not apply to correctional pharmacies, correctional clinics, or patients of the Department of Corrections and Rehabilitation.

EXISTING LAW:

1) Allows only a physician, dentist, podiatrist, veterinarian, naturopathic doctor, a pharmacist under specified conditions, registered nurse, certified nurse-midwife, optometrist, physician assistance, optometrist, or out-of-state prescriber to write or issue a prescription. (Health and Safety Code Section 11150.)

2) Provides 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. Provides that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner and the pharmacist who fills the prescription. (Health and Safety Code Section 11153.)

3) Prohibits medical professionals from prescribing, administering, or dispensing a controlled substance to an addict, as defined. (Health and Safety Code Section 11156.)

4) 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 associated with the use of opioids. (Health and Safety Code Section 11158.1.)

5) Establishes the California State Board of Pharmacy (Board) to administer and regulate the Pharmacy Law. (Business and Professions Code Section 4001.)

6) Requires labeling of all containers of prescription drugs stating information about the drug, directions for use, the names of the patient, the prescriber, and the pharmacy, the quantity of the drugs dispensed, and other information. (Business & Professions Code Section 4076.)

7) 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." (Business and Professions Code Section 4076.7.)

8) 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. (Business and Professions Code Section 4106.5 (b).)

9) Defines "safe storage products" to mean "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. Specifies that a safe storage product includes, but is not limited to, medicine lock boxes, locking medicine cabinets, locking medication bags, and prescription locking vials." (Business and Professions Code Section 4106.5 (a)(2).)

10) Provides, notwithstanding any other law, that a pharmacy may furnish naloxone hydrochloride or another opioid antagonist to a school district, county office of education, or charter school if all of the following are met:

    a) The naloxone hydrochloride or another opioid antagonist is furnished exclusively for use at a school district schoolsite, county office of education schoolsite, or charter school.

    b) A physician and surgeon provides a written order that specifies the quantity of naloxone hydrochloride or another opioid antagonist to be furnished. (Business and Professions Code Section 4119.8.)

11) Provides that a licensed health care provider who is authorized by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe and subsequently dispense or distribute an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. (Civil Code Section 1714.22 (b).)

12) Provides that a licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. (Civil Code Section 1714.22 (c)(1).)

13) Provides that a licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the administration of an opioid antagonist to a person at risk of an opioid-related overdose by a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid-related overdose. (Civil Code Section 1714.22 (c)(2).)

14) Provides that a licensed health care provider who acts with reasonable care shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution

for issuing a prescription or order pursuant to these provisions. (Civil Code Section 1714.22 (e).)

15) Provides, notwithstanding any other law, that a person who possesses or distributes an opioid antagonist pursuant to a prescription or standing order shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for this possession or distribution. Provides, notwithstanding any other law, that a person not otherwise licensed to administer an opioid antagonist, but trained as required under specified provisions, who acts with reasonable care in administering an opioid antagonist, in good faith and not for compensation, to a person who is experiencing or is suspected of experiencing an overdose shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for this administration. (Civil Code Section 1714.22 (f).)

FISCAL EFFECT: As currently in print this bill is keyed fiscal.

COMMENTS: This bill establishes requirements for pharmacies to dispense Schedule II and Schedule IIN controlled substances in locked containers, small containers that prevent unauthorized access often via an alphanumeric code (i.e., "lockable vials"). Lockable vials are designed to curb the phenomenon of "pill pilfering" whereby children and teens steal their parent's prescribed medications. This bill requires manufacturers of controlled substances to reimburse pharmacies for the cost of the vials and services rendered to comply with these requirements and establishes civil penalties for failure to reimburse within 30 days of receiving a claim. It provides qualified immunity from liability to pharmacists if the lockable vial does not prevent unauthorized access or a patient is not able to access their medication due to a lockable vial. The author states, regarding the purpose and necessity of the bill, the following:

> 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.

Prescription opioid overdoses. Millions of Americans suffer from pain and are often prescribed opioids to treat their conditions. Though the rate of opiate prescriptions rose from 1999 to 2010, it plateaued between 2010 and 2012 and had declined ever since. However, the number of opioids in morphine milligram equivalents (MME) prescribed per person is around three times higher than it was in 1999. (Centers for Disease Control and Prevention, *Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015* (July 2017).) In 2017, more than 17% of Americans had at least one opioid prescription filled, with an average of 3.4 opioid prescriptions dispensed per patient. *(*Centers for Disease Control and Prevention, *Annual Surveillance Report of Drug-Related Risks and Outcomes — United States. Surveillance Special Report 2* (Aug. 2018).)

The proliferation of opioid prescriptions has resulted in record numbers of opiate overdoses. The number of opiate deaths in the U.S. in 2019 was quadruple the number of opiate deaths in 1999. Twenty-eight percent of those deaths were due to prescription opioids. (Centers for Disease Control and Prevention, *Wide-ranging online data for epidemiologic research* (2020).) In 2019, 1,073 Californians died due to prescription opioid overdoses. The most common prescription opioids involved in overdose deaths include methadone, oxycodone (OxyContin) and

hydrocodone (Vicodin). More recently, fentanyl, a pain reliever that is 50 to 100 times more potent than morphine, has been found in what individuals thought was Norco, a prescription pain killer, killing thousands across the country. During just one two-week period in 2016, counterfeit Norco was suspected of causing 42 overdoses and killing ten people in the Sacramento area. (KRON4, *Fake pain pills cause 42 overdoses in two weeks in Sacramento* (April 2016) available at: https://www.kron4.com/news/fake-pain-pills-cause-42-overdoses-in-two-weeks-in-sacramento/.)

Children and adolescents are victims of the opiate crisis as well. Nationally, nearly 5,000 children under 6 years old are evaluated annually in emergency departments for opioid exposures. (Lovegrove, *Trends in Emergency Department Visits for Unsupervised Pediatric Medication Exposures, 2004–2013* (2015).) As opiate overdose deaths have increased, so have deaths of children and adolescents due to opiates. Between 1999 and 2016, nearly 9,000 children and adolescents died due to prescription and illicit opioid poisonings. (Gaither, *US National Trends in Pediatric Deaths From Prescription and Illicit Opioids, 1999-2016* (2018).) Within this group, the highest rate of increase has been among teenagers 15-19 years old. (*Ibid.)*

The most common sources of opioids for teenagers are friends, relatives, and prescriptions from doctors. In one survey, among teenagers who misused prescription pain relievers in 2017, more than half (53.1 percent) obtained the pain relievers from a friend or relative. (Bose, et al., *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health* (Sep. 2018).) Thirty-five percent were prescribed the opioids by a doctor. (*Ibid.)* Only 6 percent bought from a drug dealer or stranger. (*Ibid.)* Germane to this bill is that about 4% of teens who misused prescription pain relievers reported taking them from a friend or relative without asking. (*Ibid.)* The vast majority of adolescents who abused opiates from a friend or relative simply reported receiving them for free. (*Ibid.)*

Advocates have argued that "pill pilfering," in which teens and children steal prescription medications from a friend or parent, is a significant driver of opiate addiction and heroin use among youth. One study by the National Center for Drug Abuse Statistics, reported that many teenagers reported misusing prescription medications because they were accessible via pilfering. In a study by the Partnership for Drug-Free Kids, almost three-quarters of teens (73 percent) report that it is easy to access prescription drugs from their parents' medicine cabinet. This phenomenon has motivated advocates in other states, including Indiana, Florida, and Tennessee, to push for the passage of bills that require opioids to be dispensed in lockable vials.

Safe Storage Products, Including Lockable Vials. To prevent prescription drug abuse, the FDA and CDC explicitly recommend that any prescription narcotic, such as morphine, codeine and other opioids, should be secured in a locked cabinet or drawer. Patient safety advocates have championed the use of safe storage products designed to ensure that children and adolescents cannot access dangerous medications kept within the home. A number of manufacturers have begun to market products aimed at providing safe storage options within the home. Current law requires that these products are carried and displayed at the majority of larger pharmacy chains. This bill would go a step further and require, except as specified, that every Schedule II or Schedule IIN of the federal Controlled Substances Act is dispensed in a lockable vial. The cost of the vials and the labor required to instruct patients on the use of lockable vials is paid for by the manufacturer of the drug.

Though lockable vials may serve as an obstacle to pill pilfering, they are not foolproof. In a 2018 investigation published in Forbes, a security expert evaluated four major brands of locked security containers. (Tobias, *Security Containers for Prescription Drugs that Can be Opened by Kids* (July 2018).) The expert discovered simple methods for opening all of the containers without the code and without leaving evidence that the container was opened. For example, by introducing sugar into the spaces between each combination wheel on a lockable vial cap, the investigator was able to open the container, rinse the sugar off the cap with water, and replace the cap with no evidence of tampering. The manufacturer of the vial added a water sensor to the cap to allow an individual to detect tampering, but the investigators contend that this does not solve fundamental design flaws with the product. This led the investigators to caution that "no lock that only costs a few dollars to produce is secure."

The investigator described these containers as relying on "the appearance of security," arguing that "real security is usually inconsistent with inexpensive components, especially when made of plastic." The perception of security may result in unintended consequences. As the investigator pointed out, "If an adult relies upon the security of one of these containers to protect their meds from theft or pilfering, they may have a false sense of security and not be as vigilant as required to actually count their mediation to make sure that no doses are missing."

This bill requires pharmacies to provide Schedule II and IIN substances in lockable vials, to be reimbursed by the manufacturer. This bill enumerates several requirements to ensure that highly addictive and potentially lethal, prescribed medications are provided to patients in a manner consistent with the risks involved with the medication. The bill requires pharmacies to dispense Schedule II and IIN controlled substances in a lockable vial, allow patients to choose the code of the vial, and provide patients with an opioid factsheet and the phone number and website of the vial manufacturer to assist with the vial. It allows patients to opt out of receiving a lockable vial and exempts inpatient care facilities from the lockable vial requirement if the prescription, dispensation, and administration of the controlled substance occurs in the facility.

The bill also addresses the problem of individuals having trouble accessing their medications in a lockable vial. It prohibits pharmacists from dispensing medications in a lockable vial to patients who, to the best of their knowledge, would have trouble opening the vial. It also requires vendors who provide the vials to pharmacies to provide online assistance and a toll-free number for patients at all times.

The manufacturers of Schedule II and IIN controlled substances are required to reimburse pharmacies for the cost of the vial and services provided related to the vial. Manufacturers who fail to reimburse within 30 days of the receipt of the claim are liable for a civil penalty of one thousand dollars ($1,000) per day for each day the manufacturer is delinquent in reimbursing the pharmacy. The manufacturer may appeal this penalty, and the penalty may be waived or reduced for good cause.

This bill provides qualified immunity from liability to a prescriber, or the prescriber's professional corporation or other business entity, who prescribes a controlled substance dispensed in a lockable vial from liability for any adverse consequences that result from either 1) the failure of any lockable vial to prevent unauthorized access, or 2) A patient not being able to access medication in a lockable vial. Importantly, the bill states that the immunity provisions do not affect a person's liability under existing law for damages caused by defective products, or as a result of willful or wanton misconduct, recklessness, or gross negligence.

Author's Amendments. The author proposes several amendments to the bill. First, to indicate the intent of the bill, including that it is not intended to increase costs to patients and insurers because of these requirements, the author has agreed to the following clarifying amendments to the legislative intent of the bill:

(j) It is, therefore, the intent of the Legislature to enact legislation that would do all of the following:

- ***a. Expand safety precautions for the administration of Schedule II and Schedule IIN pharmaceuticals.***
- ***b. Require a pharmacist who dispenses in solid oral dosage form a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.) to dispense the substance in a lockable vial, except as specified.***
- ***c. Require the manufacturer of a controlled substance covered by this section to reimburse a pharmacy for the cost of the vial, services rendered, and dispensing costs.***
- ***d. Require the State Board of Pharmacy to establish a reasonable minimum and maximum amount of reimbursement to a pharmacy for the cost of the vial, services rendered, and dispensing costs.***
- ***e. Ensure that the cost of administering controlled substances in lockable vials does not increase costs to patients and insurers.***

As in print today, the bill prohibits pharmacists from dispensing Schedule II, but not Schedule IIN, substances to patients who, because of a physical or mental condition, would have difficulty opening the lockable vial. (Section 4178.1 (c)(1).) The amendments would add Schedule IIN substances to this provision to address the omission. Because pharmacists may not be in a position to adequately assess a patient's physical and mental condition, especially for mail orders, the following amendments would amend Section paragraph (1) of subdivision (c) of Section 4178.1 as follows:

> (c) (1) A pharmacist shall not dispense a controlled substance in Schedule II ***or Schedule IIN*** of the federal Controlled Substances Act in a lockable vial directly to a patient who, ***to the best of the pharmacist's knowledge***, ~~because of a physical or mental condition,~~ would have difficulty opening the lockable vial.

The bill in print specifies a maximum acquisition cost for vials at $2 and a minimum reimbursement cost to pharmacies for services provided at $2.50 per vial, though this latter rate must be established by the Board of Pharmacy. Within the context of supply chain shortages and inflation, it is conceivable that the maximum acquisition cost of vials may need to be adjusted more regularly than the legislative process allows. The author has agreed to an amendment to require the Board of Pharmacy to set the minimum and maximum costs of labor and the vials, and to strike the requirements specifying the specific costs of labor and the vials. Subdivision (d) of Section 4178.1 would be amended as follows:

> (1) The manufacturer of a controlled substance covered by this section shall reimburse the pharmacy within 30 days of receiving a claim for the acquisition cost of lockable vials used by the pharmacy to dispense controlled substances covered by this section. ~~**The acquisition cost shall not exceed two dollars ($2) per lockable vial.**~~

(2) The manufacturer of a controlled substance covered by this section shall compensate the pharmacy within 30 days of receiving the claim for dispensing costs and services rendered, including any patient consultation and instruction or any other professional services rendered to comply with this section**. ~~The board shall establish a reasonable rate of compensation that is not less than two dollars and fifty cents ($2.50) per lockable vial.~~** A pharmacy technician or other pharmacy staff may complete all tasks in this section that are not otherwise prohibited by law.

(3) (A) A manufacturer of a controlled substance that fails to reimburse a pharmacy within the time period and for the amount specified in this subdivision is liable for a civil penalty of one thousand dollars ($1,000) per day for each day the manufacturer is delinquent in reimbursing the pharmacy.

(B) The civil penalty shall be assessed and recovered in a civil action brought by the board in the name of the people of the State of California.

(C) Assessment of a civil penalty, at the request of the manufacturer of the controlled substance that was assessed the penalty, may be reviewed on appeal and the penalty may be reduced or waived for good cause.

(4) The State Board of Pharmacy shall, by October 1, 2023, establish a reasonable maximum and minimum amount of reimbursement as specified in (d) that includes the cost of the vial, services rendered, and dispensing costs.

***ARGUMENTS IN SUPPORT**:* In support of the bill, A New Path argues that, though Schedule II and IIN substances are strictly controlled, once they are taken home, there is very little security in place to prevent unauthorized access. The group argues that pilfering is the leading cause of substance use disorder among young teens and adults. In describing the importance of lockable vials, they write:

> AB 2265 will require controlled substances be dispensed in lockable vials. This will ensure that prescribed controlled substances are only accessible to whom they are prescribed and prevent pilfering of these highly addictive and potentially dangerous medications. It is urgent that we increase measures to control access to prescription medication and ensure that these medications do not become a gateway to substance use disorder.

***ARGUMENTS IN OPPOSITION**:* Arguments opposed have stressed the burden that this bill would have on pharmacies and manufacturers and, in turn, patients. The California Retailers Association and the National Association of Chain Drug Stores are opposed unless amended, arguing that this bill would impose "unwarranted and significant pharmacy workflow challenges" due to the labor required to store vials and develop systems for tracking patients' passcodes. They also argue that time spent on tasks related to lockable vials takes away from time spent on patient care. The upfront cost of purchasing vials before being reimbursed may present cashflow issues to smaller pharmacies, according to one group.

Opponents also argue that the cost on manufacturers makes producing generic prescriptions much less profitable, which may result in fewer manufacturers producing generics. Mallinckrodt Pharmaceuticals argues that this would result in the lower availability of generics, which would impose a cost on insurers, including Medicare and Medicaid.

Previous legislation. AB 1430 (Arambula, 2021) was substantially similar to this measure. Unlike this bill, however, it did not require the Board of Pharmacy to determine the total rate of compensation for the vials and labor and did not provide an opt-out provision by the prescriber.

AB 2592 (Cooper, 2016) would have established a pilot program, under the Department of Public Health, to award grants to pharmacies to combat opioid abuse through the safe prescribing of opioids. Recipients of this grant would have been required to offer patients prescribed an opioid a medicine locking closure container, similar to those described in this bill.

REGISTERED SUPPORT / OPPOSITION:

Support

California Consortium of Addiction Programs and Professionals (CCAPP) (co-sponsor)
Shatterproof (co-sponsor)
A New Path
Fred Brown Recovery Services
Opus Health, LLC

Opposition

Association for Accessible Medicines
Mallinckrodt, LLC

Opposed Unless Amended

California Chamber of Commerce
California Retailers Association
National Association of Chain Drug Stores

Analysis Prepared by: Alec Watts / JUD. / (916) 319-2334