

Date of Hearing: June 28, 2022

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Marc Berman, Chair

SB 1259 (Laird) – As Amended June 13, 2022

SENATE VOTE: 33-0

SUBJECT: Pharmacists: furnishing opioid antagonists

SUMMARY: Expands existing authorization for a pharmacist to furnish specified opioid overdose reversal drugs without a prescription, in accordance with standardized procedures or protocols, to cover any approved opioid antagonist.

EXISTING LAW:

- 1) Establishes the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq.*)
- 2) Establishes the California State Board of Pharmacy (BOP) to administer and enforce the Pharmacy Law, comprised of seven pharmacists and six public members. (BPC § 4002)
- 3) Provides that protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. (BPC § 4001.1)
- 4) Authorizes the BOP to adopt rules and regulations as may be necessary for the protection of the public. (BPC § 4005)
- 5) Defines “pharmacist” as a natural person to whom a license has been issued by the BOP which is required for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription. (BPC § 4036; BPC § 4051)
- 6) Declares pharmacy practice to be “a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes” and that “pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.” (BPC § 4050)
- 7) Authorizes a pharmacist to do all of the following, among other permissible activities, as part of their scope of practice:
 - a) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.
 - b) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

- c) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies in coordination with the patient's provider or prescriber.
- d) Administer immunizations pursuant to a protocol with a prescriber.
- e) Furnish emergency contraception drug therapy, self-administered hormonal contraceptives, HIV preexposure and postexposure prophylaxis, and nicotine replacement products, subject to specified requirements.
- f) Administer drugs and biological products that have been ordered by a prescriber.

(BPC § 4052)

- 8) Authorizes a pharmacist to furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by the BOP and the Medical Board of California, in consultation with stakeholders; requires a pharmacist to take one hour of continuing education in the use of naloxone hydrochloride prior to furnishing that drug. (BPC § 4052.01)
- 9) Requires a prescriber to offer their patient prescription for naloxone hydrochloride or another drug approved for the reversal of opioid-induced respiratory depression when prescribing an opioid or benzodiazepine prescription under certain conditions. (BPC § 741)
- 10) Authorizes a licensed health care provider to 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 § 1714.22)

THIS BILL:

- 1) Expands the existing authority of a pharmacist to furnish naloxone hydrochloride in accordance with standardized procedures or protocols to allow for a pharmacist to furnish any other opioid antagonist approved by the federal Food and Drug Administration (FDA).

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

COMMENTS:

Purpose. This bill is sponsored by the author. According to the author:

“SB 1259 ensures pharmacists can distribute more innovative reversal agents, otherwise known as antagonists, that are faster and more effective to reverse overdose in cases involving fentanyl. The Centers for Disease Control released a report for 2021 stating there was a record number of overdose deaths in the United States, reaching nearly 108,000. Additionally, the number of fentanyl-related overdose deaths has also climbed to nearly 70% of this overall number. Under current law, pharmacists can furnish naloxone, a common opioid antagonist. SB 1259 updates California's prescriptive authority statute to equip pharmacists with the ability to distribute the most appropriate and effective opioid antagonists to the public.”

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.

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 investigated by law enforcement. In recent years, however, a 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 significant 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 that 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.

Naloxone hydrochloride and other opioid antagonists. Naloxone hydrochloride is an opioid antagonist. This means that naloxone acts blocks the effects of opioids on the central nervous system, stopping the effects of an opioid overdose such as suppressed breathing. Naloxone can be administered through an intravenous injection, through an intramuscular injection, or via a nasal spray (under the brand name Narcan). Naloxone was approved by the FDA for the treatment of opioid overdose in 1971 and is available as a generic medication. Because naloxone is relatively simple to administer and does not pose significant risk to the patient, it can be used by lay people with minimal instruction.

As California and other policymakers across the United States has worked to curb prescription drug abuse and diversion, a troubling rise in fentanyl overdoses and deaths has changed the nature of the discussion around how to approach the opioid crisis. Fentanyl is a synthetic opioid that is 50 to 100 times more potent than more commonly prescribed pain medications.

According to the National Institute on Drug Abuse, fentanyl and similar synthetics are now the most common drugs involved in drug overdose deaths in the United States, with approximately 60 percent of opioid-related deaths involving fentanyl in 2017 compared to 14 percent in 2010.

The significantly increased strength of fentanyl compared to other controlled substances like oxycodone, hydrocodone, and codeine means that naloxone hydrochloride does not have the same effectiveness that it does for those less potent medications. In response, the manufacturers of Narcan are in the process of seeking approval for new rescue medication that, while similar to naloxone hydrochloride, is a chemically distinct form of opioid antagonist. This bill seeks to ensure that as new opioid antagonist drugs become approved by the FDA to reverse the effects of overdose from fentanyl and similar substances, they will be afforded the same availability as naloxone hydrochloride has been through prior passage of legislation aimed at reducing the rate of deaths from opioid misuse.

Current Related Legislation. AB 2055 (Low) would have transferred responsibility for the maintenance and operation of the CURES prescription drug monitoring program from the Department of Justice to a department specified by the Governor. *This bill was held on the Assembly Appropriations Committee's suspense file.*

Prior Related Legislation. AB 2760 (Wood, Chapter 324, Statutes of 2018) required a prescriber to offer a prescription for naloxone hydrochloride or another drug federally approved for the complete or partial reversal of opioid depression for patients when certain conditions are present and to provide specified education to those patients and provide education about how these drugs may be used to prevent an overdose.

AB 1535 (Bloom, Chapter 326, Statutes of 2014) authorized a pharmacist to furnish naloxone hydrochloride pursuant to standardized procedures or protocols developed and approved by the BOP and the Medical Board of California.

REGISTERED SUPPORT:

None on file.

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301