
**SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT**
Senator Richard Roth, Chair
2021 - 2022 Regular

Bill No: SB 1259
Author: Laird
Version: June 13, 2022
Urgency: No
Consultant: Dana Shaker

Hearing Date: August 16, 2022

Fiscal: Yes

Subject: Pharmacists: furnishing opioid antagonists

SUMMARY: Authorizes a pharmacist to furnish an opioid antagonist approved by the federal Food and Drug Administration, instead of only naloxone hydrochloride, subject to certain requirements, including completing continuing education (CE) on the use of opioid antagonists.

NOTE: The Assembly amendments create a new bill and this measure has been referred to the Committee pursuant to Senate Rule 29.10 (d) for consideration. The Committee may, by a vote of the majority, either: (1) hold the bill, or (2) return the bill to the Senate floor for consideration of the bill as amended in the Assembly.

Existing law:

- 1) Establishes the Board of Pharmacy (BOP) to administer and enforce pharmacy law. (Business and Professions Code (BPC) § 4001)
- 2) Authorizes the Board to adopt rules and regulations as necessary for the protection of the public. (BPC § 4005)
- 3) Authorizes a pharmacist to furnish naloxone hydrochloride (NH) in accordance with standardized procedures or protocols developed and approved by both the BOP and the Medical Board of California (MBC), in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities, as specified. (BPC § 4052.01(a))
- 4) Requires BOP and MBC to include certain procedures in its standardized procedures and protocols, including but not limited to procedures to ensure the person to whom the drug is furnished is educated on matters including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient. (BPC § 4052.01(a)(1))
- 5) Prohibits a pharmacist from allowing the person to whom the drug is furnished to waive a BOP- and MBC-required consultation. (BPC § 4052.01(b))

- 6) Requires a pharmacist to complete a training program on the use of opioid antagonists that consists of at least one hour of approved CE on the use of NH before furnishing. (BPC § 4052.01(c))

This bill replaces reference to NH in the Pharmacy Law with “federal Food and Drug Administration-approved opioid antagonist” to authorize a pharmacist to furnish opioid antagonists other than only NH.

FISCAL EFFECT: This bill is keyed fiscal by Legislative Counsel. According to the Assembly Appropriations Committee, this bill will result in negligible costs to the Board of Pharmacy and the Medical Board of California.

COMMENTS:

1. **Purpose.** The Author is the sponsor of this bill. 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.”
2. **Background.**

[2021 Centers for Disease Control](#) (CDC) data released on May 11, 2022 show that there were an estimated 107,622 drug overdose deaths in 2021 in the United States. This is an increase of almost 15% from the estimated 93,655 deaths in 2020. Overdose death rose 30% from 2019-2020. The new data also demonstrates an increase in deaths involving opioids from an estimated 70,029 in 2020 to 80,816 in 2021.

Over the past few years, California and other states have enacted legislation to address the public health concern of prescription drug overdose. Most notably, programs that have required police officers to carry opioid antagonists like naloxone hydrochloride (NH) have been proven successful at curbing overdose deaths. According to a report by CNN, “The police department in Quincy, Massachusetts was the first in the nation to require its officers to carry naloxone and has successfully reversed 211 overdoses with a success rate of over 95%.” New York implemented a similar idea in Suffolk County.

Eight years ago, the California Legislature passed AB 1535 (Bloom, Chapter 326, Statutes of 2014), which permitted a pharmacist to furnish naloxone hydrochloride (NH) by name, pursuant to standardized procedures and protocols developed and approved jointly by the BOP and the MBC. The bill largely mirrored an NH distribution approach by the Center for Pharmacy Services (CPS), a community pharmacy in Pittsburg, Pennsylvania. CPS had collaborated with the Overdose Prevention Project to enlist pharmacists in overdose prevention. This project used

pharmacists to educate patients and physicians about opioid safety and the effectiveness of NH to prevent fatal overdose. After training, patients who arrived at CPS with a NH prescription were offered counseling on opioid safety, taught how to take opioid pain relievers safely, and demonstrated how to safely dispose of unused prescription medicines. The caregiver and patient were additionally taught how to identify an overdose and how to administer NH.

Opioid antagonists like NH are predominantly utilized to treat opioid overdose and reverse respiratory depression associated with opioid use. They are commonly used when a person excessively uses morphine, oxycodone, methadone, fentanyl, or illegal opioids such as heroin. Opioid antagonists function by blocking one or more opioid receptors in the central or peripheral nervous system so that opioid drugs cannot bind to these opioid receptors, thereby blocking the respiratory depression, analgesia, and euphoria that result from a person taking opioid drugs. NH and similarly acting opioid antagonists allow a patient who has overdosed on opioids to resume breathing while awaiting treatment from emergency medical services. NH is the most common opioid antagonist to be administered during an overdose emergency, but other opioid antagonists, such as naltrexone and methylnaltrexone, can be used to minimize opioid cravings to reduce the chance of drug relapse and to treat opioid-induced constipation. These drugs are non-narcotic as they inhibit opioid receptors in the body, do not produce intoxication, and have no potential for addiction or abuse. Administration of an opioid antagonist such as NH to a patient who is overdosing or who has taken a significant amount of an opioid can save their life from a potentially lethal overdose, but it may cause withdrawal, nausea, vomiting, diarrhea, dehydration, and distress. Opioid antagonists typically also only cause pharmacological effects if there are opioids in someone's body.

Today, these other FDA-approved opioid antagonists besides NH are not permitted to be provided to California patients by pharmacists in California because of the existing statutory reference to only NH. Naltrexone, which is used primarily to help treat opioid and alcohol use disorders, and methylnaltrexone, which is used to treat opioid-induced constipation, are not referenced in statute. The company Opiant has also developed a [nasal spray](#) nalmefene product, which is also an opioid overdose reversal agent with a higher potency and longer duration in the body than NH. Specifying that a pharmacist may furnish federal FDA-approved opioid antagonists rather than just NH will allow pharmacists to furnish these additional opioid antagonists in addition to NH.

3. **Arguments in Support.** The California Retailers Association and the National Association of Chain Drug Stores writes in support: "According to the Centers for Disease Control and Prevention (CDC), overdose deaths involving opioids like fentanyl, heroin and prescription opioids have increased by more than eight times since 1999, and nearly 75% of drug overdose deaths in the U.S. in 2020 were the result of an opioid. Over 82% of those deaths involved synthetic opioids like fentanyl. Opioid antagonists are life-saving medications used to treat patients experiencing overdose by reversing the respiratory depression associated with opioid use. Currently, pharmacists in California are authorized to furnish only one opioid antagonist without a prescription (naloxone). SB 1259 takes an important

step in combatting the opioid crisis by broadening pharmacists' ability to expand access to essential life-saving opioid antagonist medications.

As healthcare providers on the front lines of the opioid abuse crisis, the chain pharmacy community is strongly committed to combating the opioid abuse plaguing the communities we serve. We are steadfast in our dedication to pursuing and implementing targeted and workable policy solutions, like SB 1259, to prevent misuse and abuse of prescription opioids. For these reasons, we are proud to support this critical legislation."

The City of Santa Monica writes in support: "In October of 2017, the White House declared the opioid crisis a public health emergency, formally recognizing a growing epidemic responsible for devastation in communities across the country. As California 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. The Centers for Disease Control released a report for 2021 stating there was a record number of overdose deaths in the United States, reaching close to 108,000 deaths. Additionally, the number of fentanyl-related overdose deaths has also climbed to nearly 70% of this overall number, 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."

SUPPORT AND OPPOSITION:

Support:

California Retailers Association
City of Santa Monica
National Association of Chain Drug Stores

Opposition:

None received

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