

SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2021-2022 Regular Session

AB 381 (Davies)
Version: June 14, 2021
Hearing Date: June 22, 2021
Fiscal: Yes
Urgency: No

SUBJECT

Licensed facilities: duties

DIGEST

This bill requires alcoholism and drug abuse residential treatment facilities licensed by the Department of Health Care services to maintain at least two doses of naloxone hydrochloride (NH), or another opioid antagonist approved by the United States Food and Drug Administration (FDA,) on the premises and ensure that, at all times, there is at least one staff member on the premises who has been trained on the administration of the antagonist, as specified.

EXECUTIVE SUMMARY

Current law requires licensed alcoholism and drug abuse residential treatment facilities (facilities) to develop a plan to address when a resident relapses, including when a resident is on the premises after using illicit drugs and how the resident will be monitored while the resident is still under the influence. This bill requires facilities to maintain at least two unexpired doses of NH or other FDA-approved opioid antagonist and ensure that, at all times, there is at least one staff member on the premises who has been trained in the administration of the antagonist pursuant to regulations that will be promulgated by the State Department of Health Care Services. This bill further provides that a trained staff member who administers NH or other FDA-approved opioid antagonist in good faith to a person appearing to experience an opioid-related overdose shall not be liable in a civil action or subject to criminal prosecution, except where the person acted with gross negligence or engaged in willful and wanton misconduct.

This bill is sponsored by the author and supported by the County Behavioral Health Directors Association of California, the County Health Executives Association of California, the Office of the District Attorney of San Diego, and the San Francisco Department of Public Health. There is no known opposition. This bill passed out of the Senate Health Committee with a 10-0 vote.

PROPOSED CHANGES TO THE LAW

Existing law:

- 1) Defines an “alcoholism or drug abuse recovery or treatment facility” or “facility” to mean any premises, place, or building that provides residential nonmedical services to adults who are recovering from problems related to alcohol, drug, or alcohol and drug misuse or abuse, and who need alcohol, drug, or alcohol and drug recovery treatment or detoxification services. (Health & Saf. Code, § 11834.02(a).)
- 2) Grants the State Department of Health Care Services (DHCS) the sole authority to license facilities. (Health & Saf. Code, §§ 11752, 11834.01.)
- 3) Prohibits the operation, establishment, management, or maintenance of a facility without a valid license issued by DHCS. (Health & Saf. Code, § 11834.30.)
- 4) Generally prohibits a facility from providing at the premises of the facility any medical or health care services or any other services that require a higher level of care than the care that may be provided within a licensed facility, with exceptions for incidental medical services and urgent/emergency services, set forth below. (Health & Saf. Code, § 11834.026(f).)
- 5) Defines “incidental medical services” to mean services that are in compliance with the community standard of practice and are not required to be performed in a licensed clinic or licensed health facility, to address medical issues associated with either detoxification from alcohol or drugs or the provision of alcoholism or drug abuse recovery or treatment services, including:
 - a) Monitoring health status to determine whether the health status warrants transfer of the patient in order to receive urgent or emergent care;
 - b) Testing associated with detoxification from alcohol or drugs.
 - c) Overseeing patient self-administered medications. (Health & Saf. Code, § 11834.026(a).)
- 6) Authorizes a licensed facility to permit incidental medical services to be provided to a resident at the facility by, or under the supervision of, one or more licensed physicians or surgeons who are knowledgeable about addiction medicine, or one or more other health care practitioners acting within the scope and practice of their license under the direction of a surgeon and who are knowledgeable about addiction medicine, under specified circumstances. (Health & Saf. Code, § 11834.026(c).)
- 7) Authorizes a licensed facility to provide urgent or emergent care in the case of a life-threatening emergency. (Health & Saf. Code, § 11834.026(f).)
- 8) Requires a licensed facility to develop a plan to address when a resident relapses, including when a resident is on the licensed premises after consuming alcohol or

using illicit drugs and how the resident will be treated and supervised while under the influence of alcohol or illicit drugs. (Health & Saf. Code, § 11834.26(d).)

This bill:

- 1) Clarifies that the administration of NH or another opioid antagonist approved by the FDA for treatment of an opioid overdose (FDA-approved antagonist; collectively with NH, opioid antagonist) is included as a type of urgent or emergent care in a life-threatening emergency that a facility may provide, notwithstanding the general prohibition on facilities providing medical services.
- 2) Requires a licensed facility to, at all times, maintain at least two unexpired doses of NH or another FDA-approved antagonist on the premises and to have, at all times, at least one staff member on the premises who knows the specific location of the opioid antagonist and who has been trained on the administration of the opioid antagonist for the treatment of the opioid antagonist in accordance with the training requirements set forth by the Department. The facility must maintain documentation of a staff member's completion of the training on the administration of the opioid antagonist in the staff member's file.
- 3) Requires DHCS to promulgate regulations for the implementation of the above provisions no later than July 1, 2024.
- 4) Provides that a trained staff member shall not be liable for damages in a civil action or subject to criminal prosecution for the administration, in good faith, of an opioid antagonist to a person appearing to experience an opioid-related overdose, except where the person who administers the opioid antagonist acts with gross negligence or engages in willful and wanton misconduct.

COMMENTS

1. Author's comment

According to the author:

The opioid epidemic has ravaged our state and has unfortunately torn families apart. According to the Orange County Health Agency "In Orange County, the rate of opioid-related emergency department (ED) visits has increased 141 percent since 2005, and there were 7,457 opioid overdose/abuse cases treated in the ED between 2011 and 2015. Importantly, seven of every ten overdose deaths investigated by the Orange County Sheriff-Coroner during this five-year period involved opioids." Luckily, with the development of naloxone, or commonly referred as "narcan", these types of unfortunate tragedies can be prevented. This life-saving drug should be on-site at all drug treatment centers in order to ensure timely access and help to patients who relapse during treatment. AB 381

guarantees this as well as ensures that someone at these facilities is trained on how to administer this drug to a patient in need. In short, this bill can save lives.

2. In response to the opioid epidemic, the state has implemented requirements for numerous facilities and entities to maintain opioid antagonists on-hand in case of overdose

Since 1999, nearly 841,000 people have died from a drug overdose in the United States.¹ In the last decade, deaths from synthetic opioids (such as fentanyl) have increased *1,040 percent*, with the largest relative increase occurring in the western U.S.² The opioid epidemic has not spared California: in 2018, an estimated 45 percent of the state’s drug overdose deaths were the result of opioids.³ In addition to the loss of life, the prevalence of opioid addiction has caused incalculable losses in the form of broken families, lost potential, and shattered lives. According to the San Diego District Attorney, who supports this bill, opioid withdrawal is particularly painful and results in a high rate of relapse, and relapse is particularly dangerous because a user’s tolerance decreases over time, increasing the likelihood of overdose.

NH—also known as naran— is a chemical compound that functions as an opioid antagonist by reversing or inhibiting an opioid’s effects.⁴ It functions by attaching to opioid receptors and blocking the effects of other opioids, but will have no effect on someone who does not have opioids in their system.⁵ According to the California Department of Public Health (CDPH), NH works almost immediately to reverse opiate overdose and “has few known adverse effects, no potential for abuse, and can be rapidly administered through intramuscular injection or nasal spray.”⁶ In the wake of the massive rise in opioid addictions and overdoses, the Legislature has passed numerous bills requiring various emergency workers and other personnel to maintain naloxone hydrochloride or related opioid antagonists. CDPH has also issued a standing order allowing eligible state community organizations or entities to apply for

¹ Centers for Disease Control and Prevention, Opioid Overdose: Drug Overdose Deaths (Mar. 3, 2021), <https://www.cdc.gov/drugoverdose/data/statedeaths.html> [last visited Jun. 17, 2021].

² Mattson, et al., *Morbidity and Mortality Weekly Report*, Centers for Disease Control and Prevention (Feb. 12, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7006a4.htm?s_cid=mm7006a4_w [last visited Jun. 17, 2021].

³ National Institute on Drug Abuse, *California: Opioid-Involved Deaths and Related Harms*, National Institutes of Health (Apr. 3, 2020), <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/california-opioid-involved-deaths-related-harms> [last visited Jun. 17, 2021].

⁴ National Institute on Drug Abuse, *Naloxone DrugFacts* (June 2021), <https://www.drugabuse.gov/publications/drugfacts/naloxone> [last visited Jun. 17, 2021].

⁵ *Ibid.*

⁶ California Department of Public Health, Injury and Violence Prevention Branch (IVP), *Naloxone Information* (last updated Jul. 10, 2020), <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/Pages/NaloxoneGrantProgram.aspx> [last visited Jun. 17, 2021].

authorization to administer NH to those experiencing an opioid-related overdose.⁷ At this time, NH is the preferred antagonist for counteracting an opioid overdose,⁸ but this bill gives facilities the flexibility to use an alternative if approved by the FDA.

This bill expands on the state's existing requirements that certain facilities maintain doses of, and have staff members trained to administer, NH or other opioid antagonists. Specifically, this bill requires a facility to maintain at least two unexpired doses of an opioid antagonist and, at all times, to have at least one staff member on the premises who has been trained in the use of the opioid antagonist. The bill further requires DHCS to promulgate regulations to implement this provision by July 1, 2024; the regulations must include the training requirements for staff to be trained in the administration of an opioid antagonist.

3. This bill creates a limited liability waiver for trained facility staff who administer an opioid antagonist in good faith, except in cases of gross negligence or willful and wanton misconduct

In addition to the provisions requiring a facility to maintain doses of an opioid antagonist and have staff trained in its use, this bill provides that a trained staff member shall not be liable for damages in a civil action or subject to criminal prosecution for the administration, in good faith, of an opioid antagonist to a person appearing to experience an opioid-related overdose, except in a case where the person administering the dose acts with gross negligence or engages in willful and wanton misconduct. The scope of the waiver is consistent with other statutes providing for the administration of NH,⁹ as well as for persons administering emergency medical care.¹⁰

Additionally, while the bill does not spell out the training requirements necessary for a staff person to be eligible for the liability waiver – instead leaving it to DHCS to develop training requirements by regulation – the nature of NH makes the risk of harm from merely negligent administration reasonably low. As noted above, NH has no negative effects when administered to a person who does not have opioids in their system, and it can be administered through straightforward means such as a nasal spray. Thus, given the apparent low probability of serious harm when a trained staff member, in good faith, administers an opioid antagonist to a person they believe is experiencing an opioid overdose, it appears reasonable to permit liability only for gross negligence or willful and wanton misconduct.

⁷ California Department of Public Health, IVP Branch, *Statewide Standing Order for Naloxone* (last updated Apr. 27, 2020), <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/Pages/Naloxone-Standing-Order.aspx> [last visited Jun. 17, 2021].

⁸ E.g., Substance Abuse and Mental Health Services Administration, *Opioid Overdose Prevention Toolkit*, Health and Human Services Publication No. (SMA) 18 4742 (2018), at p. 6, available at <https://store.samhsa.gov/system/files/sma18-4742.pdf> [last visited Jun. 17, 2021].

⁹ E.g., Educ. Code, § 49414.3 (school nurse or trained staff member may administer naloxone hydrochloride, with liability for injuries waived except in cases of gross negligence or willful and wanton misconduct).

¹⁰ Health & Saf. Code, § 1799.102.

4. Arguments in support

According to bill supporter County Health Executives Association of California:

According to a policy brief released [in April 2021] by California Health Policy Strategies, the rate of drug overdose deaths in California is up 15 percent over the last three years, and nationwide drug-related overdose is now a top-10 leading cause of death. Data from the California Department of Public Health (CDPH) indicate that 3,244 Californians died due to opioid-related overdoses in 2019. Opioid misuse, overdose injuries, and opioid-related deaths have exacted a significant economic burden on the state, resulting in increased health care and substance use disorder treatment and costs, in addition to lost productivity. According to a study conducted by the American Journal of Managed Care in 2019, they estimate opioid use disorders cost Medicaid nationwide, over a 15-year period, \$72.4 billion.

In 2016, the American Society of Addiction Medicine recommended that all addiction treatment agencies have on-site supplies of naloxone to treat opioid overdose that may appear in patients of the facility. AB 381 is a harm-reduction strategy that seeks to ensure this life-saving reversal tool is accessible to those that may be at a higher risk of overdosing.

SUPPORT

County Behavioral Health Directors Association of California
County Health Executives Association of California
Office of the District Attorney of San Diego
San Francisco Department of Public Health

OPPOSITION

None known.¹¹

RELATED LEGISLATION

Pending Legislation:

SB 367 (Hurtado, 2021) requires the governing board of each community college district and the Trustees of the California State University, and requests the Regents of the University of California, to require that each campus health center apply to use the statewide standing order issued by the State Public Health Officer to distribute dosages of a federally approved opioid overdose reversal medication and to participate in the Naloxone Distribution Project administered by the DHCS; upon approval for use of the

¹¹ County Behavioral Health Directors Association opposed prior versions of the bill, but formally withdrew its opposition following the amendments taken in the Senate Health Committee.

statewide standing order and participation in the Naloxone Distribution Project, a campus health center shall distribute a federally approved opioid overdose reversal medication obtained through the Naloxone Distribution Project in accordance with its terms and conditions. SB 367 is pending before the Assembly Higher Education Committee.

SB 349 (Umberg, 2021) requires every treatment provider, as defined, operating in the state to adopt and make available a client bill of rights that ensures those seeking substance use disorder treatment at facility have the right to safe and ethical treatment; and prohibits treatment providers from making false or misleading statements in marketing or advertising, as specified. SB 349 is pending in the Assembly Health Committee.

AB 77 (Petrie-Norris, 2021) requires all substance use disorder treatment programs to be licensed by DHCS and imposes certain requirements for licensure, including maintaining a supply of NH. AB 77 is pending before the Assembly Health Committee.

Prior Legislation:

AB 2256 (Santiago, Ch. 259, 2018) authorizes a pharmacy, wholesaler, or manufacturer to furnish naloxone hydrochloride to law enforcement agencies for use by employees who have completed training in administering it.

AB 2256 (Santiago, Ch. 259, Stats. 2018) authorized a pharmacy, wholesaler, or manufacturer to furnish NH or other opioid antagonists to a law enforcement agency for use by law enforcement agents who have been trained in the administration of those antagonists.

AB 1748 (Mayes, Ch. 557, Stats. 2016) authorized a pharmacy to furnish NH or another opioid antagonist to a school district, county office of education, or charter school, and for trained personnel to provide those antagonists to persons suffering, or believed to be suffering, from an opioid overdose.

PRIOR VOTES:

Senate Health Committee (Ayes 10, Noes 1)

Assembly Floor (Ayes 77, Noes 0)

Assembly Appropriations Committee (Ayes 16, Noes 0)

Assembly Health Committee (Ayes 15, Noes 0)
