Date of Hearing: March 28, 2023

ASSEMBLY COMMITTEE ON JUDICIARY
Brian Maienschein, Chair
AB 1166 (Bains) – As Amended March 23, 2023

PROPOSED CONSENT

SUBJECT: LIABILITY FOR OPIOID ANTAGONIST ADMINISTRATION

KEY ISSUE: SHOULD THE LAW CLARIFY THAT A PERSON WHO IN GOOD FAITH AND NOT FOR COMPENSATION, EITHER RENDERS EMERGENCY CARE BY MEANS OF ADMINISTERING AN OPIOID ANTAGONIST, OR FURNISHES AN OPIOID ANTAGONIST, IS GENERALLY NOT LIABLE FOR CIVIL DAMAGES RESULTING FROM AN ACT OR OMISSION RELATED TO SUCH ACTIONS?

SYNOPSIS

Despite multi-faceted efforts to address the public health epidemic of opioid overdoses in California, the crisis continues, killing thousands of Californians, and more than 100,000 Americans every year. According to the Overdose Surveillance Dashboard of the California Department of Public Health (CDPH), opioid prescriptions have dropped by half in the last four years, but opioid overdose deaths in that same time have tripled, killing over 7,000 Californians in 2021.

Under existing common law tort rules, a person who voluntarily comes to the aid of another person suffering a medical emergency is immune from liability for injuries and even death, so long as that person acts in a reasonably prudent manner under the circumstances. In recent years this Committee has heard, the Legislature has approved, and the Governor has signed numerous bills providing express immunity from liability for lay people (as well as off-duty professionals) who voluntarily render medical aid in a specific emergency situation, such as administering CPR, using an AED, or applying a tourniquet, among other voluntary actions.

This bill seeks to encourage increased access to opioid antagonists, including to laypersons, in the community by clarifying that a person who in good faith and not for compensation, either renders emergency care by means of administering an opioid antagonist, or furnishes an opioid antagonist, is generally not liable for civil damages resulting from an act or omission related to such actions. While providing express immunity for specific medical emergencies or for using special medications or medical supplies may be unnecessary in light of the Good Samaritan statute, one could argue that bills like this one are a harmless and potentially useful clarification of existing law. The bill is supported by California Catholic Conference; Civil Justice Association of California; League of California Cities; and the National Health Law Program, and has no opposition on file.

SUMMARY: Clarifies that a person who in good faith and not for compensation, either renders emergency care by means of administering an opioid antagonist, or furnishes an opioid antagonist, is generally not liable for civil damages resulting from an act or omission related to such rendering or furnishing. Specifically, **this bill**:

1) Provides that a person who, in good faith and not for compensation, renders emergency treatment at the scene of an opioid overdose or suspected opioid overdose by administering an opioid antagonist shall not be liable for civil damages resulting from an act or omission related to the rendering of the emergency treatment.

2) Provides that a person who, in good faith and not for compensation, furnishes an opioid antagonist to a person for use at the scene of an opioid overdose or suspected opioid overdose shall not be liable for civil damages resulting from an act or omission related to the furnishing of the opioid antagonist.

3) Clarifies that the bill does not apply to an act or omission related to the rendering of emergency treatment at the scene of an opioid overdose or suspected opioid overdose by means of an opioid antagonist that constitutes gross negligence or willful or wanton misconduct.

4) Clarifies that for purposes of the bill, the following apply:

    a) A person who renders emergency treatment by means of an opioid antagonist, or who furnishes an opioid antagonist at the scene of an opioid overdose or suspected opioid overdose and who is not compensated for doing so, but receives compensation for other actions as a result of their unrelated employment, is not "rendering emergency medical care or furnishing opioid antagonist for compensation."

    b) "Opioid antagonist" means naloxone hydrochloride or any other opioid antagonist that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose.

EXISTING LAW:

1) Provides that, "everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself." (Civil Code Section 1714 (a).)

2) Provides that a "Good Samaritan" who in good faith, and not for compensation, renders medical or nonmedical care at the scene of an emergency shall not be liable for any civil damages resulting from any act or omission other than an act or omission constituting gross negligence or willful or wanton misconduct. (Health and Safety Code Section 1799.102.)

3) Provides that notwithstanding any other law, 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. Further provides that a person not otherwise licensed to administer an opioid antagonist, but trained as required and 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).)

4) Requires the State Department of Public Health, upon appropriation in the Budget Act of 2016, to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide FDA-approved opioid antagonists for the treatment of an opioid overdose, to first responders and to at-risk opioid users through programs that serve at-risk drug users, including, but not limited to, syringe exchange and disposal programs, homeless programs, and substance use disorder treatment providers. (Health & Safety Code Section 1179.80 (a).)

5) Provides that notwithstanding any other law, school personnel who volunteer to be trained to administer naloxone hydrochloride (naloxone) or another opioid antagonist, in good faith and not for compensation, to a person who appears to be experiencing an opioid overdose shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for his or her acts or omissions in administering the opioid antagonist. (Education Code Section 49414.3 (j)(1).)

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

COMMENTS: Despite multi-faceted efforts to address the public health epidemic of opioid overdoses in California, the crisis continues, killing thousands of Californians, and more than 100,000 Americans every year. This bill seeks to encourage increased access to opioid antagonists, including to laypersons, in the community by clarifying that a person who in good faith and not for compensation, either renders emergency care by means of administering an opioid antagonist, or furnishes an opioid antagonist, is generally not liable for civil damages resulting from an act or omission related to such actions. According to the author:

> California has taken several steps over the years to make naloxone more available and accessible and federal regulators are currently considering making this prescription medical available over the counter. The Naloxone Distribution Project at DHCS supplies naloxone to numerous entities for use and distribution including EMS, harm reduction organizations, organizations that serve the unhoused populations, substance use recovery facilities, and emergency departments. The state has also repeatedly expanded the protections afforded under the Good Samaritan Law to encourage, but not require, the administration of naloxone at the scene of an opioid overdose. . . . In addition, given the state's numerous efforts to make naloxone readily available to persons at risk of overdose as well as persons who live or work in and around persons at risk of overdose, statute should be made clear that no one acting in good faith can be held liable for furnishing naloxone to another person via secondary distribution.

Background on the opioid overdose epidemic in California. According to the Overdose Surveillance Dashboard of the California Department of Public Health (CDPH), opioid prescriptions have dropped by half in the last four years, but opioid overdose deaths in that same time have tripled, killing over 7,000 Californians in 2021. (*California Overdoes Surveilance Dashboard, Welcome to the California Overdoes Surveillance Dashboard* (Feb. 15, 2023), available at https://skylab.cdph.ca.gov/ODdash/?tab=Home.) According to a recent study of opioid deaths during the COVID-19 pandemic, there were 8605 fatal drug overdoses in 2021—a 44% increase over the same period one year prior. (Mathew V. Kiang, et al, *Sociodemographic and geographic disparities in excess fatal drug overdoses during the COVID-19 pandemic in*

California: A population-based study, The Lancet Regional Health - Americas, Volume 11, 2022, available at https://www.sciencedirect.com/science/article/pii/S2667193X22000540.) Non-white populations have been disproportionately affected by this phenomenon, having fatal drug overdose rates that are roughly double those in the non-Hispanic white population. (*Ibid.*) According to the National Institute on Drug Abuse (NIDA) within the National Institutes of Health (NIH), more than 106,000 persons in the U.S. died from a drug-involved overdose in 2021, including illicit drugs and prescription opioids. (Trends and Statistics, *Drug Overdose Drug Rates*, NIH/NIDA (February 9, 2023), available at https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates.)

The number of overdose deaths in California and nationwide has continued to grow in recent years, despite numerous public health efforts to address the problem in the past decade. For example, when overdose and substance use involving *prescription drugs*, particularly opioids, emerged as a major public health and safety concern in both California and the United States in the early 2000s, CDPH convened a State Opioid Safety Workgroup composed of state agencies and local health jurisdictions to facilitate and coordinate state responses to the opioid epidemic. Initial efforts comprised promoting safe prescribing, increasing medication for opioid use disorder services, and reducing opioid-related overdose deaths. In 2015, the state secured funding from the Centers for Disease Control and Prevention (CDC) and the United States Bureau of Justice Assistance for the California Prescription Drug Overdose Prevention (PDOP) Initiative, a 4-year, multi-pronged effort to reduce deaths involving prescription opioids. The two major areas of focus for the PDOP Initiative were (1) leveraging recent improvements to California's prescription drug monitoring program (PDMP); and local advisory councils. Mandatory PDMP registration was associated with a 35% decrease and local advisory councils with a 21% decrease, respectively, in prescription opioid overdose deaths. Both interventions were also associated with significantly lower prescription rates, fewer deaths involving any opioid, but had no significant association with non-fatal overdose rates. (Stephen G. Henry, et al, *Impacts of prescription drug monitoring program policy changes and county opioid safety coalitions on prescribing and overdose outcomes in California, 2015–2018*, Preventive Medicine, Volume 153, 2021, available at https://doi.org/10.1016/j.ypmed.2021.106861.) Prescription-related opioid deaths (excluding synthetics) peaked in 2009 at 1,483 deaths, and decreased in 2018 to 1,091 deaths (a 26% decrease) indicating progress on promoting safe opioid prescribing practices. (*California Overdoes Surveillance Dashboard, supra.*) The total number of prescriptions dispensed has decreased 14%, from 23 million in 2010, to 19.8 million in 2018. (*Ibid.*) Meanwhile, overdose deaths from illicit drugs have skyrocketed: Heroin overdose deaths increased 117% between 2012 and 2018; fentanyl overdose deaths increased 858%; and amphetamine overdose deaths increased 212% during that same time period. (*Ibid.*)

Background on the properties of naloxone, a common opioid antagonist. An opioid overdose is characterized by central nervous system and respiratory depression, leading to coma and death. Opioid antagonists attach to opioid receptors and block the effects of opioids, enabling the ability to counteract depression of the central nervous and respiratory system caused by an opioid overdose. An opioid antagonist has no effect if administered to a person who is not experiencing an opioid overdose (because there are no opioid receptors to bind to).

Opioid antagonists are a group of drugs routinely used in hospitals and in pre-hospital settings (i.e. by paramedics in the field) on patients who are suspected to be experiencing overdose of an opioid, such as heroin, methadone, or oxycodone. The most common type of opioid antagonist is

known as naloxone hydrochloride (or as "Narcan," its brand name), which is approved by the federal Food and Drug Administration (FDA) for the treatment of an opioid overdose. Naloxone is not effective, however, in treating overdoses of benzodiazepines, barbiturates, clonidine, GHB, or ketamine. It is also not effective to treat overdoses of stimulants, such as cocaine and amphetamines (including methamphetamine and MDMA). (U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), *SAMHSA Opioid Overdose Prevention Toolkit* (2018), p. 2; available at https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.)

Approved by the FDA since the 1970s, naloxone is considered to be a very safe medication. According to SAMHSA:

> The safety profile of naloxone is remarkably high, especially when used in low doses and titrated to effect. [fn] If given to individuals who are not opioid intoxicated or opioid dependent, naloxone produces no clinical effects, even at high doses. Moreover, although rapid opioid withdrawal in opioid-tolerant patients may be unpleasant, it is not life threatening. (*SAMHSA Opioid Overdose Prevention Toolkit*, *supra*, at p. 13.)

While in theory, there is a risk of allergic reaction to naloxone, such allergic reactions have never been documented. On rare occasions, reviving an opioid overdose victim with naloxone may restart existing health problems or uncover the effect of other drugs the victim had taken. More commonly, the use of naloxone will send the patient into opioid withdrawal, triggering nausea/vomiting, diarrhea, chills, sweating, anxiety, and combativeness or disorientation. (New Mexico Department of Health, Overdose and Prevention Program, Epidemiology & Response Division, Opioid Fact Sheet, *Are there any adverse effects from naloxone?* (July 2021), available at POS-More-About-Naloxone-20210716.pdf.) When given to individuals who are not opioid intoxicated or opioid dependent, naloxone produces no clinical effects, even at high doses. Naloxone can also be used in life-threatening opioid overdose circumstances in pregnant women. Moreover, although rapid opioid withdrawal in opioid-tolerant individuals may be unpleasant, it is not life threatening. (*SAMHSA Opioid Overdose Prevention Toolkit*, *supra*, at p. 6.) Multiple models and programs cited by the National Institute of Drug Abuse have demonstrated that increasing naloxone or opioid antagonist access by increased distribution of naloxone to laypersons, could decrease opioid overdose deaths by up to 21%. (NIH/NIDA, Policy Brief, *Naloxone for Opioid Overdose: Life-Saving Science* (2016), available at: https://nida.nih.gov/publications/effective-treatments-opioid-addiction.)

In response to the opioid crisis, many states, including California, have expanded access to opioid antagonists. According to SAMHSA, prior to 2012, just six states had laws that expanded access to naloxone or limited criminal liability. By mid-2017, every state and the District of Columbia had enacted statutes that provide criminal liability protections to laypersons or first responders who administer naloxone. Forty-six states and the District of Columbia have statutes that provide civil liability protections to laypersons or first responders who administer naloxone. Thirty-seven states have statutes that offer criminal liability protections for prescribing or distributing naloxone. Forty-one states have statutes that offer civil liability protections for prescribing or distributing naloxone, and 46 states have statutes that allow naloxone distribution to third parties or first responders via direct prescription or standing order. (*SAMHSA Opioid Overdose Prevention Toolkit*, *supra*, at p. 3.) To find relevant laws for each state, visit the Prescription Drug Abuse Policy System at http://www.pdaps.org/.

In the past decade, California statues have expanded policies to make naloxone and other opioid antagonists more accessible in pharmacies, schools, and licensed detox facilities. Current law authorizes licensed health care providers to prescribe and distribute opioid antagonists for emergency treatment of drug overdose without being subject to civil liability or criminal prosecution. (Civil Code Section 1714.22 (f).) Current law also requires alcohol and other drug residential treatment facilities licensed by the Department of Health Care Services (DHCS) to maintain at least two unexpired doses of naloxone, a common opioid antagonist, on the premises. Pharmacists are also authorized by law to stock naloxone in their pharmacies, school districts, and law enforcement agencies. 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. (Business and Professions Code Section 4052.01 (a) and (c).) A person who is not otherwise licensed to administer an opioid antagonist, but trained as required and 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. (*Ibid.*) A pharmacist may furnish an FDA-approved opioid antagonist in accordance with standardized procedures or other protocols developed and approved by both the Board of Pharmacy and the Medical Board of California, in consultation with other appropriate entities. (*Ibid.*) A pharmacist must complete a training program on the use of opioid antagonists that consist of at least one hour of approved continuing education on the use of opioid antagonists. (*Ibid.*) A pharmacist, wholesaler, or manufacturer may furnish opioid antagonists to a law enforcement agency as long as the opioid antagonist is furnished exclusively for use by employees of the law enforcement agency who have completed training provided by the law enforcement agency, in administering opioid antagonists. (Business & Professions Code Section 4119.9 (a).)

School personnel who volunteer to be trained to administer naloxone or another opioid antagonist, in good faith and not for compensation, to a person who appears to be experiencing an opioid overdose are not subject to professional review, liable in a civil action, or subject to criminal prosecution for his or her acts or omissions in administering the opioid antagonist. (Education Code Section 49414.3 (j)(1).) A pharmacist may furnish an FDA-approved opioid antagonist to a school district, county office of education, or charter school if the opioid antagonist is furnished exclusively for use at the school and a physician and surgeon provides a written order that specifies the quantity of opioid antagonist to be furnished. (Business & Professions Code Section 4119.8 (a).)

***The "Good Samaritan" Law*.** Under existing common law tort rules, a person who voluntarily comes to the aid of another person suffering a medical emergency is immune from liability for injuries and even death, so long as that person acts in a reasonably prudent manner under the circumstances. In addition, in 2009, California adopted a so-called "Good Samaritan" statute. (The term refers to the parable in the Gospel of Luke about the "lowly" Samaritan who came to the aid of a stranger left for dead while supposedly more upstanding citizens ignored the cries of the dying man.) California's Good Samaritan statute (Health & Safety Code Section 1799.102) grants qualified immunity to any person who renders medical or non-medical aid in an emergency, so long as that person acts in good faith and not for compensation, and so long as

that person's conduct is not grossly negligent or does not constitute willful or wanton misconduct.

In recent years this Committee has heard, the Legislature has approved, and the Governor has signed numerous bills providing express immunity from liability for lay people (as well as off-duty professionals) who voluntarily render medical aid in a specific emergency situation, such as administering cardiopulmonary resuscitation (CPR), using an AED, or applying a tourniquet, among other voluntary actions. These provisions may be unnecessary given that any of these methods of administering medical or non-medical care by a lay rescuer at the scene of an emergency would most certainly qualify as rendering medical aid in an emergency by a Good Samaritan, regardless of the mechanism by which the care is administered. While providing express immunity for specific medical emergencies or for using special medications or medical supplies may be unnecessary in light of the Good Samaritan statute, one could argue that bills like this one are a harmless and potentially useful clarification of existing law.

This bill seeks to encourage increased access to opioid antagonists, including to laypersons, in the community by clarifying that a person who in good faith and not for compensation, either renders emergency care by means of administering an opioid antagonist, or furnishes an opioid antagonist, is generally not liable for civil damages resulting from an act or omission related to such actions. As introduced, the bill was problematic for a number of reasons. First, it did not exempt acts of gross negligence or willful or wanton misconduct. Therefore, a lay rescuer who administered naloxone to a person with a known allergy to naloxone (indicated by perhaps a medic-alert bracelet or necklace) or administered it to a person who clearly was not experiencing an overdose, would be immune from all liability for adverse reaction or trauma from such administration. While naloxone is generally safe, has no documented history of allergic reactions, and the alternative to administration is generally death, the likelihood of anyone being held liable for grossly negligent use of naloxone is therefore rare, it is important that the bill align with other similar Good Samaritan statutes. Second, it did not clarify that in order to qualify as a good Samaritan/lay rescuer who is entitled to immunity, that the person must, in fact, be a lay person and not a paid/professional rescuer. Finally, the introduced language used a specific name for the opioid antagonist--naloxone hydrochloride--rather than the general term "opioid antagonist" that is used in other statutes addressing the topic. Naloxone hydrochloride may not be the preferred opioid antagonist in the future. The statute should not need to be amended if and when a more popular opioid antagonist comes into widespread use.

As recently amended, the bill now addresses all of these issues. In line with existing law that deals with paid school employees who volunteer to be trained to administer an opioid antagonist, and provides immunity to those who do so in good faith and "not for compensation," although they are paid to perform duties unrelated to emergency medical care (See Education Code Section 49414.3 (j)), it clarifies the following:

> A person who renders emergency treatment by means of an opioid antagonist, or who furnishes an opioid antagonist at the scene of an opioid overdose or suspected opioid overdose and who is not compensated for doing so, but receives compensation for other actions as a result of their unrelated employment, is not "rendering emergency medical care or furnishing opioid antagonist for compensation."

ARGUMENTS IN SUPPORT: League of California Cities cites, as a reason why the bill is needed, the unique and deadly toll that fentanyl is taking on users:

> A recent study by the Center for Disease Control (CDC) names fentanyl the deadliest drug in the United States. Fentanyl is often disguised as other synthetic opioids or drugs, then sold on the street to users who are unaware that fentanyl is a key ingredient. Users who unknowingly ingest these substances believing they are taking a less powerful drug are much more susceptible to overdose or even death. When abused, fentanyl affects the brain and nervous system and is 50 times stronger than heroin and 100 times stronger than morphine.

This bill, they argue, is part of a multi-pronged public policy approach to address the public health and safety crisis:

> This measure would provide that a person who is not trained in emergency medical services or as a health care provider and who, in good faith and not for compensation, renders treatment at the scene of an opioid overdose or suspected opioid overdose by administering naloxone hydrochloride is not liable for civil damages resulting from an act or omission. . . .
>
> Cal Cities supports additional funding and resources to address the substance use crisis through appropriate prevention and intervention efforts, educational awareness campaigns, and increased access to life-saving overdose treatment aids such as naloxone. Additionally, Cal Cities supports "Good Samaritan" protections that include both medical and non-medical care when applicable to volunteer emergency, law enforcement, and disaster recovery personnel.

REGISTERED SUPPORT / OPPOSITION:

Support

California Catholic Conference
Civil Justice Association of California
League of California Cities
National Health Law Program

Opposition

None on file

Analysis Prepared by: Alison Merrilees / JUD. / (916) 319-2334