

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 758

INTRODUCER: Senator Evers

SUBJECT: Prescription and Use of Opioid Antagonists for Emergency Treatment of Opioid Overdoses

DATE: February 25, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Pre-meeting
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

I. Summary:

SB 758 establishes the “Florida Opioid Overdose Prevention Act” (Act). The Act encourages the administration of opioid antagonists for the emergency treatment of known or suspected opioid overdoses when a health care practitioner is not available.

The bill authorizes health care practitioners to prescribe and dispense opioid antagonists to patients, caregivers, first responders, and emergency medical personnel. Each patient and caregiver to whom an opioid antagonist is prescribed or dispensed must receive emergency overdose treatment information from the prescribing health care practitioner, his or her agent, or other entities.

Pharmacists are authorized to dispense an appropriately labeled opioid antagonist based on a prescription that has been issued in the name of a patient or caregiver. The patient or caregiver may store and possess a dispensed opioid antagonist for later administration to a person he or she believes in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an opioid antagonist.

Civil liability protection is extended to any person, including health care practitioners, pharmacists, first responders, and emergency medical personnel who possess, administer, or store an approved opioid antagonist in accordance with the Act. A health care practitioner acting in good faith and exercising reasonable care is not subject to discipline under the applicable professional licensure statute and is also immune from civil or criminal liability for prescribing or dispensing an opioid antagonist in accordance with the Act.

This Act does not create a duty or standard of care for a person to prescribe or administer an opioid antagonist.

The fiscal impact on local governmental agencies is indeterminate since the purchase and use of opioid antagonists is optional for first responders and emergency medical personnel.

II. Present Situation:

An opioid can be a prescription medication or an illegal drug, such as heroin, and is used to treat pain. Opioids work by binding to certain receptors in the brain, spinal cord, and gastrointestinal tract to minimize the body's perception of pain. A variety of effects can occur after a person takes opioids, ranging from pleasure to nausea, vomiting, severe allergic reactions (anaphylaxis) and overdose, in which breathing and heartbeat slow or even stop.¹ Opioid antagonists have been developed to reverse the effects of opioid overdoses and have been around for decades.

Opioid Deaths Nationwide

From 1999 through 2012, the age-adjusted drug-poisoning (drug overdose) death rate nationwide more than doubled, from 6.1 per 100,000 of the population in 1999 to 13.1 in 2012, while death from opioid analgesics alone more than tripled, from 1.4 per 100,000 to 5.1 during the same time period.² The 2012 total deaths due to drug poisoning was over 41,000, with opioid analgesics involved in 16,007 of that number and heroin involved in 5,925.³ On January 12, 2015, the White House Office of National Drug Control Policy announced that drug deaths related to prescription opioids for 2013 had remained stable since 2012, with a 1 percent increase in deaths, while deaths associated with heroin and cocaine had increased 39 percent and 12 percent, respectively.⁴

Drug poisoning deaths involving opioids for the time period of 2009-2010 nationally shows that the highest death rate occurs in the 35 - 54 age bracket at 9.9 deaths per 100,000 and was more prevalent in males at 8.1 compared to 5.1 for females and for white, non-Hispanic individuals.⁵

Opioid Deaths in Florida

Drug overdose deaths in Florida rose 61 percent from 1,804 to 2,905 during 2003 - 2009, with especially large increases in deaths related to opioid pain relievers and benzodiazepine.⁶ After implementing several laws and enforcement actions relating to prescription drugs and pain management clinics, death rates for prescription drugs decreased 16.7 percent from 3,201 to 2,666, representing a 16.7 percent decrease from 2010 - 2012.⁷ However, reports of increasing

¹ U.S. Department of Health and Human Services, *SAMSHA Opioid Overdose Toolkit*, pg. 4, http://store.samhsa.gov/shin/content//SMA14-4742/Overdose_Toolkit.pdf (last visited Feb. 28, 2015).

² Centers for Disease Control and Prevention, *Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999-2012*, http://www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning_deaths_1999-2012.pdf (last visited Feb. 28, 2015).

³ *Id.*

⁴ Press Release, Centers for Disease Control and Prevention, *2013 Drug Overdose Mortality Data Announced*, (Jan. 20, 2015) <http://www.cdc.gov/media/releases/2015/p0114-drug-overdose.html> (last visited Feb. 28, 2015).

⁵ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States 2013 with Special Feature on Prescription Drugs*, pg. 29, (on file with the Senate Committee on Health Policy).

⁶ Centers for Disease Control and Prevention, *Decline in Drug Overdose Deaths After State Policy Changes - Florida 2010-2012* (July 4, 2014) <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm> (last visited Feb. 28, 2015).

⁷ *Id.*

deaths from heroin overdose, sometimes attributed to the crackdown on “pill mills” and the overprescribing of controlled substances for the treatment of pain, is being termed an epidemic.⁸

For Florida, the 2013 total year data from the Centers for Disease Control and Prevention (CDC), shows over 2,600 individuals died from a drug-induced cause. While the CDC number was not just from opioid deaths, the partial year data from the Florida Medical Examiners Commission indicate that prescription drugs, such as benzodiazepines, carisoprodol/meprobamate, zolpidem and all opioids, continue to be found more often than illicit drugs, both as the cause of death and present at death.⁹ These drugs are often prescribed for medical conditions such as muscle relaxation, anxiety, insomnia, and panic attacks. Opioids include:

Opioid Drug Occurrences in Florida - January - June 2013¹⁰			
Opioid	Present at Death	Cause of Death	Total Occurrences
Buprenorphine	10	7	17
Codeine	38	50	88
Fentanyl	85	52	137
Heroin	68	2	70
Hydrocodone	158	273	431
Hydromorphone	89	131	220
Meperidine	2	6	8
Methadone	221	103	324
Morphine	268	189	457
Oxycodone	279	262	541
Oxymorphone	24	100	124
Tramadol	51	177	228
TOTAL:	1,293	1,352	2,645

Naloxone: An Opioid Antagonist

Naloxone injection is in a class of medications called opiate antagonists. It works by blocking the effects of opiates to relieve dangerous symptoms caused by high levels of opiates in the blood.¹¹ Naloxone displaces opiates from receptor sites in the brain and reverses respiratory depression

⁸ See for example: National Institute on Drug Abuse, *What Can We Do About the Heroin Overdose Epidemic?* (June 24, 2014) <http://www.drugabuse.gov/about-nida/noras-blog/2014/06/what-can-we-do-about-heroin-overdose-epidemic> (last visited Feb 28, 2015); National Institute on Drug Abuse, *Drug Abuse Patterns and Trends in Miami-Dade and Broward Counties, Florida—Update: January 2014* (February 2014) <http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg/meeting-reports/highlights-summaries-january-2014/miami> (last visited Feb. 28, 2015); Reuters, *Heroin Abuse at ‘Epidemic’ Level in South Florida – Drug Report*, (January 30, 2014) <http://www.reuters.com/article/2014/01/30/us-usa-florida-heroin-idUSBREA0T24D20140130> (last visited Feb. 28, 2015), and 8WFLA.com, *Heroin Deaths on the Rise in Tampa Bay* (February 10, 2015) <http://www.wfla.com/story/28073721/heroin-deaths-on-the-rise-in-tampa-bay> (last visited Feb. 28, 2015).

⁹ Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners*, pg. ii (Interim Report 2013) (May 2014) [http://www.fdle.state.fl.us/Content/getdoc/5de77741-a6bd-4a88-8000-ce9431321a6c/2013-Interim-Report-Final-\(1\).aspx](http://www.fdle.state.fl.us/Content/getdoc/5de77741-a6bd-4a88-8000-ce9431321a6c/2013-Interim-Report-Final-(1).aspx) (last visited Feb. 28, 2015).

¹⁰ *Id* at pg. 3.

¹¹ *Supra* note 1.

that usually is the cause of overdose deaths. During the period of time when an overdose can become fatal, respiratory depression can be reversed by giving the individual naloxone.¹² Naloxone injection and naloxone pre-filled auto-injection device are used along with emergency medical treatment to reverse the life-threatening effects of opiate overdose. Naloxone injection is also used after surgery to reverse the effects of opiates given during surgery and is given to newborns to decrease the effects of opiates received by the pregnant mother prior to delivery.¹³

Naloxone can be used when someone believes an individual is suffering either an opioid or a heroin overdose. Naloxone injection comes as a solution (liquid) to be injected intravenously (into a vein), intramuscularly (into a muscle), or subcutaneously (just under the skin) and as a pre-filled auto-injection device containing a solution (liquid) to be injected intramuscularly (into a muscle) or subcutaneously (under the skin).¹⁴ It is usually given as needed to treat opiate overdoses. However, it does not work on benzodiazepine overdoses.^{15,16} Naloxone is also known by its brand names of Narcan or Evzio.

First responders have been regularly carrying the drug for 40 years and the CDC reports that many law enforcement agencies across the nation have also been equipped with naloxone.¹⁷ The federal government has made a tool-kit available through a Department of Justice grantee website on the use of naloxone that is geared toward the law enforcement community.¹⁸ One version of the product comes with a trainer that talks the caregiver through the drug administration.

As of December 31, 2014, 24 states authorize health care practitioners to prescribe opioid antagonists to third parties.¹⁹

Regulatory Landscape

Barriers may exist to the access to and the administration of the opioid antagonist where state health care practice laws prevent a non-patient from being issued a prescription as a caregiver or a friend and a dispenser from filling such a prescription, or where prescribers or dispensers have liability concerns.

The Florida Board of Medicine reviewed this issue at its December 5, 2014 meeting. A health care practitioner had raised the issue whether he could prescribe an opioid antagonist to his patient for administration by a third party at a later date and to teach overdose prevention and

¹² *Supra* note 1 at pg. 5.

¹³ Medline Plus, *Naloxone Injection* (May 15, 2014) <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a612022.html> (last visited Feb. 28, 2015)

¹⁴ *Id.*

¹⁵ *Supra* note 12.

¹⁶ Examples of benzodiazepines include Valium, Xanax, or Klonopin.

¹⁷ *Supra* note 4 and note 12.

¹⁸ *Infra* note 29.

¹⁹ These states are: California, Colorado, Georgia, Illinois, Kentucky, Massachusetts, Maryland, Maine, Michigan, North Carolina, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Virginia, Vermont, Washington, and Wisconsin. See Law Atlas, The Policy Surveillance Portal, Public Health Law Research, Robert Wood Johnson Foundation, <http://lawatlas.org/query?dataset=laws-regulating-administration-of-naloxone> (last visited Feb. 28, 2015).

response education without violating certain provisions of the practice act.²⁰ The areas of concern covered by those provisions are:²¹

- Aiding or assisting an unlicensed person to practice medicine;
- Failing to perform any statutory or legal obligation placed on a licensed physician;
- Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including a controlled substance, other than in the course of the physician's practice;
- Committing medical malpractice; and
- Delegating professional responsibilities to a person when the licensee delegating those responsibilities knows or has reason to know that such a person is not qualified to perform them.

The board granted the practitioner's request noting that its approval was specific only to his petition and suggested that a legislative change be sought.²²

A pharmacist is subject to discipline for dispensing a drug pursuant to a prescription when the pharmacist knows or has reason to believe that the prescription is not based on a valid practitioner-patient relationship.²³

The Florida Legislature and the federal government have already enacted legislation allowing third parties to receive prescriptions for the benefit of others relating to a variety of other health care services. For example:

- The Emergency Allergy Treatment Act authorizes a variety of persons, such as camp counselors, scout leaders, and tour guides, and entities to possess and store epinephrine auto-injectors for later use on a person who the individual believes in good faith is experiencing a severe allergic reaction.²⁴
- Pharmacists may administer, in the event of an allergic reaction, epinephrine using an auto injection delivery system within the framework of an established protocol with a physician when providing immunizations.²⁵
- School personnel may purchase and maintain a supply of epinephrine auto-injectors in a secure, locked location on its premises for use if a student has an anaphylactic reaction.²⁶

²⁰ The specific practice acts include ss. 458.331(1)(f), (g), (q), (t) or (w), F.S., or any other rule of the board. See Florida Bd of Medicine, Florida Dep't of Health, *Final Order on Petition for Declaratory Statement* (February 6, 2015) pp.144 of the *Public Book Addendum*,

http://www10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Books/2015/February/02062015_FBAddendum_PublicBook.pdf (last visited: Feb. 27, 2015).

²¹ Florida Bd of Medicine, Florida Dep't of Health, *Final Order on Petition for Declaratory Statement* (February 6, 2015) pp.144 of the *Public Book Addendum*,

http://www10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Books/2015/February/02062015_FBAddendum_PublicBook.pdf (last visited Feb. 27, 2015).

²² Florida Bd of Medicine, Florida Dep't of Health, *Minutes for December 5, 2015 Meeting*, p. 20,

http://www10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Minutes/2015/February/02062015_FB_Minutes.pdf (last visited Feb. 27, 2015).

²³ Section 465.016(1)(s), F.S.

²⁴ Chapter 2014-141, Laws of Fla.

²⁵ Chapter Law 2012-60, s. 1, Laws of Fla.

²⁶ Chapter Law 2013-63, ss. 1 and 3, Laws of Fla.

- *Federal School Access to Emergency Epinephrine Act* provides a financial incentive to schools to maintain a supply of the epinephrine medication and to permit trained personnel to administer it.²⁷

The Emergency Allergy Treatment Act also authorizes a health care practitioner to prescribe epinephrine auto-injectors in the name of an authorized entity and pharmacists to dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity. Under that act, immunity from liability is provided to persons, authorized entities, and health care practitioners when acting in accordance with authorizations in the act.

Good Samaritan Act

Florida's Good Samaritan Act, found in s. 768.13, F.S., provides, in part:

(2)(a) Any person, including those licensed to practice medicine, who gratuitously and in good faith renders emergency care or treatment either in direct response to emergency situations related to and arising out of a public health emergency ..., a state of emergency ..., or at the scene of an emergency outside of a hospital, doctor's office, or other place having proper medical equipment, without objection of the injured victim or victims thereof, shall not be held liable for any civil damages as a result of such care or treatment or as a result of any act or failure to act in providing or arranging further medical treatment where the person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.

III. Effect of Proposed Changes:

SB 758 creates the "Florida Opioid Overdose Prevention Act" as s. 381.887, F.S., and provides definitions. The following definitions are created specific to the Act:

- Administer or administration means the introduction of an opioid antagonist approved by the United States Food and Drug Administration (FDA) into the body of a person;
- Authorized health care practitioner means a Florida licensed practitioner authorized to prescribe drugs;
- Caregiver means a family member, friend, or any other person who may assist a person at risk of an opioid overdose;
- Emergency overdose treatment information means information relating to:
 - Recognition of an opioid overdose and prevention,
 - How to perform rescue breathing,
 - Opioid antagonist dosage and administration,
 - The importance of calling 911, and
 - How to care for an overdose victim after an opioid antagonist administration;
- Opioid antagonist means naloxone hydrochloride or any similar acting drug that blocks the effects of opioids that is administered outside of the body and is approved by the FDA for treatment of opioid overdose; and

²⁷ Pub. Law 113-48, H.R. 2094, 113th Cong. (Nov. 13, 2013)

- Patient means a person at risk of experiencing an opioid overdose.

The bill authorizes the prescription of an opioid antagonist to a patient or a caregiver and to encourage the administration of that antagonist for the emergency treatment of a known or expected opioid overdose when a physician or other authorized health care practitioner is not available.

SB 758 establishes which provider types, such as health care practitioners or pharmacists, and other health care and social organizations can perform the specific activities related to prescribing, dispensing and administering the opioid antagonist and educating patients, caregivers and first responders. The chart below shows the authorizations set forward under the bill:

Provider Type	Prescribe	Dispense	Administer	Educate
Health Care Practitioner	X	X	X	X
Pharmacist		X	X	
First Responders			X w/conditions	
Medical or Social Organization, Governmental Entity, or Substance Abuse Organization			X	X

The bill requires the prescription to be appropriately labeled with instructions for use and to be issued in the name of the patient or the caregiver.

If a medical or social organization is used to provide the emergency overdose treatment information, additional requirements are applicable. The organization must:

- Address medical or social issues related to drug addiction;
- Maintain a written agreement with the prescribing health care practitioner; and
- Be exempt from taxation pursuant to 26 U.S.C. s. 501.

The written agreement between the organization and the health care practitioner must include procedures for how the emergency overdose treatment is provided, the training process for volunteers, and how patients and caregivers will be educated.

The bill permits the patient or caregiver who has an opioid antagonist prescription to store and possess the drug. The patient or caregiver is also permitted to administer the drug to a person whom he or she believes in good faith may be experiencing an opioid overdose, regardless of whether that person has his or her own prescription for an opioid antagonist.

An authorized health care practitioner may directly or through a standing order, prescribe and dispense an opioid antagonist to first responders. The bill identifies first responders as including law enforcement officers and emergency medical technicians. First responders are authorized to administer an approved opioid antagonist in accordance with his or her employers' policies.

Civil liability immunity protection is extended under the Good Samaritan Act to any person, an authorized or dispensing health care practitioner, or a first responder who possesses, administers, or stores an approved opioid antagonist under the provisions of this bill.

The bill also provides civil and criminal liability and protection from professional licensure action or other adverse action for any licensed health care practitioner or pharmacist, acting in good faith and exercising reasonable care as a result of prescribing or dispensing an opioid antagonist under the provisions of this bill.

The bill does not limit any immunities that currently exist for first responders and others that are provided under statute or rule. Also, the bill does not create a duty or standard of care for a person to prescribe or to administer an opioid antagonist.

The bill is effective upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Caregivers or other persons in a position to help someone at risk of an opioid overdose who have received emergency overdose treatment information would be eligible under the bill to acquire a prescription for an opioid antagonist. Individuals participating in this process would incur costs to acquire the opioid antagonist after receiving the required information.

C. Government Sector Impact:

The Bureau of Health Care Practitioner Regulation at the Department of Health reports no fiscal impact for SB 758.²⁸

To the extent that local governments opt to stock a supply of opioid antagonists to address drug over-doses for their emergency medical services, police and fire departments or other first responders, there could be a cost incurred to acquire the drugs.

According to the Bureau of Justice Assistance, the cost of a single rescue kit ranges from \$22 to \$60.²⁹

There may also be training costs to educate first responders or other volunteers on how to use the rescue kits. Community organizations may offer free training classes for family members or friends and provider groups may also sponsor training and patient education classes at reduced rates or no cost.

VI. Technical Deficiencies:

Lines 62 – 69 identify who may provide to a patient or caregiver the emergency overdose treatment information. The distinction between a substance abuse organization and an organization that addresses medical or social issues related to drug addiction is unclear. The bill requires an organization that addresses medical or social issues related to drug addiction to maintain a written agreement with the prescribing health care practitioner and to be exempt from federal taxation. However, those requirements do not appear to be applicable to a substance abuse organization.

VII. Related Issues:

Under s. 112.1815, first responders include:

- Law enforcement officers as defined in s. 943.10, F.S.;
- Firefighters as defined in s. 633.102, F.S.;
- Emergency medical technicians or paramedics as defined in s. 401.23, F.S., employed by state or local government; and
- Volunteer law enforcement officers, firefighters, emergency medical technicians or paramedics engaged by the state or local governments.

SB 758 uses the term first responders, “including law enforcement officers and emergency medical technicians.” It may be confusing to identify only two types of first responders when other definitions in the statutes include additional categories of first responders who may also encounter overdose patients.

²⁸ Department of Health, Bureau of Health Care Practitioner Regulation, *Senate Bill 758 Analysis*, p. 4 (Feb. 11, 2015) (on file with the Senate Committee on Health Policy).

²⁹ This information is provided by the Bureau of Justice Programs, a contractor of the Office of Justice Programs, U.S. Department of Justice whose mission is to support state, local and tribal justice professionals to achieve safer communities. The Bureau has a Law Enforcement Naloxone Toolkit available at: <https://www.bjatrain.org/tools/naloxone/Naloxone%2BBackground> (last visited Feb. 26, 2015).

The bill requires emergency overdose treatment information, as defined in the bill, to be provided by the prescribing health care practitioner, his or her agent, governmental entities, or substance abuse entities. It is unclear whether the intention is to require training with respect to providing the emergency overdose treatment information or whether a hand-out that communicates the specified elements is sufficient.

VIII. Statutes Affected:

This bill creates section 381.887, Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.