

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 Appropriations

BILL: CS/CS/SB 758

INTRODUCER: Appropriations Committee; Health Policy Committee; and Senator Evers

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

DATE: April 20, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Brown</u>	<u>Pigott</u>	<u>AHS</u>	<u>Favorable</u>
3.	<u>Brown</u>	<u>Kynoch</u>	<u>AP</u>	<u>Fav/CS</u>

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 758 establishes the “Emergency Treatment and Recovery Act.” The bill encourages the prescription and administration of emergency opioid antagonists for the treatment of known or suspected opioid overdoses in an emergency when a health care practitioner is not available.

The bill authorizes health care practitioners to prescribe and dispense opioid antagonists to patients, caregivers, and first responders.

Pharmacists are authorized to dispense an appropriately labeled emergency 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, and first responders, who prescribe, possess, administer, or store an approved opioid antagonist under the bill. A health care practitioner acting in good faith 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 under the bill.

The bill has no fiscal impact.

The bill provides that it takes effect upon becoming law.

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 ingests 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 available 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 one-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-to-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

¹ U.S. Department of Health and Human Services, *SAMSHA Opioid Overdose Toolkit*, p. 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*, p. 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).

2,666, representing a 16.7 percent decrease from 2010-2012.⁷ However, reports of increasing 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 U.S. Centers for Disease Control and Prevention (CDC), shows over 2,600 individuals died from a drug-induced cause. The CDC number is not limited to opioid deaths, but the partial-year data from the Florida Medical Examiners Commission indicate that prescription drugs such as 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

⁷ *Id.*

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*, p. 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 p. 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 devices 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.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 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 entities – including individuals such as camp counselors, scout leaders, and tour guides – to possess and store epinephrine auto-injectors for later use on a person who is believed in good faith to be 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 (p.144 of the Public Book Addendum)* (February 6, 2015)

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 (p.144 of the Public Book Addendum)* (February 6, 2015)

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.

- The 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 (EATA) 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 the EATA, 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:

The bill creates the "Emergency Treatment and Recovery Act" as s. 381.887, F.S., and provides definitions. The following definitions are created:

- Administer or administration means the introduction of an emergency opioid antagonist 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 opioid antagonist means naloxone hydrochloride or any similarly acting drug that blocks the effects of opioids that is administered from outside of the body and is approved by the United States Food and Drug Administration for treatment of opioid overdose; and
- Patient means a person at risk of experiencing an opioid overdose.

The bill authorizes the prescription of an emergency opioid antagonist to a patient or a caregiver and the administration of that antagonist for the emergency treatment of a known or suspected opioid overdose when a physician is not available.

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

The bill authorizes health care practitioners to prescribe an emergency opioid antagonist to either a patient or a caregiver. A pharmacist is authorized to dispense an emergency opioid antagonist based on a prescription that is issued to a patient or caregiver. The bill requires the dispensed emergency opioid antagonist to be appropriately labeled with instructions for use.

The bill permits the patient or caregiver who has the dispensed emergency opioid antagonist 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.

First responders are authorized to administer an emergency opioid antagonist as clinically indicated. First responders in this bill include, but are not limited to, law enforcement officers, paramedics, and emergency medical technicians.

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

The bill also provides civil and criminal liability and protection from professional licensure action or other adverse action for an authorized health care practitioner or pharmacist, who, acting in good faith, prescribes or dispenses 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.

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:

Under CS/CS/SB 758, caregivers or other persons in a position to help someone at risk of an opioid overdose are eligible to acquire a prescription for an emergency opioid antagonist and would incur costs to acquire it.

C. Government Sector Impact:

The Bureau of Health Care Practitioner Regulation at the Department of Health reports no fiscal impact under the bill.²⁸

The bill creates no fiscal impact on local governments; however, to the extent that local governments choose to stock a supply of opioid antagonists to address drug overdoses for their emergency medical services, police, 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

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill contemplates that an authorized health care practitioner may dispense an emergency opioid antagonist to a patient or caregiver in the immunities provisions in ss. 381.887(5) and 381.887(6)(b), F.S., as created by the bill. However, the bill does not specifically authorize the health care practitioner to dispense an emergency opioid antagonist under s. 381.887(3), F.S., as created by the bill.

VIII. Statutes Affected:

This bill creates section 381.887 of the Florida Statutes.

IX. Additional Information:

- A. Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations on April 16, 2015:

The committee substitute changes the name of the act, replaces the term “opioid antagonist” with “emergency opioid antagonist,” removes the provisions relating to

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 Assistance, 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).

emergency overdose treatment information, and authorizes emergency responders to administer emergency opioid antagonists as clinically indicated rather than authorizing a health care practitioner to prescribe or dispense the drug directly or through standing orders to the emergency responders. The CS also removes the statement that the bill does not create a duty or standard of care for a person to prescribe or administer an opioid antagonist.

CS by Health Policy on March 4, 2015:

The committee substitute makes the prescribing health care practitioner or his or her agent responsible for providing the emergency overdose treatment information to the patient or caregiver receiving the opioid antagonist prescription rather a third party organization. The committee substitute also provides a statutory cross reference for the term “first responder.”

B. Amendments:

None.