HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 751 Emergency Treatment for Opioid Overdose
SPONSOR(S): Civil Justice Subcommittee; Gonzalez; Renuart and others
TIED BILLS: None **IDEN./SIM. BILLS:** CS/SB 758

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	McElroy	O'Callaghan
2) Civil Justice Subcommittee	13 Y, 0 N, As CS	Bond	Bond
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Deaths from drug overdose have steadily increased over the past few decades and have become the leading cause of accidental death in the United States. The vast majority of these deaths involved an overdose related to opioid analgesics, which are narcotic pain relievers derived from the opium poppy, or its synthetic analogues. Although some of these deaths are unpreventable, opioid antagonists have proven successful in reversing opioid related drug overdoses when administered in a timely manner.

The bill creates the Emergency Treatment and Recovery Act, which authorizes healthcare practitioners to prescribe, and pharmacists to dispense, emergency opioid antagonists to patients and caregivers. Patients and caregivers are authorized to store and possess emergency opioid antagonists. In an emergency situation when a physician is not immediately available, patients and caregivers are authorized to administer an emergency opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.

The bill provides for civil liability protections under the Good Samaritan Act for all individuals. The bill also provides that healthcare practitioners and pharmacists are immune from civil and criminal liability, and immunity from professional discipline, related to prescribing and distributing an opioid antagonist. The bill does not limit other existing immunities currently afforded to healthcare providers.

The bill does not appear to have a fiscal impact on state or local government.

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Opioids

The drug overdose death rate has more than doubled from 1999 through 2013 and has now become the leading cause of accidental deaths in the United States.[1] In 2013, there were 43,982 drug overdose deaths in the United States of which 22,767 (51.8%) were related to pharmaceuticals.[2] The majority of the pharmaceutical related deaths, 16,235 (71.3%), involved opioid analgesic drugs (opioids).[3]

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.[4] They are commonly used as pain relievers to treat acute and chronic pain. An individual experiences pain as a result of a series of electrical and chemical exchanges among his or her peripheral nerves, spinal cord and brain.[5] Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.[6] When an individual experiences pain the body releases hormones, such as endorphins, which bind with targeted opioid receptors.[7] This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.[8] Opioids function in the same way by binding to specific opioid receptors in the brain, spinal cord and gastrointestinal tract, thereby reducing the perception of pain.[9] Opioids include[10]:

- Buprenorphine (Subutex, Suboxone)
- Codeine
- Fentanyl (Duragesic, Fentora)
- Heroin
- Hydrocodone (Vicodin, Lortab, Norco)
- Hydromorphone (Dilaudid, Exalgo)
- Meperidine
- Methadone
- Morphine
- Oxycodone (OxyContin, Percodan, Percocet)
- Oxymorphone
- Tramadol

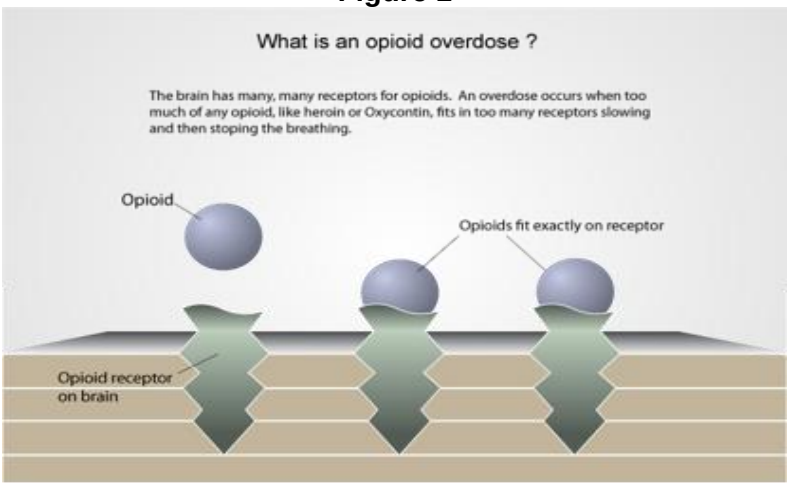
[1] More deaths occur each year due to drug overdose than deaths caused by motor vehicle crashes. *Prescription Drug Overdose in the United States: Fact Sheet*, Centers for Disease Control and Prevention. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (last visited 2/27/15).
[2] *Prescription Drug Overdose in the United States: Fact Sheet*, Centers for Disease Control and Prevention. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (last visited 2/27/15).
[3] Id.
[4] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).
[5] Mayo Clinic Health Library, http://www.riversideonline.com/health_reference/Nervous-System/PN00017.cfm (lasted visited).
[6] *Imaging of Opioid Receptors in the Central Nervous System,* Gjermund Henriksen, Frode Willoch; Brain (2008) 131 (5): 1171-1196.
[7] Id.
[8] Id.
[9] *SAMHSA Opioid Overdose Toolkit: Facts for Community Members*, Department of Health and Human Services- Substance Abuse and Mental Health Services Administration.
[10] *Drugs Identified in Deceased Persons by Florida Medical Examiners 2012 Report,* Florida Department of Law Enforcement, September 2013.

Opioids are commonly abused with an estimated 15 million people worldwide suffering from opioid dependence.[11] Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward which can lead to abuse.[12] Continued use of these drugs can lead to the development of tolerance and psychological and physical dependence.[13] This dependence is characterized by a strong desire to take opioids, impaired control over opioid use, persistent opioid use despite harmful consequences, a higher priority given to opioid use than to other activities and obligations, and a physical withdrawal reaction when opioids are discontinued.[14]

An overabundance of opioids in the body can lead to a fatal overdose. In addition to their presence in major pain pathways, opioid receptors are also located in the respiratory control centers of the brain.[15] Opioids disrupt the transmission of signals for respiration in the identical manner that they disrupt the transmission of pain signals (figure 1). This leads to a reduction, and potentially cessation, of an individual's respiration. Oxygen starvation will eventually stop vital organs like the heart, then the brain, and can lead to unconsciousness, coma, and possibly death.[16] Within 3-5 minutes without oxygen, brain damage starts to occur, soon followed by death.[17] However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.[18] An opioid overdose can be identified by a combination of three signs and symptoms referred to as the "opioid overdose triad":[19]

- Pinpoint pupils;
- Unconsciousness; and,
- Respiratory depression.

Figure 1



Source: Maya Doe-Simkins, MPH, Boston Medical Center.

[11] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).
[12] *How Do Opioids Affect the Brain and Body?,* National Institute on Drug Abuse. http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body (last visited 2/27/15).
[13] *Imaging of Opioid Receptors in the Central Nervous System,* Gjermund Henriksen, Frode Willoch; Brain (2008) 131 (5): 1171-1196.
[14] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).
[15] *Opioids and the Control of Respiration*, K.T.S. Pattinson, BJA, Volume 100, Issue 6, Pages 747-758. http://bja.oxfordjournals.org/content/100/6/747.full (last visited 2/27/15).
[16] *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, Harm Reduction Coalition, Fall 2012. http://harmreduction.org/our-work/overdose-prevention/ (last visited 2/27/15).
[17] Id.
[18] Id.
[19] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last visited 2/27/15).

Opioid Antagonist

An opioid overdose can be reversed if an opioid antagonist is administered in a timely manner. Opioid antagonists are used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally.[20] This occurs because opioid antagonists create a stronger bond with opioid receptors than opioids. This forces the opioids from the opioid receptors and allows the transmission of signals for respiration to resume.[21] This effect lasts only for a short period of time[22] with the narcotic effect of the opioids returning if still present in large quantities in the body. In this scenario additional doses of an opioid antagonist would be required and it is why it is generally recommended that anyone who has experienced an overdose seek medical attention.

Community-based opioid antagonist prevention programs can be successful in increasing the number of opioid overdose reversals. Opioid antagonists were originally prescribed and distributed only to emergency personnel (EMTs, firefighters and law enforcement). In 1996, community-based programs began offering opioid antagonists and other opioid overdose prevention services, in states authorizing such activities, to persons who use drugs, their families and friends and service providers (healthcare providers, homeless shelters and substance abuse treatment programs).[23] In October 2010, a national advocacy and capacity-building organization surveyed 50 programs known to distribute opioid antagonists in the United States, to collect data on various issues including overdose reversals.[24] Forty-eight programs responded to the survey and reported training and distributing opioid antagonists to 53,032 persons and receiving reports of 10,171[25] overdose reversals.[26] Based upon these findings, the report concluded that providing opioid overdose education and opioid antagonists to persons who use drugs and to persons who might be present at an opioid overdose can help reduce opioid overdose mortality.[27]

Multiple states have enacted statutes to allow for the prescription and lay-person use of opioid antagonists (figure 2). For example, as of November 2014:[28]

- Twenty-seven states have statutes which allow for "third-party" prescriptions of opioid antagonists.
- Fifteen states have statutes which protect prescribers from civil liability actions.
- Eighteen states have statutes which protect prescribers from criminal liability actions.

---

[20] *Understanding Naloxone,* Harm Reduction Coalition. http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited 2/27/15).

[21] *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, Harm Reduction Coalition, Fall 2012. http://harmreduction.org/our-work/overdose-prevention/ (last visited 2/27/15).

[22] The half-life for a common opioid antagonist in adults ranged from 30 to 81 minutes. Acute opiate withdrawal is a potential side-effect of naloxone; however, this would be time limited to the half-life of naloxone.

[23] *Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), February 17, 2012 / 61(06);101-105. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm (last visited 2/27/15).

[24] Id.

[25] The findings in this report are subject to at least three limitations. First, other opioid antagonist distribution programs might exist that were unknown to the national advocacy group. Second, all data is based on unconfirmed self-reports from the 48 responding programs. Finally, the numbers of persons trained in opioid antagonist administration and the number of overdose reversals involving opioid antagonists likely were underreported because of incomplete data collection and unreported overdose reversals. However, because not all untreated opioid overdoses are fatal, some of the persons with reported overdose reversals likely would have survived without opioid antagonist administration. *Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), February 17, 2012 / 61(06);101-105.

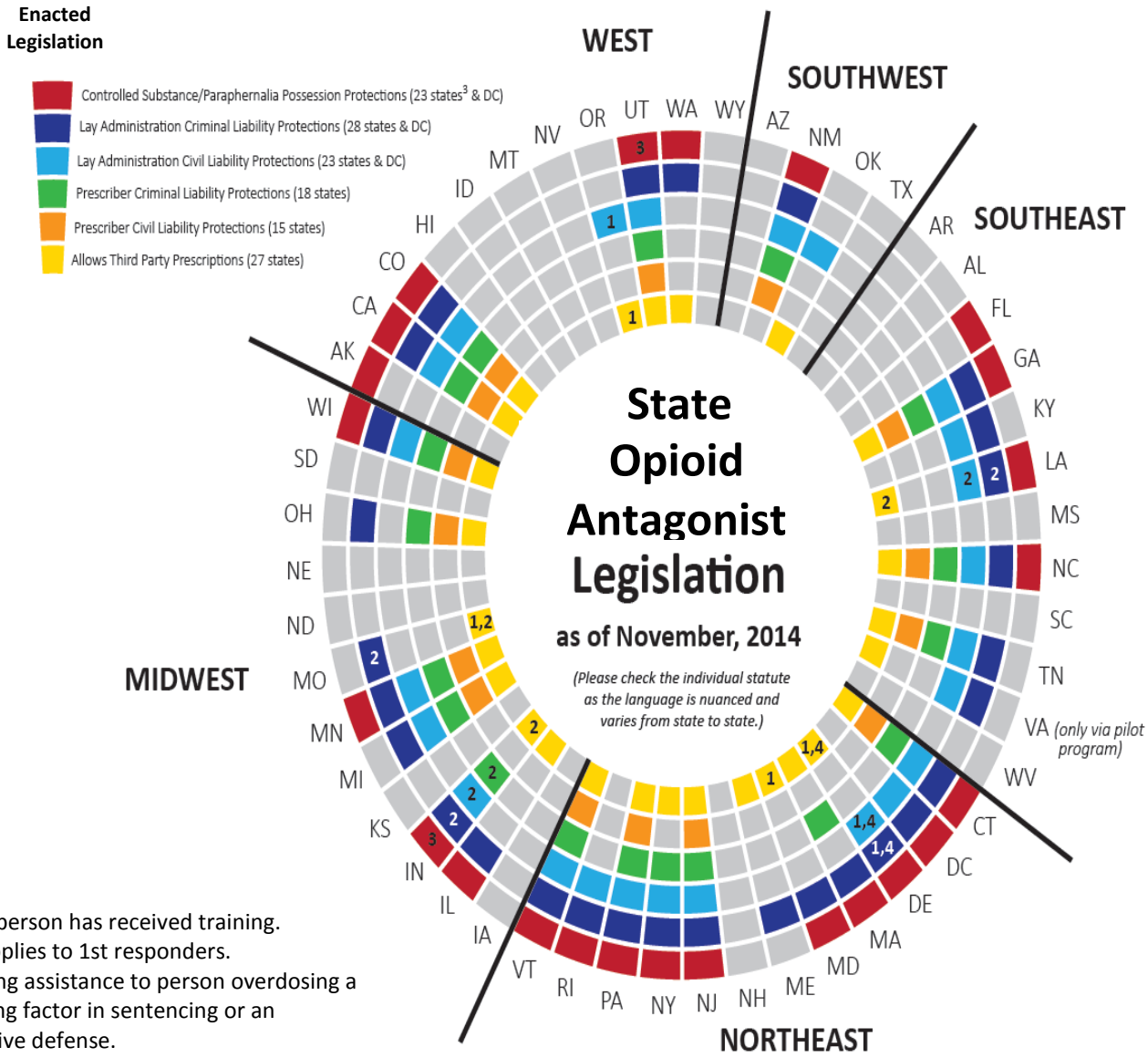
[26] *Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), February 17, 2012 / 61(06);101-105. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm (last visited 2/27/15).

[27] Id.

[28] *Updated Infographic: Overdose Prevention, State by State*, Office of National Drug Control Policy. http://www.whitehouse.gov/blog/2014/12/17/updated-infographic-overdose-prevention-state-state (last visited 2/27/15).

- Twenty-three states and the District of Columbia have statutes which protect lay persons from civil liability for administering opioid antagonists to someone believed to be experiencing an opioid induced overdose.
- Twenty-eight states and the District of Columbia have statutes which protect lay persons from criminal liability for administering opioid antagonists to someone believed to be experiencing an opioid induced overdose.
- Twenty-three states and the District of Columbia have statutes which prevent charge or prosecution for possession of a controlled substance and/or paraphernalia for persons who seek medical/emergency assistance for someone that is experiencing an opioid induced overdose.

Figure 2



[1]Only if person has received training.
[2]Only applies to 1st responders.
[3]Providing assistance to person overdosing a mitigating factor in sentencing or an affirmative defense.
[4]Only applies to peace officers.

Source: Office of National Drug Control Policy

Florida Opioid –Related Data

Opioids also play a prominent role in drug overdose deaths in Florida. In 2012, there were 8,330 drug-related deaths in the state.[29] Opioids were listed as the cause of death in 2,577 cases and were

[29] *Drugs Identified in Deceased Persons by Florida Medical Examiners 2012 Report,* Florida Department of Law Enforcement, September 2013.

present in an additional 3,029 cases.[30] The four most harmful drugs, found in more than 50 percent of the deaths in which these drugs were present, were all opioids:[31]

- Heroin (92.3 percent)
- Methadone (68.3 percent)
- Fentanyl (54.2 percent)
- Oxycodone (51.5 percent).

Florida's Good Samaritan Act

The Good Samaritan Act, found in s. 768.13, F.S., provides immunity from civil liability for those who render emergency care and treatment to individuals in need of assistance. The statute provides immunity from liability for civil damages to any person who:

- Gratuitously and in good faith renders emergency care or treatment either in direct response to emergency situation or at the scene of an emergency, without objection of the injured victim, if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances;[32]
- Participates in emergency response activities of a community emergency response team if that person acts prudently and within scope of his or her training;[33] or
- Gratuitously and in good faith renders emergency care or treatment to an injured animal at the scene of an emergency if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.[34]

Effect of Proposed Changes

HB 751 creates the Emergency Treatment and Recovery Act in s. 381.887, F.S., to authorize healthcare practitioners to prescribe, and pharmacists to dispense, emergency opioid antagonists to patients and caregivers. Patients and caregivers are authorized to store and possess emergency opioid antagonists. In an emergency situation when a physician is not immediately available, patients and caregivers are authorized to administer the emergency opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.

The bill authorizes emergency responders to possess, store, and administer approved emergency opioid antagonists. The bill does not limit any existing immunities for emergency responders or others provided under this chapter or any other applicable provision of law.

The bill provides civil liability immunity under s. 768.13, F.S., (Good Samaritan Act) for any person who possesses, administers, prescribes, dispenses, or stores an approved emergency opioid antagonist in compliance with the bill's requirements.

The bill provides that any authorized healthcare practitioner, dispensing healthcare practitioner, or pharmacist will not be subject to professional sanction or other disciplinary licensing action for acts or omissions if he or she is otherwise in compliance with the bill's requirements. Additionally, a healthcare practitioner, dispensing healthcare practititioner, or pharmacist is immune from civil or criminal liability related to the proscription or dispensing of an opioid antagonist pursuant to the provisions of this bill.

The bill defines "emergency opioid antagonist" as naloxone hydrochloride or any similarly acting drug that blocks the effects of exogenously administered opioids and is approved by the United States Food and Drug Administration for the treatment of opioid overdose.

[30] Id. It also important to note that a decedent may have more than one drug listed as the cause of death.
[31] Id.
[32] Section 768.13(2)(a), F.S.
[33] Section 768.13(2)(d), F.S.
[34] Section 768.13(3), F.S.

The bill defines caregiver as a family member, friend, or person or entity in a position to have recurring contact with a person at risk of experiencing an opioid overdose.

The act will take effect upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Provides citation for the Emergency Treatment and Recovery Act.
Section 2: Creates s. 381.887, F.S., relating to emergency treatment for suspected opioid overdose.
Section 3: Provides the act shall take effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill does not appear to have any impact on state revenues.

2. Expenditures:

   The bill does not appear to have any impact on state expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   The bill does not appear to have any impact on local government revenues.

2. Expenditures:

   The bill does not appear to have any impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill does not appear to have any direct economic impact on the private sector.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill does not appear to create a need for rulemaking or rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 11, 2015, the Civil Justice Subcommittee adopted two amendments and reported the bill favorably as a committee substitute. The amendments

- Limit the scope of the bill to only the antagonist naloxone hydrochloride or similarly acting drug, as opposed to any drug which would has the effect of blocking the effects of an opioid overdose.
- Add that a healthcare practitioner is not civilly or criminally liable for prescribing an opioid antagonist pursuant to this law.
- Add that a dispensing healthcare practitioner or pharmacist is not civilly or criminally liable for prescribing an opioid antagonist pursuant to this law.
- Make technical, grammatical and style improvements.

This analysis is drafted to the committee substitute as passed by the Civil Justice Subcommittee.