

**HOUSE OF REPRESENTATIVES  
FINAL BILL ANALYSIS**

|                             |   |                                  |          |
|-----------------------------|---|----------------------------------|----------|
| <b>BILL #:</b>              | CS/HB 751   | <b>FINAL HOUSE FLOOR ACTION:</b> |          |
| <b>SPONSOR(S):</b>          | Civil Justice Subcommittee;<br>Gonzalez and Renuart; and others | 118 Y's                          | 1 N's    |
| <b>COMPANION<br/>BILLS:</b> | CS/CS/SB 758  | <b>GOVERNOR'S ACTION:</b>        | Approved |

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**SUMMARY ANALYSIS**

CS/HB 751 passed the House on April 16, 2015. The bill was amended by the Senate on April 27, 2015, and subsequently passed the House on April 28, 2015.

Deaths from drug overdose have steadily increased over the past few decades and are 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. Opioid antagonists have proven successful in reversing some opioid-related drug overdoses when administered in a timely manner.

CS/HB 751 creates the Emergency Treatment and Recovery Act (Act). Patients and caregivers are authorized under the Act to store and possess emergency opioid antagonists. The bill also authorizes patients and caregivers 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 administration authorization only applies in an emergency situation when a physician is not immediately available.

The bill authorizes health care practitioners to prescribe and dispense, and pharmacists to dispense, emergency opioid antagonists to patients and caregivers for this purpose. The bill authorizes emergency responders to possess, store, and administer emergency opioid antagonists.

The bill grants civil liability protections under the Good Samaritan Act for all individuals who administer emergency opioid antagonists in emergency situations. The bill also grants health care practitioners and pharmacists immunity from civil and criminal liability and professional discipline, related to prescribing and dispensing an opioid antagonist. The bill states that the immunities provided by the Act do not limit any existing statutory immunities which are otherwise applicable and the Act does not create a duty or standard of care for a person to prescribe or administer an emergency opioid.

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

The bill was approved by the Governor on June 10, 2015, ch. 2015-123, L.O.F., and became effective on that date.

## I. SUBSTANTIVE INFORMATION

### A. EFFECT OF 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.<sup>1</sup> In 2013, there were 43,982 drug overdose deaths in the United States of which 22,767 (51.8%) were related to pharmaceuticals.<sup>2</sup> The majority of the pharmaceutical related deaths, 16,235 (71.3%), involved opioid analgesic drugs (opioids).<sup>3</sup>

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.<sup>4</sup> 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.<sup>5</sup> Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.<sup>6</sup> When an individual experiences pain the body releases hormones, such as endorphins, which bind with targeted opioid receptors.<sup>7</sup> This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.<sup>8</sup> 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.<sup>9</sup> Opioids include<sup>10</sup>:

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

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.<sup>11</sup> Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward which can lead to abuse.<sup>12</sup> Continued use of these drugs can lead

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<sup>1</sup> 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/homeandrecreationalafety/overdose/facts.html> (last visited 4/28/15).

<sup>2</sup> *Prescription Drug Overdose in the United States: Fact Sheet*, Centers for Disease Control and Prevention.

<http://www.cdc.gov/homeandrecreationalafety/overdose/facts.html> (last visited 4/28/15).

<sup>3</sup> Id.

<sup>4</sup> *Information Sheet on Opioid Overdose*, World Health Organization, November 2014.

[http://www.who.int/substance\\_abuse/information-sheet/en/](http://www.who.int/substance_abuse/information-sheet/en/) (last visited 4/28/15).

<sup>5</sup> Mayo Clinic Health Library, [http://www.riversideonline.com/health\\_reference/Nervous-System/PN00017.cfm](http://www.riversideonline.com/health_reference/Nervous-System/PN00017.cfm) (last visited 4/28/15).

<sup>6</sup> *Imaging of Opioid Receptors in the Central Nervous System*, Gjermund Henriksen, Frode Willoch; *Brain* (2008) 131 (5): 1171-1196.

<sup>7</sup> Id.

<sup>8</sup> Id.

<sup>9</sup> *SAMHSA Opioid Overdose Toolkit: Facts for Community Members*, Department of Health and Human Services- Substance Abuse and Mental Health Services Administration.

<sup>10</sup> *Drugs Identified in Deceased Persons by Florida Medical Examiners 2012 Report*, Florida Department of Law Enforcement, September 2013.

<sup>11</sup> *Information Sheet on Opioid Overdose*, World Health Organization, November 2014.

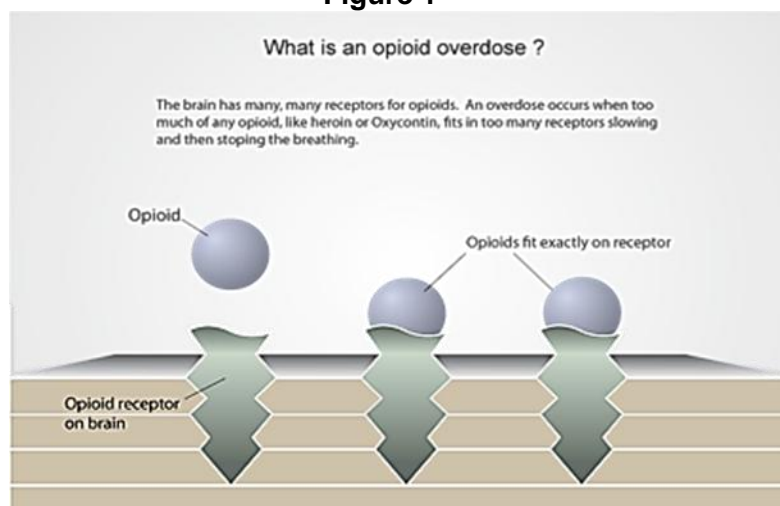
[http://www.who.int/substance\\_abuse/information-sheet/en/](http://www.who.int/substance_abuse/information-sheet/en/) (last visited 4/28/15).

<sup>12</sup> *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 4/28/15).

to the development of tolerance and psychological and physical dependence.<sup>13</sup> 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.<sup>14</sup>

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.<sup>15</sup> 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.<sup>16</sup> Within 3-5 minutes without oxygen, brain damage starts to occur, soon followed by death.<sup>17</sup> However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.<sup>18</sup> An opioid overdose can be identified by a combination of three signs and symptoms referred to as the "opioid overdose triad": pinpoint pupils, unconsciousness, and respiratory depression.<sup>19</sup>

**Figure 1**



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

## Opioid Antagonist

An opioid antagonist is a drug that blocks the effects of exogenously administered opioids. 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.<sup>20</sup> 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.<sup>21</sup>

<sup>13</sup> *Imaging of Opioid Receptors in the Central Nervous System*, Gjermund Henriksen, Frode Willoch; *Brain* (2008) 131 (5): 1171-1196.

<sup>14</sup> *Information Sheet on Opioid Overdose*, World Health Organization, November 2014.

[http://www.who.int/substance\\_abuse/information-sheet/en/](http://www.who.int/substance_abuse/information-sheet/en/) (last visited 4/28/15).

<sup>15</sup> *Opioids and the Control of Respiration*, K.T.S. Pattinson, *BJA*, Volume 100, Issue 6, Pages 747-758.

<http://bj.oxfordjournals.org/content/100/6/747.full> (last visited 4/28/15).

<sup>16</sup> *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 4/28/15).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Information Sheet on Opioid Overdose*, World Health Organization, November 2014.

[http://www.who.int/substance\\_abuse/information-sheet/en/](http://www.who.int/substance_abuse/information-sheet/en/) (last visited 4/28/15).

<sup>20</sup> *Understanding Naloxone*, Harm Reduction Coalition. <http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/> (last visited 4/28/15).

<sup>21</sup> *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 4/28/15).

This effect lasts only for a short period of time<sup>22</sup> 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 (health care providers, homeless shelters and substance abuse treatment programs).<sup>23</sup> 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.<sup>24</sup> Forty-eight programs responded to the survey and reported training and distributing opioid antagonists to 53,032 persons and receiving reports of 10,171<sup>25</sup> overdose reversals.<sup>26</sup> 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.<sup>27</sup>

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:<sup>28</sup>

- 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.
- 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

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<sup>22</sup> 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.

<sup>23</sup> *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 4/28/15).

<sup>24</sup> Id.

<sup>25</sup> 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.

<sup>26</sup> *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 4/28/15).

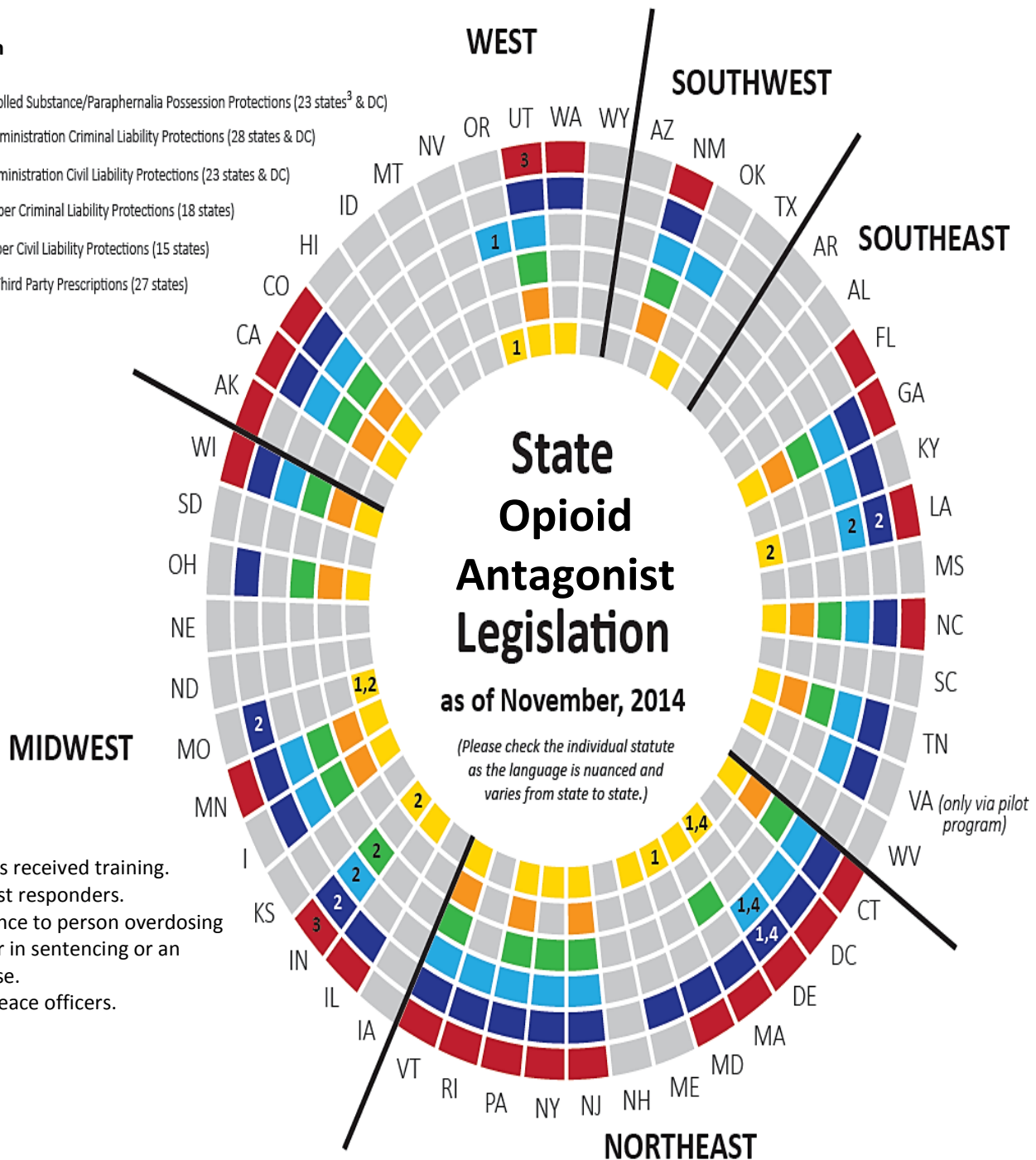
<sup>27</sup> Id.

<sup>28</sup> *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 4/28/15).

**Enacted Legislation**

- Controlled Substance/Paraphernalia Possession Protections (23 states<sup>3</sup> & DC)
- Lay Administration Criminal Liability Protections (28 states & DC)
- Lay Administration Civil Liability Protections (23 states & DC)
- Prescriber Criminal Liability Protections (18 states)
- Prescriber Civil Liability Protections (15 states)
- Allows Third Party Prescriptions (27 states)



- <sup>1</sup>Only if person has received training.
- <sup>2</sup>Only applies to 1st responders.
- <sup>3</sup>Providing assistance to person overdosing a mitigating factor in sentencing or an affirmative defense.
- <sup>4</sup>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 2013, there were 8,286 drug-related deaths in the state.<sup>29</sup> Opioids were listed as the cause of death in 2,573 cases and were present in an additional 2,730 cases.<sup>30</sup> The four most harmful drugs, found in more than 50 percent of the deaths in which these drugs were present, were all opioids:<sup>31</sup>

- Heroin (97%)

<sup>29</sup> *Drugs Identified in Deceased Persons by Florida Medical Examiners 2013 Report*, Florida Department of Law Enforcement, October 2014.

<sup>30</sup> *Id.* A decedent may have more than one drug listed as the cause of death.

<sup>31</sup> *Id.*

- Methadone (67%)
- Fentanyl (63.4%),
- Morphine (59.9%).

### 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;<sup>32</sup>
- Participates in emergency response activities of a community emergency response team if that person acts prudently and within scope of his or her training;<sup>33</sup> 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.<sup>34</sup>

### **Effect of Proposed Changes**

CS/HB 751 creates the Emergency Treatment and Recovery Act (Act). The bill authorizes patients and caregivers (family members, friends, or persons in a position to have recurring contact with a person at risk of experiencing an opioid overdose) to store, possess, and 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. This authorization only applies in an emergency situation when a physician is not immediately available. 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.

The bill authorizes health care practitioners to prescribe and dispense, and pharmacists to dispense, emergency opioid antagonists to patients and caregivers for this purpose. The bill authorizes emergency responders to possess, store, and administer approved emergency opioid antagonists.

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 health care practitioner, dispensing health care practitioner, or pharmacist will not be subject to professional sanction or other disciplinary licensing action for prescribing or dispensing an emergency opioid antagonist in compliance with the Act, if such practitioners acted in good faith and exercised reasonable care. Additionally, a health care practitioner, dispensing health care practitioner or pharmacist is immune from civil or criminal liability related to the prescribing or dispensing of an emergency opioid antagonist, if the practitioner complied with the Act, acted in good faith, and exercised reasonable care.

The bill does not limit any existing immunities for emergency responders or others provided under ch. 381, F.S., or any other applicable provision of law.

The bill states that the Act does not create a duty or standard of care for a person to prescribe or administer an emergency opioid antagonist.

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<sup>32</sup> Section 768.13(2)(a), F.S.

<sup>33</sup> Section 768.13(2)(d), F.S.

<sup>34</sup> Section 768.13(3), F.S.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

### D. FISCAL COMMENTS:

None.