

## HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

**BILL #:** HB 725 Nonopioid Alternatives Educational Materials

**SPONSOR(S):** Plakon and others

**TIED BILLS:** IDEN./SIM. BILLS: SB 530

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**FINAL HOUSE FLOOR ACTION:** 108 Y's      0 N's      **GOVERNOR'S ACTION:** Approved

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### **SUMMARY ANALYSIS**

HB 725 passed the House on April 23, 2021, as SB 530 as amended. The Senate concurred in the House amendment to the Senate bill and subsequently passed the bill as amended on April 27, 2021.

Substance abuse affects millions of people in the U.S. each year. Drug overdoses have steadily increased and now represent the leading cause of accidental death in the U.S., the majority of which involve an opioid. In Florida, opioids (licit and illicit) were responsible for more than 6,000 deaths in 2019. The National Institute of Health reports that the majority of heroin users first misused a prescription opioid.

The Department of Health (DOH) publishes an educational pamphlet regarding the use of non-opioid alternatives to treat pain on its website. Current law requires health care practitioners, except pharmacists, to discuss non-opioid alternatives with a patient or the patient's representative prior to prescribing, ordering, dispensing, or administering opioids. A health care practitioner must also provide a printed copy of the DOH-developed pamphlet to a patient or the patient's representative and document the discussion in the patient's medical record. The law exempts emergency and hospice care from these requirements.

HB 725 modifies the existing requirements by allowing practitioners to provide each patient with an electronically transmitted copy of the DOH pamphlet as an alternative to a printed pamphlet.

The bill has no fiscal impact on state or local government.

The bill was approved by the Governor on May 7, 2021, ch. 2021-12, L.O.F, and will become effective on July 1, 2021.

## I. SUBSTANTIVE INFORMATION

### A. EFFECT OF CHANGES:

#### **Present Situation**

##### **Substance Abuse**

Substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs.<sup>1</sup> Substance abuse disorders occur when the chronic use of alcohol or drugs causes significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.<sup>2</sup> Repeated drug use leads to changes in the brain's structure and function that can make a person more susceptible to developing a substance abuse disorder.<sup>3</sup> Brain imaging studies of persons with substance abuse disorders show physical changes in areas of the brain that are critical to judgment, decision making, learning and memory, and behavior control.<sup>4</sup>

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, a diagnosis of substance abuse disorder is based on evidence of impaired control, social impairment, risky use, and pharmacological criteria.<sup>5</sup> The most common substance abuse disorders in the United States are from the use of alcohol, tobacco, cannabis, stimulants, hallucinogens, and opioids.<sup>6</sup>

##### ***Opioid Abuse***

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.<sup>7</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>8</sup> Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.<sup>9</sup> When an individual experiences pain, the body releases hormones, such as endorphins, which bind with targeted opioid receptors.<sup>10</sup> This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.<sup>11</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>12</sup>

Opioids include:<sup>13</sup>

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<sup>1</sup> World Health Organization, *Substance Abuse*, available at [http://www.who.int/topics/substance\\_abuse/en/](http://www.who.int/topics/substance_abuse/en/) (last visited May 3, 2021).

<sup>2</sup> Substance Abuse and Mental Health Services Administration, *Mental Health and Substance Use Disorders*, (last rev. April 2019), available at <http://www.samhsa.gov/disorders/substance-use> (last visited May 3, 2021).

<sup>3</sup> National Institute on Drug Abuse, *Drugs, Brains, and Behavior: The Science of Addiction*, available at <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction> (last visited May 3, 2021).

<sup>4</sup> *Id.*

<sup>5</sup> *Supra* note 2.

<sup>6</sup> *Id.*

<sup>7</sup> World Health Organization, *Information Sheet on Opioid Overdose*, (Aug. 2018), available at [http://www.who.int/substance\\_abuse/information-sheet/en/](http://www.who.int/substance_abuse/information-sheet/en/) (last visited May 3, 2021).

<sup>8</sup> National Institute of Neurological Disorders and Stroke, *Pain: Hope through Research*, (last rev. Aug. 13, 2019), available at <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Pain-Hope-Through-Research> (last visited May 3, 2021).

<sup>9</sup> Gjermund Henriksen, Frode Willoch; *Brain Imaging of Opioid Receptors in the Central Nervous System*, 131 BRAIN 1171-1196 (2007), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2367693/> (last visited May 3, 2021).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *SAMHSA Opioid Overdose Prevention Toolkit: Facts for Community Members* (2013, rev. 2014) 3, available at [https://www.integration.samhsa.gov/Opioid\\_Toolkit\\_Community\\_Members.pdf](https://www.integration.samhsa.gov/Opioid_Toolkit_Community_Members.pdf) (last visited May 3, 2021).

<sup>13</sup> Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2019 Annual Report*, (Nov. 2020), available at <http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2019-Annual-Drug-Report.aspx> (last visited May 3, 2021).

- Buprenorphine (Subutex, Suboxone);
- Codeine;
- Fentanyl (Duragesic, Fentora);
- Fentanyl Analogs;
- Heroin;
- Hydrocodone (Vicodin, Lortab, Norco);
- Hydromorphone (Dilaudid, Exalgo);
- Meperidine;
- Methadone;
- Morphine;
- Oxycodone (OxyContin, Percodan, Percocet);
- Oxymorphone;
- Tramadol; and
- U-47700.

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.<sup>14</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>15</sup> Continued use of these drugs can lead to the development of tolerance and psychological and physical dependence.<sup>16</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>17</sup> Nearly 80 percent of people who use heroin first misused prescription opioids.<sup>18</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>19</sup> Opioids disrupt the transmission of signals for respiration in the identical manner that they disrupt the transmission of pain signals. 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>20</sup> Within three to five minutes without oxygen, brain damage starts to occur, soon followed by death.<sup>21</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>22</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>23</sup>

The drug overdose death rate involving opioids has increased by 200% since 2000 and has now become the leading cause of accidental deaths in the United States.<sup>24</sup> Opioid-involved overdoses

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<sup>14</sup> *Supra* note 7.

<sup>15</sup> National Institute on Health, National Institute on Drug Abuse, *Misuse of Prescription Drugs: What Classes of Prescription Drugs Are Commonly Misused?*, (rev. Dec. 2018), available at <https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/which-classes-prescription-drugs-are-commonly-misused> (last visited May 3, 2021).

<sup>16</sup> *Supra* note 9.

<sup>17</sup> *Supra* note 7.

<sup>18</sup> National Institute on Health, National Institute on Drug Abuse, *Prescription Opioids and Heroin: Prescription Opioid Use Is a Risk Factor for Heroin Use*, (rev. Jan. 2018), available at <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use> (last visited May 3, 2021).

<sup>19</sup> K.T.S. Pattinson, *Opioids and the Control of Respiration*, BRITISH JOURNAL OF ANAESTHESIA, Volume 100, Issue 6, pp. 747-758, available at <http://bja.oxfordjournals.org/content/100/6/747.full> (last visited May 3, 2021).

<sup>20</sup> Harm Reduction Coalition, *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects* (Fall 2012), <http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf> (last visited May 3, 2021).

<sup>21</sup> *Id.* at 9.

<sup>22</sup> *Id.* at 9.

<sup>23</sup> *Supra* note 7.

<sup>24</sup> Rose Rudd, MSPH, et. al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Morbidity and Mortality Weekly Report (MMWR) 64(50); Jan. 1, 2016, at 1378-82, available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s\\_cid=mm6450a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w) (last visited May 3, 2021).

accounted for 69 percent of drug overdose deaths in 2018.<sup>25</sup> Nationwide, in 2017, there were 47,600 deaths that involved an opioid (licit or illicit), and 17,029 people died from overdoses involving prescription opioids.<sup>26</sup> In 2019, Florida had the following opioid-involved deaths:<sup>27</sup>

Opioid	Caused Death	Present at Death
Oxycodone	510	671
Hydrocodone	165	393
Methadone	174	144
Morphine	984	871
Fentanyl	3,244	411
Fentanyl Analogs	922	496
Heroin	809	145

### Controlled Substance Prescribing in Florida: Chronic Pain

Every physician, podiatrist, or dentist, who prescribes controlled substances in the state to treat chronic nonmalignant pain,<sup>28</sup> must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.<sup>29</sup> Before prescribing controlled substances to treat chronic nonmalignant pain, a practitioner must:<sup>30</sup>

- Complete a medical history and a physical examination of the patient which must be documented in the patient's medical record and include:
  - The nature and intensity of the pain;
  - Current and past treatments for pain;
  - Underlying or coexisting diseases or conditions;
  - The effect of the pain on physical and psychological function;
  - A review of previous medical records and diagnostic studies;
  - A history of alcohol and substance abuse; and
  - Documentation of the presence of one or recognized medical indications for the use of a controlled substance.
- Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment;
- Develop a written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success;
- Discuss the risks and benefits of using controlled substances, including the risks of abuse and addiction, as well as the physical dependence and its consequences with the patient; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or legal representative and by the prescribing practitioner and include:
  - The number and frequency of prescriptions and refills;
  - A statement outlining expectations for patient's compliance and reasons for which the drug therapy may be discontinued; and
  - An agreement that the patient's chronic nonmalignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.

<sup>25</sup> Centers for Disease Control and Prevention, *Drug Overdose Deaths*, (last rev. Mar 19, 2020), available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited May 3, 2021).

<sup>26</sup> L. Scholl, et. al. *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017*, Morbidity and Mortality Weekly Report (MMWR) 64(50); Jan. 4, 2019, at 1378-82, available at [https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s\\_cid=mm675152e1\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w) (last visited May 3, 2021).

<sup>27</sup> *Supra* note 13. "Caused death" means that the medical examiner determined the drug played a causal role in the death. "Present at death" means the medical examiner determine that the drug is present or identifiable but may not have played a causal role in the death.

<sup>28</sup> "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 456.44(1)(e), F.S.

<sup>29</sup> Chapter 2011-141, s. 3, Laws of Fla. (creating s. 456.44, F.S., effective July 1, 2011).

<sup>30</sup> Section 456.44(3), F.S.

A prescribing practitioner must see a patient being treated with controlled substances for chronic nonmalignant pain at least once every three months and must maintain detailed medical records relating to such treatment.<sup>31</sup> Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.<sup>32</sup> The prescribing practitioner must immediately refer a patient exhibiting signs or symptoms of substance abuse to a pain management physician, an addiction medicine specialist, or an addiction medicine facility.<sup>33</sup>

### Controlled Substance Prescribing in Florida: Acute Pain

The Boards of Dentistry, Medicine, Nursing, Optometry, Osteopathic Medicine, and Podiatric Medicine, have adopted rules for prescribing a controlled substance to treat acute pain.<sup>34</sup> Under these rules, a health care practitioner must:<sup>35</sup>

- Conduct a medical history and physical examination of the patient and document the patient's medical record, including the presence of one or more recognized medical indications for the use of a controlled substance;
- Create and maintain a written treatment plan, including any further diagnostic evaluations or other treatments planned including non-opioid medications and treatments;
- Obtain informed consent and agreement for treatment, including discussing the risks and benefits of using a controlled substance; expected pain intensity, duration, options; and use of pain medications, non-medication therapies, and common side effects;
- Periodically review the treatment plan;
- Refer the patient, as necessary, for additional evaluation and treatment in order to meet treatment goals;
- Maintain accurate and complete medical records; and
- Comply with all controlled substance laws and regulations.

A health care practitioner who fails to follow the guidelines established by the appropriate regulatory board is subject to disciplinary action against his or her license.

### Continuing Education on Controlled Substance Prescribing

All health care practitioners who are authorized to prescribe controlled substances must complete a board-approved 2-hour continuing education course, if not already required to complete such a course under his or her practice act.<sup>36</sup> The course must address:

- Current standards on prescribing controlled substances, particularly opiates;
- Alternatives to the current standards on controlled substance prescribing;
- Nonpharmacological therapies;
- Prescribing emergency opioid antagonists; and
- Information on the risks of opioid addiction following all stages of treatment in the management of acute pain.

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<sup>31</sup> Section 456.44(3)(d), F.S.

<sup>32</sup> Section 456.44(3)(e), F.S.

<sup>33</sup> Section 456.44(3)(g), F.S.

<sup>34</sup> Rules 64B5-17.0045, 64B8-9.013, 64B9-4.017, 64B13-3.100, 64B15-14.005, 64B18-23.002, F.A.C., respectively. See also s. 456.44(4), F.S.

<sup>35</sup> *Id.*

<sup>36</sup> Section 456.0301, F.S. Pursuant to s. 464.013(3)(b), F.S., an advanced registered nurse practitioner must complete at least 3 hours of continuing education hours on the safe and effective prescribing of controlled substances each biennial renewal cycle. Section 466.0135, F.S., requires dentists to complete at least 2 continuing education hours on the safe and effective prescribing of controlled substances for license renewal. Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C., requires physician assistants who prescribe controlled substances to complete 3 hours of continuing education on the safe and effective prescribing of controlled substance medications.

The course may be taken in a long-distance format and must be included in the continuing education required for the biennial renewal of a health care practitioner's license. The Department of Health (DOH) may not renew the license of a prescriber who fails to complete this continuing education requirement.

### Non-Opioid Alternatives

Using a non-opioid treatment option may eliminate the need for an opioid or reduce the amount of opioids used. The federal Centers for Disease Control and Prevention (CDC) guidelines for treating chronic pain indicate that non-pharmacologic therapy and non-opioid pharmacologic therapy are the preferred manners of treatment for chronic pain.<sup>37</sup> Examples of non-opioid treatments include:<sup>38</sup>

- Non-opioid medications, such as non-steroidal anti-inflammatory agents (NSAIDs), acetaminophen, corticosteroids, and topical products;
- Behavioral interventions, such as meditation;
- Environmental-based interventions, such as lighting alterations and music therapy; and
- Physical interventions, such as surgery, chiropractic care, acupuncture, physical therapy, and massage therapy.

The CDC also advises that opioid therapy should only be considered if the expected benefit to the patient outweighs the risk, and if used, should be combined with non-pharmacologic and non-opioid pharmacologic therapy.<sup>39</sup>

Current law requires all health care practitioners, except pharmacists, to discuss non-opioid alternatives for treating pain with their patients prior to providing anesthesia or prescribing, ordering, dispensing, or administering an opioid.<sup>40</sup> The health care practitioner must discuss the advantages and disadvantages of using a non- opioid alternative and document the discussion in the patient's record.<sup>41</sup> The only exception to this requirement is when a health care practitioner is providing emergency care or hospice services.<sup>42</sup>

The law also allows a practitioner to inform the patient's representative, instead of the patient, of non-opioid alternatives for treating pain and discuss the advantages and disadvantages of using such alternatives. A health care practitioner must document any such discussion in the patient's medical record.<sup>43</sup>

In addition, DOH is required to develop and publish on its website, an educational pamphlet regarding the use of non-opioid alternatives to treat pain under current law.<sup>44</sup> The pamphlet addresses:<sup>45</sup>

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<sup>37</sup> Centers for Disease Control and Prevention, *Nonopioid Treatments for Chronic Pain*, available at [https://www.cdc.gov/drugoverdose/pdf/nonopioid\\_treatments-a.pdf](https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf) (last visited May 3, 2021).

<sup>38</sup> The Joint Commission, *Non-Pharmacologic and Non-Opioid Solutions for Pain Management*, QUICK SAFETY 44 (Aug. 2018), available at [https://www.jointcommission.org/assets/1/23/QS\\_Nonopioid\\_pain\\_mgmt\\_8\\_15\\_18\\_FINAL1.PDF](https://www.jointcommission.org/assets/1/23/QS_Nonopioid_pain_mgmt_8_15_18_FINAL1.PDF) (last visited May 3, 2021).

<sup>39</sup> *Supra* note 37.

<sup>40</sup> Section 456.44(7)(c), F.S.

<sup>41</sup> *Id.*

<sup>42</sup> "Emergency care and services" means medical screening, examination, and evaluation by a physician or other authorized personnel under the supervision of a physician to determine if an emergency medical condition exists and, if it does, the care, treatment, or surgery by a physician necessary to relieve or eliminate the emergency medical condition, within the service capability of the facility (s. 395.002, F.S.). "Hospice services" means items and services furnished to a patient and family by a hospice, or by others under arrangements with such a program, in a place of temporary or permanent residence used as the patient's home for the purpose of maintaining the patient at home; or, if the patient needs short-term institutionalization, the services shall be furnished in cooperation with those contracted institutions or in the hospice inpatient facility (s. 400.601, F.S.).

<sup>43</sup> *Supra* note 40.

<sup>44</sup> Chapter 2019-123, L.O.F., codified at s. 456.44(7), F.S. The website and pamphlet may be accessed at <http://www.floridahealth.gov/programs-and-services/non-opioid-pain-management/index.html> (last visited May 3, 2021).

<sup>45</sup> *Id.*

- Nonopioid alternatives, including non-opioid medications and non-pharmacological therapies; and
- Advantages and disadvantages of using each of the non-opioid alternatives.

A practitioner must give patients considering opioid therapy this printed pamphlet.

**Effect of the Bill**

HB 725 modifies the existing requirements on practitioners by allowing them to provide each patient with an electronically transmitted copy of the DOH pamphlet as an alternative to a printed pamphlet.

The bill provides an effective date of July 1, 2021.

**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.