HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 743 Nonopioid Alternatives
SPONSOR(S): Plakon
TIED BILLS: **IDEN./SIM. BILLS:** SB 1080

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

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 5,000 deaths in 2018. 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 that health care practitioners, except pharmacists, discuss non-opioid alternatives with patients prior to prescribing, ordering, dispensing, or administering opioids. A health care practitioner must also provide a copy of the DOH-developed pamphlet to a patient and document the discussion in the patient's medical record. The only exception to these requirements is when a health care practitioner is providing emergency care and services.

HB 743 revises these requirements by:

- Exempting hospice services and any care provided in a hospital critical care unit or emergency department from the requirement to discuss non-opioid alternatives with a patient;
- Removing the requirement to address non-opioid alternatives when a drug is dispensed or administered;
- Authorizing a health care practitioner to discuss non-opioid alternatives with the patient's representative rather than the patient; and
- Requiring that a health care practitioner provide a printed copy of the DOH-developed pamphlet to the patient or patient's representative.

The bill has an insignificant, negative fiscal impact on DOH, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Substance Abuse

Substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs.[1] 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.[2] 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.[3] 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.[4]

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.[5] The most common substance abuse disorders in the United States are from the use of alcohol, tobacco, cannabis, stimulants, hallucinogens, and opioids.[6]

Opioid Abuse

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.[7] 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.[8] Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.[9] When an individual experiences pain, the body releases hormones, such as endorphins, which bind with targeted opioid receptors.[10] This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.[11] 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.[12] Opioids include:[13]

---

[1] World Health Organization, *Substance Abuse*, available at http://www.who.int/topics/substance_abuse/en/ (last visited December 17, 2019).
[2] 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 December 17, 2019).
[3] 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 December 17, 2019).
[4] Id.
[5] *Supra* note 2.
[6] Id.
[7] World Health Organization, *Information Sheet on Opioid Overdose*, (Aug. 2018), available at http://www.who.int/substance_abuse/information-sheet/en/ (last visited December 17, 2019).
[8] 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 December 17, 2019).
[9] 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 December 17, 2019).
[10] Id.
[11] Id.
[12] 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 (last visited December 17, 2019).
[13] Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2018 Annual Report*, (Nov. 2019), available at https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2018-Annual-Drug-Report.aspx (last visited December 18, 2019).

- 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.[14] Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward, which can lead to abuse.[15] Continued use of these drugs can lead to the development of tolerance and psychological and physical dependence.[16] 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.[17] Nearly 80 percent of people who use heroin first misused prescription opioids.[18]

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.[19] 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.[20] Within three to five minutes without oxygen, brain damage starts to occur, soon followed by death.[21] However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.[22] 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.[23]

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.[24] Opioid-involved overdoses accounted for 68 percent of drug overdose deaths in 2017.[25] Nationwide, in 2017, there were 47,600

---

[14] *Supra* note 7.
[15] 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 December 18, 2019).
[16] *Supra* note 9.
[17] *Supra* note 7.
[18] 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 December 18, 2019).
[19] 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 December 18, 2019).
[20] 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 December 18, 2019).
[21] Id. at 9.
[22] Id. at 9.
[23] *Supra* note 7.
[24] 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 (last visited December 18, 2019).
[25] Centers for Disease Control and Prevention, *Drug Overdose Deaths*, (last rev. June 27, 2019), available at https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited December 18, 2019).

deaths that involved an opioid (licit or illicit), and 17,029 people died from overdoses involving prescription opioids.[26] The most common drugs involved in prescription opioid overdose deaths were methadone, oxycodone, and hydrocodone.[27] In 2018, Florida had the following opioid-involved deaths:[28]

Opioid	Caused Death	Present at Death
Oxycodone	535	646
Hydrocodone	168	425
Methadone	228	173
Morphine	1,102	761
Fentanyl	2,348	355
Fentanyl Analogs	874	178
Heroin	806	134

Controlled Substance Prescribing in Florida: Chronic Pain

Every physician, podiatrist, or dentist, who prescribes controlled substances in the state to treat chronic nonmalignant pain,[29] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[30] Before prescribing controlled substances to treat chronic nonmalignant pain, a practitioner must:[31]

- 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.

[26] 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 (last visited December 18, 2019).
[27] Centers for Disease Control and Prevention, *Overdose Death Maps: Overdose Deaths Involving Prescription Opioids*, (last rev. Aug. 13, 2019), available at https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html (last visited December 18, 2019).
[28] *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.
[29] "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.
[30] Chapter 2011-141, s. 3, Laws of Fla. (creating s. 456.44, F.S., effective July 1, 2011).
[31] 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.[32] Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.[33] 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.[34]

Controlled Substance Prescribing in Florida: Acute Pain

The Boards of Dentistry, Medicine, Nursing, Optometry, Osteopathic Medicine, and Podiatric Medicine, have adopted rules establishing guidelines for prescribing a controlled substance to treat acute pain.[35] Under these guidelines, a health care practitioner must:[36]

- 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.[37] 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.

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.

---

[32] Section 456.44(3)(d), F.S.
[33] Section 456.44(3)(e), F.S.
[34] Section 456.44(3)(g), F.S.
[35] 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.
[36] Id.
[37] 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.

Non-Opioid Alternatives

Using a non-opioid treatment option may eliminate the need for an opioid or reduce the amount of opioids used. The Center for Disease Control and Prevention's (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.[38] Examples of non-opioid treatments include:[39]

- 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.[40]

Florida Law on Non-Opioid Alternatives

In 2019, the Legislature enacted a law that requires DOH to develop and publish on its website, an educational pamphlet regarding the use of non-opioid alternatives to treat pain.[41] The pamphlet addresses:[42]

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

All health care practitioners, except pharmacists, must discuss non-opioid alternatives for treating pain with their patients prior to providing anesthesia or prescribing, ordering, dispensing, or administering an opioid.[43] The health care practitioner must discuss the advantages and disadvantages of using a non-opioid alternative, document the discussion in the patient's record, and provide the patient with the DOH-developed pamphlet.[44] The only exception to this requirement is when a health care practitioner is providing emergency care or services.[45]

There is currently no requirement that the patient must receive a printed copy of the pamphlet. Current law does not authorize a health care practitioner to provide the information to the patient's representative instead of the patient.

Effect of the Proposed Changes

[38] Centers for Disease Control and Prevention, *Nonopioid Treatments for Chronic Pain,* available at https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf (last visited December 18, 2019).
[39] 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 (last visited December 18, 2019).
[40] *Supra* note 38.
[41] 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 December 17, 2019).
[42] Id.
[43] Section 456.44(7)(c), F.S.
[44] Id.
[45] "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 relive or eliminate the emergency medical condition, within the service capability of the facility (s. 395.002, F.S.).

HB 743 revises the circumstances under which a health care practitioner must counsel a patient about non-opioid alternatives. The bill exempts health care practitioners providing hospice services[46] and those providing care in a hospital critical care unit or emergency department from the requirement to provide information about non-opioid alternatives.

The bill authorizes a health care 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, prior to administering anesthesia that involves the use of an opioid drug or prescribing or ordering an opioid drug. A health care practitioner must document the discussion in the patient's medical record and provide a printed copy of the pamphlet produced by DOH to the patient or the patient's representative.

The bill provides an effective date of July 1, 2020.

B. SECTION DIRECTORY:

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH may incur insignificant costs associated with printing the non-opioid alternatives brochure to provide to appropriate patients in county health departments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners may incur costs associated with purchasing or printing the DOH-developed pamphlet on non-opioid alternatives.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

[46]"Hospice services are provided to individuals who have been admitted to a hospice program after or upon a diagnosis and prognosis of terminal illness by a licensed physician. Hospice services may include physician care, nursing services, social work services, pastoral or counseling services, dietary counseling, bereavement counseling, and other palliative and support services needed by the patients. *See* ss. 400.609 and 400.6095, F.S.

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES