

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 Health Policy

BILL: SB 630

INTRODUCER: Senators Perry and Baxley

SUBJECT: Nonopioid Directives

DATE: March 29, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	Pre-meeting
2.			JU	
3.			RC	

I. Summary:

SB 630 amends s. 456.44, F.S., to require the Department of Health (DOH) to establish a form that a patient may execute and file with a physician, physician assistant, or advanced practice registered nurse who is registered to treat chronic nonmalignant pain (registrant) in order to inform the registrant that he or she may not be prescribed opioid drugs, be the subject of an order for opioid drugs, or be administered an opioid drug. The registrant must provide the form to any patient who may be treated using an opioid drug prior to prescribing, ordering, or administering the opioid drug to the patient.

The bill provides exemptions from liability for pharmacists who dispense opioid medications in compliance with a valid prescription and to registrants who refuse to treat a patient with opioids based on the patient's nonopioid directive form, or who treat a patient with an opioid in a hospital's emergency department in contradiction to the patient's form, under certain circumstances.

The bill provides an effective date of July 1, 2019.

II. Present Situation:

Opioid Abuse

Both nationally and in Florida, opioid addiction and abuse has become an epidemic. The Florida Department of Law Enforcement (FDLE) reported that, when compared to 2016, 2017 saw:

- 6,178 (8 percent more) opioid-related deaths;
- 6,932 (4 percent more) individuals died with one or more prescription drugs in their system;¹

¹ The drugs were identified as either the cause of death or merely present in the decedent. These drugs may have also been mixed with illicit drugs and/or alcohol. These drugs were not necessarily opioids.

- 3,684 (4 percent more) individuals died with at least one prescription drug in their system that was identified as the cause of death;
- Occurrences of heroin increased by 3 percent and deaths caused by heroin increased by 1 percent;
- Occurrences of fentanyl increased by 27 percent and deaths caused by fentanyl increased by 25 percent;
- Occurrences hydrocodone increased by 6 percent while deaths caused by hydrocodone decreased by 8 percent;
- Occurrences of buprenorphine and deaths caused by buprenorphine increased by 19 percent.²

The federal Centers for Disease Control and Prevention (CDC) estimates that the nationwide cost of opioid misuse at \$78.5 billion per year.³

History of the Opioid Crisis in Florida

In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and health care providers began to prescribe them at greater rates. This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive.⁴ Between the early 2000s and the early 2010s, Florida was infamous as the “pill mill capital” of the country. At the peak of the pill mill crisis, doctors in Florida bought 89 percent of all the oxycodone sold in the county.⁵

Between 2009 and 2011, the Legislature enacted a series of reforms to combat prescription drug abuse. These reforms included strict regulation of pain management clinics; creating the Prescription Drug Monitoring Program (PDMP); and stricter regulation on selling, distributing, and dispensing controlled substances.⁶ In 2016, the opioid prescription rate was 75 per 100 persons in Florida. This rate was down from a high of 83 per 100.

Drug overdose is now the leading cause of non-injury related death in the United States. Since 2000, drug overdose death rates increased by 137 percent, including a 200 percent increase in the rate of overdose deaths involving opioids. In 2015, over 52,000 deaths in the U.S. were attributed to drug poisoning, and over 33,000 (63 percent) involved an opioid. In 2015, 3,535 deaths occurred in Florida where at least one drug was identified as the cause of death. More specifically, 2,535 deaths were caused by at least one opioid in 2015. Stated differently, seven lives per day were lost to opioids in Florida in 2015. Overall the state had a rate of opioid-caused deaths of 13 per 100,000. The three counties with the highest opioid death rate were Manatee

² FDLE, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2017 Annual Report* (Nov. 2018) <http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2017-Annual-Drug-Report.aspx> (last visited on Mar. 20, 2019).

³ National Institute on Drug Abuse, *Opioid Overdose Crisis* (Jan. 2018) <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last visited on Mar. 20, 2019).

⁴ Id.

⁵ Lizette Alvarez, *Florida Shutting ‘Pill Mill’ Clinics*, *The New York Times* (Aug. 31, 2011), available at <http://www.nytimes.com/2011/09/01/us/01drugs.html> (last visited on Mar. 20, 2018).

⁶ See chs. 2009-198, 2010-211, and 2011-141, Laws of Fla.

County (37 per 100,000), Dixie County (30 per 100,000), and Palm Beach County (22 per 100,000).⁷

Early in 2017, the CDC declared the opioid crisis an epidemic and shortly thereafter, on May 3, 2017, Governor Rick Scott signed Executive Order 17-146 declaring the opioid epidemic a public health emergency in Florida.

House Bill 21

In 2018, the Florida Legislature passed HB 21 (ch. 2018-13, L.O.F.) to combat the opioid crisis. HB 21:

- Required additional training for practitioners on the safe and effective prescribing of controlled substances;
- Restricted the length of prescriptions for Schedule II opioid medications to 3 days or up to 7 days if medically necessary;
- Reworked the PDMP statute to require that prescribing practitioners check the PDMP prior to prescribing a controlled substance and to allow the integration of PDMP data with electronic health records and the sharing of PDMP data between Florida and other states; and
- Provided for additional funding for treatment and other issues related to opioid abuse.

III. Effect of Proposed Changes:

SB 630 amends s. 456.44, F.S., to establish a voluntary nonopioid directive form. The bill:

- States legislative findings that every competent adult has the fundamental right to self-determination regarding decisions pertaining to his or her own health, including the right to refuse an opioid drug listed as a schedule II controlled substance;
- Requires the Department of Health (DOH) to establish a voluntary nonopioid directive form. The form:
 - Must inform registrants that a patient may not be prescribed opioid drugs, may not be the subject of an order for opioid drugs, and may not be administered an opioid drug; and
 - Must be posted on the DOH's website.
- Allows a patient to execute the form and file it with a registrant and requires the registrant to document the receipt of the form in the patient's medical record.
- Allows a patient to appoint and list on the form a guardian or health care proxy who may revoke the directive. Exempts such proxy from liability for revoking a directive if acting in good faith.
- Requires a registrant to provide the form to a patient before prescribing, ordering, or administering an opioid drug to the patient.
- Requires a pharmacist to presume that an electronically transmitted prescription for an opioid drug is valid and exempts such a pharmacist from civil, criminal, and administrative liability for dispensing an opioid to a patient with reasonable care.
- A registrant is not civilly, criminally, or administratively liable if the registrant:
 - Refuses to prescribe, order, or administer an opioid pursuant to a directive; or

⁷ Attorney General's Opioid Working Group, *Florida's Opioid Epidemic: Recommendations and Best Practices* (March 1, 2019), available at [https://myfloridalegal.com/webfiles.nsf/WF/TDGT-B9UTV9/\\$file/AG+Opioid+Working+Group+Report+Final+2-28-2019.pdf](https://myfloridalegal.com/webfiles.nsf/WF/TDGT-B9UTV9/$file/AG+Opioid+Working+Group+Report+Final+2-28-2019.pdf), (last visited on March 14, 2019).

- Prescribes, orders, or administers an opioid in contradiction of a directive if the registrant is employed by a hospital's emergency department, exercises reasonable care, and had no knowledge of the directive at the time of the prescribing, ordering, or administering.
- A registrant who fails to comply with a patient's directive, or the revocation of such directive, is subject to disciplinary action pursuant to s. 456.072, F.S.

The bill provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

SB 630 may have an indeterminate negative fiscal impact on the DOH related to the development of the voluntary nonopioid directive form but such impact would likely be absorbed within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 456.44 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
