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 1442
INTRODUCER:	Senator Boyd
SUBJECT:	Substance Abuse Prevention
DATE:	March 16, 2021
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1442 amends and creates several sections of the Florida statutes related to substance abuse prevention. The bill amends s. 381.887, F.S., to allow a pharmacist[1] to dispense an emergency opioid antagonist without a prescription to any person specified by the bill and to allow such person to store, possess, and, in an emergency situation, administer the opioid antagonist. The bill provides immunity from civil and criminal liability related to the administering of an opioid antagonist to emergency responders, crime laboratory personnel, law enforcement personnel, and any person dispensed an opioid antagonist pursuant to the above provision.

The bill requires the Department of Health (DOH) to develop and implement a statewide awareness campaign to educate the public regarding the risk factors and signs and symptoms of opioid overdoses as well as how to respond to such overdoses, including the safe storage and administration of emergency opioid antagonists.

The bill creates s. 381.888, F.S., to require the DOH, in coordination with the Board of Pharmacy (BOP), to establish and administer the At-home Drug Deactivation and Disposal System Program (Program) for the purpose of identifying and distributing a suitable at-home drug deactivation and disposal system which pharmacies must co-dispense with each opioid prescription. The DOH, in coordination with the BOP, must develop relevant educational materials for the program and adopt rules to implement the program. The bill amends ss. 456.44 and 465.0276, F.S., to require the concurrent prescription of the at-home deactivation and disposal system with the prescription of an opioid drug listed as a schedule II controlled substance.

The bill also amends s. 401.253, F.S., to require a health care facility, a basic life support service (BLS), or an advanced life support service (ALS) to report the treatment and release or transport

[1] Licensed under ch. 465, F.S.

of a person in response to an emergency call for a suspected or actual overdose of a controlled substance. Currently, reporting of such incidents is authorized, but not required, for ALS and BLS.

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

II. Present Situation:

History of the Opioid Crisis in Florida

According to the National Institute on Drug Abuse:[2]

- "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" and
- "This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive."

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.[3]

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.[4] "In 2016, the opioid prescription rate was 75 per 100 persons in Florida. This rate was down from a high of 83 per 100."[5]

As reported by the Florida Attorney General's Opioid Working Group:

> 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

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[2] National Institute on Drug Abuse, *Opioid Overdose Crisis* (Rev. Jan. 2019), *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last visited Mar. 12, 2021).
[3] 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 Mar. 12, 2021).
[4] *See* Chapters 2009-198, 2010-211, and 2011-141, Laws of Fla.
[5] Attorney General's Opioid Working Group, *Florida's Opioid Epidemic: Recommendations and Best Practices*, 7 (Jan. 25, 2021), *available at* https://myfloridalegal.com/webfiles.nsf/WF/TDGT-B9UTV9/$file/AG+Opioid+Working+Group+Report+Final+2-28-2019.pdf (last visited Mar. 12, 2021).

opioid death rate were Manatee County (37 per 100,000), Dixie County (30 per 100,000), and Palm Beach County (22 per 100,000).[6]

Early in 2017, the federal Centers for Disease Control and Prevention (CDC) declared the opioid crisis an epidemic.[7] Shortly thereafter, on May 3, 2017, Governor Rick Scott signed Executive Order 17-146 declaring the opioid epidemic a public health emergency in Florida.[8]

House Bill 21 (2018)

In 2018, the Florida Legislature passed CS/CS/HB 21 (Chapter 2018-13, Laws of Florida) to combat the opioid crisis. CS/CS/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 three days or up to seven 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.

Opioid Antagonists

Opioid receptor antagonists block one or more of the opioid receptors in the central or peripheral nervous system. Opioid receptors are specific transmembrane neurotransmitter receptors that couple G-proteins, which upon stimulation by endogenous or exogenous opioids, leading to the intracellular process of signal transduction. The two most commonly used centrally acting opioid receptor antagonists are naloxone and naltrexone. Naloxone comes in intravenous, intramuscular, and intranasal formulations and is FDA-approved for the use in an opioid overdose and the reversal of respiratory depression associated with opioid use. Naltrexone is available in both oral and long-acting injectable formulations and is FDA-approved for the treatment of opioid and/or alcohol maintenance treatment. The most commonly used peripheral opioid receptor antagonist is methylnaltrexone, which is a potent competitive antagonist acting at the digestive tract and is also FDA-approved for the treatment of opioid-induced constipation.[9]

Prescription Drug Disposal

Currently, the recommended method of disposing of unused prescription medications is to take them to a drug take-back location.[10] However, if there is not a drug take-back location in the area

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[6] *Id.*
[7] *See* Exec. Order No. 17-146, *available at* https://www.flgov.com/wp-content/uploads/2017/05/17146.pdf. (last visited Mar. 12, 2021).
[8] *Id.*
[9] *Opioid Antagonists*, Theriot, Jonathan, et. al., (last updated July 27, 2020), *available at* https://www.ncbi.nlm.nih.gov/books/NBK537079/#:~:text=3%5D%5B4%5D-,The%20two%20most%20commonly%20used%20centrally%20acting%20opioid%20receptor%20antagonists,depression%20associated%20with%20opioid%20use. (last visited March 12, 2021).
[10] *See* https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know (last visited Mar. 12, 2021).

or if the person cannot go to one promptly, the U.S. Food and Drug Administration (FDA) provides two recommendations:

- That drugs on the drug flush list be disposed of immediately by being flushed down a toilet. The FDA has identified and created a list of drugs that are either dangerous to be kept unused for an extended period of time or are sought-after for their misuse and abuse potential. Many of the drugs on the flush list are prescription opioids.[11]
- If the drug is not on the flush list, the FDA recommends that the drug be mixed with an unappealing substance in a sealed container and thrown away in the trash.[12]
- In either case, the FDA also recommends that all personal information on the prescription label be deleted before throwing away or recycling the drug container.

Drug Disposal Products

There are numerous drug disposal products available, many of which are sold directly to consumers. A 2019 report from the San Francisco Department of the Environment examined and compared ten of these products, eight of which are available for consumers to buy for use in the home.[13, 14] The report prefaces its findings by stating that "none of the medicine disposal products [looked at] are approved by any federal agency; no federal agency endorses such products, and none appear to be actively evaluating these products at this time."[15] The report looked at each product with four questions in mind:

- Is the product safe for use?
- Are the drugs disposed of made undesirable?
- Are the drugs disposed of made non-retrievable?[16]
- Is the product safe for solid waste disposal?

The products used a variety of methods to dispose of drugs and make them non-retrievable, including activated carbon, bentonite clay, mixtures of calcium hypochlorite with other ingredients, and other proprietary methods not fully described by the products.

Activated Carbon

Four of the eight products are available for home purchase. Deterra, Drug Buster, Narc X, and Rx Destroyer identify activated carbon as a key active ingredient.[17] These products works with a process called adsorption in which the chemicals in the drugs attach to the surface of the

[11] *See* https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-fdas-flush-list-certain-medicines (last visited Mar. 12, 2021).
[12] *See* https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-dispose-non-flush-list-medicine-trash (last visited Mar. 12, 2021).
[13] *Medicine Disposal Products: An Overview of Products and Performance Questions*, Community Environmental Health Strategies LLC, March 2019, *available at* https://sfenvironment.org/sites/default/files/fliers/files/medicinedisposalproducts_march2019.pdf (last visited Mar. 15, 2021).
[14] The products available for home use include Deterra, DisposeRx, Drug Buster, Element MDS, NarcX, Pill Catcher, Pill Terminator, and Rx Destroyer.
[15] Id. at p. 2.
[16] The report used the U.S. Drug Enforcement Agency final rule definition of non-retrievable which is identical to the definition in 21 C.F.R. s. 1300.05(b).
[17] Id. n. 13 at p. 26.

activated carbon in the disposal product.[18] The process of adsorption typically takes between eight hours and several days. However the products using this process typically recommend the placement of the drug into the trash within two hours of placement of the drug into the carbon solution.[19] Testing of these products (reviewed but not conducted by the study) showed that the rate and amount of adsorption of drugs placed into the products varied from product to product and with different kinds of drugs tested.[20] Additionally, it is unclear whether the adsorption process renders the drugs non-retrievable.[21]

Bentonite Clay

The product Pill Catcher is the only product listed which uses a chemically altered sodium bentonite clay. Bentonite clay interacts with chemicals through an adsorption process, similar to that of activated carbon.[22] The product manufacturer cites testing of the product for environmental soundness but not for the non-retrievability of the drugs on which the product is used. Other testing of similar methods of disposal show that it is unlikely that bentonite clay treatment without other agents could achieve the DEA's non-retrievable standard of permanent physical or chemical alteration of a controlled substance.[23]

Calcium Hypochlorite

The product Pill Terminator lists calcium hypochlorite as an ingredient on its Material Safety Data Sheet (MSDS), which also lists Fuller's earth and a proprietary "absorbent polymer."[24] Because calcium hypochlorite is a strong oxidizing agent, the Pill Terminator product must carry a warning label about its toxicity through skin contact, eye exposure or ingestion, and a warning to keep away from children. If combined with other substances, calcium hypochlorite can release chlorine gas and can also react explosively with ammonia and metals. As an oxidizing agent, hypochlorite will react with and chemically alter some pharmaceuticals, depending on their chemical composition. The degree of chemical degradation and resulting chemical byproducts will depend on the pharmaceuticals being treated.[25]

The Pill Terminator website provides analysis by an independent test laboratory that the product renders aspirin pills unpalatable and foul smelling. Unpublished test results from academic researchers on treatment of morphine show release of 45 percent of the morphine by simple water extraction after 48 hours of treatment by the Pill Terminator. The testing did not fully characterize the chemical composition of the product-drug mixture as it would be disposed. *See* the Pill Terminator's profile in Section V of this analysis for more details.[26]

[18] Id.
[19] Supra n. 13 at p. 27.
[20] Id. at p. 29.
[21] Id. at p. 28.
[22] Id. at p. 30.
[23] Id.
[24] Id.
[25] Id. at p. 31.
[26] Id.

Unknown Mechanisms of Action

The other products available for consumer use, DisposeRX and Element MDS, use methods of destruction that are not fully specified by the product manufacturers.

DisposeRx's mechanism of action is described as "chemically and physically sequester(ing) medications in a viscous gel" that becomes solid over time. The product ingredients are described as safe and approved for use in oral medications and food.[27]

V23, LLC, the manufacturer of Element MDS, describes the mechanism of action on medicines as "holds the medication in suspension and forms a solid gel making the medication undesirable." Descriptions on the Element MDS website do not claim that it makes drugs non-retrievable but indicate the medicines become "undesirable." Descriptions of the product's ingredients as an "organic, plant-based powder" seem out of sync with the product label's warnings about avoiding skin and eye contact and "Caution: harmful if swallowed." Element MDS recommends trash disposal of the product-drug mixture but does not provide any waste determination data.[28]

III. Effect of Proposed Changes:

SB 1442 amends and creates several sections of the Florida statutes related to substance abuse prevention.

Availability of Opioid Antagonists

The bill amends s. 381.887, F.S., to expand the section to provide for the ordering and dispensing, in addition to prescribing, of emergency opioid antagonists to persons who may come in contact with a controlled substance or who are at risk of experiencing an opioid overdose. The bill requires the DOH to develop and implement a statewide awareness campaign to educate the public regarding the risk factors of opioid overdoses, the signs and symptoms of opioid overdoses, and how to respond to such overdoses, including the safe storage and administration of emergency opioid antagonists.

The bill allows pharmacists licensed under ch. 465, F.S., to order or dispense emergency opioid antagonists without a prescription to any person who:

- Is at risk of an opioid overdose due to his or her medical condition or history;
- Is a caregiver of someone who is at risk of an opioid overdose;
- Is in a position to assist another person who is at risk of an opioid overdose; or
- May come into contact with a controlled substance.

The bill provides authorization for such persons to store, possess, and administer the opioid antagonist to a person believed in good faith to be experiencing an opioid overdose in an emergency situation when a physician is not immediately available. The bill also provides immunity from civil and criminal liability stemming from the administering of an emergency opioid antagonist. Such immunity is provided to:

[27] Supra n. 13 at p. 31.
[28] Id.

- Emergency responders, including, but not limited to, law enforcement officers, paramedics, and emergency medical technicians.
- Crime laboratory personnel for the statewide criminal analysis laboratory system as described in s. 943.32, F.S., including, but not limited to, analysts, evidence intake personnel, and their supervisors.
- Personnel of a law enforcement agency or other agency, including, but not limited to, correctional probation officers and child protective investigators who, while acting within the scope or course of employment, come into contact with a controlled substance or a person who is at risk of experiencing an opioid overdose.
- A person who is dispensed an emergency opioid antagonist pursuant to the provisions added by the bill and comes into contact with a controlled substance or a person who is at risk of experiencing an opioid overdose.

The bill also amends s. 401.253, F.S., to require BLS, ABS, and health care facilities to report the treatment and release of a suspected or actual overdose of a controlled substance to the DOH.

Drug Deactivation and Disposal System Program

SB 1442 creates s. 381.888, F.S., to establish the At-home Drug Deactivation and Disposal System Program. The bill defines the terms:
- "Board" to mean the Board of Pharmacy.
- "Department" to mean the Department of Health.
- "Nonretrievable" with the same meaning as provided in 21 C.F.R. s. 1300.05(b), as that definition exists on the bill's effective date.[29]
- "Pharmacy" with the same meaning as provided in s. 465.003(11), F.S.
- "Program" to mean the At-home Drug Deactivation and Disposal System Program.

The Program requires the DOH, in coordination with the BOP, to establish and administer the Program for the purpose of identifying and distributing a suitable at-home drug deactivation and disposal system that pharmacies must co-dispense with each opioid prescription. The at-home drug deactivation and disposal system must permanently render the active pharmaceutical ingredient nonretrievable, nonusable, and fully nontoxic at the point it enters the state's municipal waste systems. The DOH and the BOP must develop relevant educational materials and a plan for distribution of the at-home drug deactivation and disposal systems and educational materials to Florida pharmacies and adopt rules to administer the Program.

The bill also amends ss. 456.44 and 465.0276, F.S., to require an at-home drug deactivation and disposal system to be prescribed in conjunction with any schedule II controlled substance prescribed for the treatment of specified level of pain resulting from a traumatic injury.

[29] The definition of non-retrievable in 21 CFR s. 1300.05(b) is "Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes."

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

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:

SB 1442 may have an indeterminate negative fiscal impact on ALS, BLS, and health care facilities that are required to report suspected and actual controlled substance overdoses under the bill.

C. Government Sector Impact:

Lines 130-138 of SB 1442 appear to require the state to purchase and distribute an at-home drug deactivation and disposal system to pharmacies that must co-dispense such a system with each opioid prescription filled. Such a system may cost, on average, between $1.60 and $16, depending on the size of the system provided.[30] According to the CDC, the opioid dispensing rate in Florida in 2019 was 45.4 prescriptions dispensed per 100 residents.[31] Florida's current population estimate, as of 2019, is approximately 21.5

[30] Supra n. 13 at p. 44.
[31] *See* US State Opioid Dispensing Rates, 2019, *available at* https://www.cdc.gov/drugoverdose/maps/rxstate2019.html, (last visited Mar. 15, 2021).

million.[32] Based on these numbers, the number of opioid prescriptions dispensed in 2019 was approximately 9.75 million.

Given the estimated cost of $1.60 to $16 per drug disposal system and assuming that opioid prescription rates remain steady, to provide a drug disposal system for every opioid prescription dispensed may cost between $15.6 and $156 million dollars annually.

VI. Technical Deficiencies:

SB 1442 amends s. 401.253, F.S., to add health care facilities to the providers who must report controlled substance overdoses. However, the section requiring reporting of such overdoses is specific to ALS and BLS providers and does not contain a definition of the term "health care facility." It may be advisable to define health care facility within the context of this change.

VII. Related Issues:

Lines 95-97 of SB 1442 provide immunity "from any civil liability or criminal liability as a result of administering an emergency opioid antagonist." Although the bill specifies on lines 85-92 when such opioid antagonists may be administered, it does not appear that the immunity from liability is limited to the instances specified by the bill. It may be advisable to limit the immunity from liability to those instances in which the opioid antagonist is administered according to the limitations established in the bill.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.887, 401.253, 456.44, and 465.0276.

This bill creates section 381.888 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.

[32] *See* https://www.census.gov/quickfacts/FL (last visited Mar. 15, 2021).