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 Criminal Justice

BILL:	SB 1476
INTRODUCER:	Senator Brodeur
SUBJECT:	Controlled Substances
DATE:	March 22, 2021
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Erickson	Jones	CJ	**Pre-meeting**
2.			HP	
3.			RC	

I. Summary:

SB 1476 amends s. 893.03, F.S., Florida's controlled substance schedules, to remove the following substance from Schedule V: a drug product in finished dosage formulation which has been approved by the U.S. Food and Drug Administration (FDA) and which contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent tetrahydrocannabinols.

In 2019, the Legislature placed the previously-described language in Schedule V. From that time to the present date, the scheduling language has only applied to Epidiolex®, the first pharmaceutical oral solution containing highly purified CBD to be approved by the FDA. It is used for the treatment of seizures associated with two rare and severe forms of epilepsy. While making Epidiolex® a Schedule V controlled substance was consistent with the federal scheduling in 2019, the substance has since been descheduled by the U.S. Drug Enforcement Administration (DEA). Therefore, the bill's removal of the Schedule V language (and the descheduling of Epidiolex®) would be consistent with federal descheduling action.

The bill takes effect upon becoming a law.

II. Present Situation:

Florida's Controlled Substance Schedules

Section 893.03, F.S., classifies controlled substances into five categories or classifications, known as schedules. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed in the schedules. The most important factors in determining which schedule may apply to a substance are the "potential for abuse"[1] of the substance and

[1] Pursuant to s. 893.035(3)(a), F.S., "potential for abuse" means a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of the substance being: (1) used in amounts that

whether there is a currently accepted medical use for the substance. The controlled substance schedules are as follows:

- Schedule I substances (s. 893.03(1), F.S.) have a high potential for abuse and no currently accepted medical use in treatment in the United States. Use of these substances under medical supervision does not meet accepted safety standards.
- Schedule II substances (s. 893.03(2), F.S.) have a high potential for abuse and a currently accepted but severely restricted medical use in treatment in the United States. Abuse of these substances may lead to severe psychological or physical dependence.
- Schedule III substances (s. 893.03(3), F.S.) have a potential for abuse less than the Schedule I and Schedule II substances and a currently accepted medical use in treatment in the United States. Abuse of these substances may lead to moderate or low physical dependence or high psychological dependence. Abuse of anabolic steroids may lead to physical damage.
- Schedule IV substances (s. 893.03(4), F.S.) have a low potential for abuse relative to Schedule III substances and a currently accepted medical use in treatment in the United States. Abuse of these substances may lead to limited physical or psychological dependence relative to Schedule III substances.
- Schedule V substances (s. 893.03(5), F.S.) have a low potential for abuse relative to the substances in Schedule IV and a currently accepted medical use in treatment in the United States. Abuse of these substances may lead to limited physical or psychological dependence relative to Schedule IV substances.

Prescribing and Dispensing a Schedule V Controlled Substance

A prescriber[2] or dispenser[3] of controlled substances in Florida is required to consult the Prescription Drug Monitoring Program (PDMP) system each time a controlled substance is prescribed or dispensed to a patient age 16 or over unless a statutory exemption applies.[4] A dispenser is required to report to the PDMP each time a controlled substance in Schedule V is dispensed to a patient.[5] Willful and knowing failure to report the dispensing of a controlled substance is a first degree misdemeanor.[6]

Numerous pieces of information are required to appear on the face or written record of the prescription for a controlled substance[7] and the prescription must be retained by the prescribing pharmacy for two years.[8] There are also numerous labeling requirements relating to the container in which a controlled substance is delivered.[9] There are also limitations on filling or refilling a

create a hazard to the user's health or the safety of the community; (2) diverted from legal channels and distributed through illegal channels; or (3) taken on the user's own initiative rather than on the basis of professional medical advice.

[2] A "prescriber" is a prescribing physician, prescribing practitioner, or other prescribing health care practitioner authorized by the laws of this state to order controlled substances. Section 893.055(1)(k), F.S.

[3] A "dispenser" is a dispensing health care practitioner, pharmacy, or pharmacist licensed to dispense controlled substances in or into this state. Section 893.055(1)(e), F.S.

[4] Section 893.055(8), F.S.

[5] Section 893.055(3), F.S. Schedule I substances are not included because, by definition, a Schedule I substance has no accepted medical use, and therefore, is not prescribed or dispensed.

[6] Section 893.055(9), F.S. A first degree misdemeanor is punishable by up to one year in county jail and a fine of up to $1,000. Sections 775.082 and 775.083, F.S.

[7] Section 893.04(1)(c), F.S.

[8] Section 893.04(1)(d), F.S.

[9] Section 893.04(1)(d), F.S.

prescription for a controlled substance: no more than five times within a period of six months after the date on which the prescription was written unless the prescription is renewed by a practitioner.[10]

Punishment of Prohibited Drug Acts Involving Cannabis and Schedule V Controlled Substances

Cannabis is a Schedule I controlled substance.[11] Schedule I is the most restrictive controlled substance schedule. Section 893.13, F.S., in part, punishes unlawful possession, sale, purchase, manufacture, delivery, and importation of a Schedule I controlled substance. Simple possession of 20 grams or less of cannabis is a first degree misdemeanor,[12] and simple possession of more than 20 grams of cannabis is a third degree felony.[13] Purchase, or possession with intent to purchase, cannabis is a third degree felony.[14] Delivery, without consideration, of 20 grams or less of cannabis is a first degree misdemeanor.[15] Generally, it is a third degree felony to deliver, sell, manufacture, import, or possess with the intent to sell, manufacture, or deliver cannabis.[16] Section 893.135, F.S., punishes drug trafficking. Trafficking in significant quantities of cannabis is a first degree felony, which is subject to a 3, 7, or 15-year mandatory minimum term and mandatory fine based on the quantity of cannabis trafficked.[17]

Schedule V is the least restrictive controlled substance schedule. Section 893.13, F.S., in part, punishes unlawful possession, sale, purchase, manufacture, delivery, and importation of a Schedule V controlled substance. Simple possession of a Schedule V controlled substance is a second degree misdemeanor.[18] Purchase, or possession with intent to purchase, a Schedule V controlled substance is a first degree misdemeanor.[19] Generally, it is a first degree misdemeanor to deliver, sell, manufacture, import, or possess with the intent to sell, manufacture, or deliver a Schedule V controlled substance.[20] Drug trafficking offenses in s. 893.135, F.S., do not apply to Schedule V controlled substances.[21]

[10] Section 893.04(1)(g), F.S.
[11] Section 893.03(1)(c)7., F.S.
[12] Section 893.13(6)(b), F.S.
[13] Section 893.13(6)(a), F.S. A third degree felony is punishable by up to five years in state prison and a fine of up to $5,000. Sections 775.082 and 775.083, F.S.
[14] Section 893.13(2)(a)2., F.S.
[15] Section 893.13(3), F.S.
[16] Section 893.13(1)(a)2. and (5)(b), F.S.
[17] Section 893.135(1)(a), F.S. A first degree felony is generally punishable by up to 30 years in state prison and a fine of up to $10,000. Sections 775.082 and 775.083, F.S.
[18] Section 893.13(6)(d), F.S. A second degree misdemeanor is punishable by up to 60 days in county jail and a fine of up to $500. Sections 775.082 and 775.083, F.S.
[19] Section 893.13(2)(a)3., F.S.
[20] Section 893.13(1)(a)3. and (5)(c), F.S.
[21] *See* s. 893.135(1)(a)-(n), F.S.

Scheduling of Epidiolex®

Epidiolex® is an oral solution developed by GW Pharmaceuticals (GW).[22] According to GW, Epidiolex® is "a pharmaceutical formulation of highly purified cannabidiol (CBD)[.]"[23] CBD is "a chemical constituent of the cannabis plant (commonly referred to as marijuana)."[24] "However, CBD does not cause intoxication or euphoria (the 'high') that comes from tetrahydrocannabinol (THC)."[25]

In June of 2018, the FDA announced that it approved Epidiolex® for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older.[26] Epidiolex® "is the first FDA-approved drug that contains a purified drug substance derived from marijuana."[27]

On September 28, 2018, the DEA rescheduled Epidiolex® from Schedule I to Schedule V of the federal Controlled Substance Act (CSA).[28] Because Epidiolex® was approved by the FDA, the DEA determined it has a currently accepted medical use in treatment in the United States, and no longer met criteria for placement in Schedule I of the CSA.[29] Epidiolex® was a Schedule I substance under federal law because it contains CBD, a chemical component of the cannabis plant, which is a Schedule I controlled substance.[30]

---

[22] *EPIDIOLEX® (cannabidiol) Oral Solution – the First FDA-approved Plant-derived Cannabinoid Medicine – Now Available by Prescription in the U.S*., Press Release (Nov. 1, 2018), GW Pharmaceuticals, Ltd., available at http://ir.gwpharm.com/news-releases/news-release-details/epidiolexr-cannabidiol-oral-solution-first-fda-approved-plant (last visited on March 16, 2021). According to GW, Epidiolex® "will be marketed in the U.S. by its subsidiary, Greenwich Biosciences." *Id*.

[23] *FDA-approved drug Epidiolex placed in schedule V of Controlled Substance Act*, Press Release (Sept. 27, 2018), U.S. Drug Enforcement Administration, available at https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act (last visited on March 16, 2021).

[24] *Id*.

[25] *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy*, News Release (June 25, 2018), U.S. Food and Drug Administration, available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm (last visited on March 16, 2021).

[26] *Id*.

[27] *Id*.

[28] *Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements*, 83 FR 48950 (Sept. 28, 2018), available at https://www.federalregister.gov/documents/2018/09/28/2018-21121/schedules-of-controlled-substances-placement-in-schedule-v-of-certain-fda-approved-drugs-containing (last visited on March 16, 2021). The U.S. Department of Health and Human Services advised the DEA "that it found the Epidiolex formulation to have a very low potential for abuse[.]" *Id*. The federal Controlled Substance Act is codified at 21 U.S.C. ss. 801-978.

[29] *Id*.

[30] *Id*.

On October 31, 2018, former Florida Attorney General Pam Bondi, pursuant to her emergency scheduling authority under s. 893.0355, F.S.,[31] rescheduled Epidiolex® from Schedule I of the Florida controlled substance schedules (s. 893.03, F.S.) to Schedule V of the schedules.[32]

In 2019, the Legislature placed the following language in Schedule V: "a drug product in finished dosage formulation which has been approved by the U.S. Food and Drug Administration (FDA) and which contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent tetrahydrocannabinols."[33] From that time to the present date, the scheduling language has only applied to Epidiolex®.

In 2020, the DEA removed Epidiolex® from Schedule V and descheduled it entirely, meaning Epidiolex® is no longer subject to the federal CSA.[34] Epidiolex® remains a Schedule V controlled substance in Florida's controlled substance schedules until or unless the Legislature removes the scheduling language applicable to Epidiolex®.

"Low-THC Cannabis" and Epidiolex®

The Compassionate Medical Cannabis Act of 2014[35] legalized "low-THC cannabis," a low THC and high CBD form of cannabis,[36] for medical use[37] by patients suffering from cancer, epilepsy, and certain other specified medical conditions.[38]

A "low-THC cannabis" product obtained from a medical marijuana treatment center is not an FDA-approved CBD product. As previously described, Epidiolex® is the only CBD product that is currently approved by the FDA. Further, Epidiolex® is *prescribed* by a physician. A "low-

[31] Section 893.0355(2), F.S., delegates to the Attorney General the authority to adopt rules rescheduling specified substances to a less controlled schedule, or deleting specified substances from a schedule, upon a finding that reduced control of such substances is in the public interest. Rulemaking under s. 893.0355, F.S., must be in accordance with the procedural requirements of ch. 120, F.S., including the emergency rule provisions found in s. 120.54, F.S., except that s. 120.54(7), F.S. (petition to initiate rulemaking), does not apply. Section 893.0355(4), F.S.

[32] The text of Emergency Rule 2ER18-1 is available at https://www.flrules.org/gateway/notice_Files.asp?ID=21109642 (last visited on March 16, 2021).

[33] Section 893.03(5)(d), F.S.

[34] *See Implementation of the Agriculture Improvement Act of 2018* (interim final rule), Drug Enforcement Administration, 85 FR 51639 (Aug. 21, 2020), available at https://www.federalregister.gov/documents/2020/08/21/2020-17356/implementation-of-the-agriculture-improvement-act-of-2018 (last visited March 16, 2021). The interim final rule, in part, removed "from control in schedule V under 21 CFR 1308.15(f) a "drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols." *Id.* "… [I]nterim final rules are considered final rules that carry the force and effect of law." Todd Gravey, *A Brief Overview of Rulemaking and Judicial Review* (March 27, 2017), Congressional Research Service, at p. 9 and n. 79 (citing *Career College Ass'n v. Riley*, 74 F.3d 1265 (D.C. Cir. 1996)), available at https://fas.org/sgp/crs/misc/R41546.pdf. (last visited March 16, 2021). *See also* prescription information for Epidiolex® (on file with the Senate Committee on Criminal Justice).

[35] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.

[36] "Low-THC cannabis" means a plant of the genus *Cannabis*, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed from a medical marijuana treatment center. Section 381.986(1)(e), F.S.

[37] With specified exceptions, "medical use" means the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. Section 381.986(1)(j), F.S.

[38] Section 381.986(2), F.S.

THC cannabis" product is not prescribed. In addition to other requirements, a *physician certification* from a qualified physician is required for a qualified patient to obtain a "low-THC cannabis" product from a medical marijuana treatment center.[39]

Epidiolex® was subject to extensive nonclinical and clinical studies to determine its safety and efficacy for the treatment of Lennox-Gastaut syndrome and Dravet syndrome in patients two years of age and older.[40] In contrast, a "low-THC cannabis" product dispensed by a medical marijuana treatment center is tested by a medical marijuana testing laboratory to determine that the product meets the definition of "low-THC cannabis," the THC concentration meets the potency requirements of s. 381.986, F.S., the labeling of the concentration of THC and CBD is accurate, and the product is safe for human consumption and free from contaminants that are unsafe for human consumption.[41]

"Low-THC cannabis" described in s. 381.986(1)(e), F.S., is still cannabis and cannabis is a Schedule I controlled substance. As previously described, unlawful acts involving a Schedule I controlled substance are generally subject to significant criminal penalties. However, when a qualified patient lawfully obtains "low-THC cannabis" (as provided in s. 381.986, F.S.), he or she is not subject to criminal penalties.[42] In contrast, as previously described, Epidiolex® is a Schedule V controlled substance pursuant to Florida law, and unlawful acts involving a Schedule V controlled substance are punished less severely than unlawful acts involving a Schedule I controlled substance.

III. Effect of Proposed Changes:

The bill amends s. 893.03, F.S., Florida's controlled substance schedules, to remove the following substance from Schedule V: a drug product in finished dosage formulation which has been approved by the FDA and which contains CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols. This drug product is referenced in s. 893.03(5)(d), F.S. The bill also amends the definition of "cannabis," which is relevant to ch. 893, F.S., to remove a sentence in the definition that currently states that the term "cannabis" does not include a drug product described in s. 893.03(5)(d), F.S.

In 2019, the Legislature placed the previously-described language relevant to Epidiolex® in Schedule V. From that time to the present date, the scheduling language has only applied to Epidiolex®, the first pharmaceutical oral solution containing highly purified CBD to be approved by the FDA. It is used for the treatment of seizures associated with two rare and severe forms of epilepsy. While making Epidiolex® a Schedule V controlled substance was consistent with the federal scheduling in 2019, the substance has since been descheduled by the DEA, and

[39] Section 381.986(2)-(8), F.S.
[40] *See* footnote 23, *supra*.
[41] Section 381.986(8)(e)10.d., F.S.
[42] Notwithstanding s. 893.13, F.S., s. 893.135, F.S., s. 893.147, F.S., or any other provision of law, but subject to the requirements of this section, a qualified patient and the qualified patient's caregiver may purchase from a medical marijuana treatment center for the patient's medical use a marijuana delivery device and up to the amount of marijuana authorized in the physician certification, but may not possess more than a 70-day supply of marijuana at any given time and all marijuana purchased must remain in its original packaging. Section 381.986(14)(a), F.S.

therefore, the bill's removal of the Schedule V language (and the descheduling of Epidiolex®) is consistent with federal scheduling action.

The bill takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The bill does not appear to require cities and counties to expend funds or limit their authority to raise revenue or receive state-shared revenues as specified by Article VII, s. 18, of the State Constitution.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The descheduling of Epidiolex® means that a prescriber would no longer have to consult the PDMP system before prescribing Epidiolex®, and a dispenser would no longer have to report to the PDMP system each time the prescriber dispenses Epidiolex®. Other requirements relating to Schedule V controlled substances (information-reporting, recordkeeping, labeling containers, and filling and refilling prescriptions) would no longer apply.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Although the bill removes language from Schedule V applicable to Epidiolex®, there is nothing in the bill or in current law that specifically states that a drug product in finished dosage formulation which has been approved by the FDA and which contains CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols is not "cannabis" as defined in ch. 893, F.S., or a controlled substance under ch. 893, F.S. A statement to this effect would preclude any interpretation that such drug product is cannabis, a Schedule I controlled substance.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 893.03 and 893.02.

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.