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:	SPB 7082
INTRODUCER:	Criminal Justice Committee
SUBJECT:	Controlled Substances
DATE:	March 15, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Erickson	Jones		**CJ Submitted as Comm. Bill/Fav**

I. Summary:

SPB 7082 amends s. 893.03, F.S., Florida's controlled substance schedules, to reschedule the following substance from Schedule I to 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.

This scheduling language currently applies only to Epidiolex®, a pharmaceutical oral solution which contains highly purified CBD and which is used for the treatment of seizures associated with two rare and severe forms of epilepsy. Epidiolex® is the only CBD product currently approved by the FDA.

The bill codifies an emergency rule adopted by the Florida Attorney General, which reschedules the described drug product from Schedule I to Schedule V. The codification of this scheduling is consistent with federal law.

The Legislature's Office of Economic and Demographic Research preliminarily estimates that the bill will have a "negative insignificant" prison bed impact (a decrease of 10 or fewer prison beds). See Section V. Fiscal Impact Statement.

The bill is effective 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 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.

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

Cannabis is a Schedule I controlled substance.[2] 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,[3] and simple possession of more than 20 grams of cannabis is a third degree felony.[4] Purchase, or possession with intent to purchase, cannabis is a third degree felony.[5] Delivery, without consideration, of 20 grams or less of cannabis is a first degree misdemeanor.[6] Generally, it is a third degree felony to deliver, sell, manufacture, import, or possess with the intent to sell, manufacture, or deliver cannabis.[7] Section 893.135, F.S., punishes drug trafficking. Trafficking in significant quantities of cannabis is a first

[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 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] Section 893.03(1)(c)7., F.S.
[3] Section 893.13(6)(b), 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.
[4] 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.
[5] Section 893.13(2)(a)2., F.S.
[6] Section 893.13(3), F.S.
[7] Section 893.13(1)(a)2. and (5)(b), F.S.

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.[8]

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.[9] Purchase, or possession with intent to purchase, a Schedule V controlled substance is a first degree misdemeanor.[10] 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.[11] Drug trafficking offenses in s. 893.135, F.S., do not apply to Schedule V controlled substances.[12]

Scheduling of Epidiolex®

Epidiolex® is an oral solution developed by GW Pharmaceuticals (GW).[13] According to GW, Epidiolex® is "a pharmaceutical formulation of highly purified cannabidiol (CBD)[.]"[14] CBD is "a chemical constituent of the cannabis plant (commonly referred to as marijuana)."[15] "However, CBD does not cause intoxication or euphoria (the 'high') that comes from tetrahydrocannabinol (THC)."[16]

In June of 2018, the U.S. Food and Drug Administration (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.[17] Epidiolex® "is the first FDA-approved drug that contains a purified drug substance derived from marijuana."[18]

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[8] 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.
[9] 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.
[10] Section 893.13(2)(a)3., F.S.
[11] Section 893.13(1)(a)3. and (5)(c), F.S.
[12] *See* s. 893.135(1)(a)-(n), F.S.
[13] *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 13, 2019). According to GW, Epidiolex® "will be marketed in the U.S. by its subsidiary, Greenwich Biosciences." *Id*.
[14] *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 13, 2019).
[15] *Id*.
[16] *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 13, 2019).
[17] *Id*.
[18] *See* footnote 14, *supra*.

According to the FDA,

> Epidiolex's effectiveness was studied in three randomized, double-blind, placebo-controlled clinical trials involving 516 patients with either Lennox-Gastaut syndrome or Dravet syndrome. Epidiolex, taken along with other medications, was shown to be effective in reducing the frequency of seizures when compared with placebo.
>
> The most common side effects that occurred in Epidiolex-treated patients in the clinical trials were: sleepiness, sedation and lethargy; elevated liver enzymes; decreased appetite; diarrhea; rash; fatigue, malaise and weakness; insomnia, sleep disorder and poor quality sleep; and infections.
>
> Epidiolex must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks. As is true for all drugs that treat epilepsy, the most serious risks include thoughts about suicide, attempts to commit suicide, feelings of agitation, new or worsening depression, aggression and panic attacks. Epidiolex also caused liver injury, generally mild, but raising the possibility of rare, but more severe injury. More severe liver injury can cause nausea, vomiting, abdominal pain, fatigue, anorexia, jaundice and/or dark urine.[19]

On September 28, 2018, the U.S. Department of Justice and the U.S. Drug Enforcement Administration (DEA) rescheduled Epidiolex® from Schedule I to Schedule V of the federal Controlled Substance Act (CSA).[20] 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.[21] 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.[22]

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[19] *See* footnote 16, *supra*.
[20] *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 13, 2019). 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.
[21] *Id*.
[22] *Id*.

On October 31, 2018, former Florida Attorney General Pam Bondi, pursuant to her emergency scheduling authority under s. 893.0355, F.S.,[23] rescheduled Epidiolex® from Schedule I of the Florida controlled substance schedules (s. 893.03, F.S.) to Schedule V of the schedules.[24] The full text of the emergency rule is:

> 2ER18-1 Rescheduling of 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 Percent (w/w) Residual Tetrahydrocannabinols. Under the authority of Section 893.0355, Florida Statutes, 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 percent (w/w) residual Tetrahydrocannabinols, is hereby rescheduled from a Schedule I to a Schedule V controlled substance.[25]

Former Attorney General Bondi indicated in her findings in support of the emergency rule that she was required to give great weight to the scheduling rules adopted by the U.S. Attorney General "in order to achieve the original legislative purpose of the Florida Comprehensive Drug Abuse Prevention and Control Act of maintaining uniformity between the laws of Florida and those of the United States with respect to controlled substances."[26] In addressing factors she was required to consider in making her decision whether to promulgate the emergency rule,[27] former Attorney General Bondi adopted the FDA's findings regarding its approval of Epidiolex®, which she concluded had "fully and comprehensively" addressed all of those factors.[28]

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[23] 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.

[24] The text of Emergency Rule 2ER18-1 is available at https://www.flrules.org/gateway/notice_Files.asp?ID=21109642 (last visited on March 13, 2019).

[25] *Id*.

[26] *Findings of the Attorney General in Support of Emergency Rule 2ER18-1, F.A.C.*, dated Oct. 31, 2018 (on file with the Senate Committee on Criminal Justice). In making the public interest determination, the Attorney General must give great weight to the scheduling rules adopted by the United States Attorney General subsequent to such substances being listed in Schedules I, II, III, IV, and V, to achieve the original legislative purpose of the Florida Comprehensive Drug Abuse Prevention and Control Act of maintaining uniformity between the laws of Florida and the laws of the United States with respect to controlled substances. Section 893.0355(3), F.S.

[27] In determining whether reduced control of a substance is in the public interest, the Attorney General must consider the following: whether the substance has been rescheduled or deleted from any schedule by rule adopted by the United States Attorney General pursuant to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811; the substance's actual or relative potential for abuse; scientific evidence of the substance's pharmacological effect, if known; the state of current scientific knowledge regarding the substance; the substance's history and current pattern of abuse; the scope, duration, and significance of abuse; what, if any, risk there is to the public health; and the substance's psychic or physiological dependence liability. Section 893.0355(2), F.S.

[28] *See* footnote 26, *supra*.

Former Attorney General Bondi provided the following justification for promulgating the emergency rule:

> There are currently approximately 64 patients in the state of Florida who are legally using a FDA approved cannabidiol product for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome pursuant to clinical trial programs that have either ended or will end soon. Any delay caused by the rescheduling of the FDA approved cannabidiol product through the regular rulemaking process or by waiting for legislative action during the 2019 legislative session will likely cause a disruption in the supply of the product that will result in serious bodily harm to seriously ill Floridians. Attorney General Bondi recognizes that such circumstances constitute an immediate danger to the health, safety, and welfare of a limited but extremely vulnerable population of Floridians, and therefore, concludes that such circumstances justify the promulgation of emergency rule 2ER18-1 pursuant to Section 893.055 and Section 120.54(4).[29]

The findings further provided that the above-described cannabidiol product "will become a Schedule V controlled substance in Florida and will become immediately legal and available to children who suffer illnesses such Lennox-Gastaut syndrome or Dravet syndrome."[30] However, "non-FDA approved CBD extracts or any material, compound, mixture, or preparation other than Epidiolex that fall under the term Cannabis as set forth in Section 893.03(1)(c), remain a Schedule I controlled substance under the Florida Comprehensive Drug Abuse Prevention and Control Act."[31]

Emergency Rule 2ER18-1 became effective upon filing with the Secretary of State on October 31, 2018.[32] Rules adopted pursuant to s. 893.0355, F.S., must be reviewed each year by the Legislature, and each rule remains in effect until the effective date of legislation that provides for a different scheduling of a substance than that set forth in such rule.[33]

[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Certification of Department of Legal Affairs Emergency Rule Filed with the Department of State*, date stamped Oct. 31, 2018 (on file with the Senate Committee on Criminal Justice). Section 120.54(4)(d), F.S., provides that, subject to applicable constitutional and statutory provisions, an emergency rule becomes effective immediately on filing, or on a date less than 20 days thereafter if specified in the rule, if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.
[33] Section 893.0355(6), F.S.

"Low-THC Cannabis" and Epidiolex®

The Compassionate Medical Cannabis Act of 2014[34] legalized "low-THC cannabis," a low THC and high CBD form of cannabis,[35] for medical use[36] by patients suffering from cancer, epilepsy, and certain other specified medical conditions.[37]

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-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.[38]

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.[39] 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.[40]

"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.[41] In contrast, as previously described, Epidiolex® is a Schedule V controlled substance pursuant to federal law and the Florida Attorney's General's emergency rule, and unlawful acts involving a Schedule V controlled substance are punished less severely than unlawful acts involving a Schedule I controlled substance.

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

[35] "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.

[36] 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.

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

[38] Section 381.986(2)-(8), F.S.

[39] *Basis for the Recommendation to Place Cannabidiol in Schedule V of the Controlled Substance Act*, U.S. Food and Drug Administration, included as Addendum A to *Findings of the Attorney General in Support of Emergency Rule 2ER18-1, F.A.C. See* footnote 26, *supra*.

[40] Section 381.986(8)(e)10.d., F.S.

[41] 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.

III. Effect of Proposed Changes:

The bill amends s. 893.03, F.S., Florida's controlled substance schedules, to reschedule the following substance from Schedule I to Schedule V: "[a] drug product in finished dosage formulation which has been approved by the U. S. Food and Drug Administration and which contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and not more than 0.1 percent (w/w) residual tetrahydrocannabinols."

This scheduling language currently applies only to Epidiolex®, a pharmaceutical oral solution which contains highly purified CBD and which is used for the treatment of seizures associated with two rare and severe forms of epilepsy. Epidiolex® is the only CBD product currently approved by the FDA.

The bill codifies an emergency rule adopted by the Florida Attorney General, which reschedules the described drug product from Schedule I to Schedule V. The codification of this scheduling is consistent with federal law.

As previously described, unlawful acts involving Schedule V controlled substances are punished less severely than unlawful acts involving Schedule I controlled substances.

The bill is effective upon becoming a law.

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 identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Legislature's Office of Economic and Demographic Research (EDR) preliminarily estimates that the bill will have a "negative insignificant" prison bed impact (a decrease of 10 or fewer prison beds).[42]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 893.03 of the Florida Statutes.

This bill reenacts the following sections of the Florida Statutes: 817.563, 831.31, 893.07, and 893.13.

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.

[42] The EDR estimate is on file with the Senate Committee on Criminal Justice.