HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 6095 Scheduling of Drug Products Containing Cannabidiol
SPONSOR(S): Fischer
TIED BILLS: **IDEN./SIM. BILLS:** SB 1476

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Professions & Public Health Subcommittee	17 Y, 0 N	Morris	McElroy
2) Criminal Justice & Public Safety Subcommittee	18 Y, 0 N	Padgett	Hall
3) Health & Human Services Committee	20 Y, 0 N	Morris	Calamas

SUMMARY ANALYSIS

Federal and state law both classify controlled substances into five schedules. The scheduling determination for a controlled substance is based on a substance's potential for abuse, accepted medical use, and potential for addiction. The classifications range from a Schedule I substance, which has a high potential for abuse, with no accepted medical use, and high potential for addiction; to a Schedule V substance, which has a low potential for abuse, an accepted medical use, and a mild potential for addiction.

Generally, cannabis and compounds derived from cannabis are listed in Schedule I of both federal and Florida law. Cannabis contains delta-9-tetrahydrocannabinol (THC), which is the psychoactive chemical in marijuana which produces the "high" commonly associated with marijuana use.

Epidiolex is a prescription cannabidiol, a non-psychoactive compound derived from the cannabis plant which is used to treat seizures. Epidiolex does not contain THC. On June 25, 2018, the U.S. Food and Drug Administration approved Epidiolex for use by patients two years of age or older and the federal Drug Enforcement Administration (DEA) rescheduled Epidiolex in Schedule V of the federal Controlled Substances Act (CSA). In 2019, the Legislature, mirroring federal law, formally rescheduled Epidiolex as a Schedule V controlled substance.

On April 6, 2020, the DEA removed Epidiolex from Schedule V and descheduled it entirely, meaning Epidiolex is no longer subject to the CSA and its tracking and monitoring requirements. Epidiolex remains a Schedule V controlled substance under Florida law.

HB 6095 amends s. 893.03(5)(d), F.S., to remove Epidiolex as a Schedule V controlled substance, mirroring federal law, and makes conforming changes to the definition of cannabis in s. 893.02(3), F.S.

The bill does not have a fiscal impact on state or local governments.

The bill is effective upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Controlled Substances Law

Chapter 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, classifies controlled substances into five categories, called schedules. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed therein. The distinguishing factors between the different drug schedules are the "potential for abuse"[1] of the substance and whether there is a currently accepted medical use for the substance.[2]

The controlled substance schedules are as follows:

- Schedule I substances have a high potential for abuse and currently have no accepted medical use in the United States, including substances such as cannabis and heroin.[3]
- Schedule II substances have a high potential for abuse and have a currently accepted but severely restricted medical use in the United States, including substances such as raw opium, fentanyl, and codeine.[4]
- Schedule III substances have a potential for abuse less than the substances contained in Schedules I and II and have a currently accepted medical use in the United States, including substances such as stimulants and anabolic steroids.[5]
- Schedule IV substances have a low potential for abuse relative to substances in Schedule III and have a currently accepted medical use in the United States, including substances such as benzodiazepines and barbiturates.[6]
- Schedule V substances have a low potential for abuse relative to the substances in Schedule IV and have a currently accepted medical use in the United States, including substances such as mixtures that contain small quantities of opiates, narcotics, or stimulants.[7]

A prescriber[8] or dispenser[9] 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.[10] A dispenser is required to report to the PDMP each time a controlled substance in schedules II, III, IV, and V are dispensed to a patient.[11]

[1] S. 893.035(3)(a), F.S., defines "potential for abuse" to mean that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being: 1) used in amounts that create a hazard to the user's health or 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] *See* s. 893.03, F.S.
[3] S. 893.03(1), F.S.
[4] S. 893.03(2), F.S.
[5] S. 893.03(3), F.S.
[6] S. 893.03(4), F.S.
[7] S. 893.03(5), F.S.
[8] "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner authorized by the laws of this state to order controlled substances. S. 893.055(1)(k), F.S.
[9] "Dispenser" means a dispensing health care practitioner, pharmacy, or pharmacist licensed to dispense controlled substances in or into this state. S. 893.055(1)(e), F.S.
[10] S. 893.055, F.S.
[11] S. 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.

Cannabis

Generally, cannabis is listed as a Schedule I controlled substance in Florida.[12] Cannabis, for the purposes of ch. 893, F.S., is all parts of the plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin, except:[13]

- Marijuana used for medical purposes under s. 381.986, F.S.;
- Hemp or industrial hemp; and
- The prescription drug product Epidiolex, which is derived from the cannabis plant.

Hemp is the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof, and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers thereof, whether growing or not, that has a total delta-9-tetrahydrocannabinol (THC) concentration that does not exceed 0.3 percent on a dry-weight basis.[14] THC is the psychoactive chemical in marijuana which produces the "high" commonly associated with marijuana use.[15] Thus, any product derived from the cannabis plant with a THC content below 0.3 percent is excluded from the definition of "cannabis" in ch. 893, F.S., and likewise excluded from classification as a Schedule I controlled substance.

Federal Controlled Substances Law

The Federal Controlled Substances Act[16] (CSA) also classifies controlled substances into schedules based on the potential for abuse and whether there is a currently accepted medical use for the substance. The Drug Enforcement Administration (DEA) is required to consider the following when determining where to schedule a substance:[17]

- 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 public health;
- The substance's psychic or physiological dependence liability; and
- Whether the substance is an immediate precursor of a substance already controlled.

A controlled substance subject to regulation under the CSA is subject to strict distribution and inventory controls. The CSA requires a controlled substance to be tracked and inventoried from the time it is manufactured or imported until it is dispensed to a patient.[18] Additionally, the CSA also restricts how specified controlled substances may be prescribed, requires minimum security precautions for controlled substances, and requires each person or entity authorized to handle a controlled substance to register with the DEA.[19]

[12] S. 893.03(1)(c)7., F.S.
[13] S. 893.02(3), F.S.
[14] S. 581.217(3)(d), F.S.
[15] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know (last visited Apr. 9, 2021).
[16] 21 U.S.C. § 812.
[17] 21 U.S.C. § 811(c).
[18] 21 U.S.C. §827.
[19] 21 U.S.C. Part C.

Epidiolex

Epidiolex is a prescription cannabidiol, a compound derived from the cannabis plant, which is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.[20] Epidiolex does not contain the psychoactive chemical THC.[21] On June 25, 2018, the U.S. Food and Drug Administration (FDA) approved Epidiolex for use in patients two years of age or older.[22] The DEA rescheduled Epidiolex in schedule V of the federal Controlled Substances Act effective September 27, 2018.[23] In 2018, the Florida Attorney General rescheduled Epidiolex by emergency rule[24] as a Schedule V controlled substance, and in 2019, the Legislature formally rescheduled Epidiolex as a Schedule V controlled substance.[25]

On April 6, 2020, the DEA announced it was removing Epidiolex from Schedule V and descheduling it entirely, meaning Epidiolex is no longer subject to the CSA and its tracking and monitoring requirements.[26] Epidiolex remains a Schedule V controlled substance under Florida law.[27]

Effect of Proposed Changes

HB 6095 amends s. 893.03(5)(d), F.S., to delete Epidiolex from the list of Schedule V controlled substances, mirroring federal law, and makes conforming changes to the definition of cannabis in s. 893.02(3), F.S. Since Epidiolex is derived from the cannabis plant and contains no THC, it meets the definition of hemp under Florida law and will not revert to classification as a Schedule I controlled substance.

Descheduling Epidiolex under Florida law enables practitioners to prescribe and dispense Epidiolex free of Schedule V reporting requirements.

The bill is effective upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Amends s. 893.03, F.S., relating to standards and schedules.
Section 2: Amends s. 893.02, F.S., relating to definitions.
Section 3: Provides the bill shall take effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

[20] Greenwich Biosciences, *The Epidiolex Story*, https://www.epidiolex.com/about-epidiolex/story (last visited Apr. 9, 2021).
[21] S. 893.03(5)(d), F.S. Epidiolex is defined under Florida law as a drug product in finished dosage formulation that has been approved by the United States 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. *See also* 85 Fed. Reg. 51639 (Aug. 21, 2020).
[22] U.S. Food and Drug Administration, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy,* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm (last visited Apr. 9, 2021).
[23] United State Drug Enforcement Administration, *FDA-approved drug Epidiolex placed in schedule V of Controlled Substance Act*, https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act (last visited Apr. 9, 2021).
[24] Office of the Attorney General, Findings of the Attorney General in Support of Emergency Rule 2ER18-1, F.A.C. (Oct. 31, 2018).
[25] Ch. 19-166, Laws of Florida.
[26] 85 Fed. Reg. 51639 (Aug. 21, 2020). GW Pharmaceuticals, *GW Pharmaceuticals plc and Its U.S. Subsidiary Greenwich Biosciences, Inc. Announce That Epidiolex (cannabidiol) Oral Solution Has Been Descheduled And Is No Longer A Controlled Substance*, April 6, 2020, https://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-plc-and-its-us-subsidiary-greenwich-1 (last visited Apr. 9, 2021)
[27] S. 893.03(5)(d), F.S.

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Descheduling Epidiolex allows doctors and pharmacies to prescribe and dispense the drug without having to comply with burdensome regulations and reporting requirements.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law provides sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES