HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1345 Pharmaceutical Products Containing Cannabis
SPONSOR(S): Persons-Mulicka and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1738

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Criminal Justice & Public Safety Subcommittee	16 Y, 0 N	Padgett	Hall
2) Professions & Public Health Subcommittee	15 Y, 0 N	Guzzo	McElroy
3) Judiciary Committee			

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. With the exception of Epidiolex, which is the only pharmaceutical product derived from the cannabis plant approved for medical use by the U.S. Food and Drug Administration (FDA), cannabis and compounds derived from cannabis are listed in Schedule I of both federal and Florida law.

HB 1345 amends s. 893.03(1)(c)7., F.S., to exclude from Schedule I any pharmaceutical product containing cannabis that has been approved by the FDA. The Legislature retains the authority to schedule a pharmaceutical product through future legislation, including as a Schedule I controlled substance.

Although there are currently no other FDA approved pharmaceutical products besides Epidiolex derived from the cannabis plant, the bill would prevent any future pharmaceutical product from being automatically placed in Schedule I, which includes controlled substances that have no currently accepted medical use.

Preventing an FDA approved pharmaceutical product derived from the cannabis plant from being automatically included in Schedule I could increase the availability of the product to Florida residents, and allow doctors and pharmacies to prescribe and dispense such a product without burdensome regulations and reporting requirements.

The bill does not appear to 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 Law

Controlled Substances

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]

Attorney General

[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.

The Legislature delegated to the Florida Attorney General the authority to adopt rules rescheduling or deleting controlled substances from a schedule if reduced control of a substance is in the best interest of the public.[12] In making this determination, the Attorney General is required to give great weight to the scheduling of the substance under federal law and consider scientific evidence of a substance's medical benefits.[13] The Attorney General also has the authority to schedule or reschedule any substance which is not already controlled under s. 893.03, F.S., if the substance has the potential for abuse.[14]

Federal Law

The Federal Controlled Substances Act[15] (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:[16]

- 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.[17] 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.[18]

Epidiolex

Epidiolex, which is currently the only prescription pharmaceutical approved by the U.S. Food and Drug Administration (FDA) containing cannabidiol, a non-psychoactive compound derived from the cannabis plant, is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.[19] Since Epidiolex is derived from the cannabis plant, it would have been designated a Schedule I controlled substance under state and federal law. However, on June 25, 2018, the FDA approved Epidiolex for use in patients two years of age or older.[20] The DEA responded by rescheduling Epidiolex in schedule V of the federal Controlled Substances Act effective September 27, 2018.[21] Although Epidiolex was still subject to the requirements under the CSA, the rescheduling allowed doctors to legally prescribe Epidiolex to patients. In 2018, the Florida Attorney General rescheduled Epidiolex by emergency rule[22] as a Schedule V controlled substance, and in 2019, the Legislature formally rescheduled Epidiolex in statute as a Schedule V controlled substance.[23]

[12] S. 893.0355, F.S.
[13] *Id.*
[14] S. 893.035, F.S.
[15] 21 U.S.C. § 812.
[16] 21 U.S.C. § 811(c).
[17] 21 U.S.C. §827.
[18] 21 U.S.C. Part C.
[19] Greenwich Biosciences, *The Epidiolex Story*, https://www.epidiolex.com/about-epidiolex/story (last visited Mar. 20, 2021).
[20] 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 Mar. 16, 2021).
[21] 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 Mar. 20, 2021).
[22] Office of the Attorney General, Findings of the Attorney General in Support of Emergency Rule 2ER18-1, F.A.C. (Oct. 31, 2018).
[23] Ch. 19-166, Laws of Florida.

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.[24] Epidiolex remains a Schedule V controlled substance under Florida law.[25]

Effect of Proposed Changes

HB 1345 amends s. 893.03(1)(c)7., F.S., to exclude from Schedule I any pharmaceutical product containing cannabis that has been approved by the FDA. The Legislature retains the authority to schedule a pharmaceutical product through future legislation, including as a Schedule I controlled substance.

Although there are currently no other FDA approved pharmaceutical products derived from the cannabis plant besides Epidiolex, the bill would prevent any future pharmaceutical product from being automatically placed in Schedule I, which includes controlled substances that have no currently accepted medical use.

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: Provides the bill is effective upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Preventing an FDA approved pharmaceutical product derived from the cannabis plant from being automatically included in Schedule I could increase the availability of the product to Florida residents, and allow doctors and pharmacies to prescribe and dispense such a product without burdensome regulations and reporting requirements.

[24] 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 Mar. 20, 2021)
[25] S. 893.03(5)(d), F.S.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES