HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7107 PCB CRJ 19-04 Controlled Substances
SPONSOR(S): Judiciary Committee, Criminal Justice Subcommittee, Sabatini
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Criminal Justice Subcommittee	13 Y, 0 N	Padgett	Hall
1) Health & Human Services Committee	17 Y, 0 N	Royal	Calamas
2) Judiciary Committee	18 Y, 0 N, As CS	Padgett	Poche

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. Cannabis and compounds derived from cannabis are listed in Schedule I of both federal and Florida law.

Epidiolex is a prescription cannabidiol, a non-psychoactive compound derived from the cannabis plant, which is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome. On June 25, 2018, the U.S. Food and Drug Administration approved Epidiolex for use by patients two years of age or older. The federal Drug Enforcement Administration rescheduled Epidiolex in Schedule V of the federal Controlled Substances Act effective September 27, 2018. On October 31, 2018, the Florida Attorney General rescheduled Epidiolex as a Schedule V controlled substance under an emergency rule.

CS/HB 7107 classifies Epidiolex as a Schedule V controlled substance, mirroring federal law. The Schedule V classification reflects the substance's newly approved medical use. Rescheduling Epidiolex in Schedule V will prevent an interruption in the supply of the drug to Florida patients.

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]

Attorney General

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.[8] To determine whether rescheduling a controlled substance is in the public interest, the Attorney General must consider:

- Whether the controlled substance has been rescheduled under federal law;
- The substance's potential for abuse;
- Scientific evidence of the substance's pharmacological effect;
- The state of current scientific knowledge regarding the substance;
- The substance's history and current pattern of abuse;

[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] S. 893.0355, F.S.

- The scope, duration, and significance of abuse;
- The public health risk; and
- The substance's psychic or psychological dependency.[9]

Federal Law

The Federal Controlled Substances Act[10] 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:[11]

- 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.

Epidiolex

Epidiolex is a prescription cannabidiol, a non-psychoactive compound derived from the cannabis plant, which is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.[12] On June 25, 2018, the U.S. Food and Drug Administration approved Epidiolex for use in patients two years of age or older.[13] The DEA rescheduled Epidiolex in schedule V of the federal Controlled Substances Act effective September 27, 2018.[14]

Because Epidiolex was not scheduled under Florida law, there was concern the substance would be treated in the same manner as cannabis, which is classified as a Schedule I substance. In response, on October 31, 2018, the Florida Attorney General filed an emergency rule with the Secretary of State rescheduling Epidiolex as a schedule V controlled substance. As of that date, there were approximately 64 patients in Florida taking Epidiolex pursuant to clinical drug trial programs, which were nearing an end.[15] A delay in rescheduling Epidiolex would likely have disrupted the supply of the drug to Florida patients.[16] The emergency rule will remain in effect until the effective date of legislation that provides a different schedule for the substance.[17]

Effect of Proposed Changes

CS/HB 7107 classifies Epidiolex as a Schedule V controlled substance, mirroring federal law. The Schedule V classification reflects the substance's newly approved medical use. The rescheduling will prevent an interruption in the supply of Epidiolex to Florida patients currently taking the drug.

[9] S. 893.0355(2)(a)–(h), F.S.
[10] 21 U.S.C. § 812.
[11] 21 U.S.C. § 811(c).
[12] Greenwich Biosciences, *The Epidiolex Story*, https://www.epidiolex.com/about-epidiolex/story (last visited Apr. 12, 2019).
[13] 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. 12, 2019).
[14] 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. 12, 2019).
[15] Office of the Attorney General, Findings of the Attorney General in Support of Emergency Rule 2ER18-1, F.A.C. (Oct. 31, 2018).
[16] *Id.*
[17] S. 893.0355(6), F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 893.02, F.S., relating to definitions.
Section 2: Amends s. 893.03, F.S., relating to standards and schedules.
Section 3: Reenacts s. 817.563, F.S., relating to controlled substance named or described in s. 893.03; sale of substance in lieu thereof.
Section 4: Reenacts s. 831.31, F.S., relating to counterfeit controlled substance; sale, manufacture, delivery, or possession with intent to sell, manufacture, or deliver.
Section 5: Reenacts s. 893.07, F.S., relating to records.
Section 6: Reenacts s. 893.13, F.S., relating to prohibited acts; penalties.
Section 7: Provides an effective date of 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:

Classifying Epidiolex as a Schedule V controlled substance ensures there is no disruption in supply for future Florida patients.

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

On April 16, 2019, the Judiciary Committee adopted one amendment and reported the bill favorably as a committee substitute. The amendment reenacted ss. 817.563, 831.31, 893.07, and 893.13, F.S., to incorporate the rescheduling of Epidiolex as a Schedule V controlled substance.

This analysis is drafted to the committee substitute as passed by the Judiciary Committee.