

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 Criminal Justice Committee

BILL: CS/SB 336

INTRODUCER: Criminal Justice Committee and Senator Fasano

SUBJECT: Controlled Substances

DATE: March 21, 2011 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Erickson	Cannon	CJ	Fav/CS
2.			HR	
3.			JU	
4.			BC	
5.				
6.				

Please see Section VIII. for Additional Information:

- | | | |
|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes |
| B. AMENDMENTS..... | <input type="checkbox"/> | Technical amendments were recommended |
| | <input type="checkbox"/> | Amendments were recommended |
| | <input type="checkbox"/> | Significant amendments were recommended |

I. Summary:

The bill schedules a number of chemicals as controlled substances. The proposed scheduling of these chemicals is consistent with federal scheduling of these chemicals.

This bill substantially amends section 893.03, Florida Statutes.

II. Present Situation:

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Provided below is a description of the different schedules:

- Schedule I (s. 893.03(1), F.S.): A substance in Schedule I has a high potential for abuse and has no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards.

- Schedule II (s. 893.03(2), F.S.): A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence.
- Schedule III (s. 893.03(3), F.S.): A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage.
- Schedule IV (s. 893.03(4), F.S.): A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.
- Schedule V (s. 893.03(5), F.S.): A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

The following table provides information about the chemicals proposed for scheduling as controlled substances by the bill:

CHEMICALS REFERENCED IN SB 336¹

CHEMICAL	DESCRIPTION	FEDERAL SCHEDULE	PROPOSED FLORIDA SCHEDULE
Alpha-Methyltryptamine	Tryptamine derivative that shares pharmacological similarities with Schedule I hallucinogens.	I	I
1- (1-Phenylcyclohexyl) pyrrolidine	Pyrrolidine analog of phencyclidine, a controlled substance.	I	I
2, 5-Dimethoxy-4- (n) - Propylthiophenethylamine	Phentylamine hallucinogen that is structurally related to Schedule I hallucinogens.	I	I

¹ Unless otherwise indicated, information in this table relevant to the description of chemicals was compiled from numerous Internet search inquiries of the following sources (last accessed on March 11, 2011): Office of Diversion Control, U.S. Drug Enforcement Administration, <http://www.dea.gov/index.html>; U.S. Food and Drug Administration, <http://www.fda.gov>; United States National Library of Medicine of the National Institutes of Health, <http://www.nlm.nih.gov>; Online Encyclopedia of Chemistry of Chemie.DE Information Service GmbH (a Life Science Network Division), <http://www.chemie.de/lexikon/e/>; and PubChem Public Chemical Database of the National Center for Biotechnology Information, <http://www.ncbi.nlm.nih.gov/>.

Information regarding federal scheduling of these chemicals is from 21 CFR §§ 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15.

CHEMICAL	DESCRIPTION	FEDERAL SCHEDULE	PROPOSED FLORIDA SCHEDULE
5-Methoxy-N, N-Diisopropyltryptamine	Tryptamine derivative that elicits subjective effects, including hallucinations, similar to those produced by several Schedule I hallucinogens.	I	I
N-Benzylpiperazine	Piperazine derivative that is used as an intermediate in chemical synthesis but has no approved medical use. Pharmacological effects are qualitatively similar to those of amphetamine, a controlled substance.	I	I
Lisdexamfetamine	Central nervous system stimulant that is used as part of a treatment program to control symptoms of attention deficit hyperactivity disorder (Vyvanse®).	II	II
Dihydroetorphine	Derivative of thebaine, a controlled substance. Not currently marketed or used medically in the U.S.	II	II
Remifentanyl	Opioid analgesic (Ultiva®).	II	II
Embutramide	Central nervous system depressant and derivative of gamma hydroxybutyric acid, a controlled substance. Used in veterinary euthanasia (Tributame® Euthanasia Solution).	III	III
Zopiclone	Central nervous system depressant. Eszopiclone, an active isomer of zopiclone, is used for short-term treatment of insomnia (Lunesta®). Pharmacological properties are substantially similar to benzodiazepines.	IV	IV
Zaleplon	Central nervous system depressant that is used for short-term treatment of insomnia (Sonata®).	IV	IV
Zolpidem	Central nervous system depressant that is used for short-term treatment of insomnia (Ambien®).	IV	IV

CHEMICAL	DESCRIPTION	FEDERAL SCHEDULE	PROPOSED FLORIDA SCHEDULE
Modafinil	Central nervous system stimulant and neuroprotective agent that is used in the treatment of excessive daytime sleepiness associated with narcolepsy (Provigil®).	IV	IV
Petrichloral	Sedative/hypnotic (Periclor®). ²	IV	IV
Sibutramine	Blocks the uptake of various neurotransmitters and is used in the management of obesity (Meridia®).	IV	IV
Dichloralphenazone	Sedative that is typically used in combination with other chemicals in formulating prescription pharmaceuticals for the relief of tension and vascular headaches (Iso-Acetazone®, Isocom®, Midchlor®, Midrin®, Migratine®, and Mitride®).	IV	IV
Pregabalin	Anticonvulsant that is used for neuropathic pain, partial seizures (adjunct therapy), and generalized anxiety disorder (Lyrica®).	V	V
Not more than 0.5 milligrams of Difenoxin and not less than 25 micrograms of Atropine sulfate per dosage unit	Difenoxin is a 4-phenylpiperidine derivative that is chemically related to the narcotic meperidine. It is used in combination with atropine to treat diarrhea (Motofen®). Atropine discourages deliberate overdose.	V	V

Federal law provides that Schedule III listed stimulants and depressants also include their salts, isomers, and salts of isomers whenever the existence of such salts, isomers is possible within the specific chemical designation.³ Florida's Schedule III does not currently contain similar language.⁴

Health care practitioners in Florida who are authorized to prescribe include medical physicians, physician assistants, osteopathic physicians, advanced registered nurse practitioners, podiatrists, naturopathic physicians, dentists, optometrists, and veterinarians. However, s. 893.02, F.S., defines which practitioners may prescribe a controlled substance under Florida law. A "practitioner" is defined to mean a licensed medical physician, dentist, veterinarian, osteopathic

² Sample Selected Controlled Medication List (II-V), American Society of Consultant Pharmacists, http://www.med-pass.com/Docs/Products/samples/A96975RCK_sp.pdf (last accessed on March 11, 2011).

³ 21 CFR § 1308.13

⁴ See s. 893.03(3), F.S.

physician, naturopathic physician, or podiatrist, if such practitioner holds a valid federal controlled substance registry number. Accordingly, the prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

III. Effect of Proposed Changes:

The bill amends s. 893.03, F.S., to schedule a number of chemicals as controlled substances. The proposed scheduling of these chemicals is consistent with federal scheduling of these chemicals.

Consistent with federal scheduling (see “Present Situation” section of this bill analysis), the bill also schedules a number of other chemicals as follows:

Schedule I:

- Alpha-Methyltryptamine.
- 1- (1-Phenylcyclohexyl) pyrrolidine.
- 2, 5-Dimethoxy-4- (n) -Propylthiophenethylamine.
- 5-Methoxy-N, N-Diisopropyltryptamine.
- N-Benzylpiperazine.

Schedule II:

- Dihydroetorphine.
- Lisdexamfetamine.
- Remifentanil.

Schedule III:

Embutramide.

Schedule IV:

- Zopiclone.
- Zaleplon.
- Zolpidem.
- Modafinil.
- Petrichloral.
- Sibutramine.
- Dichloralphenazone.

Schedule V:

- Pregabalin.
- Not more than 0.5 milligrams of Difenoxin and not less than 25 micrograms of Atropine sulfate per dosage unit.

The bill also provides that Schedule III listed stimulants and depressants include their salts, isomers, and salts of isomers whenever the existence of such salts, isomers is possible within the specific chemical designation. This language, which is not currently included in Schedule III, appears in federal scheduling laws. (See “Present Situation” section of this bill analysis.)

The effective date of the bill is July 1, 2011.

Other Potential Implications:

The Florida Department of Law Enforcement (FDLE) has provided the following comments regarding proposed scheduling in the bill:

Because all of the proposed chemical substances are currently scheduled federally ... , there would be no impact on physicians, pharmacies, or patients who are prescribed any of these substances which are scheduled II-IV. The proposed substances that have been recommended as a Schedule I have no accepted medical use and have very limited legitimate use for the private citizen. There would be a potential impact on individuals in possession of the proposed additional substances, since currently they are not covered by state statute, however, persons in possession of the substances are already violating federal law and subject to federal prosecution.

Aligning Florida law with the federal controlled substances list creates consistency for those entities and/or persons involved in the manufacturing, distribution, and dispensing of any controlled substance. It reduces the amount of confusion related to the handling of these substances, and helps close the “loophole” which allows diversion of legal substances for illicit purposes throughout the state without fear of local enforcement. It makes the training for law enforcement simpler, since there is only “one set of rules” instead of two sets to deal with. It also acknowledges and maximizes the use of the time and research devoted to the scheduling process at the federal level. The Food & Drug Administration (FDA), the Department of Health & Human Services (DH&HS), and the Drug Enforcement Agency (DEA) conduct extensive research on any product that is recommended for scheduling and provide the industry and public numerous opportunities throughout the process to produce independent research, legal remedy, and public opinion as an alternative to scheduling. The ability of these three federal agencies to monitor and detect substances of concern from a national level provides them with a unique opportunity to predict what substances may threaten the population long before a specific substance may reach the state of Florida and threaten health and public safety.⁵

According to the FDLE, providing that Schedule III listed stimulants and depressants include their salts, isomers, and salts of isomers whenever the existence of such salts, isomers is possible within the specific chemical designation, “would close current gaps in the statute that allow potential ‘exemptions’ of various forms of substances already controlled in Florida.”⁶

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

⁵ Analysis of SB 336 (January 14, 2011), Florida Department of Law Enforcement (on file with the Senate Criminal Justice Committee). Cited in further references as the “FDLE analysis.”

⁶ FDLE analysis.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The FDLE states: “SB 336 should have little or no impact of the private sector. All of the proposed substances have been federally scheduled ... as being illegal.”⁷

C. Government Sector Impact:

The Criminal Justice Impact Conference, which provides the final, official estimate of the prison bed impact, if any, of legislation, has determined that the bill has an insignificant prison bed impact (possibly a small number of additional prison beds).

The FDLE states: “Local agencies that fund and maintain their own crime lab with a chemistry section would potentially be facing a rise in submissions associated with the additions of the proposed chemical substances.”⁸

The FDLE further states: “The passage of SB 336 would add chemical substances to Florida’s controlled substances list. Any resulting increase in volume of evidence submissions to FDLE’s Crime Laboratory System, as well as costs to acquire and maintain additional required chemical standards, will be assimilated as part of the laboratories’ cost of doing business.”⁹

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

⁷ FDLE analysis.

⁸ *Id.*

⁹ *Id.*

VIII. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Criminal Justice on March 22, 2011:

Deletes from the bill scheduling references to several synthetic cannabinoids and mephedrone.

- B. **Amendments:**

None.