

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 Health Regulation Committee

BILL: SB 1260

INTRODUCER: Senators Fasano and Gaetz

SUBJECT: Controlled Substances

DATE: April 10, 2010

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Erickson</u>	<u>Cannon</u>	<u>CJ</u>	Favorable
2.	<u>Bell</u>	<u>Wilson</u>	<u>HR</u>	Favorable
3.	_____	_____	<u>JA</u>	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

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 s. 893.03, F.S.

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 1260¹

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	Phenethylamine hallucinogen that is structurally related to schedule I hallucinogens.	I	I
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

¹ Information in this table relevant to the description of chemicals was compiled from numerous Internet search inquiries of the following sources:

Office of Diversion Control, U.S. Drug Enforcement Administration, found at

<<http://www.dea.gov/diversion/index.html>> (Last visited on April 9, 2010);

U.S. Food and Drug Administration, found at <<http://www.fda.gov>> (Last visited on April 9, 2010);

United States National Library of Medicine of the National Institutes of Health, found at <<http://www.nlm.nih.gov/>> (Last visited on April 9, 2010);

Online Encyclopedia of Chemistry of Chemie.DE Information Service GmbH (a Life Science Network Division), found at

<<http://www.chemie.de/lexikon/e/>> (Last visited on April 9, 2010); and

PubChem Public Chemical Database of the National Center for Biotechnology Information, found at

<<http://www.ncbi.nlm.nih.gov/>> (Last visited on April 9, 2010).

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
Lisdexamfetamine	Central nervous 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 used for the short-term treatment of insomnia (Sonata®).	IV	IV
Zolpidem	Central nervous system depressant used for the short-term treatment of insomnia (Ambien®).	IV	IV
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	Central nervous system depressant and sedative and hypnotic drug related to chloral hydrate. Information could not be found on approved uses.	IV	IV
Sibutramine	Blocks the uptake of various neurotransmitters and is used in management of obesity (Meridia®).	IV	IV
Dichloralphenazone	Sedative typically used in combination with other chemicals in formulating prescription	IV	IV

CHEMICAL	DESCRIPTION	FEDERAL SCHEDULE	PROPOSED FLORIDA SCHEDULE
	pharmaceuticals for the relief of tension and vascular headaches(Iso-Acetazone®, Isocom®, Isopap®, Midchlor®, Midrin®, Migratine®, and Mitride®).		
Pregabalin	Anticonvulsant. 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 atrophine sulfate per dosage unit	A 4-pheylpiperdine derivative. Chemically related to the narcotic meperidine. Not used by itself but used in combination with atropine to treat diarrhea (Motofen®). Atropine discourages deliberate overdosage.	V	V

The chemicals which the bill proposes to schedule as controlled substances would appear (as indicated) in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, F.S.

The federal law provides that Schedule III listed stimulants and depressants include also their salts, isomers, and salts of isomers whenever the existence of such salts, isomers is possible within the specific chemical designation.² Florida’s Schedule III does not currently contain similar language.³

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., in the controlled substances act, defines which practitioners may prescribe a controlled substance under Florida law. A “practitioner” is defined to mean a licensed medical physician, dentist, veterinarian, osteopathic 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. The proposed scheduling of these chemicals is as follows:

² 21 CFR § 1308.13.

³ See s. 893.03(3), F.S.

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 atrophine sulfate per dosage unit.

The bill also provides that Schedule III listed stimulants and depressants include also their salts, isomers, and salts of isomers whenever the existence of such salts, isomers is possible within the specific chemical designation. This language is consistent with federal scheduling laws.

The effective date of the bill is July 1, 2010.

Other Potential Implications:

The Florida Department of Law Enforcement (FDLE) states:

- “The proposed chemical substances are currently scheduled federally but ... have never been added to the Florida controlled substances list. The proposed list of schedule I additions include substances that have no legitimate medical use and have a high potential for abuse. The proposed schedules II through V substances vary in their legitimate medical use but ... many have increasingly become the target of abuse and diversion statewide. Currently, state and local law enforcement agencies are unable to intercede in cases involving any of the proposed chemical substances[,] thus ... creating an environment where individuals are able

to possess, distribute, and/or use harmful substances without fear of intervention by state and local law enforcement unless federal authorities are involved. Additionally, the current language in [s. 893.03(3)(a), F.S.] does not include salts, isomers, or salts of isomers of current substances already scheduled. This ... creates a gap in current law, which creates the potential for certain variations of currently scheduled drugs to be “exempt” from scheduling. Clearly this was an unintended consequence of the original drafting of [s. 893.03, F.S.]”

- “Should SB 1260 pass in its current format, the proposed chemical substances ... would be added to [s. 893.03, F.S.] lists of controlled substances in Florida. As a result, the state list of controlled substances would move closer to being aligned with the federal list of controlled substances. The importance of aligning the two lists revolves around consistency. Even though these proposed substances are already federally scheduled, the discrepancy between the two lists could minimize the inappropriate use and diversion of these drugs within Florida because of variances between state and federal law. The addition of these proposed chemical substances into Florida’s current controlled substances list would give state and local law enforcement the ability to affect a lawful arrest and seek criminal prosecution against an individual engaged in the possession, distribution, and unlawful use of these chemical substances. In addition, the added language in [s. 893.03(3)(a), F.S.] would close current gaps in the statute that allows potential ‘exemptions’ of various forms of substances already controlled within Florida.”
- “The Food & Drug Administration (FDA), the Department of Health & Human Services (DH&HS), and the Drug Enforcement Agency (DEA) are the three primary entities responsible for moving a substance forward for scheduling at the federal level. All of these agencies monitor chemical substances at the national and international level that are being used in a variety of commercial manufacturing venues to include; products intended for human consumption and/or other forms of human exposure. The intent of the scheduling process at the federal level is most often based on consumer protection and public health. Each of the three agencies 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 federal time, funding, and science involved in this process are extensive and surpass what is able to be accomplished at the state level. In reality, at the state level, we are fiscally unable to routinely engage in this same extensive process for ourselves. 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.”⁴

Staff of the Florida Office of Drug Control have represented to Senate professional staff that the Florida Drug Policy Advisory Council approved the proposed scheduling of the chemicals referenced in the bill, and the FDLE, the Agency for Health Care Administration, and the

⁴ Analysis of SB 1260 (March 4, 2010), Florida Department of Law Enforcement. Cited in further references as the “FDLE analysis.”

Department of Education also reviewed and approved the proposed scheduling of these chemicals. The proposed scheduling also went through the Governor's review process.⁵

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

It appears unlikely that manufacturers of and health care practitioners prescribing products containing chemicals proposed for scheduling as controlled substances under the bill would be adversely affected since the referenced chemicals are already scheduled under federal law.

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 indeterminate impact.

The FDLE states: "Local agencies which fund and maintain their own crime lab with a chemistry section would potentially be facing similar costs associated with a slight increase in case submission and additional or new equipment needed to test the added proposed chemical substances."⁶

⁵ E-mail from Claude Shipley, Florida Office of Drug Control, Senate professional staff, Committee on Criminal Justice, dated March 16, 2010.

⁶ FDLE analysis.

The FDLE further states: “The passage of SB 1260 would add additional chemical substances to Florida’s controlled substances list. These additions could potentially increase the number of evidence submissions into the Florida Department of Law Enforcement (FDLE) Crime Laboratory System. The lab system will need to acquire all of the required standards and potentially new or additional equipment required to test the proposed chemical substances.” No projected costs are noted by the FDLE in its analysis.⁷

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill’s introducer or the Florida Senate.

⁷ *Id.*