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: T	he Professional St	taff of the Criminal	Justice Committee
BILL:	SB 336			
INTRODUCER:	Senator Fasano			
SUBJECT:	Controlled Substances			
DATE:	March 10, 2011	REVISED:		
ANAL	YST STA	FF DIRECTOR	REFERENCE	ACTION
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2.			HR	
3.			JU	
1.			ВС	
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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 U.S. Drug Enforcement Administration (DEA) has temporarily scheduled five synthetic cannabinoids as Schedule I controlled substances. Florida law does not currently schedule any of these synthetic cannabinoids (the bill schedules some of the synthetic cannabinoids). The synthetic cannabinoids temporarily scheduled by the DEA are:

- 1-pentyl-3-(1- naphthoyl)indole (JWH-018).
- 1-butyl-3-(1-naphthoyl)indole (JWH-073).
- [2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200).
- 5-(1,1- dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497).
- 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue).¹

Mephedrone is not specifically scheduled under federal law but the DEA has indicated that the chemical "can be considered an analogue of methcathinone (schedule I substance) under the analogue provision of the CSA (Title 21 United States Code 813). Therefore, law enforcement cases involving mephedrone can be prosecuted under the Federal Analog Act of the CSA." Further, the Florida Office of the Attorney General, through emergency rulemaking, has temporarily scheduled this substance along with a number of similar substances as Schedule I controlled substances.³

The following table provides information about the chemicals proposed for scheduling as controlled substances by the bill (excluding synthetic cannabinoids and mephedrone):

¹ 21 CFR Part 1308 (effective March 1, 2011); *Federal Register*, vol. 76, n. 40 (March 1, 2011), http://www.deadiversion.usdoj.gov/fed_regs/rules/2011/fr0301.htm (last accessed on March 15, 2011).

² Drugs and Chemicals of Concern, Office of Diversion Control, U.S. Drug Enforcement Administration, http://www.deadiversion.usdoj.gov/drugs_concern/mephedrone.htm (last accessed on March 15, 2011).

³ Notice of Emergency Rule, 2ER11-1 (effective January 26, 2011), *Florida Administrative Weekly*, vol. 37/06 (published February 11, 2011), https://www.flrules.org/gateway/ruleNo.asp?id=2ER11-1 (last accessed on March 15, 2011).

CHEMICALS REFERENCED IN SB 336 (EXCLUDING SYNTHETIC CANNABINOIDS AND MEPHEDRONE)⁴

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	Phenthylamine 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
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
Remifentanil	Opioid analgesic (Ultiva®).	II	II

Unless otherwise indicated, information regarding federal scheduling of these chemicals is from 21 CFR §§ 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15.

⁴ 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.deadiversion.usdoj.gov/index.html; U.S. Food and Drug Administration, 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/.

CHEMICAL	DESCRIPTION	FEDERAL SCHEDULE	PROPOSED FLORIDA SCHEDULE
Embutramide	Central nervous system depressant	III	III
	and derivative of gamma		
	hydroxybutyric acid, a controlled		
	substance. Used in veterinary		
	euthanasia (Tributame®		
	Euthanasia Solution).		
Zopiclone	Central nervous system	IV	IV
	depressant. Eszopiclone, an active		
	isomer of zopiclone, is used for		
	short-term treatment of insomnia		
	(Lunesta®). Pharmacological		
	properties are substantially similar		
	to benzodiazepines.		
Zaleplon	Central nervous system depressant	IV	IV
	that is used for short-term		
	treatment of insomnia (Sonata®).		
Zolpidem	Central nervous system depressant	IV	IV
	that is used for short-term		
	treatment of insomnia		
	(Ambien®).		
Modafinil	Central nervous system stimulant	IV	IV
	and neuroprotective agent that is		
	used in the treatment of excessive		
	daytime sleepiness associated with		
	narcolepsy (Provigil®).		
Petrichloral	Sedative/hypnotic (Periclor®). ⁵	IV	IV
Sibutramine	Blocks the uptake of various	IV	IV
	neurotransmitters and is used in		
	the management of obesity		
	(Meridia®).		
Dichloralphenazone	Sedative that is typically used in	IV	IV
_	combination with other chemicals		
	in formulating prescription		
	pharmaceuticals for the relief of		
	tension and vascular headaches		
	(Iso-Acetazone®, Isocom®,		
	Midchlor®, Midrin®,		
	Migratine®, and Mitride®).		

⁵ 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).

CHEMICAL	DESCRIPTION	FEDERAL SCHEDULE	PROPOSED FLORIDA SCHEDULE
Pregabalin	Anticonvulsant that is used for	V	V
	neuropathic pain, partial seizures		
	(adjunct therapy), and generalized		
	anxiety disorder (Lyrica®).		
Not more than 0.5	Difenoxin is a 4-phenylpiperidine	V	V
milligrams of Difenoxin	derivative that is chemically		
and not less than 25	related to the narcotic meperidine.		
micrograms of Atropine	It is used in combination with		
sulfate per dosage unit	atropine to treat diarrhea		
	(Motofen®). Atropine discourages		
	deliberate overdosage.		

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. ⁶ Florida's Schedule III does not currently contain similar language. ⁷

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 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 bill schedules the following synthetic cannabinoids in Schedule I:

- 2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-195 yl)phenol (also known as CP 47,497 and its dimethyl octyl (C8) 196 homologue).
- (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-198 methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c] chromen-1-ol 199 (also known as HU-210).
- 1-Pentyl-3-(1-naphthoyl)indole (also known as JWH-018).
- 1-Butyl-3-(1-naphthoyl)indole (also known as JWH-073).

The bill schedules some of the synthetic cannabinoids that the DEA has temporarily scheduled as Schedule I controlled substances. (See "Present Situation" section of this bill analysis.)

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^{6 21} CFR § 1308.13

⁷ See s. 893.03(3), F.S.

The bill schedules mephedrone in Schedule I. Although not specifically scheduled in federal law, the DEA considers mephedrone to be an analogue of methcathinone, a Schedule I controlled substance. Further, the Florida Office of the Attorney General, through emergency rulemaking, has temporarily scheduled this substance as a Schedule I controlled substance. (See "Present Situation" section of this bill analysis.)

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 (...with the exception of the synthetic cannabinoids which are currently under a notice of intent to be 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.⁸

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."

CS/CS SB 204 addresses synthetic cannabinoid scheduling and includes a more comprehensive list of synthetic cannabinoids than SB 336. SB 1886 addresses mephedrone and includes a more comprehensive list of similar chemicals. SB 1886 also uses more specific chemical nomenclature for mephedrone than SB 336. ¹⁰

⁸ 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."

⁹ FDLE analysis.

¹⁰ Staff of the bill sponsor has indicated to Senate professional staff that the sponsor intends to remove reference to the synthetic cannabinoids and mephedrone.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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 (or are currently under notice of intent as being emergency federally scheduled) as being illegal."¹¹

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." ¹²

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." ¹³

VI. Technical Deficiencies:

None.

¹¹ FDLE analysis.

¹². *Id*.

¹³ Id

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None.

VIII. **Additional Information:**

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

None.

В. Amendments:

None.

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