

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1135 Nitazene Derivatives
SPONSOR(S): Judiciary Committee, Overdorf
TIED BILLS: IDEN./SIM. BILLS: SB 736

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Criminal Justice Subcommittee	17 Y, 0 N	Leshko	Hall
2) Justice Appropriations Subcommittee	14 Y, 0 N	Saag	Keith
3) Judiciary Committee	22 Y, 0 N, As CS	Leshko	Kramer

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 and whether the substance has a currently accepted medical use. The classifications range from a Schedule I substance, which has a high potential for abuse and no accepted medical use; to a Schedule V substance, which has a low potential for abuse and an accepted medical use. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed therein.

The Legislature delegated to the Florida Attorney General the authority to adopt rules to add a substance to a schedule established under s. 893.03, F.S., or transfer a substance between schedules, if the substance has the potential for abuse and meets other requirements, or to remove a scheduled substance if it no longer meets the requirements for inclusion in that schedule. If the Attorney General finds that the scheduling of a substance in Schedule I of s. 893.03, F.S., on a temporary basis is necessary to avoid an imminent hazard to the public safety, he or she may bypass certain requirements and by rule schedule such substance in Schedule I.

Nitazene is a synthetic opioid, a subclass of benzimidazole-opioids, that can appear yellow, brown, or off-white in color when in powder form, and is 10 to 20 times stronger than fentanyl, which itself is 50 to 100 times more potent than morphine. Nitazene was created as potential pain reliever medication in the 1950s but has never been approved for medical use in the United States based on early testing showing high rates of overdose and potential for abuse. Drug Enforcement Administration laboratories have encountered this drug mixed into heroin and fentanyl. Adding nitazene to another drug makes the drug more potent and addictive, and cheaper. In other instances, it has been pressed into counterfeit pills and falsely marketed as pharmaceutical medication.

On April 26, 2022, the Florida Attorney General filed Emergency Rule 2ER22-1 to add eight nitazene derivatives to Schedule I of s. 893.03, F.S. The emergency rule became effective on the date of filing and will expire on June 30, 2023. Ten nitazene derivatives have been added to the federal Controlled Substance Act as Schedule I substances. These include the eight that the Florida Attorney General added through the emergency rule filed in April 2022.

CS/HB 1135 amends s. 893.03, F.S., to add nitazene derivatives to the list of Schedule I controlled substances including, but not limited to: butonitazene, clonitazene, etodesnitazene, etonitazene, flunitazene, isotodesnitazene, isotonitazene, metodesitazene, metonitazene, nitazene, *N*-desethyl etonitazene, *N*-desethyl isotonitazene, *N*-piperidino etonitazene, *N*-pyrrolidino etonitazene, and protonitazene.

The bill may have a positive indeterminate impact on jail and prison beds by making the manufacture, distribution, possession, or sale of more substances illegal which may result in more jail and prison admissions.

The bill provides an effective date of July 1, 2023.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h1135e.JDC

DATE: 3/31/2023

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Law

Controlled Substance Schedules

Chapter 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, classifies controlled substances¹ 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 controlled substance schedules are the “potential for abuse”² of the substance and whether there is a currently accepted medical use for the substance.³

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 and their use under medical supervision does not meet accepted safety standards.⁴
- Schedule II substances have a high potential for abuse and have a currently accepted but severely restricted medical use in the United States, and abuse of the substance may lead to severe psychological or physical dependence.⁵
- 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, and the 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.⁶
- 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, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.⁷
- Schedule V substances, compounds, mixtures, or preparation of 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, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.⁸

Attorney General Emergency Scheduling Authority

The Legislature delegated to the Florida Attorney General the authority to adopt rules to add a substance to a schedule established under s. 893.03, F.S., or transfer a substance between schedules, if the substance has the potential for abuse and meets other classification requirements, or to remove a substance previously added to a schedule if it no longer meets the requirements for inclusion in that schedule.⁹ Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial likelihood that such activities will take place, in other than isolated or

¹ “Controlled substance” means any substance named or described in Schedules I-V of s. 893.03, F.S. S. 893.02(4), F.S.

² “Potential for abuse” means that a substance has properties of 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. S. 893.02(22), F.S.

³ See s. 893.03, F.S.

⁴ S. 893.03(1), F.S.

⁵ S. 893.03(2), F.S.

⁶ S. 893.03(3), F.S.

⁷ S. 893.03(4), F.S.

⁸ S. 893.03(5), F.S.

⁹ S. 893.035(2), F.S.; Potential for abuse has the same meaning as provided in s. 893.02(22), F.S.

occasional instances.¹⁰ Any findings and conclusions provided by the U.S. Attorney General with respect to any substance is admissible as evidence in any rulemaking proceeding, including an emergency rulemaking proceeding.¹¹

If the Attorney General finds that the scheduling of a substance in Schedule I of s. 893.03, F.S., on a temporary basis is necessary to avoid an imminent hazard to public safety, he or she may by rule¹² schedule such substance in Schedule I if the substance is not listed in any other schedule of s. 893.03, F.S. The Attorney General shall be required to consider, with respect to his or her finding of imminent hazard to public safety, only:

- The substance's potential for abuse;¹³
- The substance's history and current pattern of abuse;
- The scope, duration, and significance of abuse;
- What, if any, risk there is to the public health;¹⁴
- Diversion from legitimate channels, if any; and
- Clandestine importation, manufacture, or distribution.¹⁵

The Attorney General must provide specific facts and reasons for finding an immediate danger to the public health, safety, or welfare.¹⁶ The Attorney General shall report to the Legislature by March 1 of each year concerning any rules adopted to schedule or reschedule any substance during the previous year. Each such rule expires on the following June 30 unless the Legislature adopts the provisions in statute.¹⁷

Department of Legal Affairs Emergency Rule 2ER22-1 (2022)

On April 26, 2022, the Attorney General filed Emergency Rule 2ER22-1 to add the following nitazene derivatives to Schedule I of s. 893.03, F.S.:

- Butonitazene;
- Etodesnitazene/etazene;
- Flunitazine;
- Metodesnitazene;
- Metonitazene;
- *N*-pyrrolidino etonitazene/etonitazepyne;
- Protonitazene; and
- Isotonitazene.¹⁸

The emergency rule became effective on the date of filing and will expire on June 30, 2023, if the Legislature does not adopt the provisions through amendment to s. 893.03, F.S. The Attorney General found:

- That the chemical structures of the nitazene compounds are dissimilar to any currently scheduled substance in Schedule I under s. 893.03, F.S.
- That nitazenes have no currently accepted medical use.
- The potential for abuse of nitazene compounds is significant given that many of them are equivalent to or several times more potent than fentanyl and morphine.
- That many nitazene derivatives have already been added to Schedule I of the federal Controlled Substances Act.

¹⁰ S. 893.035(3)(a), F.S.

¹¹ *Id.*

¹² In an emergency rulemaking proceeding, the Attorney General may proceed without regard to the requirements to request a medical and scientific evaluation of the substance from and consider recommendations regarding scheduling from the Department of Health and the Department of Law Enforcement. S. 893.035(5) and (7), F.S.

¹³ S. 893.035(3)(a), F.S.

¹⁴ S. 893.035(4)(d-f), F.S.

¹⁵ S. 893.035(7), F.S.

¹⁶ S. 120.54(4)(a)3., F.S.

¹⁷ These expiration provisions are notwithstanding the 90-day expiration described in s. 120.54(4)(c), F.S.

¹⁸ R. 2ER22-1, Vol. 48, No. 82, Fla. Admin. Reg. (April 27, 2022), <https://www.flrules.org/gateway/ruleno.asp?id=2ER22-1&PDate=4/27/2022&Section=4> (last visited Mar. 24, 2023).

- That synthetic opioid overdose deaths are on the rise nationwide and, in Florida, at least fifteen deaths since 2020 have been confirmed related to nitazene derivatives.¹⁹

Federal Law

The federal Controlled Substances Act²⁰ (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 U.S. Attorney General is required to consider the following when determining where to schedule a substance:²¹

- 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.

Nitazene Derivatives

The following nitazene derivatives have been added to the CSA as Schedule I controlled substances:

- Butonitazene;
- Clonitazene;
- Etodesnitazene/etazene;
- Etonitazene;
- Flunitazene;
- Isotonitazene;
- Metodesnitazene;
- Metonitazene;
- *N*-pyrrolindino etonitazene/etonitazepyne; and
- Protonitazene.

The above nitazene derivatives, except for isotonitazene, were scheduled effective April 12, 2022. Isotonitazene was scheduled effective August 20, 2020.²²

Nitazene

Nitazene is a synthetic opioid, a subclass of benzimidazole-opioids, that can appear yellow, brown, or off-white in color when in powder form, and is 10 to 20 times stronger than fentanyl, which itself is 50 to 100 times more potent than morphine.²³ Nitazene was created as potential pain reliever medication in the 1950s but has never been approved for medical use in the United States based on early testing showing high rates of overdose and potential for abuse.²⁴

¹⁹ Florida Attorney General, *Findings of the Attorney General in Support of Emergency Rule 2ER22-1*, [http://myfloridalegal.com/webfiles.nsf/WF/CPAL-CDUPT2/\\$file/Web+Link.pdf](http://myfloridalegal.com/webfiles.nsf/WF/CPAL-CDUPT2/$file/Web+Link.pdf) (last visited Mar. 24, 2023).

²⁰ 21 U.S.C. § 812.

²¹ 21 U.S.C. § 811(c).

²² Drug Enforcement Administration (DEA), *Controlled Substances*, https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf (last visited Mar. 24, 2023); DEA, *Scheduling Actions*, https://www.deadiversion.usdoj.gov/schedules/orangebook/a_sched_alpha.pdf (last visited Mar. 24, 2023).

²³ Opioid Treatment, *Nitazenes: New Opioids 20 Times Stronger Than Fentanyl*, <https://www.opioidtreatment.net/blog/nitazenes/> (last visited Mar. 24, 2023); DEA, *New, Dangerous Synthetic Opioid in D.C., Emerging in Tri-State Area*, <https://www.dea.gov/stories/2022/2022-06/2022-06-01/new-dangerous-synthetic-opioid-dc-emerging-tri-state-area> (last visited Mar. 24, 2023); National Institute on Drug Abuse, *Fentanyl*, <https://www.drugabuse.gov/publications/drugfacts/fentanyl> (last visited Mar. 14, 2023).

²⁴ DEA, *Benzimidazole-Opioids: Other Name: Nitazenes*, https://www.deadiversion.usdoj.gov/drug_chem_info/benzimidazole-opioids.pdf#search=nitazenes (last visited Mar. 24, 2023); Centers for Disease Control and Prevention, *Notes from the Field: Nitazene-Related Deaths – Tennessee, 2019-2021*, <https://www.cdc.gov/mmwr/volumes/71/wr/mm7137a5.htm> (last visited Mar. 24, 2023); Addiction Center, *Nitazene Addiction and Abuse*, <https://www.addictioncenter.com/opiates/nitazenes/> (last visited Mar. 24, 2023).

Drug Enforcement Administration laboratories have encountered this drug mixed into heroin and fentanyl. Adding nitazene to another drug makes the drug more potent and addictive, and cheaper.²⁵ In other instances, it has been pressed into counterfeit pills and falsely marketed as pharmaceutical medication.²⁶ Many people who have died of a nitazene overdose were unaware they were ingesting nitazene given the frequency with which it is mixed with other drugs and purposely mislabeled.²⁷ Isotonitazene was the most common cause of nitazene-related deaths nationwide in 2020. In 2021, however, nitazene-related deaths were most frequently caused by metonitazene.²⁸

Effect of Proposed Changes

CS/HB 1135 amends s. 893.03, F.S., to add nitazene derivatives to the list of Schedule I controlled substances including, but not limited to:

- Butonitazene;
- Clonitazene;
- Etodesnitazene;
- Etonitazene;
- Flunitazene;
- Isotodesnitazene;
- Isotonitazene;
- Metodesitazene;
- Metonitazene;
- Nitazene;
- *N*-desethyl etonitazene;
- *N*-desethyl isotonitazene;
- *N*-piperidino etonitazene;
- *N*-pyrrolidino etonitazene; and
- Protonitazene.

As such, under the bill, Florida law regulates the manufacture, distribution, preparation, and dispensing of such nitazene derivatives.

The bill provides an effective date of July 1, 2023.

B. SECTION DIRECTORY:

Section 1: Amends s. 893.03, F.S., relating to standards and schedules.

Section 2: Provides an effective date of July 1, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

²⁵ GoodRx Health, *Nitazenes: What to Know About the Illegal Opioids That Can Be More Potent Than Fentanyl*, <https://www.goodrx.com/classes/opioids/nitazene-synthetic-opioid> (last visited Mar. 24, 2023).

²⁶ *Supra* note 23.

²⁷ *Supra* note 23.

²⁸ *Supra* note 26.

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill may have a positive indeterminate impact on jail and prison beds by making the manufacture, distribution, possession, or sale of more substances illegal which may result in more jail and prison admissions.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 31, 2023, the Judiciary Committee adopted one amendment and reported the bill favorably as a committee substitute. The amendment changed the effective date of the bill from October 1, 2023, to July 1, 2023.

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