

**Senate Study Bill 1085 - Introduced**

SENATE/HOUSE FILE \_\_\_\_\_  
BY (PROPOSED BOARD OF PHARMACY  
BILL)

**A BILL FOR**

1 An Act making changes to the controlled substance schedules,  
2 modifying the regulation of precursor substances, and  
3 providing penalties, and including effective date  
4 provisions.  
5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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DIVISION I

CONTROLLED SUBSTANCES

Section 1. Section 124.204, subsection 2, Code 2017, is amended by adding the following new paragraph:

NEW PARAGRAPH. *bd.* AH-7921 (3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl]benzamide.

Sec. 2. Section 124.204, subsection 9, Code 2017, is amended by adding the following new paragraphs:

NEW PARAGRAPH. *p.* N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: Furanyl fentanyl.

NEW PARAGRAPH. *q.* N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: Butyryl fentanyl.

NEW PARAGRAPH. *r.* N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: beta-hydroxythiofentanyl.

NEW PARAGRAPH. *s.* 3,4-Dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: U-47700.

Sec. 3. Section 124.206, subsection 2, paragraph a, unnumbered paragraph 1, Code 2017, is amended to read as follows:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following:

Sec. 4. Section 124.206, subsection 2, paragraph d, Code 2017, is amended to read as follows:

*d.* Coca leaves and any salt, compound, derivative, or preparation of coca leaves. ~~Decocainized coca leaves or~~

1 ~~extractions of coca leaves, which extractions do not contain~~  
2 ~~cocaine or ecgonine, are excluded from this paragraph. The~~  
3 ~~following substances and their salts, optical and geometric~~  
4 ~~isomers, derivatives, and salts of derivatives and optical~~  
5 ~~and geometric isomers~~ including cocaine and ecgonine and  
6 their salts, isomers, derivatives and salts of isomers and  
7 derivatives, and any salt, compound, derivative, or preparation  
8 thereof that is chemically equivalent or identical to any of  
9 such substances, ~~are included in this paragraph~~ except that the  
10 substances shall not include:

11 (1) Cocaine Decocainized coca leaves or extractions of coca  
12 leaves, which extractions do not contain cocaine or ecgonine.

13 (2) Ecgonine [123]ioflupane.

14 Sec. 5. Section 124.206, subsection 3, Code 2017, is amended  
15 by adding the following new paragraph:

16 NEW PARAGRAPH. *ac.* Thiafentanil.

17 Sec. 6. Section 124.208, subsection 5, paragraph a,  
18 subparagraphs (3) and (4), Code 2017, are amended by striking  
19 the subparagraphs.

20 Sec. 7. Section 124.210, subsection 2, Code 2017, is amended  
21 by adding the following new paragraph:

22 NEW PARAGRAPH. *c.* 2-[(dimethylamino)methyl]-1-  
23 (3-methoxyphenyl)cyclohexanol, its salts, optical and geometric  
24 isomers and salts of these isomers (including tramadol).

25 Sec. 8. Section 124.210, subsection 3, Code 2017, is amended  
26 by adding the following new paragraphs:

27 NEW PARAGRAPH. *bb.* Alfaxalone.

28 NEW PARAGRAPH. *bc.* Suvorexant.

29 Sec. 9. Section 124.210, subsection 7, Code 2017, is amended  
30 by adding the following new paragraph:

31 NEW PARAGRAPH. *c.* Eluxadolone (5-[[[(2S)-2-amino-3-  
32 [4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-  
33 (4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-  
34 methoxybenzoic acid) (including its optical isomers) and its  
35 salts, isomers, and salts of isomers.

1 Sec. 10. Section 124.212, subsection 5, Code 2017, is  
2 amended by adding the following new paragraph:

3 NEW PARAGRAPH. *d.* Brivaracetam ((2S)-2-[(4R)-2-oxo-4-  
4 propylpyrrolidin-1-yl] butanamide), including its salts. Other  
5 names: BRV, UCB-34714, Briviact.

6 DIVISION II

7 CODE CHAPTER 124B (PRECURSOR SUBSTANCES) REPEAL

8 Sec. 11. Section 124.401, subsection 5, unnumbered  
9 paragraph 1, Code 2017, is amended to read as follows:

10 It is unlawful for any person knowingly or intentionally  
11 to possess a controlled substance unless such substance was  
12 obtained directly from, or pursuant to, a valid prescription  
13 or order of a practitioner while acting in the course of the  
14 practitioner's professional practice, or except as otherwise  
15 authorized by [this chapter](#). Any person who violates this  
16 subsection is guilty of a serious misdemeanor for a first  
17 offense. A person who commits a violation of [this subsection](#)  
18 and who has previously been convicted of violating [this chapter](#)  
19 or [chapter 124A, 124B, or 453B](#), or chapter 124B as it existed  
20 prior to the effective date of this Act, is guilty of an  
21 aggravated misdemeanor. A person who commits a violation of  
22 this subsection and has previously been convicted two or more  
23 times of violating [this chapter](#) or [chapter 124A, 124B, or 453B](#),  
24 or chapter 124B as it existed prior to the effective date of  
25 this Act, is guilty of a class "D" felony.

26 Sec. 12. Section 155A.6, subsection 3, Code 2017, is amended  
27 to read as follows:

28 3. The board shall establish standards for  
29 pharmacist-intern registration and may deny, suspend,  
30 or revoke a pharmacist-intern registration for failure to meet  
31 the standards or for any violation of the laws of this state,  
32 another state, or the United States relating to prescription  
33 drugs, controlled substances, or nonprescription drugs, or for  
34 any violation of [this chapter](#) or [chapter 124, 124A, 124B, 126,](#)  
35 [147, or 205](#), or any rule of the board.

1     Sec. 13. Section 155A.6A, subsection 5, Code 2017, is  
2 amended to read as follows:

3     5. The board may deny, suspend, or revoke the registration  
4 of, or otherwise discipline, a registered pharmacy technician  
5 for any violation of the laws of this state, another state, or  
6 the United States relating to prescription drugs, controlled  
7 substances, or nonprescription drugs, or for any violation of  
8 this chapter or [chapter 124](#), [124A](#), ~~[124B](#)~~, [126](#), [147](#), [205](#), or  
9 [272C](#), or any rule of the board.

10    Sec. 14. Section 155A.6B, subsection 5, Code 2017, is  
11 amended to read as follows:

12    5. The board may deny, suspend, or revoke the registration  
13 of a pharmacy support person or otherwise discipline the  
14 pharmacy support person for any violation of the laws of  
15 this state, another state, or the United States relating to  
16 prescription drugs, controlled substances, or nonprescription  
17 drugs, or for any violation of [this chapter](#) or [chapter 124](#),  
18 [124A](#), ~~[124B](#)~~, [126](#), [147](#), [205](#), or [272C](#), or any rule of the board.

19    Sec. 15. Section 155A.13A, subsection 5, paragraph d, Code  
20 2017, is amended to read as follows:

21    d. Any violation of [this chapter](#) or [chapter 124](#), [124A](#), ~~[124B](#)~~,  
22 [126](#), or [205](#), or rule of the board.

23    Sec. 16. Section 155A.13C, subsection 5, paragraph d, Code  
24 2017, is amended to read as follows:

25    d. Any violation of [this chapter](#) or [chapter 124](#), [124A](#), ~~[124B](#)~~,  
26 [126](#), or [205](#), or rule of the board.

27    Sec. 17. Section 155A.17, subsection 2, Code 2017, is  
28 amended to read as follows:

29    2. The board shall establish standards for drug wholesaler  
30 licensure and may define specific types of wholesaler licenses.  
31 The board may deny, suspend, or revoke a drug wholesale license  
32 for failure to meet the applicable standards or for a violation  
33 of the laws of this state, another state, or the United  
34 States relating to prescription drugs, devices, or controlled  
35 substances, or for a violation of [this chapter](#), [chapter 124](#),

1 124A, ~~124B~~, 126, or 205, or a rule of the board.

2 Sec. 18. Section 155A.42, subsection 4, Code 2017, is  
3 amended to read as follows:

4 4. The board may deny, suspend, or revoke a limited drug and  
5 device distributor's license for failure to meet the applicable  
6 standards or for a violation of the laws of this state, another  
7 state, or the United States relating to prescription drugs or  
8 controlled substances, or for a violation of ~~this chapter~~,  
9 chapter 124, 124A, ~~124B~~, 126, 205, or 272C, or a rule of the  
10 board.

11 Sec. 19. REPEAL. Chapter 124B, Code 2017, is repealed.

12 DIVISION III

13 EFFECTIVE DATE

14 Sec. 20. EFFECTIVE UPON ENACTMENT. This Act, being deemed  
15 of immediate importance, takes effect upon enactment.

16 EXPLANATION

17 The inclusion of this explanation does not constitute agreement with  
18 the explanation's substance by the members of the general assembly.

19 This bill makes changes to the controlled substance  
20 schedules and modifies the regulation of precursor substances.

21 DIVISION I — CONTROLLED SUBSTANCES. The bill classifies  
22 four synthetic opioids as schedule I controlled substances in  
23 conformance with scheduling actions taken by the United States  
24 department of justice, drug enforcement administration. The  
25 bill also classifies as a schedule I controlled substance a  
26 micro-opioid receptor agonist with analgesic activity similar  
27 to morphine.

28 The bill classifies thiafentanil, an opioid and analogue of  
29 fentanyl, as a schedule II controlled substance.

30 The bill removes hydrocodone-combination products from  
31 the list of substances classified as schedule III controlled  
32 substances. Currently, hydrocodone, as a single-entity  
33 substance, is classified as a schedule II controlled  
34 substance. The change under the bill effectively makes all  
35 hydrocodone-containing products subject to the controls,

1 security, reporting, and penalty provisions for schedule II  
2 controlled substances.

3 The bill removes naloxegol, a new molecular entity and  
4 derivative of naloxone, from control as a schedule III  
5 controlled substance. The federal food and drug administration  
6 approved naloxegol for the treatment of opioid-induced  
7 constipation in adults with chronic non-cancer pain.

8 The bill also removes [\123\I]ioflupane from control as  
9 a schedule II controlled substance. This substance is a new  
10 molecular entity and is the active pharmaceutical ingredient  
11 in the drug DaTscan, approved by the federal food and drug  
12 administration for use in diagnosis of patients suspected of  
13 having Parkinson's disease.

14 The bill classifies the substance commonly known as  
15 tramadol, a centrally acting opioid analgesic, as a schedule  
16 IV controlled substance. This substance was previously  
17 marketed and distributed as a noncontrolled prescription  
18 drug. Effective August 18, 2014, the federal drug enforcement  
19 administration classified tramadol as a schedule IV controlled  
20 substance under federal law.

21 The bill classifies alfaxalone, a neurosteroid with central  
22 nervous system depressant properties, as a schedule IV  
23 controlled substance. The federal food and drug administration  
24 approved this intravenous injectable anesthetic for use by or  
25 on the order of a licensed veterinarian. Alfaxalone is not  
26 available by prescription and is approved for use in veterinary  
27 practice.

28 The bill classifies suvorexant, an insomnia treatment  
29 approved by the federal food and drug administration,  
30 as a schedule IV controlled substance. This is a novel,  
31 first-in-class, chemical substance and information on actual  
32 abuse data is not available. However, data from clinical  
33 studies supports the classification in schedule IV.

34 The bill classifies eluxadoline, a new entity with central  
35 nervous system opioid properties approved by the federal food

1 and drug administration for the treatment of irritable bowel  
2 syndrome with diarrhea, as a schedule IV controlled substance.

3 The bill classifies brivaracetam, also known as briviact  
4 or BRV, as a schedule V controlled substance. Briviact is a  
5 new molecular entity with central nervous system depressant  
6 properties and has been approved as an add-on treatment to  
7 other medications to treat partial onset seizures in patients  
8 age 16 years and older with epilepsy.

9 It is a class "C" felony pursuant to Code section  
10 124.401(1)(c)(8) for any unauthorized person to violate a  
11 provision of Code section 124.401 involving a classified  
12 substance placed on schedule I, II, or III pursuant to the  
13 bill. A class "C" felony for this particular offense is  
14 punishable by confinement for no more than 10 years and a fine  
15 of at least \$1,000 but not more than \$50,000.

16 It is an aggravated misdemeanor pursuant to Code section  
17 124.401(1)(d) for any unauthorized person to violate a  
18 provision of Code section 124.401 involving a classified  
19 substance placed on schedule IV pursuant to the bill. An  
20 aggravated misdemeanor is punishable by confinement for no more  
21 than two years and a fine of at least \$625 but not more than  
22 \$6,250.

23 If a person possesses a controlled substance in violation of  
24 Code section 124.401(5) as a first offense, the person commits  
25 a serious misdemeanor. A serious misdemeanor is punishable by  
26 confinement for no more than one year and a fine of at least  
27 \$315 but not more than \$1,875.

28 DIVISION II — PRECURSOR SUBSTANCES. The bill repeals  
29 Code chapter 124B relating to the regulation of precursor  
30 substances. Code section 124B.1 defines "precursor substance"  
31 to mean a substance which may be used as a precursor in  
32 the illegal production of a controlled substance and is  
33 specified in Code section 124B.2. Under Code section 124B.2, a  
34 manufacturer, retailer, or other person who sells, transfers,  
35 or otherwise furnishes to any person in this state a substance



1 listed in Code section 124B.2 is required to file a report with  
2 the board of pharmacy unless certain exceptions apply under  
3 Code section 124B.6. A person who commits a violation of Code  
4 chapter 124B is subject to criminal penalties ranging from a  
5 simple misdemeanor to a class "C" felony.

6 DIVISION III — EFFECTIVE DATE. The bill takes effect upon  
7 enactment.