



MINNESOTA BOARD OF PHARMACY

Report to the Legislature on Changes the Board Proposes to Make to the Controlled Substance Schedules Maintained by the Board in Minnesota Rules. (In compliance with Minnesota Statutes Section 152.02, Subd. 12)

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COST OF REPORT

[Minnesota Statutes §3.197](#) states that a “report to the legislature must contain, at the beginning of the report, the cost of preparing the report, including any costs incurred by another agency or another level of government”. The estimated cost of preparing this report was **\$150.00**. That is the approximate value, in terms of salary and benefits, of the time that Board staff spent preparing the report.

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Introduction

The Board of Pharmacy (Board) is submitting this report to the Legislature in compliance with Minnesota Statutes §152.02, subdivision 12. That section states, in part:

“The state Board of Pharmacy shall annually submit a report to the legislature on or before December 1 that specifies what changes the board made to the controlled substance schedules maintained by the board in Minnesota Rules, parts 6800.4210 to 6800.4250, in the preceding 12 months. The report must also specify any orders issued by the board under this subdivision. The report must include specific recommendations for amending the controlled substance schedules contained in subdivisions 2 to 6, so that they conform with the controlled substance schedules maintained by the board in Minnesota Rules, parts 6800.4210 to 6800.4250, and with the federal schedules.”

The Board has not engaged in rule-making to make any changes to the controlled substance schedules found in Minnesota Rules Chapter 6800 during calendar year 2018. However, the Board has issued two Scheduling Orders, pursuant to the authority granted to it in Minn. Stats. §152.02, subdivision 12 (a).

Scheduling Orders

The Board issued the following Scheduling Orders during calendar year 2018. The Board recommends that the Legislature make these orders permanent by passing legislation to make the appropriate changes to the Schedules found in Minn. Stats. §152.02.

Fentanyl analogs and synthetic cannabinoids order

Synthetic cannabinoids are human-made chemicals that are related to the natural cannabinoids found in the marijuana plant. They are often dissolved with a solvent and sprayed onto dried plant material, which is then smoked. Alternatively, they are sometimes sold in liquid form for use in electronic vaporizing devices. They are sold as “safe” alternatives to marijuana but, according to the United States Centers for Disease Control, synthetic cannabinoids can cause: agitation and irritability; confusion and concentration problems; hallucinations, delusions, psychosis, suicidal thoughts, and violent behavior; seizures; sleepiness and dizziness; breathing problems; kidney failure; muscle damage; and heart attack, fast heart rate, high blood pressure, and stroke.

The fentanyl analogs are human-made chemicals that are related to fentanyl, a powerful opioid analgesic. Unlike fentanyl, none of them have been approved by the U.S. Food and Drug Administration for medical use. These drugs are often many times more potent than FDA approved opioid pain relievers. They can cause drowsiness, lethargy, paranoia, nausea, vomiting, slowed breathing, and addiction. In overdose situations, the effects on breathing can cause death. Some fentanyl analogs are so potent that, when they cause an overdose, treatment with the opioid antidote naloxone can be ineffective. The CDC recently issued a Health Alert Network Update to warn of the increasing abuse of these substances, which lead to a doubling of opioid overdoses deaths between 2015 and 2016. Preliminary data shows that the increase in such deaths continued in 2017. Deaths from synthetic opioids have also been steadily increasing in Minnesota, with 99 reported deaths in 2016. The Minnesota Bureau of Criminal Apprehension has also informed the Board that nearly a dozen separate synthetic opioids have been identified during their analyses of substances submitted to them for analysis by law enforcement agencies.

STATE OF MINNESOTA

BOARD OF PHARMACY

In the Matter of the Temporary
Scheduling of Certain Substances
as Controlled Substances

**ORDER TO DESIGNATE
CONTROLLED SUBSTANCES**

WHEREAS, Minn. Stats. § 152.02, subd. 12 (a), contains the following provision:

If any substance is designated, rescheduled, or deleted as a controlled substance under federal law, the Board of Pharmacy may similarly and temporarily control the substance under this chapter by issuing an order and causing it to be published in the State Register and filed with the secretary of state. In issuing the order, the board is not required to engage in rulemaking. The order expires no later than 12 months after the date of issue and may not be renewed. After issuing the order, the board may permanently schedule the substance only by exercising the authority granted to it under subdivision 8.

WHEREAS, the United States Drug Enforcement Administration, acting under federal law, has designated the following substances as Schedule I controlled substances:

Cannabinoids

1-(5-FLUOROPENTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-PYRROLO[2,3-B]PYRIDINE-3-CARBOXAMIDE (5FCUMYLP7AICA). **Scheduled 7/10/2018**

1-(4-CYANOBTYL)-N-(2-PHENYLPROPAN-2-YL)-1 H-INDAZOLE-3-CARBOXAMIDE (4-CN-CUMYL-BUTINACA). **Scheduled 7/10/2018**

NAPHTHALEN-1-YL 1-(5-FLUOROPENTYL)-1 H-INDOLE-3-CARBOXYLATE (NM2201; CBL2201) **Scheduled 7/10/2018**

N-(1-AMINO-3-METHYL-1-OXOBUTAN-2-YL)-1-(5-FLUOROPENTYL)-1 H-INDAZOLE-3-CARBOXAMIDE (5F-ABPINACA) **Scheduled 7/10/2018**

METHYL 2-(1-(CYCLOHEXYLMETHYL)-1H-INDOLE-3- CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (MDMB CHMICA) **Scheduled 4/10/2017**

METHYL2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3- CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (5F-ADB) **Scheduled 4/10/2017**

N-(1-AMINO-3,3-DIMETHYL-1-OXOBUTAN-2-YL)-1-(4- FLUOROBENZYL)1H-INDAZOLE-3-CARBOXAMIDE (ADB-FUBINACA) **Scheduled 4/10/2017**

Opioids

CYCLOPROPYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLCYCLOPROPANECARBOXAMIDE) **Scheduled 1/4/2018**

Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, meaning **(Schedule 2/6/2018):**

any substance not otherwise listed under another federal Administration Controlled Substance Code Number or not otherwise listed in Minn. Stats. § 152.02, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], that is structurally related to fentanyl by one or more of the following modifications:

- (A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;
- (B) Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;
- (C) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;
- (D) Replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or
- (E) Replacement of the N-propionyl group by another acyl group.

1-CYCLOHEXYL-4-(1,2- DIPHENYLETHYL)PIPERAZINE (MT-45) **Scheduled 1/12/2018**

N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLBUTANAMIDE (BUTYRYL FENTANYL) **Scheduled 4/20/18**

N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLCYCLOPENTANECARBOXAMIDE (CYCLOPENTYL FENTANYL)

N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLISOBUTYRAMIDE (ISOBUTYRYL FENTANYL) **Scheduled 2/1/2018**

N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLPENTANAMIDE (VALERYL FENTANYL) **Scheduled 2/1/2018**

N-(2-FLUOROPHENYL)-2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)ACETAMIDE (OCFENTANIL) **Scheduled 2/1/2018**

N-(4-CHLOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (PARA-CHLOROISOBUTYRYL FENTANYL) **Scheduled 2/1/2018**

N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)BUTYRAMIDE (PARA-FLUOROBUTYRYL FENTANYL) **Scheduled 2/1/2018**

N-(4-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)ISOBUTYRAMIDE (4-FLUOROISOBUTYRYL FENTANYL) **Scheduled 5/23/2017**

N-(4-METHOXYPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL)BUTYRAMIDE (PARA-METHOXYBUTYRYL FENTANYL)
Schedule 2/1/2018

ACRYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACRYLAMIDE) **Scheduled 7/14/2017**

METHOXYACETYL FENTANYL (2-METHOXY-N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLACETAMIDE) **Scheduled 10/26/2017**

ORTHO-FLUOROFENTANYL or 2-FLUOROFENTANYL (N-(2-FLUOROPHENYL)-N-(1-PHENETHYLPIPERIDIN-4-YL))
Scheduled 10/26/2017

TETRAHYDROFURANYL FENTANYL (N-(1-PHENETHYLPIPERIDIN-4-YL)-N-PHENYLTETRAHYDROFURAN-2-CARBOXAMIDE) **Scheduled 10/26/2017**

WHEREAS, a quorum of the Minnesota Board of Pharmacy met during an emergency meeting held on July 30, 2018 to consider the temporary scheduling of the aforementioned substances; and

WHEREAS, the Board Members in attendance at the meeting voted unanimously to use the authority given to the Board in Minn. Stats. § 152.02, subdivision 12 (a) to order the scheduling of the aforementioned substances.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to Minn. Stat. § 152.02, subdivision 12 (a), that the aforementioned substances are temporarily placed into Schedule I of Minnesota's schedules of controlled substances and that this order shall expire one year from the date of its publication in the *Minnesota State Register*.

Dated: July 30, 2018

MINNESOTA BOARD OF PHARMACY

By: _____
STUART WILLIAMS (Board President)

Cannabidiol (Epidiolex) Scheduling Order

The U.S. Food and Drug Administration recently approved a new drug for use in the treatment of certain pediatric seizures. The drug contains cannabidiol (CBD) that is derived from marijuana plants (not hemp

plants). CBD derived from marijuana is normally a Schedule I controlled substance. However, the U.S. Drug Enforcement Administration, in consultation with the FDA, has placed CBD approved by the FDA (in the form of this product) into Schedule V. Since this drug was shown during clinical trials to be very beneficial in the treatment of these seizures, the Board used its authority to place it into Schedule V so that it could be distributed, prescribed and dispensed within Minnesota.

STATE OF MINNESOTA

BOARD OF PHARMACY

In the Matter of the Temporary
Scheduling of Cannabidiol

**ORDER TO DESIGNATE
CONTROLLED SUBSTANCES**

WHEREAS, Minn. Stats. § 152.02, subd. 12 (a), contains the following provision:

If any substance is designated, rescheduled, or deleted as a controlled substance under federal law, the Board of Pharmacy may similarly and temporarily control the substance under this chapter by issuing an order and causing it to be published in the State Register and filed with the secretary of state. In issuing the order, the board is not required to engage in rulemaking. The order expires no later than 12 months after the date of issue and may not be renewed. After issuing the order, the board may permanently schedule the substance only by exercising the authority granted to it under subdivision 8;

WHEREAS, on September 21, 2018, the United States Drug Enforcement Administration, acting under federal law, designated the following substance as a Schedule V controlled substance:

- a drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols;

WHEREAS, a drug product in finished dosage formulation has been approved for medical use by the United States Food and Drug Administration and is currently marketed under the name, Epidiolex;

WHEREAS, a quorum of the Minnesota Board of Pharmacy met during a regularly scheduled meeting held on October 17, 2018 and considered the temporary scheduling of the aforementioned substance; and

WHEREAS, the Board Members in attendance at the meeting voted unanimously to use the authority given to the Board in Minn. Stats. § 152.02, subdivision 12 (a) to order the scheduling of the aforementioned substance.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to Minn. Stat. § 152.02, subdivision 12 (a), that the aforementioned substance is temporarily placed into Schedule V of Minnesota's schedules of controlled substances and that this order shall expire one year from the date of its publication in the *Minnesota State Register*.

Dated: October 17, 2018

MINNESOTA BOARD OF PHARMACY

By: _____
STUART WILLIAMS (Board President)