



Phone: (785) 296-4056 Fax: (785) 296-8420 pharmacy@ks.gov www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

January 22, 2024

The Honorable Ty Masterson President of the Senate Capitol Building, Room 332-E Topeka, Kansas 66612

The Honorable Daniel Hawkins Speaker of the House Capitol Building, Room 368-W Topeka, Kansas 66612

RE: Report on Substances Proposed for Scheduling, Rescheduling or Deletion

Dear Mister President and Mister Speaker:

Pursuant to K.S.A. 65-4102(b), the Kansas State Board of Pharmacy is required to submit to the Speaker of the House of Representatives and the President of the Senate a report on substances proposed by the Board for scheduling, rescheduling or deletion by the legislature with respect to any one of the schedules as set forth in the Kansas Uniform Controlled Substances Act, K.S.A. 65-4101 *et seq*. In its determination, the Board shall consider the following:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the substance;
- (4) The history and current pattern of abuse;
- (5) The scope, duration and significance of abuse;
- (6) The risk to the public health;
- (7) The potential of the substance to produce psychological or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under the Act.

Congress created five schedules or classifications with varying qualifications for a substance to be included in each. The Drug Enforcement Agency ("DEA") and the Food and Drug Administration ("FDA") make recommendations after considering various factors that indicate the drug should have more restrictions.

- Schedule I are those drugs that have a high potential for abuse and have no accepted medical use in treatment in the United States.
- Schedule II substances have a high potential for abuse but have an accepted medical use in the United States or a currently accepted medical use with severe restrictions. Abuse of the drug may lead to severe psychological or physical dependence.
- Schedule III substances have less potential for abuse than drugs in Schedule I or II and they have an accepted medical use in treatment in the United States. Abuse may lead to moderate or low physical dependence or high psychological dependence.

- Schedule IV substances have a low potential for abuse relative to the drugs in Schedule III. The substances have a currently accepted medical use in treatment in the United States. Abuse may lead to limited physical dependence or psychological dependence relative to drugs or substances in Schedule III.
- Schedule V substances have a low potential for abuse relative to the drugs in Schedule IV. The drug or substance has a currently accepted medical use in treatment in the United States. Abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs or substances in Schedule IV.

The Board regularly works with the Kansas Bureau of Investigation (KBI) and conducted a side-by-side comparison of the controlled substances listed in Kansas Schedules I-V to the Federal Controlled Substances list. In addition, deference is given to the information provided by the DEA's Deputy Administrator and Department of Health and Human Services, as reported in the *Federal Register*. Generally, the Board recommends amending the state laws to match the federal laws in order to facilitate uniformity while maintaining and enhancing the consumer protections afforded by the regulatory system.

The Board has identified the need for modifications to the Act. As a result, the Board plans to introduce legislation during the 2024 session. Please note that the Board has emergency scheduling authority for any new substance which may emerge outside the legislative session in order to ensure ongoing protection of the public, which it exercised twice during 2023 for the drugs flubromazolam and clonazolam.

The Board has identified the following federal changes since January 2022 which should be implemented in Kansas:

- Add to KSA 65-4105 (Schedule I)
 - o Section (b)
 - https://www.federalregister.gov/documents/2021/03/18/2021-05589/schedules-of-controlled-substances-placement-of-four-specific-fentanyl-related-substances-in
 - Fentanyl carbamate (ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate) 9851
 - ortho-Fluoroacryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide) 9852
 - ortho-Fluoroisobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) 9853
 - para-Fluoro furanyl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide) 9854
 - https://www.federalregister.gov/documents/2022/11/21/2022-25206/schedules-of-controlled-substances-placement-of-zipeprol-in-schedule-i
 - Zipeprol (1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol) 9873
 - <a href="https://www.federalregister.gov/documents/2021/04/27/2021-08720/schedules-of-controlled-substances-placement-of-10-specific-fentanyl-related-substances-in-schedule-controlled-substances-in-schedule-c
 - beta-Methyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propionamide; also known as β-methyl fentanyl) 9856
 - beta'-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N, 3-diphenylpropanamide; also known as β'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) 9842
 - 2'-Fluoro ortho-fluorofentanyl (N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide; also known as 2'-fluoro 2-fluorofentanyl) 9855

- 4'-Methyl acetyl fentanyl (N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide) 9819
- ortho-Fluorobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide; also known as 2-fluorobutyryl fentanyl) 9846
- ortho-Methyl acetylfentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl acetylfentanyl) 9848
- ortho-Methyl methoxyacetyl fentanyl (2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl methoxyacetyl fentanyl) 9820
- para-Methylfentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide; also known as 4-methylfentanyl) 9817
- Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide; also known as benzoyl fentanyl) 9841
- Thiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide; also known as 2-thiofuranyl fentanyl; thiophene fentanyl) 9839
- https://www.federalregister.gov/documents/2023/08/18/2023-17778/schedules-of-controlled-substances-placement-of-metonitazene-in-schedule-i
 - Metonitazene (N,N-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine) 9757
- https://www.federalregister.gov/documents/2023/12/07/2023-26694/schedules-of-controlled-substances-placement-of-nine-specific-fentanyl-related-substances-in?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federal_register.gov
 - alpha'-Methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide) 9864
 - 2',5'-Dimethoxyfentanyl (N-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-N-phenylpropionamide) 9861
 - 3-Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-3-carboxamide) 9860
 - Isovaleryl fentanyl (3-methyl- N -(1-phenethylpiperidin-4-yl)- N-phenylbutanamide) 9862
 - meta -Fluorofentanyl (N -(3-fluorophenyl)- N -(1-phenethylpiperidin-4-yl)propionamide) 9857
 - meta -Fluoroisobutyryl fentanyl (N -(3-fluorophenyl)-N -(1-phenethylpiperidin-4-yl)isobutyramide) 9858
 - ortho -Fluorofuranyl fentanyl (N -(2-fluorophenyl)- N -(1-phenethylpiperidin-4-yl)furan-2-carboxamide) 9863
 - para -Methoxyfuranyl fentanyl (N -(4-methoxyphenyl)-N -(1-phenethylpiperidin-4-yl)furan-2-carboxamide 9859
 - para -Methylcyclopropyl fentanyl (N -(4-methylphenyl)-N -(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide) 9865
- o Section (d)
 - 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE) 7286
 - https://www.federalregister.gov/documents/2021/12/07/2021-26293/schedules-of-controlled-substances-placement-of-methoxetamine-mxe-in-schedule-i

- 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: paramethoxymethamphetamine, PMMA) 1245
 - https://www.federalregister.gov/documents/2021/06/25/2021-13460/schedules-of-controlled-substances-placement-of-para-methoxymethamphetamine-pmma-in-schedule-i
- o Section (e)
 - <a href="https://www.federalregister.gov/documents/2023/07/26/2023-15748/schedules-of-controlled-substances-temporary-placement-of-etizolam-flualprazolam-clonazolam-clonazolam-clonazolam-controlled-substances-temporary-placement-of-etizolam-flualprazolam-clonazo
 - 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flualprazolam) 2785
 - 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: clonazolam) 2786
 - 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flubromazolam) 2788
 - 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one, its salts, isomers, and salts of isomers (Other name: diclazepam) 2789
- o Section (f)
 - Methiopropamine (N-methyl-1-(thiophen-2-yl)propan-2-amine) 1478
 - https://www.federalregister.gov/documents/2021/09/02/2021-18843/schedules-of-controlled-substances-placement-of-methiopropamine-in-schedule-i
 - 4,4'-Dimethylaminorex (4,4'-DMAR; 4,5-dihydro-4-methyl-5-(4-methylphenyl)-2-oxazolamine; 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine) 1595
 - https://www.federalregister.gov/documents/2021/08/12/2021-17052/schedules-of-controlled-substances-placement-of-44-dmar-in-schedule-i
 - Amineptine (7-[(10,11-dihydro-5 H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid)
 1219
 - https://www.federalregister.gov/documents/2021/07/22/2021-15331/schedules-of-controlled-substances-placement-of-amineptine-in-schedule-i
 - Mesocarb (N-phenyl-N '-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate) 1227
 - https://www.federalregister.gov/documents/2022/11/22/2022-25219/schedules-of-controlled-substances-placement-of-mesocarb-in-schedule-i
- KSA 65-4111 (Schedule IV)
 - Add to Section (b)
 - Daridorexant 2410
 - https://www.federalregister.gov/documents/2022/09/30/2022-21253/schedules-of-controlled-substances-placement-of-daridorexant-in-schedule-iv
 - o Remove from Section (c)
 - Fenfluramine 1670
 - https://www.federalregister.gov/documents/2022/12/23/2022-27400/schedules-of-controlled-substances-removal-of-fenfluramine-from-control
 - o Add to Section (e)
 - Serdexmethylphenidate 1729

- https://www.federalregister.gov/documents/2021/05/07/2021-09738/schedules-of-controlled-substances-placement-of-serdexmethylphenidate-in-schedule-iv
- Add to KSA 65-4113 (Schedule V)
 - o Section (f)
 - Ganaxolone 2401
 - https://www.federalregister.gov/documents/2022/11/09/2022-24157/schedules-of-controlled-substances-placement-of-ganaxolone-in-schedule-v

In addition, the Board recommends amending K.S.A. 65-4107(b)(1) as follows:

Opium and opiate and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, <u>thebaine-derived butorphanol</u>, <u>dextrorphan</u>, nalbuphine, <u>naldemedine</u>, nalmefene, <u>naloxegol</u>, naloxone, 6β -naltrexol <u>and</u>, naltrexone, <u>and samidorphen</u>, and their respective salts, but including the following:

The 2023 Legislature also passed SB 174, which made updates to K.S.A. 21-5701 by defining "fentanyl-related controlled substances" in subsection (g). The Board and KBI recommend updating this section with all fentanyl substances recommended for addition in K.S.A. 65-4105(b), above.

Please feel free to contact me with any questions or concerns.

Respectfully,

Alexandra Blasi, JD, MBA Executive Secretary

alexatein

cc:

Robert Jacobs, Executive Officer Kansas Bureau of Investigation

Rep. Brenda Landwehr, Chair Committee on Health and Human Services

Sen. Beverly Gossage, Chair Committee on Public Health and Welfare