

INSPECTIONS, APPEALS, AND LICENSING DEPARTMENT[481]

Regulatory Analysis

Notice of Intended Action to be published: 481—Chapter 553
“Controlled and Precursor Substances”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124.201
State or federal law(s) implemented by the rulemaking: Iowa Code section 124.201

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

October 20, 2026
10 a.m.

6200 Park Avenue, Suite 100
Des Moines, Iowa

Virtual participation for the public hearing will be available on the Department of Inspections, Appeals, and Licensing website.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis, which must be received by the Board of Pharmacy no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

The purpose of this proposed rulemaking is to add 20 substances to Schedule I, one substance to Schedule IV, and three substances to the list of precursor substances in the Iowa controlled substances Act (CSA) in response to similar scheduling action taken by the federal Drug Enforcement Administration. This proposed rulemaking would temporarily add marijuana and delta-9-tetrahydrocannabinols, which are components of an FDA-approved product or subject to the State’s medical cannabidiol Act, to Schedule III of the Iowa CSA in response to similar action by the federal Drug Enforcement Administration.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

• Classes of persons that will bear the costs of the proposed rulemaking:

For Schedule I substances, law enforcement and the Department of Public Safety will bear the cost of enforcement to ensure these illicit substances are removed from the public to prevent public harm from exposure. For precursor substances, entities that engage in the utilization of these substances will bear the cost of the reporting requirements of such substances.

• Classes of persons that will benefit from the proposed rulemaking:

For Schedule I substances, Iowa residents will benefit from the removal of these illicit substances or prosecution for the distribution of these illicit substances. For precursor substances, Iowa residents will benefit from the removal of these substances for illicit purposes.

Iowa residents who currently hold medical cannabidiol program certifications will benefit due to the deregulation of medical cannabis products from federal Schedule I to Schedule III, recognizing the approved medical use and relieving the threat of federal law enforcement action for legitimate use.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- **Quantitative description of impact:**

The quantitative impact is variable and unknown but is likely to be minimal as all entities impacted would already have processes and systems in place to comply with State and federal laws and regulations relating to the handling of controlled substances.

- **Qualitative description of impact:**

The qualitative impact is on public health and safety. The addition of illicit substances that have no medicinal value and are likely to be addictive allows law enforcement and the Department of Public Safety to remove such substances from the public and prevent exposure and likely harm from such exposure.

3. Costs to the State:

- **Implementation and enforcement costs borne by the agency or any other agency:**

The cost of implementation and enforcement by this Board or the Department of Public Safety is negligible as no new processes are needed.

- **Anticipated effect on State revenues:**

There is minimal anticipated impact to State revenues by way of Iowa CSA registration application fees from State-licensed medical cannabidiol manufacturers and dispensers.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

As noted above, the costs are negligible, but the cost of inaction would likely increase exposure and result in public harm from illicit substances.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

There are no identified methods that are less costly or less intrusive.

6. Alternative methods considered by the agency:

- **Description of any alternative methods that were seriously considered by the agency:**

There were no alternative methods identified.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

As noted above, the cost and impact of the addition of substances does not outweigh the benefit to the public or the likely harm to public health and safety from inaction.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.

- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.

- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.

- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

While not specifically identified in this proposed rulemaking, any registrant would be authorized to petition the Board for a waiver of Board rules that are not required by the Iowa Code (in accordance with 481—Chapter 6). This opportunity is available to any business entity regardless of its size. A petition for waiver of one or more Board rules would include information that would demonstrate how the petitioner would continue to protect the public by alternate means if the rule is waived, in whole or in part.

Text of Proposed Rulemaking

ITEM 1. Rescind rule 481—553.13(124,124B) and adopt the following **new** rule in lieu thereof:

481—553.13(124,124B) Temporary designation of controlled and precursor substances.

553.13(1) For cannabis-derived products, the board will modify the schedule of controlled substances in accordance with Iowa Code section 124.201A.

553.13(2) Amend Iowa Code section 124.204(4) by adding the following new paragraph:

cr. 1-(4-chlorophenyl)-2-(methylamino)propan-1-one. Other names: 4—CMC, 4-Chloromethcathinone.

cs. 3-methoxyphencyclidine. Other names: 1-(1-(3-methoxyphenyl)cyclohexyl)piperidine; 3-MeO—PCP.

553.13(3) Amend Iowa Code section 124.204(9) by adding the following new paragraphs:

y. 2-(2-((2,3-dihydrobenzofuran-5-yl)methyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers. Other name: Ethyleneoxynitazene.

z. 2-(2-(benzodioxol-5-ylmethyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers. Other names: Methylenedioxyntazene; 3',4'-methylenedioxyntazene.

aa. 2-(2-(4-ethoxybenzyl)-5-methyl-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers. Other name: 5-methyl etodesnitazene.

ab. 2-(2-(4-ethoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N-ethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers. Other name: N-desethyl etonitazene.

ac. N-ethyl-2-(5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers. Other name: N-desethyl protonitazene.

ad. 2-(2-(4-ethoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-dimethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers. Other name: N,N-dimethylamino etonitazene.

ae. 2-(4-isopropoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers. Other name: N-pyrrolidino isotonitazene.

af. 8-bromo-1-methyl-6-phenyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine, its salts, isomers, and salts of isomers. Other name: bromazolam.

ag. 2-Fluorodeschloroketamine, its salts, isomers, and salts of isomers. Other names: 2-(2-fluorophenyl)-2-(methylamino)cyclohexan-1-one, 2-FDCK.

ah. O-Desmethyltramadol. Other names: O-DSMT; desmetramadol; 3-[(1R,2R)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol.

ai. Methyl (E)-2-((1'S,6'S,7'S)-6'-ethyl-4-methoxy-3-oxo-3',5',6',7',8',8a'-hexahydro-2'H-spiro[indoline-2,1'-indolizine]-7'-yl)-3-methoxyacrylate including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts

is possible. Other name: mitragynine pseudoindoxyl. Since nomenclature of this substance is not internationally standardized, compounds of this structure, regardless of numerical designation of atomic positions, are covered.

aj. Methyl (E)-2-((2S,3S,7aS,12aR,12bS)-3-ethyl-7a-hydroxy-8-methoxy-1,2,3,4,6,7,7a,12,12a,12b-decahydroindolo[2,3-a]quinolizin-2-yl)-3-methoxyacrylate including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible. Other names: MGM—15; dihydro-7-hydroxymitragynine. Since nomenclature of this substance is not internationally standardized, compounds of this structure, regardless of numerical designation of atomic positions, are covered.

ak. Methyl (E)-2-((2S,3S,7aS,12aR,12bS)-3-ethyl-9-fluoro-7a-hydroxy-8-methoxy-1,2,3,4,6,7,7a,12,12a,12b-decahydroindolo[2,3-a]quinolizin-2-yl)-3-methoxyacrylate including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible. Other names: MGM—16; 9-fluoro-dihydro-7-hydroxymitragynine; 10-fluoro-dihydro-7-hydroxymitragynine (depending on numbering convention). Since nomenclature of this substance is not internationally standardized, compounds of this structure, regardless of numerical designation of atomic positions, are covered.

al. 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-5,6-dichloro-1,3-dihydro-2H-benzo[d]imidazol-2-one, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers. Other names: 5,6-dichloro bromphine; SR—14968.

am. 5,6-dichloro-1-(1-(4-chlorobenzyl)piperidin-4-yl)-1,3-dihydro-2H-benzo[d]imidazol-2-one, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers. Other names: 5,6-dichloro desmethylchlorphine; SR—17018.

an. 3-(3-(1-(1-(4-chlorophenyl)ethyl)piperidin-4-yl)-2-oxo-2,3-dihydro-1H-benzo[d]imidazol-1-yl)propanenitrile, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers. Other names: N-propionitrile chlorphine; cychlorphine.

ao. 8-(1-(4-chlorophenyl)ethyl)-1-phenyl-1,3,8-triazaspiro[4.5]decan-4-one, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers. Other names: spirochlorphine; R—6890.

553.13(4) Amend Iowa Code section 124B.2(1) by adding the following new paragraphs:

ak. 1-boc-4-piperidone (tert-butyl 4-oxopiperidine-1-carboxylate) and its salts.

al. Propionyl chloride.

am. P2P methyl glycidic acid (2-methyl-3-phenyloxirane-2-carboxylic acid; BMK glycidic acid) and its esters, its optical and geometric isomers, its salts, salts of its optical and geometric isomers and its esters, and any combination thereof, whenever the existence of such is possible, including the following:

(i) Methyl ester of P2P methyl glycidic acid (methyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P methyl glycidate; BMK methyl glycidate).

(ii) Ethyl ester of P2P methyl glycidic acid (ethyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P ethyl glycidate; BMK ethyl glycidate).

(iii) Propyl ester of P2P methyl glycidic acid (propyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P propyl glycidate; BMK propyl glycidate).

(iv) Isopropyl ester of P2P methyl glycidic acid (isopropyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P isopropyl glycidate; BMK isopropyl glycidate).

(v) Butyl ester of P2P methyl glycidic acid (butyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P butyl glycidate; BMK butyl glycidate).

(vi) Isobutyl ester of P2P methyl glycidic acid (isobutyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P isobutyl glycidate; BMK isobutyl glycidate).

(vii) sec-Butyl ester of P2P methyl glycidic acid (sec-butyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P sec-butyl glycidate; BMK sec-butyl glycidate).

(viii) tert-Butyl ester of P2P methyl glycidic acid (tert-butyl 2-methyl-3-phenyloxirane-2-carboxylate; P2P tert-butyl glycidate; BMK tert-butyl glycidate).

553.13(5) Amend Iowa Code section 124.204(6) by adding the following new paragraph:

n. 1-(4-fluorophenyl)propan-2-amine. Other names: para-fluoroamphetamine, 4—FA, 4-Fluoroamphetamine.

553.13(6) Amend Iowa Code section 124.208(9) by adding the following new paragraphs:

c. Marijuana, as defined in Iowa Code section 124.101(20), in a U.S. Food and Drug Administration-approved product or subject to a state medical marijuana license in accordance with Iowa Code chapter 124E.

d. Marijuana extract, as defined in 21 CFR 1308.11(d), in a U.S. Food and Drug Administration-approved product or subject to a state medical marijuana license in accordance with Iowa Code chapter 124E.

e. Naturally derived delta-9-tetrahydrocannabinols in a U.S. Food and Drug Administration-approved product or in marijuana subject to a state medical marijuana license in accordance with Iowa Code chapter 124E.

(1) Naturally derived delta-9-tetrahydrocannabinols means those delta-9-tetrahydrocannabinols, except as in paragraphs 553.13(6) “*c*” and “*d*,” that are naturally contained in a plant of the genus *Cannabis* (cannabis plant).

(2) Naturally derived delta-9-tetrahydrocannabinols do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. §1639o.

(3) Naturally derived delta-9-tetrahydrocannabinols do not include any delta-9-tetrahydrocannabinols contained in substances excluded from the definition of marijuana as set forth in Iowa Code section 124.101(20).

553.13(7) Amend Iowa Code section 124.210(3) by adding the following new paragraph:

bi. Cipepofol.