PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 10, "Controlled Substances," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 124.201.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 124.201.

Purpose and Summary

The proposed amendments temporarily amend Iowa Code to add 15 substances to schedule I (brorphine, a synthetic opioid, and 14 fentanyl-related substances) and specifically exclude one substance from schedule II (samidorphan, an opioid receptor antagonist) of the Iowa Controlled Substances Act, conforming with scheduling action taken by the federal Drug Enforcement Administration.

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on , 2021. Comments should be directed to:

Sue Mears, RPh

Board of Pharmacy

400 SW 8th Street, Suite E

Des Moines, IA 50309

Sue.mears@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1) "b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Rescind rule 657—10.39(124) and adopt the following <u>new</u> rule in lieu thereof:

657—10.39(124) Temporary designation of controlled substances.

- **10.39** (1) Amend Iowa Code section 124.204(2) by adding the following new paragraphs:
- *bt. N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide. Other name: *beta*-methyl fentanyl.
- *bu. N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide. Other names: *beta*-phenyl fentanyl, 3-phenylpropanoyl fentanyl.
- *bv. N*-(1-(2-flourophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide. Other name: 2'-Fluoro *ortho*-fluorofentanyl, 2'-fluoro 2-fluorofentanyl.
- *bw. N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide. Other name: 4'-Methyl acetyl fentanyl.
- *bx. N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide. Other names: *ortho*-Fluorbutyryl fentanyl, 2-fluorobutyryl fentanyl.
- *by.* N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide. Other names: *ortho*-Methyl acetylfentanyl, 2-methyl acetylfentanyl.
- *bz.* 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide. Other names: *ortho*-Methyl methoxyacetyl fentanyl, 2-methyl methoxyacetyl fentanyl.
- *ca. N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide. Other names: *para*-Methylfentanyl, 4-methylfentanyl.

- *cb. N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide. Other names: Phenyl fentanyl, benzoyl fentanyl.
- *cc. N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide. Other names: Thiofuranyl fentanyl, 2-thiofuranyl fentanyl, thiophene fentanyl.
 - cd. Ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate. Other name: fentanyl carbamate.
- ce. N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide. Other name: ortho-Fluoroacryl fentanyl.
- *cf. N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide. Other name: *ortho*-Fluoroisobutyryl fentanyl.
- $cg.\ N$ -(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide. Other name: para-Fluoro furanyl fentanyl.
 - **10.39 (2)** Amend Iowa Code section 124.204(9) by adding the following new paragraph:
- *y*. 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2*H*-benzo[*d*]imidazole-2-one. Other names: brorphine, 1-[1-[1-(4-bromophenyl)ethyl]-4-piperidinyl]-1,3-dihydro-2*H*-benzimidaol-2-one.
- **10.39(3)** Amend Iowa Code section 124.206(2), paragraph a, by rescinding and replacing the introductory text as follows:
- a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6beta-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following: