PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 10, "Controlled Substances," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted 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 amendments temporarily amend the 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.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on June 16, 2021, as **ARC 5705C**. The Board received one comment from the Iowa Pharmacy Association in support of the amendments. The amendments are identical to those published for notice.

Adoption of Rule Making

This rule making was adopted by the Board on , 2021.

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.

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).

Effective Date

This rule making will become effective on , 2021.

The following rule-making action is adopted:

Rescind rule 657—10.39(124) and adopt the following **new** 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-2H-benzo[d]imidazole-2-one. Other names: brorphine, 1-[1-[1-(4-bromophenyl)ethyl]-4-piperidinyl]-1,3-dihydro-2H-benzimidaol-2-one.
- **10.39(3)** Amend Iowa Code section 124.206(2) "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: