

## PHARMACY BOARD [657]

### Adopted and Filed

The Board of Pharmacy hereby amends Chapter 10, “Controlled Substances,” and Chapter 12, “Precursor Substances,” Iowa Administrative Code.

#### *Legal Authority for Rule Making*

This rule making is adopted under the authority provided in Iowa Code sections 124.201 and 124B.2 and 2020 Iowa Acts, Senate File 2119.

#### *State or Federal Law Implemented*

This rule making implements, in whole or in part, Iowa Code sections 124.201 and 124B.2 and 2020 Iowa Acts, Senate Files 2119 and 2357.

#### *Purpose and Summary*

The amendments:

- Temporarily place into the Iowa Controlled Substances Act five substances (one fentanyl precursor into Schedule II, an FDA-approved treatment for insomnia into Schedule IV, an FDA-approved treatment for seizures into Schedule V, and two chemicals used in the manufacturer of illicit fentanyl as precursor substances),
- Remove the names of prior substances temporarily scheduled by rule in response to the permanent scheduling of those substances by 2020 Iowa Acts, Senate File 2119,
- Amend subrule 10.38(3) to incorporate updated language from 2020 Iowa Acts, Senate File 2119, and
- Rescind paragraph 10.30(2)“g” in response to 2020 Iowa Acts, Senate File 2357, section 1, which removes the requirement that the name of a supervising physician be included on a prescription issued by a physician assistant.

#### *Public Comment and Changes to Rule Making*

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 26, 2020, as **ARC 5155C**. The Board received no public comments and the amendments are identical to those noticed.

#### *Adoption of Rule Making*

This rule making was adopted by the Board on \_\_\_\_\_, 2020.

*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 \_\_\_\_\_, 2020.

The following rule-making action is adopted:

ITEM 1. Rescind paragraph **10.30(2)“g.”**

ITEM 2. Amend subrule 10.38(3) as follows:

**10.38(3)** ~~*Cannabidiol investigational product*~~ *Cannabis-derived products*. If a ~~cannabidiol~~ ~~investigational~~ cannabis-derived product or investigational product approved as a prescription drug medication by the United States Food and Drug Administration is added to, eliminated from or revised in the federal schedule of controlled substances by the DEA and notice of the addition, elimination or revision is given to the board, the board shall similarly add, eliminate or revise the prescription drug medication in the schedule of controlled substances. Such action by the board shall be immediately effective upon the date of publication of the final regulation containing the addition, elimination or revision in the Federal Register.

ITEM 3. 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 124.206(6) “c” to read as follows:

*c.* Immediate precursors to fentanyl:

- (1) 4-anilino-N-phenthyl-4-piperidine (ANPP).
- (2) N-phenyl-N-(piperidin-4-yl)propionamide (norfentanyl).

**10.39(2)** Amend Iowa Code section 124.210(3) by adding the following new paragraph:

*be.* Lemborexant.

**10.39(3)** Amend Iowa Code section 124.212(5) by adding the following new paragraph:

*e.* [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester. Other name: cenobamate.

ITEM 4. Rescind and reserve rule **657—10.42(124B)**.

ITEM 5. Adopt the following **new** subrules 12.1(1) and 12.1(2):

**12.1(1)** Amend Iowa Code section 124B.2(1) by adding the following new paragraphs:

- a.* N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide (benzylfentanyl) and its salts.
- b.* N-phenylpiperidine-4-amine(4-anilinopiperidine; N-phenyl-4-piperidinamine; 4—AP), its amides, its carbamates, and its salts.

**12.1(2)** Reserved.