

## **PHARMACY BOARD [657]**

### **Notice of Intended Action**

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

#### *Legal Authority for Rule Making*

This rule making is proposed under the authority provided in Iowa Code sections 124.201, 124.201A, as amended by Senate File 2119, and 124B.2.

#### *State or Federal Law Implemented*

This rule making implements, in whole or in part, Iowa Code sections 124.201, 124.201A, as amended by Senate File 2119, 124B.2, and 147.107, subsection 5, as amended by Senate File 2357.

#### *Purpose and Summary*

The proposed amendments:

- Temporary 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 as a result of the substances being permanently scheduled via the passage of Senate File 2119 during the legislative session,
- Amend subrule 10.38(3) to incorporate updated language in Senate File 2119, and
- Rescind 10.30(2), paragraph “g”, in response to Section 1 in Senate File 2357 which removes the requirement that the name of a supervising physician is required to be included on a prescription issued by a physician assistant.

#### *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 \_\_\_\_\_, 2020. Comments should be directed to:

Sue Mears, RPh  
Iowa Board of Pharmacy  
400 SW 8<sup>th</sup> Street, Suite E  
Des Moines, IA 50309

*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:

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) by amending paragraph “c”:

c. Immediate ~~precursor~~ precursors to fentanyl:

(1) 4-anilino-N-phenethyl-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; 2*H*-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alpha*R*)-; carbamic acid (*R*)-(+)-1-(2-chlorophenyl)-2-(2*H*-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.