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 sections 124.201, 124.203 and 124.301.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.203, 124.301 through 124.305, 124.551A, 124.557, and 147.80.

Purpose and Summary

During the 2018 legislative session, changes were made to the Iowa Code that require prescribing practitioners to register for the Iowa Prescription Monitoring Program (PMP) at the same time as they obtain CSA registration, allow the Board to assess a surcharge of up to 25% of a registration fee to be deposited into the PMP fund, and align language relating to disciplinary action against CSA registrants with disciplinary actions against other licensees and registrants. The proposed amendments also:

- Temporarily place into Schedule I of the CSA six substances so scheduled by the federal Drug Enforcement Administration (DEA),
- Adds a late penalty fee for applications for registration modification which are submitted untimely,
- Adds a $15 fee for written verification of a registration,
- Adds a certified paramedic to the list of individuals who may dispose of a controlled substance as a result of administrative waste,
- Provides a correction to a referenced rule,
- Carves out butalbital products from the current list of "Exempted Prescription Products" so that such products are not exempted from the Iowa Controlled Substances Act for purposes of reporting to the PMP, and
- Allows for the disposal of controlled substances of a hospice patient by employees of a qualified hospice program, pursuant to the 2018 enacted SUPPORT Act.

Fiscal Impact

This rule making has unknown fiscal impact to the state of Iowa. While fees are being added for untimely modification applications and written registration verification requests, the board anticipates registrants submitting timely applications and utilizing the board's online verification system which has no associated fee for such verifications. With respect to the surcharge on the registration fee for deposit into the PMP fund, the board has no immediate plan to implement such surcharge due to its receipt of sufficient grant funding to support systems enhancements.

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 _____, 2019. Comments should be directed to:

Sue Mears, RPh

Iowa Board of Pharmacy

400 SW 8th Street, Suite E, Des Moines, Iowa 50309

Email: 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:

ITEM 1. Adopt the following **new** definition of "Prescription Monitoring Program" in rule **657—10.2(124)**:

"*Prescription monitoring program*" or "*PMP*" means the program established pursuant to 657—Chapter 37 for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals.

ITEM 2. Amend rule 657—10.5(124) as follows:

657—10.5(124) Application. Applicants for initial registration, registration renewal pursuant to rule 657—10.6(124), or modifications pursuant to rule 657—10.9(124) shall complete the appropriate application and shall include all required information and attachments. ~~Each registration application shall require submission of a $90 registration fee except as provided in subrule 10.5(3).~~

10.5(1) *Signature requirements.* Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

a. No change.

b. If the applicant is a business, the application and supporting documents shall be signed by the person ultimately responsible for the security and maintenance of controlled substances at the registered location. If the applicant is a pharmacy, the responsible individual shall be the pharmacist in charge, unless the applicant petitions the board for an alternate responsible individual.

10.5(2) ~~*Submission of multiple applications*~~ *Prescribing practitioner PMP registration required.* ~~Any person or business required to obtain more than one registration pursuant to rule 657—10.7(124) or 657—10.8(124) may submit all applications in one package. Each application shall be complete and shall not refer to any accompanying application or any attachment to an accompanying application for required information.~~ A prescribing practitioner, except for a licensed veterinarian, shall register for the PMP at the same time the prescribing practitioner applies for registration.

10.5(3) No change.

10.5(4) *Fees.* Each application shall include a nonrefundable registration fee, except as provided in subrule 10.5(3), of $90 per biennium, which may be prorated to the expiration date of the applicant's underlying professional license or other board license if applicable, and may include a nonrefundable surcharge of not more than twenty-five percent of the registration fee for deposit into the PMP fund.

ITEM 3. Amend rule 657—10.6(124) as follows:

657—10.6(124) Registration renewal. Each registration shall be renewed prior to its ~~biennial~~ expiration. A registrant may renew its registration up to 60 days prior to the registration expiration. The nonrefundable fee for registration renewal shall be $90 per biennium and may include a nonrefundable surcharge of not more than twenty-five percent of the registration fee for deposit into the PMP fund.

10.6(1) *Delinquent registration grace period.* A registration renewal application that is ~~not renewed prior to the first day of the month following expiration~~ submitted after expiration but within 30 days following expiration shall be considered delinquent and shall require the nonrefundable payment of the renewal fee plus a nonrefundable penalty fee of $90 and may require submission of a surcharge of not more than twenty-five percent of the applicable fees for deposit into the PMP fund. ~~Failure to renew a registration prior to the first day of the month following expiration, but when submitting a completed renewal application within the 30 days following expiration, shall require payment of the renewal fee and a penalty fee of $90.~~ A registrant that submits a completed registration renewal application, nonrefundable application fee, and nonrefundable penalty fee within 30 days following expiration shall not be subject to disciplinary action for continuing to operate in the 30 days following expiration.

10.6(2) *Delinquent registration reactivation beyond grace period.* If a registration renewal application is not postmarked or hand-delivered to the board office within 30 days following its expiration date, the registrant may not conduct operations that involve controlled substances until the registrant reactivates the registration. A registrant may apply for reactivation by submitting a registration application for reactivation ~~and a $360 fee~~. The nonrefundable fee for reactivation shall be $360 and may include a nonrefundable surcharge of not more than twenty-five percent of the applicable fee for deposit into the PMP fund. As part of the reactivation application, the registrant shall disclose the activities conducted with respect to controlled substances while the

registration was expired. A registrant that continues to conduct activities with respect to controlled substances without an active registration may be subject to disciplinary sanctions.

ITEM 4. Amend rule 657—10.9(124) as follows:

657—10.9(124) Modification or termination of registration. A registered individual or business shall apply to modify a current registration as provided by this rule. When submission of an application and fee is required, such application and fee shall be timely submitted pursuant to rule 657—10.5(124). A registrant which has timely submitted an application for registration modification and fee may continue to service Iowa patients while the registration modification is pending final approval. A registrant which has submitted an application for registration modification after the required date of submission pursuant to this rule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of $90 in addition to the application fee. A registrant which has submitted an application for registration modification 31 days or later following the required date of submission pursuant to this rule shall be assessed a nonrefundable late penalty fee of $360.

10.9(1) *Change of substances authorized.* No change.

10.9(2) Change of address of registered location.

a. Individual practitioner or researcher. No change.

b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the address of the registered location by submitting a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of address.

10.9(3) Change of registrant's name.

a. Individual practitioner or researcher. No change.

b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a

pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the registrant name by submitting a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of registrant's name.

10.9(4) *Change of ownership of registered business entity.* A change of immediate ownership of a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the submission of a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of registrant's ownership.

10.9(5) *Change of responsible individual.* No change.

a. *Individual practitioners and researchers.* No change.

b. ~~*Pharmacies*~~ *Pharmacy*, ~~*and hospitals*~~ *hospital*, *care facility*, *service program*, *manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter*. ~~The responsible pharmacist may execute a power of attorney for DEA order forms to change responsibility under the registration issued to the pharmacy or hospital. The power of attorney shall include the name, address, DEA registration number, and CSA registration number of the registrant. The power of attorney shall identify the current and new responsible individuals and shall authorize the new responsible individual to execute applications and official DEA order forms to requisition Schedule II controlled substances. The power of attorney shall be signed by both individuals, shall be witnessed by two adults, and shall be maintained by the registrant and available for inspection or copying by representatives of the board or other state or federal authorities. The responsible individual may be changed on the CSA registration by submission of a completed application and fee for registration as provided in rule 657—10.5(124).~~ The registrant

shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration within 10 days of the identification of a new responsible individual.

10.9(6) *Termination of registration.* No change.

ITEM 5. Rescind rule 657—10.10(124) and adopt the following **new** rule in lieu thereof:

657—10.10(124) Denial or discipline of registration.

10.10(1) *Grounds for denial or discipline.* The board may deny or discipline any registration upon a finding that the registrant:

a. Has furnished false or fraudulent material information.

b. Has had the registrant's federal registration to manufacture, distribute, or dispense controlled substances suspended, revoked, or otherwise sanctioned.

c. Has been convicted to a public offense under any state or federal law relating to any controlled substance. For the purpose of this rule only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant's appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even though entry of the judgment or sentence has been withheld and the individual has been placed on probation.

d. Has committed such acts as would render the registrant's registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section.

e. Has been subject to discipline by the registrant's respective professional licensing board and the discipline revokes or suspends the registrant's professional license or otherwise disciplines the registrant's professional license in a way that restricts the registrant's authority to handle or prescribe controlled substances. A copy of the record of licensee discipline or a copy of the licensee's surrender of the professional license shall be conclusive evidence.

f. Has failed to obtain or maintain active registration while engaged in activities which require registration.

10.10(2) *Considerations in denial or discipline of registration.* In determining the public interest, the board shall consider all the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

b. Compliance with applicable state and local law.

c. Any convictions of the applicant under any federal and state laws relating to any controlled substance.

d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion.

e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.

f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.

g. Any other factors relevant to and consistent with the public health and safety.

h. Failure of a prescribing practitioner, except a licensed veterinarian, to register with the PMP pursuant to subrule 10.5(4).

10.10(3) Proceedings.

a. Prior to denying a registration, the board shall serve upon the applicant a notice of intent to deny the application. An applicant has 30 days to appeal a notice of intent to deny the application. If timely appealed, a notice of hearing shall be issued, initiating a contested case proceeding governed by 657—Chapter 35. Proceedings to refuse renewal of a registration shall not abate the existing registration, which shall remain in effect pending the outcome of the contested case proceeding. A registration may be disciplined in accordance with 657—Chapters 35 and 36.

b. Prior to sanctioning a registration, the board shall serve upon the registrant a notice of hearing and statement of charges. The notice shall contain a statement of the basis therefore and shall call upon the applicant or registrant to appear before an administrative law judge or the board at a time and place not less than 30 days after the date of service of the notice. The notice shall also contain a statement of the legal basis for such hearing and for the denial or sanction of registration and a summary of the matters of fact and law asserted. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing unless the board issues an order of immediate suspension. A registration may be disciplined in accordance with 657—Chapters 35 and 36.

10.10(4) *Disposition of controlled substances.* Upon service of an order of the board suspending or revoking a registration, the registrant shall deliver all affected controlled substances

in the registrant's possession to the board or authorized agent of the board. Upon receiving the affected controlled substances from the registrant, the board or its authorized agent shall place all such substances under seal and retain the sealed controlled substances pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order's becoming final, all such controlled substances may be forfeited to the state.

ITEM 6. Adopt the following **new** rule(s) 657—10.11(124,147,155A):

657—10.11(124,147,155A) Registration verification. The board may require a nonrefundable fee of $15 for completion of a request for written verification of any registration.

ITEM 7. Amend subrule 10.22(2) as follows:

10.22(2) *Waste resulting from administration or compounding.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient from a registrant's stock or emergency supply or resulting from drug compounding operations may be destroyed or otherwise disposed of by the registrant, a certified paramedic, or a pharmacist in witness of one other licensed health care provider or a registered pharmacy technician 18 years of age or older pursuant to this subrule. A written record of the wastage shall be made and maintained by the registrant for a minimum of two years following the wastage. The record shall include the following:

a. through *f.* No change.

ITEM 8. Amend rule 657—10.23(124) as follows:

657—10.23(124) Disposal of previously dispensed controlled substances.

10.23(1) *Registrant disposal.* Except as provided in 657—Chapter 23 for care facilities, a registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient or except as provided in subrule 10.23(2), paragraph "*b*".

10.23(2) *Hospice disposal.*

a. An employee of a hospice program, acting within the scope of employment, may dispose of a controlled substance of a hospice program patient following the death of the patient or the expiration of the controlled substance pursuant to and in compliance with federal law.

b. A physician for a hospice patient may dispose of a patient's controlled substance which is no longer required due to a change in the patient's care plan.

ITEM 9. Amend subrule 10.27(2) as follows:

10.27(2) *Long-term care or terminally ill patient.* A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units as provided by this subrule.

a. through *c.* No change.

d. Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to ~~rule 657—21.4(124,155A)~~ rule 657—21.5(124,155A).

ITEM 10. Adopt the following **new** paragraphs **10.39(2)"ao" to "as"**:

ao. Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate. Other names: NM2201 or CBL2201.

ap. *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide. Other name: 5F-AB-PINACA.

aq. 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide. Other names: 4-CN-CUMYL-BUTINACA, 4-cyano-CUMYL-BUTINACA, 4-CN-CUMYL BINACA, CUMYL-4CN-BINACA, or SGT-78.

ar. Methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate. Other names: MMB-CHMICA or AMB-CHMICA.

as. 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-b]pyridine-3-carboxamide. Other name: 5F-CUMYL-P7AICA.

ITEM 11. Adopt the following **new** subrule **10.39(5)**:

10.39(5) Amend Iowa Code section 124.204(6)"i" by adding the following new subparagraph:

(27) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one. Other names: *N*-ethylpentylone or ephylone.

ITEM 12. Amend rule 657—10.40(124) as follows:

657—10.40(124) Excluded and exempt substances. The Iowa board of pharmacy hereby excludes from all schedules the current list of "Excluded Nonnarcotic Products" identified in Title 21, CFR Part 1308, Section 22~~, and~~. With the exception of listed butalbital products, the board hereby excludes from all schedules the current list of "Exempted Prescription Products" described in Title 21, CFR Part 1308, Section 32. Copies of such lists may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.