ARC 5113C

PHARMACY BOARD[657]

Notice of Intended Action

Proposing rule making related to administrative staff, service animals, equipment requirements, waivers, and a date extension and providing an opportunity for public comment

The Board of Pharmacy hereby proposes to amend Chapter 1, "Purpose and Organization," Chapter 2, "Pharmacist Licenses," Chapter 8, "Universal Practice Standards," Chapter 13, "Telepharmacy Practice," Chapter 16, "Nuclear Pharmacy Practice," Chapter 26, "Petitions for Rule Making," Chapter 34, "Rules for Waivers and Variances," and Chapter 39, "Expanded Practice Standards," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2019 Iowa Acts, House File 766 and Senate File 341, and 2020 Iowa Acts, House File 2627 and House File 2389.

Purpose and Summary

The proposed amendments bring the Board's rules in alignment with Iowa Code changes made during the 2019 and 2020 Legislative Sessions. The subjects of the Code changes include:

- Oversight of the Board's executive director (2019 Iowa Acts, House File 766),
- Service animals or service-animals-in-training (2019 Iowa Acts, Senate File 341),
- Extension of future repeal date for physician-signed immunization protocols (2020 Iowa Acts, House File 2627),
- Waivers and variances (2020 Iowa Acts, House File 2389), and
- Submission of the disposition of a petition for rule making to the Administrative Rules Review Committee (2020 Iowa Acts, House File 2389).

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 written 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 August 18, 2020. Comments should be directed to:

Sue Mears
Board of Pharmacy
400 S.W. 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 actions are proposed:

ITEM 1. Amend rule 657—1.2(17A,147,155A,272C) as follows:

657—1.2(17A,147,155A,272C) Description and organization of board. The board is comprised of five pharmacist members, one certified pharmacy technician member, and two representatives of the general public, all appointed by the governor. An administrative staff headed by a ~~board-appointed~~ public health director-appointed executive director assists board members.

The board's authority for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and devices and of precursor substances in the state of Iowa is found in Iowa Code chapters 124, 124B, 126, 147, 155A, 205, and 272C.

ITEM 2. Amend subrule 2.4(2) as follows:

2.4(2) *Timeliness.* To be eligible for a license by examination, the candidate shall pass all components in Iowa within a period of one year beginning with the date the candidate passed an initial component. A candidate may request waiver ~~or variance~~ from this deadline pursuant to the procedures and requirements of 657—Chapter 34.

ITEM 3. Amend rule 657—2.7(147) as follows:

657—2.7(147) Reexamination applications and fees. A candidate who fails to pass either the NAPLEX or the MPJE, Iowa Edition, once shall be allowed to schedule a time to retake the examination as provided in this rule. To ensure the integrity of the examinations, no waiver ~~or variance~~ of the specified waiting period between reexaminations will be granted.

2.7(1) to **2.7(4)** No change.

ITEM 4. Amend subrule 8.5(5) as follows:

8.5(5) *Orderly and clean.* The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition and maintained in a sanitary manner. Animals shall not be allowed within a licensed pharmacy unless that pharmacy is exclusively providing services for the treatment of animals or unless the animal is a service ~~dog or assistive~~ animal or service-animal-in-training as defined in Iowa Code ~~subsection 216C.11(1)~~ section 216C.1A.

ITEM 5. Amend subrule 13.16(8) as follows:

13.16(8) *Request for distance waiver.* The board shall consider a request for waiver of the distance requirement between the proposed telepharmacy site and the nearest currently licensed pharmacy that

dispenses prescription drugs to outpatients if the petitioner can demonstrate to the board that the proposed telepharmacy site is located in an area where there is limited access to pharmacy services and that there exist compelling circumstances that justify waiving the distance requirement.

a. The request for waiver shall be prepared and shall include the elements of a request for waiver ~~or variance~~ identified in 657—Chapter 34.

b. to *d.* No change.

ITEM 6. Amend rule 657—16.6(155A) as follows:

657—16.6(155A) Minimum equipment requirements. Each nuclear pharmacy shall maintain the following equipment for use in the provision of radiopharmaceutical services:

1. to 7. No change.

A pharmacy may request waiver ~~or variance~~ from a provision of this rule pursuant to the procedures and requirements of 657—Chapter 34.

ITEM 7. Amend rule 657—26.4(17A) as follows:

657—26.4(17A) Board consideration.

26.4(1) *Initial activities.* Within 14 days after the filing of a petition, the board shall submit a copy of the petition and any accompanying brief to the administrative rules coordinator and to the administrative rules review committee (ARRC). Upon request by the petitioner ~~in the petition~~, the board shall schedule a brief and informal meeting between the petitioner and the board, a member of the board, or a member of ~~the~~ board staff ~~of the board~~ to discuss the petition. The board may request that the petitioner submit additional information or argument concerning the petition. The board may also solicit comments from any person on the substance of the petition. Any person may submit to the board comments on the substance of the petition.

26.4(2) *Decision issued.* Within 60 days after the filing of the petition, or within any longer period agreed to by the petitioner, the board shall, in writing, deny the petition, and notify the petitioner and the ARRC of its action and the specific grounds for the denial, or grant the petition and notify the petitioner and the ARRC that it has ~~instituted~~ initiated rule-making proceedings on the subject of the petition. ~~Petitioner~~ The petitioner and the ARRC shall be deemed notified of the denial or grant of the petition on the date when the board mails or delivers the required notification to the petitioner and the ARRC.

26.4(3) No change.

ITEM 8. Amend **657—Chapter 34**, title, as follows:

~~RULES FOR~~ WAIVERS ~~AND VARIANCES~~

ITEM 9. Amend rule 657—34.1(17A) as follows:

657—34.1(17A) Definition. For purposes of this chapter, a "waiver" ~~or "variance"~~ means action by the board which suspends, in whole or in part, the requirements or provisions of a rule as applied to an identified person or business on the basis of the particular circumstances of that person or business. For simplicity, ~~the term "waiver" shall include both a waiver and a variance and~~ the term "person" shall include both a person and a business.

ITEM 10. Amend rule 657—34.4(17A) as follows:

657—34.4(17A) Criteria for waiver ~~or variance~~. In response to a petition for waiver, the board may in its sole discretion issue an order waiving in whole or in part the requirements of a rule if the board finds, based on clear and convincing evidence, all of the following:

1. to 4. No change.

ITEM 11. Amend rule 657—34.12(17A) as follows:

657—34.12(17A) ~~Summary reports~~ Submission of waiver information. ~~The~~ Within 60 days of granting or denying a waiver, the board shall ~~semiannually prepare a summary report identifying~~ make

a submission on the Internet site established pursuant to Iowa Code section 17A.9A for the submission of waiver information. The submission shall identify the rules for which a waiver has been granted or denied, the number of times a waiver was granted or denied for each rule, and a citation to the statutory provisions implemented by these rules. The ~~report~~ submission shall include a general summary of the reasons justifying the board's actions on waiver requests ~~and, if~~. If practicable, the submission shall detail the extent to which the granting of a waiver has established a precedent for additional waivers and the extent to which the granting of a waiver has affected the general applicability of the rule itself. ~~Copies of this report shall be available for public inspection and shall be provided semiannually to the administrative rules coordinator and the administrative rules review committee.~~

ITEM 12. Amend rule 657—39.10(155A) as follows:

657—39.10(155A) Vaccine administration by pharmacists—physician-approved protocol. Through June 30, ~~2020~~ 2021, an authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(1) to **39.10(7)** No change.