PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 3, "Pharmacy Technicians," Chapter 8, "Universal Practice Standards," Chapter 20, "Compounding Practices," 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 sections 155A.6A, as amended by 2021 Iowa Acts, House File 514; 155A.45, as amended by 2021 Iowa Acts, House File 514; 155A.46, as amended by 2021 Iowa Acts, Senate File 296; and 155A.47, as created by House File 514.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.4; 155A.6A, as amended by 2021 Iowa Acts, House File 514; 155A.45, as amended by 2021 Iowa Acts, House File 514; 155A.46, as amended by 2021 Iowa Acts, Senate File 296; 155A.47, as created by 2021 Iowa Acts, House File 514; and 2021 Iowa Acts, Senate File 296.

Purpose and Summary

The proposed amendments implement two bills enacted during the 2021 Legislative session (House File 514 and Senate File 296), specifically:

- Provide for the renewal or reactivation of a technician trainee registrant who was, due to exceptional circumstances, unable to attain national pharmacy technician registration and who seeks an additional year of training or study;
- Require pharmacies which have dispensed compounded human drug products interstate to annually report compounding data to the National Association of Boards of Pharmacy information sharing network to comply with a memorandum of understanding between the board and the federal food and drug administration;
- Update the rules relating to statewide protocols to move the training and education requirements out of administrative rule and into the statewide protocols directly;
- Move and clarify language relating to vaccine and medication administration via patient-specific prescriptions and reporting requirements in the case of serious complications; and
- Update language relating to pilot demonstration research projects.

Fiscal Impact

This rule making is not anticipated to have a fiscal impact to the state of Iowa. While it is anticipated that some technician trainees who have encountered exceptional circumstances which have prevented them from attaining national pharmacy technician certification will seek renewal or reactivation for the trainee registration, it is expected that it will result, at best, in negligible increases in revenue. It is anticipated that approximately 25 technician trainees will seek renewal or reactivation of the trainee registration annually which would be estimated to result in a net increase in board revenue of less than $200.

Jobs Impact

After analysis and review of this rule making, no impact on jobs could be determined. It is anticipated that approximately 25 technician trainees would continue in (or return to) the practice of pharmacy when they otherwise would have had to either leave the practice or register as a pharmacy support person to complete non-technical duties.

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 _____, 2021. Comments should be directed to:

Sue Mears, RPh

400 SW 8th Street, Suite E

Des Moines, IA 50309

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 proposed:

ITEM 1. Amend subrules 3.5(1) and 3.5(2) as follows:

3.5(1) *Pharmacy technician trainee.* A person who is in the process of acquiring national certification as a pharmacy technician shall register with the board as a pharmacy technician trainee pursuant to rule 657—3.9(155A). ~~The registration shall be issued for a period of one year and shall not be renewed.~~

3.5(2) *Certified pharmacy technician.* All applicants for a new pharmacy technician registration except as provided by subrule 3.5(1), and all applicants for renewal of a pharmacy technician registration pursuant to rule 657—3.10(155A), shall provide proof of current national pharmacy technician certification and shall complete the application for certified pharmacy technician registration.

ITEM 2. Amend rule 657—3.9(155A) as follows:

657—3.9(155A) Registration fee and term—technician trainee.

3.9(1) No change.

3.9(2) *Term.* A pharmacy technician trainee registration shall expire ~~on the last day of the registration month~~ 12 months following the date of registration. A pharmacy technician trainee registration ~~shall not~~ may be renewed only as provided in subrules 3.9(3) and 3.9(4).

a. No change.

b. *Expiration of registration.* ~~The~~ Except as provided in subrules 3.9(3) and 3.9(4), the registration of a pharmacy technician trainee who fails to complete national certification prior to the expiration of the registration shall expire and the technician shall cease practice as a pharmacy technician.

3.9(3) *Renewal.* A technician trainee who is unable to complete national certification prior to the expiration of the registration may seek renewal of the registration in exceptional circumstances. To the extent practicable, the trainee should submit an application and

nonrefundable fee of $20 for technician trainee renewal, on forms provided by the board, at least 30 days prior to the expiration of the registration.

3.9(4) *Reactivation*. A technician trainee who was previously registered and left the practice of pharmacy prior to obtaining national certification may seek reactivation of the registration. The individual shall submit an application and nonrefundable fee of $20 for technician trainee reactivation, on forms provided by the board. Pursuant to rule 657—3.3(155A), a technician shall obtain registration prior to commencing employment as a technician trainee in an Iowa pharmacy.

ITEM 3. Rescind and reserve rule **657—8.23(155A)**.

ITEM 4. Adopt the following **new** definition of "*NABP information sharing network*" in rule **657—20.2(124,126,155A)**:

"*NABP information sharing network*" means the information sharing network developed by the National Association of Boards of Pharmacy that collects, assesses, and allows review and sharing of pharmacy compounding information as described in the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products between the board and the United States federal food and drug administration.

ITEM 5. Adopt the following **new** rule 657—20.24(155A):

657—20.24(155A) Annual reporting of interstate distribution of compounded preparations. No later than January 1, 2022 and annually thereafter, each licensed pharmacy located in Iowa that distributed compounded preparations for human use interstate in the previous calendar year shall report compounding data to the NABP information sharing network which may include, but not be limited to:

1. Whether the pharmacy engaged in the following activities during the identified calendar year:

a. Sterile human drug compounding;

b. Non-sterile human drug compounding;

c. Patient-specific compounding; and

d. Non-patient-specific compounding.

2. The number of prescription orders for compounded human drugs sent out from the pharmacy.

3. The number of prescription orders for compounded human drugs dispensed at the pharmacy.

4. The total number of prescription orders for compounded human drugs distributed interstate.

5. The number of prescription orders for sterile compounded human drugs distributed interstate.

6. The names of states into which the pharmacy distributed compounded human drugs during the identified calendar year.

7. Whether compounded human drugs are distributed without patient-specific prescriptions.

ITEM 6. Amend rule 657—39.6(155A) as follows:

657—39.6(155A) Statewide protocols. ~~A~~ To the extent authorized in Iowa Code 155A.46, a pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and available on the board's website at pharmacy.iowa.gov, order and dispense medications pursuant to ~~rules 657—39.8(155A), 657—39.9(155A), and 657—39.11(155A)~~ the requirements identified in the statewide protocols. For the purpose of this rule, the order shall constitute a prescription.

ITEM 7. Rescind rule 657—39.8(155A) and adopt the following **new** rule in lieu thereof:

657—39.8(155A) Medications administered via prescription.

39.8(1) *Vaccine administration.* A pharmacist who is authorized to administer vaccines pursuant to the statewide protocol may administer, including via delegation to authorized pharmacy personnel, any vaccine pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a report to the Vaccine Adverse Event Reporting System (VAERS).

39.8(1) *Medication administration*. A pharmacist may administer, including via delegation to authorized pharmacy personnel if so delegated or authorized by the prescriber, any medication pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the pharmacist shall notify the prescriber who issued the prescription within 24 hours and shall submit a report to the federal food and drug administration Adverse Event Reporting System (FAERS).

ITEM 8. Rescind and reserve rule **657—39.9(155A)**.

ITEM 9. Rescind and reserve rule **657—39.10(155A)**.

ITEM 10. Rescind and reserve rule **657—39.11(155A)**.

ITEM 12. Amend rule 657—39.16(155A) as follows:

657—39.16(155A) Pharmacy pilot or demonstration research projects. The purpose of this rule is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy ~~as authorized by 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128~~. In reviewing projects, the board will consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage to a single applicant or group of applicants.

39.16(1) No change.

39.16(2) *Scope of project.* A project may not expand the definition of the practice of pharmacy. A project may include therapeutic substitution or substitution of medical devices used in patient care if such substitution is included under a collaborative ~~drug therapy management protocol established~~ pharmacy practice agreement pursuant to rule 657—39.13(155A).

39.16(3) to **39.16(6)** No change.