

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 3, “Pharmacy Technicians,” Chapter 8, “Universal Practice Standards,” Chapter 20, “Compounding Practices,” and Chapter 39, “Expanded Practice Standards,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 155A.6A, 155A.45 and 155A.46 and 2021 Iowa Acts, House File 514.

State or Federal Law Implemented

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

Purpose and Summary

The amendments implement legislation enacted during the 2021 Legislative Session (House File 514 and Senate File 296). Specifically, the amendments:

- Provide for the renewal or reactivation of registration of a technician trainee registrant who was, due to exceptional circumstances, unable to attain national pharmacy technician certification and who seeks an additional year of training or study;
- Require pharmacies that 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 United States 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.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 11, 2021, as **ARC 5833C**. The Board received written comments from one pharmacist and the Iowa Pharmacy Association which were both supportive of the amendments. The pharmacist's comment additionally suggested extending the initial technician trainee registration to 18 to 24 months and to explicitly state in the rules that a pharmacist must provide patient counseling prior to vaccine administration. The board declined these suggestions, citing that the vast majority of technicians have demonstrated the ability to achieve national certification with one year and that the board's rules already require pharmacist counseling for all new prescriptions which would inherently include vaccinations. The amendments are identical to those published for notice.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2021.

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 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 nontechnical 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.

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 _____, 2021.

The following rule-making action is adopted:

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(124,155A)**.

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 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.

20.24(1) No later than April 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.

20.24(2) Compounding data may include, but not be limited to:

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

- (1) Sterile human drug compounding;
- (2) Nonsterile human drug compounding;
- (3) Patient-specific compounding; and
- (4) Non-patient-specific compounding.

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

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

- d. The total number of prescription orders for compounded human drugs distributed interstate.
- e. The number of prescription orders for sterile compounded human drugs distributed interstate.
- f. The names of states into which the pharmacy distributed compounded human drugs during the identified calendar year.
- g. 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 section 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(2) 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 United States Food and Drug Administration Adverse Event Reporting System (FAERS).

ITEM 8. Rescind and reserve rules **657—39.9(155A)** to **657—39.11(155A)**.

ITEM 9. 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.