

PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to rescind Chapter 40, “Tech-Check-Tech Programs,” Iowa Administrative Code, and adopt a new Chapter 40 with the same name.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 147.76 and 155A.33A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.6A, 155A.33, and 155A.33A.

Purpose and Summary

During the 2018 legislative session, changes were made to the Iowa Code which amended a program by which a certified pharmacy technician may be authorized to provide the final product verification of a prescription filled by another pharmacy employee. What were formerly known as “tech-check-tech” programs are now “Technician Product Verification” (TPV) programs. The board also completed an overall review of the chapter of administrative rules relating to “tech-check-tech” programs as required by Iowa Code section 17A.7(2) as well as to incorporate the changes made to the Iowa Code to create a new chapter relating to such programs.

The proposed rules:

- Establish the minimum standards for a pharmacy to initiate a TPV program, including a pharmacist to technician ratio and program quality assurance;

- Requirements for a certified pharmacy technician to be authorized to participate in product verification activities;
- Identification of the minimum scanning technology required in a TPV program;
- Requirements for policies and procedures; and
- Requirements for record keeping.

In advance of this Notice, the board provided a draft version of the revised chapter to all pharmacy professionals licensed in Iowa to solicit feedback and comment. The board received approximately 30 comments from pharmacists, technicians, and the Iowa Pharmacy Association, which had conducted a multi-year pilot project to study the safety and outcomes for community-based technician product verification programs. Several comments expressed opposition to such programs while others offered suggestions to ensure the programs would not result in reduced pharmacist staffing. Several comments sought additional clarification for certain terms or topics. All comments were considered and incorporated into this proposed chapter as determined appropriate.

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 can be determined.

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., Compliance Officer

Iowa Board of Pharmacy

400 SW 8th Street

Des Moines, Iowa

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:

Rescind 657—Chapter 40 and adopt the following **new** chapter in lieu thereof:

CHAPTER 40

TECHNOLOGY-ASSISTED TECHNICIAN PRODUCT VERIFICATION PROGRAMS

657—40.1(155A) Purpose and scope. A pharmacy located in Iowa which provides clinical pharmaceutical services may, but shall not be required to, develop and implement a technician

product verification (TPV) program in accordance with these rules. For the purpose of this chapter, clinical pharmaceutical services shall mean services that exceed the minimum requirements of the practice of pharmacy. Clinical pharmaceutical services include, but are not limited to, medication therapy management, collaborative practice, statewide protocols, and immunizations. In a TPV program, certified pharmacy technicians provide technology-assisted final drug product verification during the prescription filling process; the pharmacist shall still be responsible for verification of the accuracy of data entry, drug utilization review, ensuring rational drug therapy, and counseling; and the onsite practice hours for a pharmacist shall not be reduced but shall be redistributed directly to clinical pharmaceutical services to improve patient care and health outcomes.

657—40.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“*Board*” means the board of pharmacy.

“*Certified pharmacy technician*” means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician pursuant to 657—Chapter 3.

“*Checking technician*” means a certified pharmacy technician who has been authorized pursuant to rule 657—40.4(155A) by the responsible pharmacist to provide drug product verification in a TPV program.

“*Representative sample*” means a subset of prescriptions that must be verified by a pharmacist for each checking technician involved in a TPV program. A subset consists of a minimum of one percent of prescriptions verified by each checking technician or 25 prescriptions per checking technician, whichever is greater.

“*Responsible pharmacist*” means the pharmacist designated by the pharmacy or pharmacist in charge to oversee a TPV program and who is responsible for ensuring the TPV program complies with these rules.

“*Technician product verification program*” or “*TPV*” means a program formally established and implemented pursuant to these rules which permits a checking technician to provide technology-assisted drug product verification during the prescription filling process. “TPV” includes programs previously approved by the board as “Tech-check-tech” or “TCT” programs.

657—40.3(155A) TPV program requirements.

40.3(1) *Site-specific.* A TPV program shall be specific to the site at which technician product verification is utilized.

40.3(2) *TPV program oversight.* A pharmacy shall, at all times, have one designated responsible pharmacist who is responsible for meeting TPV program requirements. The responsible pharmacist is not required to be on duty at all times when the TPV program is in use and may designate one or more pharmacists on duty to supervise the activities of checking technicians.

40.3(3) *Checking technician qualifications.* The responsible pharmacist shall ensure a certified pharmacy technician has met the minimum requirements of rule 657—40.4(155A) prior to authorizing the technician to conduct TPV program checking technician activities.

40.3(4) *Staff responsibilities.* Within a TPV program, each pharmacist shall optimize clinical pharmaceutical services and ensure consistent and safe implementation of the program. A pharmacist shall be on site and available to checking technicians during any period when TPV is utilized. Each individual involved in the TPV program shall be responsible for the activities performed by that individual, ensuring the activities adhere to TPV program policies and procedures and board rules.

40.3(5) *Technology required.* The pharmacy's prescription processing system shall have appropriate scanning technology to ensure each product is accurately filled and verified. Scanning technology shall include barcode scanning or superior electronic scanning to verify that the National Drug Code (NDC) of the container of product being used to fill the prescription matches the NDC of the product entered into the pharmacy's prescription processing system to fill the prescription. Only a pharmacist shall be authorized to override a scanning technology error or exception. When scanning technology does not function properly, only a pharmacist shall be authorized to visually verify the product or manually enter the drug product into the pharmacy's prescription processing system. The pharmacy's prescription processing system shall be capable of documenting each step of the dispensing process and identify which pharmacy employee was responsible for each step of the dispensing process.

40.3(6) *Pharmacist to technician ratio.* In any pharmacy which utilizes a TPV program, the ratio of pharmacists to technicians physically present in the pharmacy shall not exceed 1:2 at any time, including when technician product verification is not in use.

40.3(7) Board notification and inspection. Prior to implementing a TPV program, a pharmacy shall provide advance notice to the board, on forms provided by the board, of its intention to implement a TPV program. The board may require an onsite inspection prior to program commencement.

40.3(8) Program discontinuation. A pharmacy shall provide notice to the board when it discontinues a TPV program. A pharmacy intending to implement a previously discontinued TPV program shall provide advance notice to the board, on forms provided by the board, of its intent to implement a TPV program pursuant to subrule 40.3(7).

657—40.4(155A) Checking technician requirements. A certified pharmacy technician shall comply with the requirements of this rule prior to being authorized to engage in checking technician activities in a TPV program. The responsible pharmacist shall ensure the technician is proficient in all aspects of the TPV program and the responsibilities of a checking technician prior to authorizing the technician to engage in technician product verification activities.

40.4(1) Minimum qualifications.

a. National certification. The certified pharmacy technician's national certification as required pursuant to rule 657—3.5(155A) shall be current.

b. Iowa registration. The certified pharmacy technician's registration with the board as required pursuant to rule 657—3.3(155A) shall be current and not currently subject to disciplinary charges or sanctions.

c. Prior experience. The certified pharmacy technician shall have completed a minimum of 2,000 hours as a technician and be trained pursuant to subrule 40.4(2).

40.4(2) Training. Pursuant to the pharmacy's policies and procedures, the technician shall satisfactorily complete a training program prior to being authorized to engage in technician product verification activities. The elements of the pharmacy's training program shall be described in the advance notice provided to the board pursuant to subrule 40.3(7).

657—40.5 and 40.6 Reserved.

657—40.7(155A) Policies and procedures. Policies and procedures shall be developed and adhered to in a TPV program. Policies and procedures for a TPV program shall include, at a minimum, the following:

1. A program to train certified pharmacy technicians to be checking technicians pursuant to subrule 40.4(2), including but not limited to the scanning technology to be utilized in the TPV

program, limitations of the scanning technology, and strategies to compensate for these limitations.

2. A procedure to identify a representative sample to complete a quarterly quality assurance double check of prescriptions verified by each checking technician.

3. Redirection of pharmacist hours to clinical pharmaceutical services.

4. Identification of drug products which authorized checking technicians will be prohibited from performing final drug product verification during the prescription filling process.

657—40.8(155A) TPV program quality assurance.

40.8(1) *Quality assurance program – quarterly verification.* The responsible pharmacist shall establish and implement a quality assurance program to evaluate TPV program activities. Each quarter, a pharmacist shall verify a representative sample of prescriptions verified by each checking technician. The quarterly verification shall be documented and such documentation shall be maintained pursuant to subrule 40.11(2).

40.8(2) *Review of errors.* Any error resulting from technician product verification shall be documented and evaluated via the pharmacy’s CQI program pursuant to rule 657—8.26(155A) and shall require the technician responsible for the error to be retrained through the pharmacy’s established training program.

40.8(3) *Quarterly reports.* The responsible pharmacist shall ensure the completion of a quarterly report on forms provided by the board. The quarterly report shall be maintained in the pharmacy pursuant to subrule 40.11(3).

657—40.9 and **40.10** Reserved.

657—40.11(155A) TPV program records. The records required in this rule, in addition to any other required records of the pharmacy, shall be available for inspection and copying by the board, its authorized agent, or other authorized agency for a minimum of two years following the date of the record.

40.11(1) *Checking technician training and authorization.* TPV program records shall include all records documenting the successful completion of the pharmacy’s training program for each checking technician in the TPV program. The record for each checking technician shall include the following:

1. The name of the technician.

2. The date on which the technician completed the system-specific training for participation in the TPV program.

3. The date on which the technician was authorized to participate in the TPV program.

40.11(2) *Quality assurance program.* TPV program records shall include all records associated with the quality assurance program to evaluate each checking technician in the TPV program, including the dates and results of each quarterly verification; the dates of and reasons for any suspension or revocation of a checking technician's TPV program authorization, identification of corrective action or retraining completed, and the date of the subsequent reinstatement of a checking technician's TPV program authorization; and the dates of and reasons for any disciplinary action taken against a checking technician in connection with the TPV program.

40.11(3) *Quarterly reports.* TPV program records shall include quarterly reports as required pursuant to subrule 40.8(3).

These rules are intended to implement Iowa Code sections 155A.6A, as amended by 2018 Iowa Acts, Senate File 2322; 155A.33, as amended by 2018 Iowa Acts, Senate File 2322; and 2018 Iowa Acts, Senate File 2322, section 5.