

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby rescinds Chapter 40, “Tech-Check-Tech Programs,” and adopts new Chapter 40, “Technology-Assisted Technician Product Verification Programs,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted 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 referred to as “technician product verification” (TPV) programs. The new chapter reflects this change. 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) and incorporated the changes made to the Iowa Code to create a new chapter relating to TPV programs.

The rules:

- Establish the minimum standards for a pharmacy to initiate a TPV program, including a limitation on the number of checking technicians allowed per pharmacist within the prescription filling process and program quality assurance;
- Set requirements for a certified pharmacy technician to be authorized to participate in product verification activities;
- Identify the minimum scanning technology required in a TPV program;
- Set requirements for policies and procedures; and
- Set requirements for record keeping.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 13, 2019, as **ARC 4291C**.

The board received numerous comments for this rule making. Approximately half of the comments received related to the proposed 1:2 pharmacist-to-technician ratio to be utilized at all times in a pharmacy intending to implement a TPV program. Several suggested alternatives were proposed, one of which from the National Association of Chain Drug Stores was acceptable to

the Board. The other half of the comments provided suggestions relating to the training requirements, clarifying language to address TPV programs in institutional settings, and the commenters's overall opinions about TPV programs.

Comments or suggestions that the Board declined to accept:

- Expansion of training elements required for TPV programs;
- Adjustment to the quality assurance program related to “each” checking technician;
- Language to automatically grandfather tech-check-tech programs which previously existed; and
- Requirement that checking technicians wear a name badge with its designation while performing checking functions.

Comments or suggestions that the Board accepted and subsequently made changes:

- Change of phrase “clinical pharmaceutical services” to “clinical pharmacy services;”
- Revision of the pharmacist-to-technician ratio to be no more than three checking technicians per pharmacist within the prescription filling process; and
- Addition of clarifying language to address TPV programs in institutional settings.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2019.

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.

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 _____, 2019.

The following rule-making action is adopted:

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 pharmacy 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 pharmacy services shall mean services that exceed the minimum requirements of the practice of pharmacy. Clinical pharmacy 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 or medication distribution process. The pharmacist shall still be responsible for verification of the accuracy of data entry, drug utilization review, ensuring rational drug therapy, and counseling. The onsite practice hours for a pharmacist shall not be reduced but shall be redistributed directly to clinical pharmacy 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 1 percent of prescriptions verified by each checking technician or 25 prescriptions per checking technician, whichever is greater.

“*Responsible pharmacist*” means the pharmacist who is 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 or medication distribution 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.* Prior to authorizing a technician to conduct TPV program checking technician activities, the responsible pharmacist shall ensure the certified pharmacy technician has met the minimum requirements of rule 657—40.4(155A).

40.3(4) *Staff responsibilities.* Within a TPV program, each pharmacist shall optimize clinical pharmacy 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 or medication order matches the NDC of the product entered into the pharmacy's prescription processing system to fill the prescription or medication order. 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 or medication distribution process and identifying which pharmacy employee was responsible for each step of the dispensing or distribution process.

40.3(6) *Pharmacy responsibility.* Except in an institutional setting, a pharmacy utilizing a TPV program shall ensure that no more than three checking technicians per pharmacist are engaged in TPV activities within the prescription filling process at any time. The pharmacy shall ensure that onsite pharmacist practice hours are not reduced but are redistributed directly to clinical pharmacy services.

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. Prior to authorizing the technician to engage in TPV activities, the responsible pharmacist shall ensure the technician is proficient in all aspects of the TPV program and the responsibilities of a checking technician.

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 TPV 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 training in 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 pharmacy services.

4. Identification of drug products for which authorized checking technicians will be prohibited from performing final drug product verification during the prescription filling or medication distribution 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 TPV shall be documented and evaluated via the pharmacy's continuous quality improvement program (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 another 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:

- a. The name of the technician.
- b. The date on which the technician completed the system-specific training for participation in the TPV program.
- c. 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, 155A.33, and 155A.33A.