ARC 9557B

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 147.76 and 155A.6A, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 3, "Pharmacy Technicians," and to adopt new Chapter 40, "Tech-Check-Tech Programs," Iowa Administrative Code.

The amendments were approved at the April 26, 2011, regular meeting of the Board of Pharmacy.

The proposed amendments authorize the establishment of a tech-check-tech program in a hospital pharmacy or in a general pharmacy providing pharmaceutical services to patients in a residential care facility. The rules define terms utilized within the chapter and establish the requirements for an Iowa pharmacy that proposes to establish a tech-check-tech program. A plan for implementation of a tech-check-tech program shall be submitted to the Board for approval at least 90 days prior to the anticipated implementation of the program, and the plan shall not be implemented before the pharmacist in charge has received notification that the Board has approved the plan. The rules require that any pharmacy technician authorized by the pharmacist in charge to participate in an approved tech-check-tech program be registered with the Board and maintain national certification as a pharmacy technician. Requirements for pharmacy technician training, supervision of participating pharmacy technicians, program and participant evaluations, and record keeping are identified.

Amendments to Chapter 3 establish exceptions to the requirement for the final verification by a pharmacist of the validity of a prescription dispensed by a certified pharmacy technician when the certified pharmacy technician is participating in an approved tech-check-tech program pursuant to Chapter 40.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on July 15, 2011. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 147.107, 155A.6A, and 155A.33.

The following amendments are proposed.

ITEM 1. Amend subrule 3.21(1) as follows:

3.21(1) *Technical dispensing functions.* A pharmacist may delegate technical dispensing functions to an appropriately trained and registered pharmacy technician, but only if the pharmacist is on site and available to supervise the pharmacy technician when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9. ~~The~~ Except as provided for an approved tech-check-tech program pursuant to 657—Chapter 40, the pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. A pharmacy technician shall not delegate technical functions to a pharmacy support person.

ITEM 2. Amend rule 657—3.23(155A) as follows:

657—3.23(155A) Tasks a pharmacy technician shall not perform. A pharmacy technician shall not be authorized to perform any of the following judgmental tasks:

1. ~~Provide~~ Except for a certified pharmacy technician participating in an approved tech-check-tech program pursuant to 657—Chapter 40, provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

2. to 6. No change.

ITEM 3. Adopt the following **new** 657—Chapter 40:

CHAPTER 40
TECH-CHECK-TECH PROGRAMS

657—40.1(155A) Purpose and scope. The board may authorize a hospital pharmacy to participate in a tech-check-tech program. The board may authorize a general pharmacy providing pharmaceutical services to patients in a residential care facility as defined herein to participate in a tech-check-tech (TCT) program. The purpose of the tech-check-tech program is to authorize certified pharmacy technicians to review the work of other certified pharmacy technicians in connection with the filling of floor stock, including automated medication distribution systems (AMDS) and unit dose dispensing systems for institutionalized patients whose orders have previously been reviewed and approved by a licensed pharmacist, for the purpose of redirecting and optimizing pharmacist patient care services.

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

"Automated medication distribution system" or *"AMDS"* includes, but is not limited to, an automated device or series of devices operated by an electronic interface with one or more computers that is used to prepare, package, or dispense specified dosage units of drugs for administration or dispensing to a patient or the ultimate user. "AMDS" includes a device that prepares and packages a drug for unit dose dispensing, that prepares and packages a drug into outpatient prescription vials, and that dispenses prepackaged drugs.

"Board" means the board of pharmacy.

"Certified medication aide" means an individual who has successfully completed a medication aide course approved by the Iowa department of inspections and appeals or who has passed a medication aide challenge examination approved by the Iowa department of inspections and appeals and administered by an area community college. A "certified medication aide" is not a "licensed health care professional" as that term is used herein.

"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 by the pharmacist in charge to participate in a TCT program by checking the work of other certified pharmacy technicians.

"Component" means any single physical or electronic storage or access device that, in combination with other devices, makes up an AMDS.

"Drug bin" means a compartment in an AMDS component that is designed to contain one specific drug.

"Floor stock" means a supply of drugs consisting of emergency drugs and controlled substances that are routinely maintained on patient care units and accessible by nursing staff for patient administration.

"Hospital pharmacy" means a pharmacy licensed by the board pursuant to 657—Chapter 7 and located within a facility which is primarily engaged in providing, by or under the supervision of physicians, concentrated medical and nursing care on a 24-hour basis to inpatients and which maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients and which is registered by the board for controlled substances under Iowa Code chapter 124.

"Medication order" means a written or electronic order from a practitioner or an oral order from a practitioner or the practitioner's authorized agent for administration of a drug or device and, for purposes of this chapter, includes a prescription drug order.

"TCT program" means a board-approved tech-check-tech program implemented and formally established pursuant to these rules by the pharmacist in charge who has determined that one or more certified pharmacy technicians are qualified to safely check the work of other certified pharmacy technicians and thereby provide final verification of drugs which are dispensed for subsequent administration to patients in an institutional setting.

"Unit dose dispensing system" means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from patient care areas, enables the selection and distribution of drugs to be pharmacy-based and controlled, and improves accountability and accuracy.

657—40.3(155A) General requirements. To participate in a TCT program, a hospital pharmacy shall be located in Iowa and provide pharmaceutical services to patients receiving treatment in a hospital located in Iowa; a general pharmacy shall be located in Iowa and provide pharmaceutical services to patients in a long-term care facility located in Iowa.

40.3(1) *Site-specific.* A TCT program shall be specific to the site at which implementation of the program is proposed and shall include a site-specific training program tailored to the patient population and the drug distribution system utilized.

40.3(2) *Plan approval.* At least 90 days prior to anticipated implementation of a TCT program, the pharmacist in charge shall submit the program plan, consistent with the requirements of these rules, for board approval. A pharmacy shall not implement a TCT program prior to receipt of notification that the board has approved the submitted TCT program plan.

40.3(3) *Technician utilization plan.* The pharmacy technician utilization plan shall specifically identify the individual certified pharmacy technicians authorized to participate in the TCT program and shall identify in detail the types of work that the certified pharmacy technicians may perform and check. The pharmacy shall include participation in the TCT program in the defined duties of any certified pharmacy technician authorized to participate in the TCT program, and if the certified pharmacy technician is authorized to check the work of other certified pharmacy technicians, that function shall be clearly identified in the checking technician's duties.

40.3(4) *Certified pharmacy technician participation.* All of the following shall apply to a certified pharmacy technician authorized to participate in a TCT program.

a. National certification. The certified pharmacy technician's national certification shall be current and in good standing.

b. Iowa registration. The certified pharmacy technician's registration with the board shall be current, in good standing, and not currently subject to disciplinary charges or sanctions.

c. Prior experience. The checking technician shall be working at the pharmacy full- or part-time and shall have met the experience requirement for a checking technician as specified in policies and procedures and in the TCT program plan.

d. Training. The certified pharmacy technician shall complete site-specific training in the TCT program and the functions to be performed by the certified pharmacy technician as part of the TCT program.

e. Specialized training for checking technician. A certified pharmacy technician who is a checking technician shall receive specialized and advanced training as provided in policies and procedures, including training in the prevention, identification, and classification of medication errors. The training program for a checking technician shall be didactic in nature and shall include successful completion of a competency test.

40.3(5) *Responsible individual.* The pharmacist in charge may designate one pharmacist to be responsible for meeting TCT program training and validation requirements and may designate one or more pharmacists to supervise the activities of certified pharmacy technicians authorized to participate in the TCT program. A pharmacist supervising TCT program activities shall provide program plan

evaluation information to the responsible pharmacist or the pharmacist in charge for collection and analysis. The pharmacist in charge shall be ultimately responsible for TCT program activities.

40.3(6) *Policies and procedures.* Parameters for supervising the activities of certified pharmacy technicians participating in the TCT program, including but not limited to specialized and advanced training for checking technicians, shall be specified in policies and procedures regarding the utilization of pharmacy technicians. Policies and procedures shall provide for continuous evaluation of certified pharmacy technicians authorized to participate in the TCT program, shall identify benchmarks and sentinel events, shall define an excessive overall error rate, and shall address certified pharmacy technician retraining procedures.

40.3(7) *Staffing.* Pharmacy staffing shall be adequate to ensure consistent and safe implementation of the TCT program and to optimize pharmacist patient care services.

40.3(8) *Pharmacist review.* Except in an emergency, when the pharmacy is closed, or when the prescriber is directly supervising and overseeing the administration of the drug to the patient, a pharmacist shall review all orders against a medication profile as required by rule 657—8.21(155A). A pharmacist shall be on site and available to certified pharmacy technicians during any period that TCT functions are being performed.

40.3(9) *Additional drug check prior to administration.* The drug distribution system shall be structured so that at least one additional check of dispensed drugs, following dispensing and checking by a checking technician, is completed by a licensed health care professional in the facility prior to administration of the drug to the patient. A licensed health care professional or certified medication aide shall administer the drug to the patient. The TCT program plan shall identify the individuals authorized to administer the drug to the patient. The identification of these individuals may consist of a description of the classification of the authorized individuals, such as "registered nurse," "licensed practical nurse," or "certified medication aide," or the identification may specifically identify the authorized individuals by name and title. Alternatively, the identification may reference an existing facility policy or procedure that identifies or specifies the individuals authorized to administer a drug to a patient.

40.3(10) *Program evaluation.* Implementation of a TCT program shall result in the redirection of the pharmacist from distributive tasks to cognitive and patient care activities. As part of an ongoing program review and evaluation as provided in subrule 40.4(5), the pharmacist in charge or designee shall document the specific cognitive and patient care activities, and a summary of the approximate amount of time pharmacists spend on those activities, as a result of implementation of the TCT program. Program review and evaluation records shall be available for inspection and copying by the board or its representatives and any other authorized agencies for two years following the date of the record.

657—40.4(155A) TCT program requirements. A TCT program shall be conducted in compliance with the following requirements.

40.4(1) *Training of checking technician.* No certified pharmacy technician shall be designated or authorized by the pharmacist in charge or responsible pharmacist to perform, nor shall a certified pharmacy technician perform, the function of checking the work of another certified pharmacy technician without having received and satisfactorily completed the specialized and advanced training provided for in the pharmacy's policies and procedures. The specialized training shall include the prevention, identification, and classification of medication errors. Training requirements shall include provisions for retraining of a checking technician who fails to maintain the level of competence necessary for the performance of authorized duties as demonstrated by the technician's failure to satisfactorily meet ongoing evaluation and competency audits.

40.4(2) *Authorized checking functions.* A certified pharmacy technician authorized by the pharmacist in charge or responsible pharmacist to check the work of another certified pharmacy technician may check activities relating to the filling of floor stock, unit dose distribution systems, proprietary bag and vial systems or manufactured premix intravenous products, and AMDS components for hospital and long-term care facility patients. Medication orders shall have previously been reviewed by a licensed pharmacist against the patient's medication profile, and the prepared drugs shall be checked by at least one additional licensed health care professional in the facility at the time the drugs

are administered to a patient. The checking function performed by the checking technician shall be limited to those types of drugs identified in the written TCT program plan, and the TCT program plan shall specifically describe the method for verifying cassette or drug bin fills.

40.4(3) *Certified pharmacy technician evaluation.* The responsible pharmacist shall conduct continuous monitoring and evaluation of each certified pharmacy technician authorized to participate in the TCT program in order to ensure the continued competency of the certified pharmacy technicians and the safety of patients. As a component of the pharmacy's continuous quality improvement program and except as otherwise specifically provided by these rules, errors shall be identified and records maintained as provided in rule 657—8.26(155A).

a. *Periodic review and pharmacist check.* Evaluation shall include periodic review and checking by the pharmacist of work checked by the checking technician and identification and documentation of all errors not identified and corrected by the checking technician.

b. *Review of errors identified by pharmacist or checking technician.* The responsible pharmacist shall review with all certified pharmacy technicians involved any errors identified during the evaluation and shall discuss procedures to ensure the errors are not repeated.

c. *Review of errors identified following release by checking technician.* The responsible pharmacist shall receive, evaluate, and review with all certified pharmacy technicians involved any errors identified by a health care professional, a certified medication aide, a patient, or any other individual following release of a drug by the checking technician.

40.4(4) *Records.* The pharmacist in charge shall maintain in the pharmacy department a record for each certified pharmacy technician authorized by the pharmacist in charge or responsible pharmacist to participate in the TCT program. The record shall be available for inspection and copying by the board or its representatives and any other authorized agencies for two years beyond the term of the certified pharmacy technician's employment. The record shall include:

a. The name of the certified pharmacy technician.

b. The date on which the certified pharmacy technician completed the site-specific training for participation in the TCT program.

c. The date on which the certified pharmacy technician was authorized to participate in the TCT program and the specific TCT program functions and tasks the certified pharmacy technician is authorized to perform.

d. If the certified pharmacy technician is authorized to check the work of other certified pharmacy technicians, the date on which the checking technician completed the specialized and advanced training as provided in policies and procedures.

e. The dates and results of all competency evaluations.

f. The dates of and reasons for any suspension or revocation of the certified pharmacy technician's TCT program authorization, identification of corrective action or retraining completed, and the date of the subsequent reinstatement of the certified pharmacy technician's TCT program authorization.

g. The dates of and reasons for any disciplinary action taken against the certified pharmacy technician in connection with the certified pharmacy technician's performance of duties relating to the TCT program.

40.4(5) *TCT program evaluation.* The pharmacist in charge shall maintain in the pharmacy department program evaluation records that demonstrate the redirection of pharmacist activities from distributive tasks to cognitive and patient care activities. The approximate amount of time each pharmacist spent on specific distributive tasks and on specific cognitive and patient care activities prior to implementation of the TCT program shall be documented in the program evaluation records and shall be maintained for the duration of the TCT program. Program evaluation records shall identify the specific cognitive and patient care activities and a summary of the approximate amount of time pharmacists spend on those activities as a result of implementation of the TCT program. TCT program evaluation records shall be updated at least semiannually and shall be available for inspection and

copying by the board or its representatives and any other authorized agencies for two years following the date of the record.

These rules are intended to implement Iowa Code sections 147.107, 155A.6A, and 155A.33.