Senate Study Bill 1111 - Introduced

SENATE/HOUSE FILE _____
BY (PROPOSED BOARD OF PHARMACY BILL)

A BILL FOR

An Act relating to the practice of pharmacy, and providing for a repeal.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

S.F. _____ H.F. _____

DIVISION I

PHARMACY TECHNICIANS AND PHARMACY SUPPORT PERSONS —— REGISTRATION AND DELEGATION OF FUNCTIONS

Section 1. Section 147.107, subsection 2, paragraph d, Code 2021, is amended to read as follows:

d. A pharmacist who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions only when verification of the accuracy and completeness of the dispensing is determined by the pharmacist in the pharmacist's physical presence. The pharmacist's verification of the accuracy of the prescription drug dispensed shall not be required when verified by a certified pharmacy technician in a technician product verification program ~~or a tech-check-tech program~~ as defined in section 155A.3. The pharmacist's physical presence shall not be required when the pharmacist is remotely supervising pharmacy personnel operating in ~~an approved~~ a licensed telepharmacy site or when utilizing an automated dispensing system that utilizes an internal quality control assurance plan. When utilizing a technician product verification program ~~or tech-check-tech program~~, or when remotely supervising pharmacy personnel operating at ~~an approved~~ a licensed telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan, in accordance with rules adopted by the board of pharmacy, that ensures accuracy for dispensing. Automated dispensing verification, technician product verification, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist and shall be determined in accordance with rules adopted by the board of pharmacy.

Sec. 2. Section 155A.3, Code 2021, is amended by adding the following new subsection:

NEW SUBSECTION. 35A. "*Pharmacy support person*" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who

may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

Sec. 3. Section 155A.3, subsection 46, Code 2021, is amended by striking the subsection.

Sec. 4. Section 155A.6A, subsections 3 and 4, Code 2021, are amended to read as follows:

3. A person who is in the process of acquiring national certification as a pharmacy technician and who is in training to become a pharmacy technician shall register with the board as a pharmacy technician. ~~The registration shall be issued for a period not to exceed one year and shall not be renewable.~~

4. The board shall adopt rules in accordance with chapter 17A on matters pertaining to pharmacy technician registration, application, forms, renewals, fees, termination of registration, ~~tech-check-tech programs,~~ technician product verification programs, national certification, training, and any other relevant matters.

Sec. 5. Section 155A.33, Code 2021, is amended to read as follows:

155A.33 Delegation of ~~technical~~ functions.

A pharmacist may delegate <u>any</u> technical ~~dispensing~~ functions to pharmacy technicians <u>and any nontechnical functions to pharmacy support persons</u>, but only if the pharmacist is ~~physically present~~ <u>available</u> to ~~verify the accuracy and completeness~~ <u>provide professional oversight</u> of the ~~patient's prescription prior to the delivery of the prescription to the patient or the patient's representative~~ <u>delegated functions performed by the pharmacy technician or pharmacy support person</u>. ~~However, the physical presence requirement does not apply when a pharmacist is utilizing an automated dispensing system or a technician product verification program or when a pharmacist is remotely supervising a certified pharmacy technician practicing at a telepharmacy site approved by the board. When using an automated dispensing system or a~~

~~technician product verification program, or when remotely supervising a certified pharmacy technician practicing at an approved telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan that ensures accuracy for dispensing.~~ Verification of automated dispensing, technician product verification, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist and shall be determined in accordance with rules adopted by the board.

DIVISION II

OUTSOURCING FACILITY LICENSE

Sec. 6. Section 155A.13C, subsection 1, Code 2021, is amended by adding the following new paragraph:

NEW PARAGRAPH. *e.* Submit evidence of a satisfactory inspection conducted by the home state regulatory authority or an entity approved by the board in the two-year period immediately preceding the application which demonstrates compliance with current good manufacturing practices. In addition, the applicant shall submit evidence of correction of all deficiencies discovered in such inspections and evidence of compliance with all directives from the home state regulatory authority or entity approved by the board. The board may recover from an outsourcing facility, prior to the issuance of a license or license renewal, the costs associated with conducting an inspection by or on behalf of the board for purposes of satisfying the requirements of this paragraph.

DIVISION III

INFORMATION SHARING

Sec. 7. Section 155A.45, Code 2021, is amended to read as follows:

155A.45 ~~Inspection reports~~ Reports — disclosure.

1. Notwithstanding section 272C.6, subsection 4, paragraph *"a"*, an inspection report in possession of the board, regardless of whether the report is based on a routine inspection or an inspection prompted by one or more complaints, may be disclosed

to the national association of boards of pharmacy's inspection network.

2. Notwithstanding section 272C.6, subsection 4, paragraph "a", any complaints, investigative information, or data collected pertaining to compounded human drug products may be disclosed to the United States food and drug administration, including through the use of an information sharing network, in order to comply with any memorandum of understanding with the United States food and drug administration.

DIVISION IV

PHARMACY PILOT OR DEMONSTRATION RESEARCH PROJECTS

Sec. 8. NEW SECTION. **155A.47 Pilot or demonstration research projects.**

1. Notwithstanding any provision of section 147.107, subsection 2, or section 155A.33 to the contrary, the board may approve a pilot or demonstration research project of innovative applications in the practice of pharmacy to provide enhanced patient care.

2. The board shall adopt rules pursuant to chapter 17A for application for and approval of such projects. The rules may include exceptions to any existing rules under the purview of the board as necessary for completion of the project, limited to the duration of the project. The board may approve a project for no more than eighteen months. The board may extend or renew a project in accordance with board rules. All projects shall comply with the rules adopted for such projects.

3. The board shall not approve any project that expands the practice of pharmacy as defined in section 155A.3.

Sec. 9. REPEAL. 2011 Iowa Acts, chapter 63, section 36, is repealed.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to pharmacy practice.

Division I of the bill eliminates the tech-check-tech

program. The board of pharmacy (board) adopted administrative rules to implement and establish a technician product verification program as authorized by 2018 Iowa Acts, chapter 1142, enacting Code section 155A.33A. Division I eliminates the one-year registration limitation for a person in training to become a pharmacy technician and makes conforming terminology changes. Division I also amends provisions relating to the delegation of technical functions between a pharmacist and a pharmacy technician or pharmacy support person.

Division II of the bill requires a drug compounding outsourcing facility seeking licensure in the state to have been inspected by the facility's home state regulatory authority or other entity approved by the board in the two-year period immediately preceding the application, which inspection demonstrates compliance with federal current good manufacturing practices. Division II also allows the board to recover from an outsourcing facility costs associated with conducting an inspection to satisfy the inspection requirement.

Division III of the bill authorizes the board of pharmacy to share information collected relating to compounded human drug products with the United States food and drug administration (FDA) pursuant to any memorandum of understanding between the board of pharmacy and the FDA.

Division IV of the bill codifies the provisions of 2011 Iowa Acts, chapter 63, section 36, relating to pharmacy pilot or demonstration research projects. The language in Division IV differs from these provisions by eliminating language limiting the projects to those based solely on prescription verification and by eliminating the requirement that the board report the approval or denial of projects to the chairpersons and ranking members of the joint appropriations subcommittee on health and human services.