House Study Bill 533 - 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:

DIVISION I

PHARMACY TECHNICIAN REGISTRATION

Section 1. Section 147.107, subsection 2, paragraph d, Code 2020, 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, subsection 46, Code 2020, is amended by striking the subsection.

Sec. 3. Section 155A.6A, subsections 3 and 4, Code 2020, 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. 4. Section 155A.33, Code 2020, is amended to read as follows:

155A.33 Delegation of technical functions.

A pharmacist may delegate technical dispensing functions to pharmacy technicians, but only if the pharmacist is physically present to verify the accuracy and completeness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative. 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 licensed 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~~ a licensed 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

TELEPHARMACY PRACTICE

Sec. 5. Section 155A.13, subsection 3, Code 2020, is amended

by adding the following new paragraph:

NEW PARAGRAPH. *f.* The board may adopt rules authorizing a pharmacist or a certified pharmacy technician to supervise a pharmacy support person registered pursuant to section 155A.6B and working at a licensed telepharmacy site.

DIVISION III

OUTSOURCING FACILITY LICENSE

Sec. 6. Section 155A.13C, subsection 1, Code 2020, 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 IV

PRESCRIPTION ADAPTATION

Sec. 7. Section 155A.27, Code 2020, is amended by adding the following new subsection:

NEW SUBSECTION. 8. A pharmacist, in exercising the pharmacist's professional judgment and acting in good faith to meet the intent of the prescriber, may adapt a prescription for a substance that is not a controlled substance in compliance with this subsection. A pharmacist who adapts a prescription in compliance with this subsection shall document the adaptation in the patient's record and notify the prescriber of the adaptation.

a. No adaptation without prior consent. A pharmacist shall

not adapt a prescription pursuant to this subsection without prior consent of the prescriber if the prescriber has indicated "no adaptation" on the prescription.

b. Quantity adaptation. A pharmacist may change the quantity of the drug prescribed when deemed appropriate in the professional judgment of the pharmacist including but not limited to in any of the following situations:

(1) The prescribed quantity or package size is not commercially available.

(2) The change in quantity is related to a change in dosage form.

(3) The change in quantity is made to ensure the completion of the prescriber's intended duration of treatment.

(4) The change in quantity is made to extend a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.

c. Dosage form adaptation. A pharmacist may change the dosage form of the drug prescribed if it is in the best interest of patient care, as long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed.

d. Completion of missing information. A pharmacist may complete missing information on a prescription pursuant to this subsection if there is sufficient evidence to support the change.

e. Payment recoupment. A health benefit plan, as defined in section 514J.102, a health carrier, as defined in section 514J.102, and a pharmacy benefits manager, as defined in section 510B.1, shall not recoup payment from a pharmacy following an audit on an otherwise valid prescription based solely on a pharmacist's adaptation of a prescription pursuant to this subsection.

DIVISION V

EMERGENCY DISPENSING

Sec. 8. Section 155A.29, Code 2020, is amended to read as

follows:

155A.29 Prescription refills.

1. Except as specified in subsection 2 or 3, a prescription for any prescription drug or device which is not a controlled substance shall not be filled or refilled more than eighteen months after the date on which the prescription was issued and a prescription which is authorized to be refilled shall not be refilled more than twelve times.

2. A pharmacist may exercise professional judgment by refilling a prescription without prescriber authorization if all of the following are true:

a. The pharmacist is unable to contact the prescriber after reasonable ~~effort~~ efforts.

b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.

c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience that prescriber reauthorization is required.

~~3.~~ *d.* Prescriptions may be refilled once pursuant to this subsection ~~2~~ for a period of time reasonably necessary for the pharmacist to secure prescriber authorization.

3. *a.* In addition to the authorization for a pharmacist to refill a prescription without prescriber authorization pursuant to subsection 2, a pharmacist may exercise professional judgment and refill a prescription for a chronic maintenance drug without prescriber authorization if all of the following are applicable:

(1) The pharmacist is unable, after reasonable efforts, to obtain authorization from the prescriber or another health care provider responsible for the patient's care.

(2) In the pharmacist's professional judgment, the refusal to dispense the refill of the chronic maintenance drug will endanger the patient's life or health or will disrupt an

essential drug therapy for a chronic condition of the patient.

b. The pharmacist may dispense an amount of the chronic maintenance drug not to exceed the amount of the most recent prescription or the standard quantity of the drug dispensed.

c. The pharmacist shall dispense the chronic maintenance drug refill in accordance with standard procedures and documentation requirements adopted by rule of the board.

d. For the purposes of this subsection, "*chronic maintenance drug*" means a drug, other than a controlled substance, that is prescribed to a patient to be taken on a recurring basis, and is used as a life saving rescue drug for a chronic condition or is essential to the continuation of drug therapy for a chronic condition.

4. An authorization to refill a prescription drug order shall be transmitted to a pharmacy by a prescriber or the prescriber's authorized agent pursuant to section 155A.27, except that prescription drug orders for controlled substances shall be transmitted pursuant to section 124.308, and, if not transmitted directly by the practitioner, shall also include the name and title of the practitioner's agent completing the transmission.

DIVISION VI

IMMUNIZATIONS

Sec. 9. Section 155A.46, subsection 1, paragraph d, Code 2020, is amended to read as follows:

d. Prior to the ordering and administration of a ~~vaccination~~ non-influenza vaccine or immunization authorized by this subsection, pursuant to statewide protocols, a licensed pharmacist shall consult and review the statewide immunization registry or health information network. The board shall adopt rules requiring the reporting of the administration of vaccines and immunizations authorized by this subsection to a patient's primary health care provider, primary physician, and a statewide immunization registry or health information network. A licensed pharmacist shall not be required to report

to a statewide immunization registry or health information network the administration of an influenza vaccine administered to patients ages eighteen and older.

DIVISION VII

COLLABORATIVE PHARMACY PRACTICE

Sec. 10. Section 124.101, Code 2020, is amended by adding the following new subsections:

NEW SUBSECTION. 4A. *"Collaborative pharmacy practice"* means the same as defined in section 155A.3.

NEW SUBSECTION. 4B. *"Collaborative pharmacy practice agreement"* means the same as defined in section 155A.3.

Sec. 11. Section 124.308, subsection 2, paragraph c, subparagraph (7), Code 2020, is amended to read as follows:

(7) A prescription issued pursuant to an established and valid collaborative pharmacy practice agreement, standing order, or drug research protocol.

Sec. 12. NEW SECTION. **124.308A Collaborative pharmacy practice.**

Notwithstanding any provision to the contrary, a pharmacist may engage in a collaborative pharmacy practice under a collaborative pharmacy practice agreement to provide patient care and drug therapy management services to a patient.

Sec. 13. Section 155A.3, Code 2020, is amended by adding the following new subsections:

NEW SUBSECTION. 5A. *"Collaborative pharmacy practice"* means a practice of pharmacy whereby a pharmacist provides patient care and drug therapy management services, not otherwise permitted to be performed by a pharmacist, to patients under a collaborative pharmacy practice agreement.

NEW SUBSECTION. 5B. *"Collaborative pharmacy practice agreement"* means a written agreement between one or more pharmacists and one or more physicians, advanced registered nurse practitioners, advanced practice registered nurses, or dentists that provides for a collaborative pharmacy practice and defines the nature, scope, conditions, and limitations of

the patient care and drug therapy management services to be provided by the pharmacist or pharmacists.

Sec. 14. Section 155A.27, subsection 2, paragraph b, subparagraph (10), Code 2020, is amended to read as follows:

(10) A prescription issued pursuant to an established and valid collaborative pharmacy practice agreement, standing order, or drug research protocol.

Sec. 15. NEW SECTION. **155A.47 Collaborative pharmacy practice.**

Notwithstanding any provision to the contrary, a pharmacist may engage in a collaborative pharmacy practice under a collaborative pharmacy practice agreement to provide patient care and drug therapy management services to a patient.

DIVISION VIII

PHARMACY PILOT OR DEMONSTRATION RESEARCH PROJECTS

Sec. 16. NEW SECTION. **155A.48 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. 17. 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 also eliminates the one-year registration limitation for a person in training to become a pharmacy technician and makes conforming terminology changes.

Division II of the bill authorizes the board to adopt rules to authorize a pharmacist or a certified pharmacy technician to supervise a pharmacy support person working at a licensed telepharmacy site.

Division III 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. The bill also allows the board to recover costs associated with conducting an inspection to satisfy the inspection requirement.

Division IV of the bill authorizes a pharmacist to make certain adaptations to prescriptions for substances that are not controlled substances when appropriate to fulfill the prescriber's intent of the prescription medication therapy. Any adaptation made must be documented in the patient's record and the prescriber must be notified of the adaptation of the prescription. The bill prohibits a third-party payer from recouping payment for the prescription as a result of an audit of an otherwise valid prescription based solely on the pharmacist's adaptation of the prescription.

Division V authorizes a pharmacist to refill a prescription

for a chronic maintenance drug, excluding controlled substances, if the pharmacist, after reasonable efforts, is unable to obtain authorization from the prescriber when, in the pharmacist's professional judgment, the patient's life or health will be endangered or an essential drug therapy will be disrupted.

Division VI amends requirements to exempt influenza vaccines from the requirement that a licensed pharmacist review the statewide immunization registry or health information network prior to the ordering and administration of a vaccine or immunization authorized pursuant to statewide protocols. The bill also exempts influenza vaccines from the requirement that a licensed pharmacist report to the statewide immunization registry or health information network following administration of an influenza vaccine pursuant to statewide protocols to a patient aged 18 or older.

Division VII defines and authorizes collaborative pharmacy practice between pharmacists and physicians, advanced registered nurse practitioners, advanced practice registered nurses, and dentists under both Code chapters 124 (controlled substances) and Code chapter 155A (pharmacy).

Division VIII codifies the provisions of 2011 Iowa Acts, chapter 63, section 36, relating to pharmacy pilot or demonstration research projects. The bill language 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.