

House File 2507 - Introduced

HOUSE FILE 2507
BY COMMITTEE ON HUMAN
RESOURCES

(SUCCESSOR TO HSB 533)

A BILL FOR

- 1 An Act relating to the practice of pharmacy, and providing for
2 a repeal.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

DIVISION I

PHARMACY TECHNICIAN REGISTRATION

1
2
3 Section 1. Section 147.107, subsection 2, paragraph d, Code
4 2020, is amended to read as follows:

5 *d.* A pharmacist who dispenses prescription drugs, including
6 but not limited to controlled substances, for human use,
7 may delegate nonjudgmental dispensing functions only when
8 verification of the accuracy and completeness of the dispensing
9 is determined by the pharmacist in the pharmacist's physical
10 presence. The pharmacist's verification of the accuracy of the
11 prescription drug dispensed shall not be required when verified
12 by a certified pharmacy technician in a technician product
13 verification program ~~or a tech-check-tech program~~ as defined
14 in [section 155A.3](#). The pharmacist's physical presence shall
15 not be required when the pharmacist is remotely supervising
16 pharmacy personnel operating in ~~an approved~~ a licensed
17 telepharmacy site or when utilizing an automated dispensing
18 system that utilizes an internal quality control assurance
19 plan. When utilizing a technician product verification program
20 ~~or tech-check-tech program~~, or when remotely supervising
21 pharmacy personnel operating at ~~an approved~~ a licensed
22 telepharmacy site, the pharmacist shall utilize an internal
23 quality control assurance plan, in accordance with rules
24 adopted by the board of pharmacy, that ensures accuracy for
25 dispensing. Automated dispensing verification, technician
26 product verification, and telepharmacy practice accuracy and
27 completeness remains the responsibility of the pharmacist and
28 shall be determined in accordance with rules adopted by the
29 board of pharmacy.

30 Sec. 2. Section 155A.3, subsection 46, Code 2020, is amended
31 by striking the subsection.

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

34 3. A person who is in the process of acquiring national
35 certification as a pharmacy technician and who is in training

1 to become a pharmacy technician shall register with the board
2 as a pharmacy technician. ~~The registration shall be issued for~~
3 ~~a period not to exceed one year and shall not be renewable.~~

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

10 Sec. 4. Section 155A.33, Code 2020, is amended to read as
11 follows:

12 **155A.33 Delegation of technical functions.**

13 A pharmacist may delegate technical dispensing functions
14 to pharmacy technicians, but only if the pharmacist is
15 physically present to verify the accuracy and completeness
16 of the patient's prescription prior to the delivery of the
17 prescription to the patient or the patient's representative.
18 However, the physical presence requirement does not apply when
19 a pharmacist is utilizing an automated dispensing system or a
20 technician product verification program or when a pharmacist is
21 remotely supervising a certified pharmacy technician practicing
22 at a licensed telepharmacy site ~~approved by the board~~. When
23 using an automated dispensing system or a technician product
24 verification program, or when remotely supervising a certified
25 pharmacy technician practicing at an ~~approved~~ licensed
26 telepharmacy site, the pharmacist shall utilize an internal
27 quality control assurance plan that ensures accuracy for
28 dispensing. Verification of automated dispensing, technician
29 product verification, and telepharmacy practice accuracy and
30 completeness remains the responsibility of the pharmacist and
31 shall be determined in accordance with rules adopted by the
32 board.

33 DIVISION II

34 TELEPHARMACY PRACTICE

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

1 by adding the following new paragraph:

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

6 DIVISION III

7 OUTSOURCING FACILITY LICENSE

8 Sec. 6. Section 155A.13C, subsection 1, Code 2020, is
9 amended by adding the following new paragraph:

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

23 DIVISION IV

24 PRESCRIPTION ADAPTATION

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

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

35 *a. No adaptation without prior consent.* A pharmacist shall

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

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

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

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

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

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

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

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

26 *e. Payment recoupment.* A health benefit plan, as defined
27 in section 514J.102, a health carrier, as defined in section
28 514J.102, and a pharmacy benefits manager, as defined in
29 section 510B.1, shall not recoup payment from a pharmacy
30 following an audit on an otherwise valid prescription based
31 solely on a pharmacist's adaptation of a prescription pursuant
32 to this subsection.

33 DIVISION V

34 EMERGENCY DISPENSING

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

1 follows:

2 **155A.29 Prescription refills.**

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

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

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

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

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

21 ~~3.~~ d. Prescriptions may be refilled once pursuant to this
22 [subsection 2](#) for a period of time reasonably necessary for the
23 pharmacist to secure prescriber authorization.

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

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

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

1 essential drug therapy for a chronic condition of the patient.

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

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

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

14 4. An authorization to refill a prescription drug order
15 shall be transmitted to a pharmacy by a prescriber or the
16 prescriber's authorized agent pursuant to [section 155A.27](#),
17 except that prescription drug orders for controlled substances
18 shall be transmitted pursuant to [section 124.308](#), and, if not
19 transmitted directly by the practitioner, shall also include
20 the name and title of the practitioner's agent completing the
21 transmission.

22 DIVISION VI

23 IMMUNIZATIONS

24 Sec. 9. Section 155A.46, subsection 1, paragraph d, Code
25 2020, is amended to read as follows:

26 d. Prior to the ordering and administration of a vaccination
27 non-influenza vaccine or immunization authorized by this
28 subsection, pursuant to statewide protocols, a licensed
29 pharmacist shall consult and review the statewide immunization
30 registry or health information network. The board shall
31 adopt rules requiring the reporting of the administration of
32 vaccines and immunizations authorized by [this subsection](#) to
33 a patient's primary health care provider, primary physician,
34 and a statewide immunization registry or health information
35 network. [A licensed pharmacist shall not be required to report](#)

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

4 DIVISION VII

5 COLLABORATIVE PHARMACY PRACTICE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 DIVISION VIII

15 PHARMACY PILOT OR DEMONSTRATION RESEARCH PROJECTS

16 Sec. 16. NEW SECTION. **155A.48 Pilot or demonstration**
17 **research projects.**

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

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

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

33 Sec. 17. REPEAL. 2011 Iowa Acts, chapter 63, section 36,
34 is repealed.

35

EXPLANATION

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

3 This bill relates to pharmacy practice.

4 Division I of the bill eliminates the tech-check-tech
5 program. The board of pharmacy (board) adopted administrative
6 rules to implement and establish a technician product
7 verification program as authorized by 2018 Iowa Acts, chapter
8 1142, enacting Code section 155A.33A. Division I also
9 eliminates the one-year registration limitation for a person in
10 training to become a pharmacy technician and makes conforming
11 terminology changes.

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

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

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

35 Division V authorizes a pharmacist to refill a prescription

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

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

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

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