

Senate Study Bill 1165 - Introduced

SENATE FILE _____
BY (PROPOSED COMMITTEE ON
STATE GOVERNMENT BILL BY
CHAIRPERSON SCHULTZ)

A BILL FOR

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

1 Section 1. NEW SECTION. 155A.2B Practice of pharmacy —
2 general principles.

3 To evaluate whether an act by a licensee or registrant under
4 this chapter violates the appropriate standard of care, a
5 licensee or registrant of the board must consider all of the
6 following:

7 1. Whether performance of the act is expressly prohibited
8 by a provision of this chapter.

9 2. Whether performance of the act is expressly prohibited
10 by a rule adopted by the board.

11 3. Whether performance of the act is expressly prohibited by
12 another applicable state or federal law or regulation.

13 4. Whether performance of the act is consistent with
14 the education, training, and experience of a licensee or
15 registrant.

16 5. Whether performance of the act is within the accepted
17 standard of care that would be provided in a similar setting by
18 a reasonable and prudent licensee or registrant with similar
19 education, training, and experience.

20 Sec. 2. Section 155A.3, subsection 39, Code 2023, is amended
21 to read as follows:

22 39. "*Practitioner*" means a physician, dentist, podiatric
23 physician, prescribing psychologist, veterinarian, optometrist,
24 pharmacist, physician assistant, advanced registered nurse
25 practitioner, or other person licensed or registered to
26 prescribe, distribute, or dispense a prescription drug or
27 device in the course of professional practice in this state or
28 a person licensed by another state in a health field in which,
29 under Iowa law, licensees in this state may legally prescribe
30 drugs.

31 Sec. 3. Section 155A.3, Code 2023, is amended by adding the
32 following new subsection:

33 NEW SUBSECTION. 49A. "*Therapeutic substitution*" means the
34 replacement of a prescribed drug with an alternative molecule
35 with assumed equivalent therapeutic effect. The alternative

1 drug may be within the same class or from another class with
2 assumed therapeutic equivalence.

3 Sec. 4. Section 155A.7, Code 2023, is amended by striking
4 the section and inserting in lieu thereof the following:

5 **155A.7 Pharmacist-intern, pharmacy technician, and pharmacy**
6 **support person registration.**

7 1. Registration programs for pharmacist-interns, pharmacy
8 technicians, and pharmacy support persons are established for
9 the purposes of identification, tracking, and disciplinary
10 action for the violation of federal drug laws or regulations,
11 state drug or pharmacy laws, or rules of the board.

12 2. A person who is or desires to be a pharmacist-intern,
13 pharmacy technician, or pharmacy support person in this state
14 shall apply to the board for registration on a form prescribed
15 by the board.

16 a. A pharmacist-intern shall be registered during internship
17 training and thereafter pursuant to rules adopted by the board.

18 b. An applicant for a new pharmacy technician registration
19 or for a pharmacy technician renewal shall provide proof of
20 current certification by a national technician certification
21 authority approved by the board. A person who is in the
22 process of acquiring national certification as a pharmacy
23 technician and who is in training to become a pharmacy
24 technician shall register with the board as a pharmacy
25 technician.

26 3. The board shall adopt rules pursuant to chapter 17A on
27 matters pertaining to pharmacist-intern, pharmacy technician,
28 and pharmacy support person registration, renewals, fees,
29 training, national certification for pharmacy technicians,
30 approval of preceptors for pharmacist-interns, and other
31 relevant matters.

32 a. The board shall establish standards for pharmacist-intern
33 registration.

34 b. The board shall not adopt rules pertaining to pharmacy
35 support person registration which include any determination of

1 the competency of the registered person and, notwithstanding
2 section 272C.2, subsection 1, shall not require continuing
3 education for renewal.

4 4. The board may deny, suspend, or revoke the registration
5 of a pharmacist-intern, pharmacy technician, or pharmacy
6 support person, or otherwise impose disciplinary penalties upon
7 the registration of a pharmacy technician or pharmacy support
8 person, for any violation of the laws of this state, another
9 state, or the United States relating to prescription drugs,
10 controlled substances, or nonprescription drugs, or for any
11 violation of this chapter or chapter 124, 124B, 126, 147, 205,
12 or 272C, or any rule of the board. The board may deny, suspend,
13 or revoke a pharmacist-intern registration for failure to meet
14 the standards prescribed by the board pursuant to subsection 3.

15 5. Responsibility for the actions of a pharmacist-intern,
16 pharmacy technician, or pharmacy support person working under
17 a licensed pharmacist's delegated functions and reasonable
18 professional oversight shall remain with the licensed
19 pharmacist.

20 Sec. 5. Section 155A.8, Code 2023, is amended to read as
21 follows:

22 **155A.8 ~~Requirements for pharmacist~~ Pharmacist license.**

23 1. A person shall not engage in the practice of pharmacy in
24 this state without a license. The license shall be identified
25 as a pharmacist license.

26 2. A pharmacist may dispense, administer, manage, and
27 prescribe immunizations, prescription drugs, or devices
28 commensurate with the pharmacist's training and education and
29 in accordance with the appropriate standard of care.

30 3. To qualify for a pharmacist license, an applicant shall
31 meet the following requirements:

32 ~~1.~~ a. Be a graduate of a school or college of pharmacy
33 or of a department of pharmacy of a university recognized and
34 approved by the board.

35 ~~2.~~ b. File proof, satisfactory to the board, of internship

1 for a period of time fixed by the board.

2 ~~3. c.~~ Pass an examination prescribed by the board.

3 4. The board shall specify by rule procedures and fees to
4 renew a pharmacist license and penalties for late renewal or
5 failure to renew a pharmacist license.

6 Sec. 6. Section 155A.9, subsection 2, Code 2023, is amended
7 to read as follows:

8 2. An applicant who is a graduate of a school or college of
9 pharmacy located outside the United States but who is otherwise
10 qualified to apply for a pharmacist license in this state may
11 be deemed to have satisfied the requirements of ~~section 155A.8,~~
12 ~~subsection 1~~ section 155A.8, subsection 3, paragraph "a", by
13 verification to the board of the applicant's academic record
14 and graduation and by meeting other requirements established
15 by rule of the board. The board may require the applicant
16 to pass an examination or examinations given or approved by
17 the board to establish proficiency in English and equivalency
18 of education as a prerequisite for taking the licensure
19 examination required in [section 155A.8, subsection 3.](#)

20 Sec. 7. Section 155A.12, subsection 1, Code 2023, is amended
21 to read as follows:

22 1. Violated any provision of [this chapter](#) or any rules of
23 the board adopted under [this chapter](#), the pharmacy or drug
24 laws or rules of the United States, or any other state laws
25 or rules of the United States while under the other state's
26 jurisdiction.

27 Sec. 8. Section 155A.12, subsections 8, 9, and 10, Code
28 2023, are amended by striking the subsections.

29 Sec. 9. Section 155A.12, Code 2023, is amended by adding the
30 following new subsections:

31 NEW SUBSECTION. 11. Engaged in conduct outside the accepted
32 standard of care that would be provided in a similar setting by
33 a reasonable and prudent applicant or licensee.

34 NEW SUBSECTION. 12. Displayed incapacity of a nature
35 preventing engagement in the practice of pharmacy with

1 reasonable skill, competence, and safety to the public.

2 Sec. 10. Section 155A.13, subsection 3, paragraph b, Code
3 2023, is amended by striking the paragraph and inserting in
4 lieu thereof the following:

5 *b.* The board shall adopt rules for the issuance of a special
6 or limited-use pharmacy license to a telepharmacy site.

7 Sec. 11. Section 155A.13, subsection 3, paragraphs c, d, and
8 e, Code 2023, are amended by striking the paragraphs.

9 Sec. 12. Section 155A.13, subsection 8, Code 2023, is
10 amended by striking the subsection.

11 Sec. 13. Section 155A.13A, Code 2023, is amended by adding
12 the following new subsection:

13 NEW SUBSECTION. 6. *Nonresident pharmacy license.* The
14 board shall specify by rule procedures and fees to renew a
15 nonresident pharmacy license and the penalties for late renewal
16 or failure to renew a nonresident pharmacy license.

17 Sec. 14. Section 155A.18, Code 2023, is amended to read as
18 follows:

19 **155A.18 Penalties.**

20 1. The board shall impose penalties as allowed under section
21 272C.3. In addition, civil penalties not to exceed twenty-five
22 thousand dollars, may be imposed.

23 2. The board may impose an administrative penalty of up to
24 five hundred dollars on a licensee or registrant who does any
25 of the following:

26 a. Engages in a practice regulated by this chapter without a
27 current license or registration.

28 b. Employs a person without a current license or
29 registration to engage in a practice regulated by this chapter.

30 c. Fails to complete the continuing education required for
31 renewal of a license or registration.

32 d. Fails any component of a routine inspection conducted by
33 the board.

34 e. The assessment and payment of a penalty imposed pursuant
35 to this subsection shall not be considered a disciplinary

1 action or reported as discipline and shall be confidential.

2 Sec. 15. Section 155A.19, Code 2023, is amended by striking
3 the section and inserting in lieu thereof the following:

4 **155A.19 Notifications to board.**

5 Individuals and businesses licensed or registered pursuant
6 to this chapter shall notify the board of pertinent changes
7 related to activities performed pursuant to a license or
8 registration issued under this chapter, pursuant to rules of
9 the board.

10 Sec. 16. Section 155A.23, Code 2023, is amended by adding
11 the following new subsection:

12 NEW SUBSECTION. 4. *a.* A person found in possession of a
13 drug or device limited to dispensation by prescription, unless
14 the drug or device was so lawfully dispensed, commits a serious
15 misdemeanor.

16 *b.* Paragraph “*a*” does not apply to a licensed pharmacy,
17 licensed wholesaler, physician, veterinarian, dentist,
18 podiatric physician, optometrist, advanced registered nurse
19 practitioner, physician assistant, pharmacist, a nurse
20 acting under the direction of a physician, staff acting
21 under the direction of a person licensed to prescribe, or
22 the board of pharmacy, its officers, agents, inspectors,
23 and representatives, or to a common carrier, manufacturer’s
24 representative, or messenger when transporting the drug or
25 device in the same unbroken package in which the drug or device
26 was delivered to that person for transportation.

27 Sec. 17. Section 155A.26, unnumbered paragraph 1, Code
28 2023, is amended to read as follows:

29 The board, its officers, agents, ~~inspectors~~ compliance
30 officers, and representatives, and all peace officers
31 within the state, and all county attorneys shall enforce
32 all provisions of this chapter, except those specifically
33 delegated, and shall cooperate with all agencies charged
34 with the enforcement of the laws of the United States, of
35 this state, and of all other states relating to prescription

1 drugs. Officers, agents, ~~inspectors~~ compliance officers, and
2 representatives of the board shall have the powers and status
3 of peace officers when enforcing the provisions of this chapter
4 and chapters 124, 126, and 205. Officers, agents, ~~inspectors~~
5 compliance officers, and representatives of the board of
6 pharmacy may:

7 Sec. 18. Section 155A.26, subsection 3, Code 2023, is
8 amended to read as follows:

9 3. Conduct routine and unannounced inspections of
10 ~~pharmacies, drug wholesalers, and the offices or business~~
11 ~~locations of all individuals and institutions authorized to~~
12 ~~have possession of prescription drugs including any entity~~
13 licensed by the board or location authorized to possess
14 controlled substances or prescription devices, regardless of
15 the location of the office or business.

16 Sec. 19. Section 155A.27, subsection 2, paragraph a, Code
17 2023, is amended to read as follows:

18 a. ~~Beginning January 1, 2020, every~~ Every prescription
19 issued for a prescription drug shall be transmitted
20 electronically as an electronic prescription to a pharmacy by a
21 prescriber or the prescriber's authorized agent unless exempt
22 under paragraph "b".

23 Sec. 20. Section 155A.27, subsection 3, unnumbered
24 paragraph 1, Code 2023, is amended to read as follows:

25 For ~~prescriptions issued prior to January 1, 2020, or~~
26 ~~for~~ prescriptions exempt from the electronic prescription
27 requirement in subsection 2, paragraph "b", a prescriber or the
28 prescriber's authorized agent may transmit a prescription for a
29 prescription drug to a pharmacy by any of the following means:

30 Sec. 21. Section 155A.27, Code 2023, is amended by adding
31 the following new subsections:

32 NEW SUBSECTION. 8. Except as specified in subsection 9, a
33 prescription for any prescription drug or device which is not a
34 controlled substance shall not be filled or refilled more than
35 eighteen months after the date on which the prescription was

1 issued and a prescription which is authorized to be refilled
2 shall not be refilled more than twelve times.

3 NEW SUBSECTION. 9. A pharmacist may exercise professional
4 judgment by refilling a prescription drug order without
5 prescriber authorization in accordance with the appropriate
6 standard of care and pursuant to rules established by the
7 board.

8 NEW SUBSECTION. 10. An authorization to refill a
9 prescription drug order shall be transmitted to a pharmacy by
10 a prescriber or the prescriber's authorized agent pursuant
11 to this section, except that prescription drug orders for
12 controlled substances shall be transmitted pursuant to section
13 124.308, and, if not transmitted directly by the practitioner,
14 shall also include the name and title of the practitioner's
15 agent completing the transmission.

16 Sec. 22. Section 155A.32, Code 2023, is amended by striking
17 the section and inserting in lieu thereof the following:

18 **155A.32 Drug product selection — restrictions.**

19 1. If an authorized practitioner prescribes a drug, the
20 pharmacist may exercise professional judgment in the interest
21 of the patient by providing a therapeutic substitution for
22 dispensing and sale to the patient.

23 2. The pharmacist shall not provide a therapeutic
24 substitution if "dispense as written" is indicated on the
25 prescription.

26 3. The board shall adopt rules on proper recording and
27 notification when a therapeutic substitution is made under this
28 section.

29 Sec. 23. Section 155A.39, subsection 6, Code 2023, is
30 amended to read as follows:

31 6. Funds and surcharges collected under **this section** shall
32 be deposited in an account and may be used by the board to
33 administer a program authorized by **this section**, ~~but shall~~
34 ~~not be used for costs incurred for a participant's initial~~
35 ~~evaluation, referral services, treatment, or rehabilitation~~

1 ~~subsequent to intervention~~ and to assist licensees and
2 registrants with costs incurred for participation in the
3 program.

4 Sec. 24. Section 155A.40, subsection 1, Code 2023, is
5 amended to read as follows:

6 1. The board may request and obtain, notwithstanding
7 section 692.2, subsection 5, criminal history data for any
8 applicant for an initial or renewal license or registration
9 issued pursuant to this chapter or chapter 147, any applicant
10 for reinstatement of a license or registration issued pursuant
11 to this chapter or chapter 147, or any licensee or registrant
12 who is being monitored as a result of a board order or
13 agreement resolving an administrative disciplinary action,
14 for the purpose of evaluating the applicant's, licensee's,
15 or registrant's eligibility for licensure, registration, or
16 suitability for continued practice of the profession. Criminal
17 history data may be requested for all owners, managers, and
18 principal employees of a pharmacy, third-party logistics
19 provider, or ~~drug wholesaler~~ wholesale distributor licensed
20 pursuant to this chapter. The board shall adopt rules
21 pursuant to chapter 17A to implement this section. The board
22 shall inform the applicant, licensee, or registrant of the
23 criminal history requirement and obtain a signed waiver from
24 the applicant, licensee, or registrant prior to submitting a
25 criminal history data request.

26 Sec. 25. Section 155A.46, Code 2023, is amended by striking
27 the section and inserting in lieu thereof the following:

28 **155A.46 Statewide protocols.**

29 1. A pharmacist may, pursuant to statewide protocols
30 developed and approved by the board in consultation with the
31 department of health and human services, order and administer
32 prescription drugs, products, tests, or treatments. Each
33 protocol, as established by rule, may define the prescription
34 drugs, products, tests, or treatment allowed to be ordered
35 and administered, any training or qualification required to

1 implement the protocol, and any additional requirements deemed
2 appropriate.

3 2. Notwithstanding any provision of law to the contrary,
4 a pharmacist may develop policies, procedures, and protocols
5 to carry out the practices identified in section 155A.8,
6 subsection 2.

7 Sec. 26. Section 155A.47, subsection 1, Code 2023, is
8 amended to read as follows:

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

14 Sec. 27. REPEAL. Sections 155A.6, 155A.6A, 155A.6B,
15 155A.21, 155A.28, and 155A.29, Code 2023, are repealed.

16 EXPLANATION

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

19 This bill relates to the practice of pharmacy. The bill
20 creates general principles that licensees and registrants of
21 the board of pharmacy (board) must consider when determining
22 whether an act violates the appropriate standard of care. The
23 bill also reorganizes Code chapter 155A (pharmacy) by combining
24 and repealing certain Code sections, and makes conforming Code
25 changes. The bill combines Code section 155A.21 (unlawful
26 possession of prescription drug or device — penalty) into Code
27 section 155A.23 (prohibited acts) and Code section 155A.29
28 (prescription refills) into Code section 155A.27 (requirements
29 for prescriptions).

30 The bill adds pharmacists to the definition of
31 "practitioner" for the purposes of Code chapter 155A and
32 defines "therapeutic substitution" as the replacement of a
33 prescribed drug with an alternative molecule with assumed
34 equivalent therapeutic effect.

35 The bill repeals and amends current Code provisions

1 regarding the registration of pharmacist-interns, pharmacy
2 technicians, and pharmacy support persons. The bill requires
3 the board to adopt rules regarding the registration and
4 practice of pharmacist-interns, pharmacy technicians, and
5 pharmacy support persons. The bill prohibits the board
6 from adopting rules pertaining to pharmacy support person
7 registration which include any determination of the competency
8 of the registered person or requiring continuing education.
9 The bill allows the board to deny, suspend, or revoke a
10 registration of a pharmacist-intern, pharmacy technician,
11 or pharmacy support person based on a violation of certain
12 laws and regulations. Responsibility for the actions of a
13 pharmacist-intern, pharmacy technician, or pharmacy support
14 person working under a pharmacist remains with the pharmacist.

15 The bill allows a pharmacist to dispense, administer,
16 manage, and prescribe immunizations, prescription drugs, or
17 devices according to the pharmacist's training and education
18 and in accordance with the appropriate standard of care. The
19 bill requires the board to specify by rule the procedures and
20 fees to renew a pharmacist license and the penalties for late
21 renewal or failure to renew a pharmacist license.

22 The bill allows the board to discipline a pharmacist or
23 refuse to issue a pharmacist license to a person for engaging
24 in conduct outside the accepted standard of care that would
25 be provided in a similar setting by a reasonable and prudent
26 applicant or licensee and for displaying incapacity of a
27 nature preventing engagement in the practice of pharmacy with
28 reasonable skill, competence, and safety to the public.

29 The bill strikes provisions regarding the issuance of a
30 telepharmacy license and requires the board to adopt rules for
31 the issuance of a telepharmacy license. The bill also strikes
32 a requirement that a pharmacy license be issued in the name of
33 the pharmacist in charge and not be transferable or assignable.
34 The bill requires the board to adopt rules regarding the
35 renewal of a nonresident pharmacy license and the penalties

1 for a late renewal or failure to renew a nonresident pharmacy
2 license.

3 The bill allows the board to impose an administrative
4 penalty of up to \$500 on a licensee or registrant who engages
5 in a practice regulated by Code chapter 155A without a current
6 license or registration, employs a person without a current
7 license or registration to engage in a practice regulated by
8 Code chapter 155A, fails to complete the continuing education
9 required for renewal of a license or registration, or fails any
10 component of a routine inspection conducted by the board. An
11 administrative penalty shall not be considered a disciplinary
12 action or reported as discipline and shall be confidential.
13 Under current law, the board can impose civil penalties not to
14 exceed \$25,000.

15 The bill strikes current law regarding notifications
16 submitted by a pharmacy to the board and requires the board
17 to adopt rules for the reporting of pertinent changes related
18 to activities performed pursuant to a license or registration
19 issued under Code chapter 155A to the board by a licensed or
20 registered person or business.

21 The bill changes references to "inspectors" of the board
22 to "compliance officers" of the board. The bill allows the
23 board to conduct routine and unannounced inspections of any
24 entity licensed by the board or location authorized to possess
25 controlled substances or prescription devices.

26 The bill strikes provisions allowing prescriptions issued
27 before January 1, 2020, to be issued by nonelectronic means.
28 The bill allows a pharmacist to exercise professional judgment
29 by refilling a prescription without prescriber authorization in
30 accordance with the appropriate standard of care and pursuant
31 to rules established by the board.

32 The bill allows a pharmacist to dispense a therapeutic
33 substitution in lieu of a prescribed drug according to the
34 professional judgment of the pharmacist unless the prescription
35 states "dispense as written". The board shall adopt rules on

1 proper recording and notification of therapeutic substitutions.

2 The bill allows funds and surcharges collected for a
3 program to monitor impaired pharmacists, pharmacist-interns,
4 or pharmacy technicians to be used to assist licensees and
5 registrants with costs incurred for participation in the
6 program.

7 The bill allows the board to request criminal history
8 data for all owners, managers, and principal employees and
9 third-party logistics providers and wholesale distributors.

10 The bill strikes current provisions regarding statewide
11 protocols under which a pharmacist can order and administer
12 certain drugs. The bill allows the board to develop statewide
13 protocols for the ordering and administration of prescription
14 drugs, products, tests, or treatments in consultation with the
15 department of health and human services.

16 The bill allows the board to approve a pilot or demonstration
17 research project of innovative applications in the practice of
18 pharmacy to provide enhanced patient care, notwithstanding any
19 provision of Code chapter 155A to the contrary. Current law
20 allows the board to approve such a project notwithstanding Code
21 section 155A.33 (delegation of functions).