

Senate File 416 - Introduced

SENATE FILE 416
BY COMMITTEE ON STATE
GOVERNMENT

(SUCCESSOR TO SSB 1111)

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:

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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

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

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

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

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

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

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

21 **155A.33 Delegation of ~~technical~~ functions.**

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

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

10 DIVISION II

11 OUTSOURCING FACILITY LICENSE

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

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

27 DIVISION III

28 INFORMATION SHARING

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

31 **155A.45 ~~Inspection reports~~ Reports — disclosure.**

32 1. Notwithstanding [section 272C.6, subsection 4](#), paragraph
33 "a", an inspection report in possession of the board, regardless
34 of whether the report is based on a routine inspection or an
35 inspection prompted by one or more complaints, may be disclosed

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

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

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DIVISION IV

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PHARMACY PILOT OR DEMONSTRATION RESEARCH PROJECTS

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Sec. 8. NEW SECTION. 155A.47 Pilot or demonstration

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research projects.

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

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

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

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

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EXPLANATION

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

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This bill relates to pharmacy practice.

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

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

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

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

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