# CHAPTER 155A

## **PHARMACY**

 $\begin{array}{c} \textbf{Referred to in \$124B.6, 124B.11, 124E.9, 135.24, 135.61, 135.190, 135P1, 147.76, 147.82, 147.108, 147.136A, 147A.18, 152.1, 166.3, \\ 321J.2, 462A.12, 462A.14, 514.5, 714H.4 \end{array}$ 

 $Licensing\ board\ and\ support\ staff;\\ location,\ meetings,\ and\ powers;\ see\ \S135.11A-135.12,\ 135.31$ 

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|                    | <ul><li>exceptions.</li></ul>                                    |                    | penalty.   |
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| 155A.13C           | Outsourcing facility license —                                   |                    | pharmacist-interns, or                                   |
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#### 155A.1 Short title.

This chapter may be cited as the "Iowa Pharmacy Practice Act". 87 Acts, ch 215, §1

# 155A.2 Legislative declaration — purpose — exceptions.

1. It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized.

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2. Practitioners licensed under a separate chapter of the Code are not regulated by this chapter except when engaged in the operation of a pharmacy for the retailing of prescription drugs.

3. A family planning clinic is not regulated by this chapter when engaged in the dispensing of birth control drugs and devices pursuant to section 147.107, subsection 7.

87 Acts, ch 215, §2; 2009 Acts, ch 69, §2

#### 155A.2A Board of pharmacy — alternate members.

Notwithstanding sections 17A.11, 69.16, 69.16A, 147.12, 147.14, and 147.19, the board may have a pool of up to seven alternate members, including members licensed to practice under this chapter and members not licensed to practice under this chapter, to substitute for board members who are disqualified or become unavailable for any reason for contested case hearings.

- 1. The board may recommend, subject to approval by the governor, up to seven people to serve in a pool of alternate members.
- 2. A person serves in the pool of alternate members at the discretion of the board; however, the length of time an alternate member may serve in the pool shall not exceed nine years. A person who serves as an alternate member may later be appointed to the board and may serve nine years, in accordance with sections 147.12 and 147.19. A former board member may serve in the pool of alternate members.
- 3. An alternate member licensed under this chapter shall hold an active license and shall have been actively engaged in the practice of pharmacy in the preceding three years, with the two most recent years of practice being in Iowa.
- 4. When a sufficient number of board members are unavailable to hear a contested case, the board may request alternate members to serve.
- 5. Notwithstanding section 17A.11, section 147.14, subsection 2, and section 272C.6, subsection 5:
- a. An alternate member is deemed a member of the board only for the hearing panel for which the alternate member serves.
  - b. A hearing panel containing alternate members must include at least five people.
- c. The majority of a hearing panel containing alternate members shall be members of the board.
- d. The majority of a hearing panel containing alternate members shall be licensed to practice under this chapter.
- e. A decision of a hearing panel containing alternate members is considered a final decision of the board.
- f. An alternate member shall not receive compensation in excess of that authorized by law for a board member.

2017 Acts, ch 93, §1
Section not amended; section editorially renumbered

#### 155A.3 Definitions.

As used in this chapter, unless the context otherwise requires:

- 1. "Administer" means the direct application of a prescription drug, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by one of the following:
  - a. A practitioner or the practitioner's authorized agent.
  - b. The patient or research subject at the direction of a practitioner.
- 2. "Authorized agent" means an individual designated by a practitioner who is under the supervision of the practitioner and for whom the practitioner assumes legal responsibility.
  - 3. "Biological product" means the same as defined in 42 U.S.C. §262.
  - 4. "Board" means the board of pharmacy.
- 5. "Brand name" or "trade name" means the registered trademark name given to a drug product or ingredient by its manufacturer, labeler, or distributor.
- 6. "College of pharmacy" means a school, university, or college of pharmacy that satisfies the accreditation standards of the accreditation council for pharmacy education to the extent

those standards are adopted by the board, or that has degree requirements which meet the standards of accreditation adopted by the board.

- 7. "Controlled substance" means a drug substance, immediate precursor, or other substance listed in subchapter II of chapter 124.
  - 8. "Controlled substances Act" means chapter 124.
- 9. "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.
- 10. "Demonstrated bioavailability" means the rate and extent of absorption of a drug or drug ingredient from a specified dosage form, as reflected by the time-concentration curve of the drug or drug ingredient in the systemic circulation.
- 11. "Device" means a medical device, as classified by the United States food and drug administration, intended for use by a patient that is required by the United States food and drug administration to be ordered or prescribed for a patient by a practitioner.
- 12. "Dispense" means to deliver a prescription drug, device, or controlled substance to an ultimate user or research subject by or pursuant to the lawful prescription drug order or medication order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.
  - 13. "Distribute" means the delivery of a prescription drug or device.
- 14. "Drug product selection" means the act of selecting the source of supply of a drug product.
- 15. "Drug sample" means a drug that is distributed without consideration to a pharmacist or practitioner.
- 16. "Electronic order" or "electronic prescription" means an order or prescription which is transmitted by a computer device in a secure manner, including computer-to-computer transmission and computer-to-facsimile transmission.
- 17. "Electronic signature" means a confidential personalized digital key, code, or number used for secure electronic transmissions which identifies and authenticates the signatory.
- 18. "Facsimile order" or "facsimile prescription" means an order or prescription which is transmitted by a device which sends an exact image to the receiver.
- 19. "Generic name" means the official title of a drug or drug ingredient published in the current official United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia, or other drug compendium published by the United States pharmacopoeial convention or any supplement to any of them.
  - 20. "Interchangeable biological product" means either of the following:
- a. A biological product that the United States food and drug administration has licensed and has determined meets the standards for interchangeability pursuant to 42 U.S.C. §262(k)(4).
- b. A biological product that the United States food and drug administration has determined to be therapeutically equivalent to another biological product as set forth in the latest edition or supplement of the United States food and drug administration approved drug products with therapeutic equivalence evaluations publication.
- 21. "Internship" means a practical experience program approved by the board for persons training to become pharmacists.
- 22. "Label" means written, printed, or graphic matter on the immediate container of a drug or device.
- 23. "Labeling" means the process of preparing and affixing a label including information required by federal or state law or regulation to a drug or device container. The term does not include the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged prescription drug or device or unit dose packaging.
- 24. "Limited distributor" means a person operating or maintaining a location, regardless of the location, where prescription drugs or devices are distributed at wholesale or to a patient pursuant to a prescription drug order, who is not eligible for a wholesale distributor license or pharmacy license.
- 25. "Managing pharmacy" means a licensed pharmacy that oversees the activities of a telepharmacy site.

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26. "Manufacturer" means manufacturer as defined by the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq.

- 27. "Medical convenience kit" means a collection of devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or ultimate user.
  - 28. "Medical gas" means a gas or liquid oxygen intended for human consumption.
- 29. "Medication order" means a written order from a practitioner or an oral order from a practitioner or the practitioner's authorized agent for administration of a drug or device.
- 30. "Pedigree" means a recording of each distribution of any given drug or device, from the sale by the manufacturer through acquisition and sale by any wholesaler, pursuant to rules adopted by the board.
  - 31. "Pharmacist" means a person licensed by the board to practice pharmacy.
- 32. "Pharmacist in charge" means the pharmacist designated on a pharmacy license as the pharmacist who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.
- 33. "Pharmacist-intern" means an undergraduate student enrolled in the professional sequence of a college of pharmacy approved by the board, or a graduate of a college of pharmacy, who is participating in a board-approved internship under the supervision of a preceptor.
- 34. "Pharmacy" means a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with the pharmacy laws.
- 35. "Pharmacy license" means a license issued to a pharmacy or other place where prescription drugs or devices are dispensed to the general public pursuant to a prescription drug order.
- 36. "Pharmacy technician" means a person registered by the board who is in a technician training program or who is employed by a pharmacy under the responsibility of a licensed pharmacist to assist in the technical functions of the practice of pharmacy.
- 37. "Practice of pharmacy" is a dynamic patient-oriented health service profession that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and related drug therapy.
- 38. "Practitioner" means a physician, dentist, podiatric physician, prescribing psychologist, veterinarian, optometrist, physician assistant, advanced registered nurse practitioner, or other person licensed or registered to prescribe, distribute, or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state may legally prescribe drugs.
- 39. "Preceptor" means a pharmacist in good standing licensed in this state to practice pharmacy and approved by the board to supervise and be responsible for the activities and functions of a pharmacist-intern in the internship program.
- 40. "Prescription drug" or "drug" means a drug, as classified by the United States food and drug administration, that is required by the United States food and drug administration to be prescribed or administered to a patient by a practitioner prior to dispensation.
- 41. "Prescription drug order" means a written, electronic, or facsimile order from a practitioner or an oral order from a practitioner or the practitioner's authorized agent who communicates the practitioner's instructions for a prescription drug or device to be dispensed.
  - 42. "Product" means the same as defined in 21 U.S.C. §360eee.
- 43. "Proprietary medicine" or "over-the-counter medicine" means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.
- 44. "Repackager" means a person who owns or operates an establishment that repackages or relabels a product or package for further sale or for distribution without a further transaction.
  - 45. "Statewide protocol" means a framework developed and issued by the board that

specifies the conditions under which pharmacists are authorized to order and administer a medication or category of medications when providing a clinical service.

- 46. "Tech-check-tech program" means a program formally established by a pharmacist in charge of a pharmacy who has determined that one or more certified pharmacy technicians are qualified to safely check the work of other certified pharmacy technicians and thereby provide final verification for drugs which are dispensed for subsequent administration to patients in an institutional setting.
- 47. "Technician product verification" means the process by which a certified pharmacy technician provides the final product verification for prescription drugs or devices filled or prepared by a registered pharmacy technician, pharmacist-intern, or with an automated dispensing system.
- 48. "Telepharmacy" means the practice of pharmacy via telecommunications as provided by the board by rule.
- 49. "Telepharmacy site" means a licensed pharmacy that is operated by a managing pharmacy and staffed by one or more qualified certified pharmacy technicians where pharmaceutical care services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, are provided by a licensed pharmacist through the use of technology.
- 50. "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product nor have responsibility to direct the sale or other disposition of the product.
- 51. "Ultimate user" means a person who has lawfully obtained and possesses a prescription drug or device for the person's own use or for the use of a member of the person's household or for administering to an animal owned by the person or by a member of the person's household.
- 52. "Unit dose packaging" means the packaging of individual doses of a drug in containers which preserve the identity and integrity of the drug from the point of packaging to administration and which are properly labeled pursuant to rules of the board.
- 53. "Wholesale distribution" means the distribution of a drug to a person other than a consumer or patient, or the receipt of a drug by a person other than a consumer or patient, but does not include any of the following:
- a. Intracompany distribution of any drug between members of an affiliate, as defined in 21 U.S.C. §360eee, or within a manufacturer.
- b. The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities under common control.
- c. The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration as defined in 42 U.S.C. §247d, except that for purposes of this paragraph a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason.
  - d. The dispensing of a drug pursuant to a prescription drug order.
- e. The distribution of minimal quantities of a drug by a pharmacy to a practitioner for office use.
- f. The distribution of a drug or an offer to distribute a drug by a charitable organization to an affiliate, as defined in 21 U.S.C. §360eee, of the organization that is a nonprofit, to the extent otherwise permitted by law.
- g. The purchase or other acquisition of a drug by a dispenser, as defined in 21 U.S.C. \$360eee, hospital, or other health care entity for use by such dispenser, hospital, or other health care entity.
  - h. The distribution of a drug by the manufacturer of such drug.
- *i*. The receipt or transfer of a drug by a third-party logistics provider, provided that such third-party logistics provider does not take ownership of the drug.
- j. A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug.
- k. The distribution of a drug or an offer to distribute a drug by a repackager that has taken ownership or possession of the drug and repackages it.

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- *l.* The return of a saleable product when conducted by a dispenser.
- m. The distribution of a medical convenience kit under any of the following circumstances:
- (1) The medical convenience kit is assembled in an establishment registered with the United States food and drug administration as a device manufacturer.
  - (2) The medical convenience kit does not contain a controlled substance.
- (3) In the case of a medical convenience kit that includes a product, the person that manufacturers the kit does all of the following:
- (a) Purchases the product directly from a pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer.
- (b) Does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor.
- (4) In the case of a medical convenience kit that includes a product, the product is any of the following:
  - (a) An intravenous solution intended for the replenishment of fluids and electrolytes.
  - (b) Intended to maintain the equilibrium of water and minerals in the body.
  - (c) Intended for irrigation or reconstitution.
  - (d) An anesthetic.
  - (e) An anticoagulant.
  - (f) A vasopressor.
  - (g) A sympathomimetic.
- n. The distribution of an intravenous drug that by its formulation is intended for the replenishment of fluids and electrolytes such as sodium, chloride, and potassium, or calories such as dextrose and amino acids.
- o. The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body such as a dialysis solution.
- p. The distribution of a drug intended for irrigation or sterile water intended for irrigation or for injection.
  - q. The distribution of a medical gas.
- r. The facilitation of the distribution of a product by providing administrative services, including the processing of orders and payments.
- s. The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager for the purpose of repackaging the product for use by that hospital or other health care entity under common control, if the ownership of the product remains with the hospital or other health care entity at all times.
- 54. "Wholesale distributor" means a person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager, engaged in the wholesale distribution of a drug.

87 Acts, ch 215, §3; 88 Acts, ch 1232, §2; 95 Acts, ch 108, §13; 96 Acts, ch 1070, §1; 2002 Acts, ch 1108, §24; 2004 Acts, ch 1036, §11, 12; 2004 Acts, ch 1167, §9; 2005 Acts, ch 179, §172 – 177; 2007 Acts, ch 10, §153; 2007 Acts, ch 19, §1, 2; 2008 Acts, ch 1016, §2; 2016 Acts, ch 1093, §2; 2016 Acts, ch 1112, §13; 2017 Acts, ch 5, §1; 2017 Acts, ch 93, §2; 2018 Acts, ch 1141, §2 – 9; 2018 Acts, ch 1142, §2

# Referred to in §124.308, 124B.1, 124B.6, 135M.2, 147.107, 321J.2, 423.3, 462A.14, 510B.1, 510B.10, 514L.1, 716A.3

# 155A.4 Prohibition against unlicensed persons dispensing or distributing prescription drugs — exceptions.

- 1. A person shall not dispense prescription drugs unless that person is a licensed pharmacist or is authorized by section 147.107 to dispense or distribute prescription drugs.
  - 2. Notwithstanding subsection 1, it is not unlawful for:
- a. A limited distributor, third-party logistics provider, or wholesale distributor to distribute prescription drugs or devices as provided by state or federal law.
  - b. A practitioner, licensed by the appropriate state board, to dispense prescription drugs

to patients as incident to the practice of the profession, except with respect to the operation of a pharmacy for the retailing of prescription drugs.

- c. A practitioner, licensed by the appropriate state board, to administer drugs to patients. This chapter does not prevent a practitioner from delegating the administration of a prescription drug to a nurse, intern, or other qualified individual or, in the case of a veterinarian, to an orderly or assistant, under the practitioner's direction and supervision.
- d. A person to sell at retail a proprietary medicine, an insecticide, a fungicide, or a chemical used in the arts, if properly labeled.
- e. A person to procure prescription drugs for lawful research, teaching, or testing and not for resale.
  - f. A pharmacy to distribute a prescription drug to another pharmacy or to a practitioner.
- g. A qualified individual authorized to administer prescription drugs and employed by a home health agency or hospice to obtain, possess, and transport emergency prescription drugs as provided by state or federal law or by rules of the board.

87 Acts, ch 215, \$4; 97 Acts, ch 39, \$1; 2005 Acts, ch 179, \$178; 2007 Acts, ch 19, \$3; 2018 Acts, ch 1141, \$10, 11

## 155A.5 Injunction.

Notwithstanding the existence or pursuit of any other remedy the board may, in the manner provided by law, maintain an action in the name of the state for injunction or other process against any person to restrain or prevent the establishment, conduct, management, or operation of a pharmacy, limited distributor, third-party logistics provider, or wholesale distributor without a license, or to prevent the violation of provisions of this chapter. Upon request of the board, the attorney general shall institute the proper proceedings and the county attorney, at the request of the attorney general, shall appear and prosecute the action when brought in the county attorney's county.

87 Acts, ch 215, §5; 2018 Acts, ch 1141, §12

#### 155A.6 Pharmacist internship program.

- 1. A program of pharmacist internships is established. Each internship is subject to approval by the board.
- 2. A person desiring to be a pharmacist-intern in this state shall apply to the board for registration. The application must be on a form prescribed by the board. A pharmacist-intern shall be registered during internship training and thereafter pursuant to rules adopted by the board.
- 3. The board shall establish standards for pharmacist-intern registration and may deny, suspend, or revoke a pharmacist-intern registration for failure to meet the standards or for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124B, 126, 147, or 205, or any rule of the board.
- 4. The board shall adopt rules in accordance with chapter 17A on matters pertaining to pharmacist-intern registration standards, registration fees, conditions of registration, termination of registration, and approval of preceptors.

87 Acts, ch 215, §6; 96 Acts, ch 1070, §2, 3; 2007 Acts, ch 20, §1; 2017 Acts, ch 145, §17

## 155A.6A Pharmacy technician registration.

- 1. A registration program for pharmacy technicians is established for the purpose of establishing technician competency and for the purposes of identification, tracking, and disciplinary action for the violation of federal drug laws or regulations, state drug or pharmacy laws, or board rules. The ultimate responsibility for the actions of a pharmacy technician working under a licensed pharmacist's supervision shall remain with the licensed pharmacist.
- 2. A person who is or desires to be a pharmacy technician in this state shall apply to the board for registration. The application shall be submitted on a form prescribed by the board. A pharmacy technician must be registered pursuant to rules adopted by the board. Except as provided in subsection 3, all applicants for a new pharmacy technician registration or

for a pharmacy technician renewal shall provide proof of current certification by a national technician certification authority approved by the board. Notwithstanding section 272C.2, subsection 1, a pharmacy technician registration shall not require continuing education for renewal.

- 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.
- 5. The board may deny, suspend, or revoke the registration of, or otherwise discipline, a registered pharmacy technician for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124B, 126, 147, 205, or 272C, or any rule of the board.

2007 Acts, ch 20, §2; 2008 Acts, ch 1016, §3; 2010 Acts, ch 1193, §112, 137, 138; 2017 Acts, ch 29, §45; 2017 Acts, ch 145, §18; 2018 Acts, ch 1026, §55, 56, 182; 2018 Acts, ch 1142, §3

## 155A.6B Pharmacy support person registration.

- 1. The board shall establish a registration program for pharmacy support persons who work in a licensed pharmacy and who are not licensed pharmacists or registered pharmacy technicians for the purposes of identification, tracking, and disciplinary action for the violation of federal drug laws or regulations, state drug or pharmacy laws, or board rules. The registration shall not include any determination of the competency of the registered individual and, notwithstanding section 272C.2, subsection 1, shall not require continuing education for renewal.
- 2. A person registered with the board as a pharmacy support person may assist pharmacists by performing routine clerical and support functions. Such a person shall not perform any professional duties or any technical or dispensing duties. The ultimate responsibility for the actions of a pharmacy support person working under a licensed pharmacist's supervision shall remain with the licensed pharmacist.
- 3. Applicants for registration must apply to the board for registration on a form prescribed by the board.
- 4. The board shall adopt rules in accordance with chapter 17A on matters pertaining to pharmacy support persons, and pharmacy support person exemptions, registration, application, renewals, fees, termination of registration, training, and any other relevant matters.
- 5. The board may deny, suspend, or revoke the registration of a pharmacy support person or otherwise discipline the pharmacy support person for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124B, 126, 147, 205, or 272C, or any rule of the board.

2009 Acts, ch 69, §3; 2017 Acts, ch 145, §19

#### 155A.7 Pharmacist license.

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

87 Acts, ch 215, §7

# 155A.8 Requirements for pharmacist license.

To qualify for a pharmacist license, an applicant shall meet the following requirements:

- 1. Be a graduate of a school or college of pharmacy or of a department of pharmacy of a university recognized and approved by the board.
  - 2. File proof, satisfactory to the board, of internship for a period of time fixed by the board.

3. Pass an examination prescribed by the board.

87 Acts, ch 215, §8 Referred to in §155A.9, 155A.12

## 155A.9 Approved colleges — graduates of foreign colleges.

- 1. A college of pharmacy shall not be approved by the board unless the college is accredited by the accreditation council for pharmacy education.
- 2. An applicant who is a graduate of a school or college of pharmacy located outside the United States but who is otherwise qualified to apply for a pharmacist license in this state may be deemed to have satisfied the requirements of section 155A.8, subsection 1, by verification to the board of the applicant's academic record and graduation and by meeting other requirements established by rule of the board. The board may require the applicant to pass an examination or examinations given or approved by the board to establish proficiency in English and equivalency of education as a prerequisite for taking the licensure examination required in section 155A.8, subsection 3.

87 Acts, ch 215, §9; 2007 Acts, ch 19, §4

## 155A.10 Display of pharmacist license.

A pharmacist shall publicly display the license to practice pharmacy and the license renewal certificate pursuant to rules adopted by the board.

87 Acts, ch 215, §10

## 155A.11 Renewal of pharmacist license.

The board shall specify by rule the procedures to be followed and the fee to be paid for a renewal certificate, and penalties for late renewal or failure to renew a pharmacist license.

87 Acts, ch 215, §11

## 155A.12 Pharmacist license — grounds for discipline.

The board shall refuse to issue a pharmacist license for failure to meet the requirements of section 155A.8. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:

- 1. Violated any provision of this chapter or any rules of the board adopted under this chapter.
  - 2. Engaged in unethical conduct as that term is defined by rules of the board.
  - 3. Violated any of the provisions for licensee discipline set forth in section 147.55.
- 4. Failed to keep and maintain records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.
  - 5. Violated any provision of the controlled substances Act or rules relating to that Act.
  - 6. Aided or abetted an unlicensed individual to engage in the practice of pharmacy.
  - 7. Refused an entry into any pharmacy for any inspection authorized by this chapter.
- 8. Violated the pharmacy or drug laws or rules of any other state of the United States while under the other state's jurisdiction.
- 9. Been convicted of an offense or subjected to a penalty or fine for violation of chapter 124, 126, 147, or the Federal Food, Drug, and Cosmetic Act. A plea or verdict of guilty, or a conviction following a plea of nolo contendere, is deemed to be a conviction within the meaning of this section.
- 10. Had a license to practice pharmacy issued by another state canceled, revoked, or suspended for conduct substantially equivalent to conduct described in subsections 1 through 9. A certified copy of the record of the state taking action as set out above shall be conclusive evidence of the action taken by such state.

87 Acts, ch  $215,\ \$12;\ 89$  Acts, ch  $197,\ \$23$  Referred to in \$155A.16

#### 155A.13 Pharmacy license.

1. A person shall not establish, conduct, or maintain a pharmacy in this state without a

license. The license shall be identified as a pharmacy license. A pharmacy license issued pursuant to subsection 4 may be further identified as a hospital pharmacy license.

- 2. The board shall specify by rule the licensing procedures to be followed, including specifications of forms for use in applying for a pharmacy license and fees for filing an application.
- 3. a. The board may issue a special or limited-use pharmacy license based upon special conditions of use imposed pursuant to rules adopted by the board for cases in which the board determines that certain requirements may be waived.
- *b*. The board shall adopt rules for the issuance of a special or limited-use pharmacy license to a telepharmacy site. The rules shall address:
- (1) Requirements for establishment and operation of a telepharmacy site, including but not limited to physical requirements and required policies and procedures.
  - (2) Requirements for being a managing pharmacy.
- (3) Requirements governing operating agreements between telepharmacy sites and managing pharmacies.
- (4) Training and experience required for certified pharmacy technicians working at a telepharmacy site.
- (5) Requirements for a pharmacist providing services to and supervising a telepharmacy site.
  - (6) Any other health and safety concerns associated with a telepharmacy site.
- c. The board shall not issue a special or limited-use pharmacy license to a proposed telepharmacy site if a licensed pharmacy that dispenses prescription drugs to outpatients is located within ten miles by the shortest driving distance of the proposed telepharmacy site unless the proposed telepharmacy site is located on property owned, operated, or leased by the state or unless the proposed telepharmacy site is located within a hospital campus and is limited to inpatient dispensing. The mileage requirement does not apply to a telepharmacy site that has been approved by the board and is operating as a telepharmacy prior to July 1, 2016.
- d. An applicant seeking a special or limited-use pharmacy license for a proposed telepharmacy site that does not meet the mileage requirement established in paragraph "c" and is not statutorily exempt from the mileage requirement may apply to the board for a waiver of the mileage requirement. A waiver request shall only be granted if the applicant can demonstrate to the board that the proposed telepharmacy site is located in an area where there is limited access to pharmacy services and can establish the existence of compelling circumstances that justify waiving the mileage requirement. The board's decision to grant or deny a waiver request shall be a proposed decision subject to mandatory review by the director of public health. The director shall review a proposed decision and shall have the power to approve, modify, or veto a proposed decision. The director's decision on a waiver request shall be considered final agency action subject to judicial review under chapter 17A.
- e. The board shall issue a special or limited-use pharmacy license to a telepharmacy site that meets the minimum requirements established by the board by rule.
- 4.  $\alpha$ . The board shall adopt rules for the issuance of a hospital pharmacy license to a hospital which provides pharmacy services for its own use. The rules shall:
  - (1) Recognize the special needs and circumstances of hospital pharmacies.
- (2) Give due consideration to the scope of pharmacy services that the hospital's medical staff and governing board elect to provide for the hospital's own use.
  - (3) Consider the size, location, personnel, and financial needs of the hospital.
- (4) Give recognition to the standards of the joint commission on the accreditation of health care organizations and the American osteopathic association and to the conditions of participation under Medicare.
- b. To the maximum extent possible, the board shall coordinate the rules with the standards and conditions described in paragraph "a", subparagraph (4), and shall coordinate its inspections of hospital pharmacies with the Medicare surveys of the department of inspections and appeals and with the board's inspections with respect to controlled substances conducted under contract with the federal government.

- c. A hospital which provides pharmacy services by contracting with a licensed pharmacy is not required to obtain a hospital pharmacy license or a general pharmacy license.
- 5. A hospital which elects to operate a pharmacy for other than its own use is subject to the requirements for a general pharmacy license. If the hospital's pharmacy services for other than its own use are special or limited, the board may issue a special or limited-use pharmacy license pursuant to subsection 3.
- 6. To qualify for a pharmacy license, the applicant shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board. The application shall include the following and such other information as required by rules of the board and shall be given under oath:
  - a. Ownership.
  - b. Location.
- c. The license number of each pharmacist employed by the pharmacy at the time of application.
  - d. The trade or corporate name of the pharmacy.
- *e*. The name of the pharmacist in charge, who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.
- 7. A person who falsely makes the affidavit prescribed in subsection 6 is subject to all penalties prescribed for making a false affidavit.
- 8. A pharmacy license issued by the board under this chapter shall be issued in the name of the pharmacist in charge and is not transferable or assignable.
- 9. The board shall specify by rule minimum standards for professional responsibility in the conduct of a pharmacy.
  - 10. A separate license is required for each principal place of practice.
  - 11. The license of the pharmacy shall be displayed.
- 87 Acts, ch 215, \$13; 98 Acts, ch 1100, \$20; 2005 Acts, ch 179, \$179; 2009 Acts, ch 41, \$195; 2016 Acts, ch 1093, \$3; 2016 Acts, ch 1138, \$22

Referred to in §155A.15

Practice of pharmacy pilot or demonstration research projects relating to authority of prescription verification and the ability of a pharmacist to provide enhanced patient care; 2011 Acts, ch 63, §36; 2012 Acts, ch 1113, §31; 2013 Acts, ch 138, §128

## 155A.13A Nonresident pharmacy license — required, renewal, discipline.

- 1. License required. A pharmacy located outside of this state that delivers, dispenses, or distributes by any method, prescription drugs or devices to an ultimate user in this state shall obtain a nonresident pharmacy license from the board. The board shall make available an application form for a nonresident pharmacy license and shall require such information it deems necessary to fulfill the purposes of this section. A nonresident pharmacy shall do all of the following in order to obtain a nonresident pharmacy license from the board:
  - a. Submit a completed application form and an application fee as determined by the board.
- b. Submit evidence of possession of a valid pharmacy license, permit, or registration issued by the home state licensing authority.
  - c. (1) Submit an inspection report that satisfies all of the following requirements:
  - (a) Less than two years have passed since the date of inspection.
- (b) The inspection occurred while the pharmacy was in operation. An inspection prior to the initial opening of the pharmacy shall not satisfy this requirement.
- (c) The inspection report addresses all aspects of the pharmacy's business that will be utilized in Iowa.
- (d) The inspection was performed by or on behalf of the home state licensing authority, if available.
- (e) The inspection report is the most recent report available that satisfies the requirements of this paragraph "c".
- (2) If the home state licensing authority has not conducted an inspection satisfying the requirements of this paragraph "c", the pharmacy may submit an inspection report from the national association of boards of pharmacy's verified pharmacy program, or the pharmacy may submit an inspection report from another qualified entity if preapproved by the board, if the inspection report satisfies all of the other requirements of this paragraph "c".
  - (3) The board may recover from a nonresident pharmacy, prior to the issuance of a license

or renewal, the costs associated with conducting an inspection by or on behalf of the board for purposes of satisfying the requirement in subparagraph (1), subparagraph division (d). In addition, the nonresident pharmacy shall submit evidence of corrective actions for all deficiencies noted in the inspection report and shall submit evidence of compliance with all legal directives of the home state regulatory or licensing authority.

- d. Submit evidence that the nonresident pharmacy maintains records of the controlled substances delivered, dispensed, or distributed to ultimate users in this state.
- e. Submit evidence that the nonresident pharmacy provides a toll-free telephone service, the telephone number of which is printed on the label affixed to each prescription dispensed or distributed in Iowa, that allows patients to speak with a pharmacist who has access to patient records at least six days per week for a total of at least forty hours.
- 2. Pharmacist license requirement. The pharmacist who is the pharmacist in charge of the nonresident pharmacy shall be designated as such on the nonresident pharmacy license application or renewal. Any change in the pharmacist in charge shall be reported to the board within ten days of the change. The pharmacist in charge must be registered, not licensed, according to rules established by the board of pharmacy.
- 3. *License renewal*. A nonresident pharmacy shall renew its license on or before January 1 annually. In order to renew a nonresident pharmacy license, a nonresident pharmacy shall submit a completed application and fee as determined by the board, and shall fulfill all of the requirements of subsection 1. A nonresident pharmacy shall pay an additional fee for late renewal as determined by the board.
- 4. *License denial*. The board shall refuse to issue a nonresident pharmacy license for failure to meet the requirements of subsection 1. The board may refuse to issue or renew a license for any grounds under which the board may impose discipline. License or renewal denials shall be considered contested cases governed by chapter 17A.
- 5. *Discipline*. The board may fine, suspend, revoke, or impose other disciplinary sanctions on a nonresident pharmacy license for any of the following:
- a. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.
- b. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the nonresident pharmacy, pharmacist in charge, or individual owner, or if the pharmacy is an association, joint stock company, partnership, or corporation, by any managing officer.
- c. Refusing access to the pharmacy or pharmacy records to an agent of the board for the purpose of conducting an inspection or investigation.
  - d. Any violation of this chapter or chapter 124, 124B, 126, or 205, or rule of the board. 91 Acts, ch 233, §1; 94 Acts, ch 1009, §18; 2016 Acts, ch 1093, §4; 2017 Acts, ch 145, §20

155A.13B Pharmacy internet sites. Repealed by 2017 Acts, ch 93, §5.

# 155A.13C Outsourcing facility license — renewal, cancellation, denial, discipline.

- 1. License required. Any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. §353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state shall obtain an outsourcing facility license from the board prior to engaging in such distribution. If an outsourcing facility dispenses prescription drugs pursuant to patient-specific prescriptions to patients in Iowa, the outsourcing facility shall obtain and maintain a valid Iowa pharmacy license or Iowa nonresident pharmacy license under this chapter. The board shall make available an application form for an outsourcing facility license and shall require such information it deems necessary to fulfill the purposes of this section. An outsourcing facility shall do all of the following in order to obtain an outsourcing facility license from the board:
  - a. Submit a completed application form and application fee as determined by the board.
- b. Submit evidence of possession of a valid registration as an outsourcing facility with the United States food and drug administration.

- c. If one or more inspections have been conducted by the United States food and drug administration in the five-year period immediately preceding the application, submit a copy of any correspondence from the United States food and drug administration as a result of the inspection, including but not limited to any form 483s, warning letters, or formal responses, and all correspondence from the applicant to the United States food and drug administration related to such inspections, including but not limited to formal responses and corrective action plans. 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 United States food and drug administration.
- d. Submit evidence that the supervising pharmacist, as described in 21 U.S.C. §353b(a), holds a valid pharmacist license in the state in which the facility is located and that such license is in good standing.
- 2. License renewal. An outsourcing facility shall renew its license on or before January 1 annually. In order to renew an outsourcing facility license, an outsourcing facility shall submit a completed application and fee as determined by the board, and shall fulfill all of the requirements of subsection 1. An outsourcing facility shall pay an additional fee for late renewal as determined by the board.
- 3. License cancellation. If a facility ceases to be registered as an outsourcing facility with the United States food and drug administration, the facility shall notify the board in writing and shall surrender its Iowa outsourcing facility license to the board within thirty days of such occurrence. Upon receipt, the board shall administratively cancel the outsourcing facility license.
- 4. *License denial*. The board shall refuse to issue an outsourcing facility license for failure to meet the requirements of subsection 1. The board may refuse to issue or renew a license for any grounds under which the board may impose discipline. License or renewal denials shall be considered contested cases governed by chapter 17A.
- 5. *Discipline*. The board may fine, suspend, revoke, or impose other disciplinary sanctions on an outsourcing facility license for any of the following:
- a. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.
- b. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the outsourcing facility, supervising pharmacist, or individual owner, or if the outsourcing facility is an association, joint stock company, partnership, or corporation, by any managing officer.
- c. Refusing access to the outsourcing facility or facility records to an agent of the board for the purpose of conducting an inspection or investigation.
  - d. Any violation of this chapter or chapter 124, 124B, 126, or 205, or rule of the board. 2016 Acts, ch 1093, \$5; 2018 Acts, ch 1026, \$57

#### 155A.14 Renewal of pharmacy license.

The board shall specify by rule the procedures to be followed and the fee to be paid for a renewal certificate, and the penalties for late renewal or failure to renew a pharmacy license. 87 Acts, ch 215, §14

# 155A.15 Pharmacies — license required — discipline, violations, and penalties.

- 1. A pharmacy subject to section 155A.13 shall not be operated until a license or renewal certificate has been issued to the pharmacy by the board.
- 2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:
- a. Been convicted of a felony or a misdemeanor involving moral turpitude, or if the applicant is an association, joint stock company, partnership, or corporation, that a managing officer has been convicted of a felony or a misdemeanor involving moral turpitude, under the law of this state, another state, or the United States.

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- b. Advertised any prescription drugs or devices in a deceitful, misleading, or fraudulent manner.
- c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.
- d. Delivered without legal authorization prescription drugs or devices to a person other than one of the following:
  - (1) A pharmacy licensed by the board.
  - (2) A practitioner.
- (3) A person who procures prescription drugs or devices for the purpose of lawful research, teaching, or testing, and not for resale.
  - (4) A manufacturer or wholesaler licensed by the board.
- (5) A licensed health care facility which is furnished the drug or device by a pharmacy for storage in secured emergency pharmaceutical supplies containers maintained within the facility in accordance with rules of the department of inspections and appeals and rules of the board.
  - e. Allowed an employee who is not a licensed pharmacist to practice pharmacy.
  - f. Delivered mislabeled prescription or nonprescription drugs.
- g. Failed to engage in or ceased to engage in the business described in the application for a license.
- h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.
- *i*. Failed to establish effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by this chapter and other Iowa or federal laws or rules.

87 Acts, ch 215, §15; 91 Acts, ch 233, §2; 97 Acts, ch 39, §2; 2009 Acts, ch 133, §64 Referred to in §155A.16

#### 155A.16 Procedure.

Unless otherwise provided, any disciplinary action taken by the board under section 155A.12 or 155A.15 is governed by chapter 17A and the rules of practice and procedure before the board.

87 Acts, ch 215, §16

#### 155A.17 Wholesale distributor license.

- 1. A person shall not engage in wholesale distribution without a wholesale distributor license.
- 2. Wholesale distributors shall comply with the national standards contained in the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq., and national standards promulgated thereunder.
- 3. The board shall adopt rules establishing requirements for wholesale distributor licenses, licensure fees, and other relevant matters consistent with the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq.
- 4. The board may deny, suspend, or revoke a wholesale distributor license, or otherwise discipline a wholesale distributor, for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States, or for a violation of this chapter, chapter 124, 124B, 126, or 205, or a rule of the board.

87 Acts, ch 215, §17; 91 Acts, ch 233, §3; 2005 Acts, ch 179, §180, 181; 2017 Acts, ch 145, §21; 2018 Acts, ch 1141, §13

#### 155A.17A Third-party logistics provider license.

- 1. A person shall not operate as a third-party logistics provider in this state without a third-party logistics provider license.
- 2. Third-party logistics providers shall comply with national standards contained in the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq., and national standards promulgated thereunder.

3. The board shall adopt rules establishing requirements for a third-party logistics provider license, licensure fees, and other relevant matters consistent with the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq.

4. The board may deny, suspend, or revoke a third-party logistics provider license, or otherwise discipline a third-party logistics provider, for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States, or for a violation of this chapter, chapter 124, 124B, 126, or 205, or a rule of the board.

2018 Acts, ch 1141, §14

## 155A.18 Penalties.

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

87 Acts, ch 215, §18

#### 155A.19 Notifications to board.

- 1. A pharmacy shall report in writing to the board, pursuant to its rules, the following:
- a. Permanent closing.
- b. Change of ownership.
- c. Change of location.
- d. Change of pharmacist in charge.
- e. The sale or transfer of prescription drugs, including controlled substances, on the permanent closing or change of ownership of the pharmacy.
  - f. Change of legal name or doing-business-as name.
  - g. Theft or significant loss of any controlled substance on discovery of the theft or loss.
- h. Disasters, accidents, and emergencies that may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, and disease.
- 2. A pharmacist shall report in writing to the board within ten days a change of name, address, or place of employment.
  - 3. A wholesaler shall report in writing to the board, pursuant to its rules, the following:
  - a. Permanent closing or discontinuation of wholesale distributions into this state.
  - b. Change of ownership.
  - c. Change of location.
  - d. Change of the wholesaler's responsible individual.
  - e. Change of legal name or doing-business-as name.
  - f. Theft or significant loss of any controlled substance on discovery of the theft or loss.
- g. Disasters, accidents, and emergencies that may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, and disease.
  - h. Other information or activities as required by rule.

87 Acts, ch 215, §19; 91 Acts, ch 233, §4; 2005 Acts, ch 179, §182, 183

## 155A.20 Unlawful use of terms and titles — impersonation.

- 1. A person, other than a pharmacy or wholesaler licensed under this chapter, shall not display in or on any store, internet site, or place of business, nor use in any advertising or promotional literature, communication, or representation, the word or words: "apothecary", "drug", "drug store", or "pharmacy", either in English or any other language, any other word or combination of words of the same or similar meaning, or any graphic representation in a manner that would mislead the public.
  - 2. A person shall not do any of the following:
  - a. Impersonate before the board an applicant applying for licensing under this chapter.
  - b. Impersonate an Iowa licensed pharmacist.
- c. Use the title pharmacist, druggist, apothecary, or words of similar intent unless the person is licensed to practice pharmacy.
  - 3. A pharmacist shall not utilize the title "Dr." or "Doctor" if that pharmacist has not

acquired the doctor of pharmacy degree from an approved college of pharmacy or the doctor of philosophy degree in an area related to pharmacy.

87 Acts, ch 215, §20; 2005 Acts, ch 179, §184

## 155A.21 Unlawful possession of prescription drug or device — penalty.

- 1. A person found in possession of a drug or device limited to dispensation by prescription, unless the drug or device was so lawfully dispensed, commits a serious misdemeanor.
- 2. Subsection 1 does not apply to a licensed pharmacy, licensed wholesaler, physician, veterinarian, dentist, podiatric physician, optometrist, advanced registered nurse practitioner, physician assistant, a nurse acting under the direction of a physician, or the board of pharmacy, its officers, agents, inspectors, and representatives, or to a common carrier, manufacturer's representative, or messenger when transporting the drug or device in the same unbroken package in which the drug or device was delivered to that person for transportation.

87 Acts, ch 215, \$21; 95 Acts, ch 108, \$14; 2005 Acts, ch 179, \$185; 2007 Acts, ch 10, \$154; 2012 Acts, ch 1004, \$4

## 155A.22 General penalty.

A person who violates any of the provisions of this chapter or any chapter pertaining to or affecting the practice of pharmacy for which a specific penalty is not provided commits a simple misdemeanor.

87 Acts, ch 215, §22

#### 155A.23 Prohibited acts.

- 1. A person shall not perform or cause the performance of or aid and abet any of the following acts:
- a. Obtaining or attempting to obtain a prescription drug or device or procuring or attempting to procure the administration of a prescription drug or device by:
  - (1) Engaging in fraud, deceit, misrepresentation, or subterfuge.
- (2) Forging or altering a written, electronic, or facsimile prescription or any written, electronic, or facsimile order.
  - (3) Concealing a material fact.
  - (4) Using a false name or giving a false address.
- b. Willfully making a false statement in any prescription, report, or record required by this chapter.
- c. For the purpose of obtaining a prescription drug or device, falsely assuming the title of or claiming to be a manufacturer, wholesaler, pharmacist, pharmacy owner, physician, dentist, podiatric physician, prescribing psychologist, veterinarian, or other authorized person.
- d. Making or uttering any false or forged oral, written, electronic, or facsimile prescription or oral, written, electronic, or facsimile order.
- e. Forging, counterfeiting, simulating, or falsely representing any drug or device without the authority of the manufacturer, or using any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.
- f. Manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or that has otherwise been rendered unfit for distribution.
  - g. Adulterating, misbranding, or counterfeiting any drug or device.
- h. Receiving any drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and delivering or proffering delivery of such drug or device for pay or otherwise.
- *i.* Adulterating, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or device or committing any other act with respect to a drug or device that results in the drug or device being misbranded.
- *j.* Purchasing or receiving a drug or device from a person who is not licensed to distribute the drug or device to that purchaser or recipient.

k. Selling or transferring a drug or device to a person who is not authorized under the law of the jurisdiction in which the person receives the drug or device to purchase or possess the drug or device from the person selling or transferring the drug or device.

- l. Failing to maintain or provide records as required by this chapter, chapter 124, or rules of the board.
- m. Providing the board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the scope of this chapter, chapter 124, or rules of the board.
  - n. Distributing at wholesale any drug or device that meets any of the following conditions:
- (1) The drug or device was purchased by a public or private hospital or other health care entity.
- (2) The drug or device was donated or supplied at a reduced price to a charitable organization.
- (3) The drug or device was purchased from a person not licensed to distribute the drug or device.
  - (4) The drug or device was stolen or obtained by fraud or deceit.
- o. Failing to obtain a license or operating without a valid license when a license is required pursuant to this chapter or chapter 147.
  - p. Engaging in misrepresentation or fraud in the distribution of a drug or device.
- q. Distributing a drug or device to a patient without a prescription drug order or medication order from a practitioner licensed by law to use or prescribe the drug or device.
- r. Distributing a drug or device that was previously dispensed by a pharmacy or distributed by a practitioner except as provided by rules of the board.
  - s. Failing to report any prohibited act.
- 2. Information communicated to a physician in an unlawful effort to procure a prescription drug or device or to procure the administration of a prescription drug shall not be deemed a privileged communication.
- 3. Subsection 1, paragraphs "f" and "g", shall not apply to the wholesale distribution by a manufacturer of a prescription drug or device that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

87 Acts, ch 215, \$23; 95 Acts, ch 108, \$15; 2004 Acts, ch 1036, \$13, 14; 2005 Acts, ch 179, \$186; 2009 Acts, ch 41, \$196; 2016 Acts, ch 1112, \$14

Referred to in \$155A.24

#### 155A.24 Penalties.

- 1. Except as otherwise provided in this section, a person who violates a provision of section 155A.23 or who sells or offers for sale, gives away, or administers to another person any prescription drug or device in violation of this chapter commits a public offense and shall be punished as follows:
- a. If the prescription drug is a controlled substance, the person shall be punished pursuant to section 124,401, subsection 1, and other provisions of chapter 124, subchapter IV.
- b. If the prescription drug is not a controlled substance, the person, upon conviction of a first offense, is guilty of a serious misdemeanor. For a second offense, or if in case of a first offense the offender previously has been convicted of any violation of the laws of the United States or of any state, territory, or district thereof relating to prescription drugs or devices, the offender is guilty of an aggravated misdemeanor. For a third or subsequent offense or if in the case of a second offense the offender previously has been convicted two or more times in the aggregate of any violation of the laws of the United States or of any state, territory, or district thereof relating to prescription drugs or devices, the offender is guilty of a class "D" felony.
- 2. A person who violates any provision of this chapter by selling, giving away, or administering any prescription drug or device to a minor is guilty of a class "C" felony.
- 3. A wholesaler who, with intent to defraud or deceive, fails to deliver to another person, when required by rules of the board, complete and accurate pedigree concerning a drug prior to transferring the drug to another person is guilty of a class "C" felony.
  - 4. A wholesaler who, with intent to defraud or deceive, fails to acquire, when required by

rules of the board, complete and accurate pedigree concerning a drug prior to obtaining the drug from another person is guilty of a class "C" felony.

- 5. A wholesaler who knowingly destroys, alters, conceals, or fails to maintain, as required by rules of the board, complete and accurate pedigree concerning any drug in the person's possession is guilty of a class "C" felony.
- 6. A wholesaler who is in possession of pedigree documents required by rules of the board, and who knowingly fails to authenticate the matters contained in the documents as required, and who nevertheless distributes or attempts to further distribute drugs is guilty of a class "C" felony.
- 7. A wholesaler who, with intent to defraud or deceive, falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of drugs or devices is guilty of a class "C" felony.
- 8. A wholesaler who knowingly forges, counterfeits, or falsely creates any pedigree, who falsely represents any factual matter contained in any pedigree, or who knowingly fails to record material information required to be recorded in a pedigree is guilty of a class "C" felony.
- 9. A wholesaler who knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution is guilty of a class "C" felony.
- 10. A wholesaler who knowingly sells, barters, brokers, or transfers a drug or device to a person not authorized to purchase the drug or device under the jurisdiction in which the person receives the drug or device in a wholesale distribution is guilty of a class "C" felony.
- 11. A person who knowingly manufacturers, sells, or delivers, or who possesses with intent to sell or deliver, a counterfeit, misbranded, or adulterated drug or device is guilty of the following:
- a. If the person manufactures or produces a counterfeit, misbranded, or adulterated drug or device; or if the quantity of a counterfeit, misbranded, or adulterated drug or device being sold, delivered, or possessed with intent to sell or deliver exceeds one thousand units or dosages; or if the violation is a third or subsequent violation of this subsection, the person is guilty of a class "C" felony.
- b. If the quantity of a counterfeit, misbranded, or adulterated drug or device being sold, delivered, or possessed with intent to sell or deliver exceeds one hundred units or dosages but does not exceed one thousand units or dosages; or if the violation is a second or subsequent violation of this subsection, the person is guilty of a class "D" felony.
  - c. All other violations of this subsection shall constitute an aggravated misdemeanor.
- 12. A person who knowingly forges, counterfeits, or falsely creates any label for a drug or device or who falsely represents any factual matter contained on any label of a drug or device is guilty of a class "C" felony.
- 13. A person who knowingly possesses, purchases, or brings into the state a counterfeit, misbranded, or adulterated drug or device is guilty of the following:
- a. If the quantity of a counterfeit, misbranded, or adulterated drug or device being possessed, purchased, or brought into the state exceeds one hundred units or dosages; or if the violation is a second or subsequent violation of this subsection, the person is guilty of a class "D" felony.
  - b. All other violations of this subsection shall constitute an aggravated misdemeanor.
- 14. This section does not prevent a licensed practitioner of medicine, dentistry, podiatry, nursing, psychology, veterinary medicine, optometry, or pharmacy from acts necessary in the ethical and legal performance of the practitioner's profession.
- 15. Subsections 1 and 2 shall not apply to a parent or legal guardian administering, in good faith, a prescription drug or device to a child of the parent or a child for whom the individual is designated a legal guardian.
- 87 Acts, ch 215, \$24; 2005 Acts, ch 179, \$187; 2007 Acts, ch 22, \$42; 2008 Acts, ch 1016, \$4; 2016 Acts, ch 1112, \$15

## 155A.25 Burden of proof.

In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provisions of this chapter, it shall not be necessary to negate any exception, excuse, proviso, or exemption contained in this chapter, and the burden of proof of any such exception, excuse, proviso, or exemption shall be upon the defendant.

87 Acts, ch 215, §25

## 155A.26 Enforcement — agents as peace officers.

The board, its officers, agents, inspectors, and representatives, and all peace officers within the state, and all county attorneys shall enforce all provisions of this chapter, except those specifically delegated, and shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to prescription drugs. Officers, agents, inspectors, and representatives of the board shall have the powers and status of peace officers when enforcing the provisions of this chapter and chapters 124, 126, and 205. Officers, agents, inspectors, and representatives of the board of pharmacy may:

- 1. Administer oaths, acknowledge signatures, and take testimony.
- 2. Make audits of the supply and inventory of controlled substances and prescription drugs in the possession of any and all individuals or institutions authorized to have possession of any controlled substances or prescription drugs, regardless of the location of the individual or institution.
- 3. Conduct routine and unannounced inspections of pharmacies, drug wholesalers, and the offices or business locations of all individuals and institutions authorized to have possession of prescription drugs including controlled substances or prescription devices, regardless of the location of the office or business.
- 4. Conduct inspections and investigations related to the practice of pharmacy and the distribution of prescription drugs and devices in and into this state.
- 5. Seize controlled or counterfeit substances or articles used in the manufacture or sale of controlled or counterfeit substances which they have reasonable grounds to believe are held in violation of law.
  - 6. Seize prescription medications which they believe are held in violation of law.
  - 7. Perform other duties as specifically authorized or mandated by law or rule.
  - 87 Acts, ch 215, §26; 2007 Acts, ch 10, §155; 2008 Acts, ch 1088, §77; 2016 Acts, ch 1093, §6

### 155A.27 Requirements for prescription.

- 1. Except when dispensed directly by a prescriber to an ultimate user, a prescription drug shall not be dispensed without a prescription that is authorized by a prescriber and based on a valid patient-prescriber relationship.
- 2. a. Beginning January 1, 2020, every prescription issued for a prescription drug shall be transmitted electronically as an electronic prescription to a pharmacy by a prescriber or the prescriber's authorized agent unless exempt under paragraph "b".
  - b. Paragraph "a" shall not apply to any of the following:
- (1) A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.
  - (2) A prescription authorized by a licensed veterinarian.
  - (3) A prescription for a device.
  - (4) A prescription dispensed by a department of veterans affairs pharmacy.
- (5) A prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments.
  - (6) A prescription for a compounded preparation containing two or more components.
- (7) A prescription issued in response to a public health emergency in a situation where a non-patient specific prescription would be permitted.
- (8) A prescription issued for an opioid antagonist pursuant to section 135.190 or a prescription issued for epinephrine pursuant to section 135.185.
- (9) A prescription issued during a temporary technical or electronic failure at the location of the prescriber or pharmacy, provided that a prescription issued pursuant to

this subparagraph shall indicate on the prescription that the prescriber or pharmacy is experiencing a temporary technical or electronic failure.

- (10) A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.
- (11) A prescription issued in an emergency situation pursuant to federal law and regulation and rules of the board.
- c. A practitioner, as defined in section 124.101, subsection 27, paragraph "a", who violates paragraph "a" is subject to an administrative penalty of two hundred fifty dollars per violation, up to a maximum of five thousand dollars per calendar year. The assessment of an administrative penalty pursuant to this paragraph by the appropriate licensing board of the practitioner alleged to have violated paragraph "a" shall not be considered a disciplinary action or reported as discipline. A practitioner may appeal the assessment of an administrative penalty pursuant to this paragraph, which shall initiate a contested case proceeding under chapter 17A. A penalty collected pursuant to this paragraph shall be deposited into the drug information program fund established pursuant to section 124.557. The board shall be notified of any administrative penalties assessed by the appropriate professional licensing board and deposited into the drug information program fund under this paragraph.
- d. A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception under paragraph "b" and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription. However, a pharmacist shall exercise professional judgment in identifying and reporting suspected violations of this section to the board or the appropriate professional licensing board of the prescriber.
- 3. For prescriptions issued prior to January 1, 2020, or for prescriptions exempt from the electronic prescription requirement in subsection 2, paragraph "b", a prescriber or the prescriber's authorized agent may transmit a prescription for a prescription drug to a pharmacy by any of the following means:
  - a. Electronically.
  - b. By facsimile.
  - c. Orally.
- d. By providing an original signed prescription to a patient or a patient's authorized representative.
- 4. A prescription shall be issued in compliance with this subsection. Regardless of the means of transmission, a prescriber shall provide verbal verification of a prescription upon request of the pharmacy.
  - a. If written, electronic, or facsimile, each prescription shall contain all of the following:
  - (1) The date of issue.
- (2) The name and address of the patient for whom, or the owner of the animal for which, the drug is dispensed.
  - (3) The name, strength, and quantity of the drug prescribed.
  - (4) The directions for use of the drug, medicine, or device prescribed.
- (5) The name, address, and written or electronic signature of the prescriber issuing the prescription.
  - (6) The federal drug enforcement administration number, if required under chapter 124.
  - b. If electronic, each prescription shall comply with all of the following:
- (1) The prescriber shall ensure that the electronic system used to transmit the electronic prescription has adequate security and safeguards designed to prevent and detect unauthorized access, modification, or manipulation of the prescription.
- (2) Notwithstanding paragraph "a", subparagraph (5), for prescriptions that are not controlled substances, if transmitted by an authorized agent, the electronic prescription shall not require the written or electronic signature of the prescriber issuing the prescription.
- c. If facsimile, in addition to the requirements of paragraph "a", each prescription shall contain all of the following:
- (1) The identification number of the facsimile machine which is used to transmit the prescription.

- (2) The date and time of transmission of the prescription.
- (3) The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.
- d. If oral, the prescriber issuing the prescription shall furnish the same information required for a written prescription, except for the written signature and address of the prescriber. Upon receipt of an oral prescription, the recipient shall promptly reduce the oral prescription to a written format by recording the information required in a written prescription.
- e. A prescription transmitted by electronic, facsimile, or oral means by a prescriber's agent shall also include the name and title of the prescriber's agent completing the transmission.
- 5. An electronic, facsimile, or oral prescription shall serve as the original signed prescription and the prescriber shall not provide a patient, a patient's authorized representative, or the dispensing pharmacist with a signed written prescription. Prescription records shall be retained pursuant to rules of the board.
- 6. This section shall not prohibit a pharmacist, in exercising the pharmacist's professional judgment, from dispensing, at one time, additional quantities of a prescription drug, with the exception of a prescription drug that is a controlled substance as defined in section 124.101, up to the total number of dosage units authorized by the prescriber on the original prescription and any refills of the prescription, not to exceed a ninety-day supply of the prescription drug as specified on the prescription.
- 7. A prescriber, medical group, institution, or pharmacy that is unable to timely comply with the electronic prescribing requirements in subsection 2, paragraph "a", may petition the board for an exemption from the requirements based upon economic hardship, technical limitations that the prescriber, medical group, institution, or pharmacy cannot control, or other exceptional circumstances. The board shall adopt rules establishing the form and specific information to be included in a request for an exemption and the specific criteria to be considered by the board in determining whether to approve a request for an exemption. The board may approve an exemption for a period of time determined by the board, not to exceed one year from the date of approval, and may be annually renewed subject to board approval upon request.

87 Acts, ch 215, \$27; 97 Acts, ch 39, \$3, 4; 2004 Acts, ch 1036, \$15, 16; 2009 Acts, ch 69, \$5; 2016 Acts, ch 1060, \$1; 2017 Acts, ch 145, \$29; 2018 Acts, ch 1138, \$11; 2019 Acts, ch 59, \$53 Referred to in \$124.308, 126.11, 147.107, 155A.29

## 155A.28 Label of prescription drugs — interchangeable biological product list.

- 1. The label of any drug, biological product, or device sold and dispensed on the prescription of a practitioner shall be in compliance with rules adopted by the board.
- 2. The board shall maintain a link on its internet site to the current list of all biological products that the United States food and drug administration has determined to be interchangeable biological products.

87 Acts, ch 215, §28; 2017 Acts, ch 5, §2

#### 155A.29 Prescription refills.

- 1. Except as specified in subsection 2, 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.
- 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. Prescriptions may be refilled once pursuant to subsection 2 for a period of time reasonably necessary for the pharmacist to secure prescriber authorization.
- 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.

87 Acts, ch 215, \$29; 2007 Acts, ch 19, \$5; 2009 Acts, ch 69, \$6; 2018 Acts, ch 1138, \$12

## 155A.30 Out-of-state prescription orders.

Prescription drug orders issued by out-of-state practitioners who would be authorized to prescribe if they were practicing in Iowa may be filled by licensed pharmacists operating in licensed Iowa pharmacies.

87 Acts, ch 215, §30

## 155A.31 Reference library.

A licensed pharmacy in this state shall maintain a reference library pursuant to rules of the board.

87 Acts, ch 215, §31

## 155A.32 Drug product selection — restrictions.

- 1. a. If an authorized prescriber prescribes, in writing, electronically, by facsimile, or orally, a drug by its brand or trade name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated bioavailability as the drug product prescribed for dispensing and sale to the patient. If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a drug product with the same generic name and demonstrated bioavailability as the drug product prescribed for dispensing and sale.
- b. If an authorized prescriber prescribes a biological product, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a biological product that is an interchangeable biological product for the biological product prescribed for dispensing and sale to the patient. If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a biological product that is an interchangeable biological product for the biological product prescribed for dispensing and sale
- 2. The pharmacist shall not exercise the drug or biological product selection described in this section if any of the following is true:
- a. The prescriber specifically indicates that no drug or biological product selection shall be made.
- b. The person presenting the prescription indicates that only the specific drug product prescribed should be dispensed. However, this paragraph does not apply if the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A.
- 3. If selection of a generically equivalent drug product or an interchangeable biological product is made under this section, the pharmacist making the selection shall inform the patient and note that fact and the name of the manufacturer of the selected drug on the prescription presented by the patient or the patient's adult representative or transmitted by the prescriber or the prescriber's authorized agent.
- 4. a. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The entry shall be electronically accessible to the prescriber through one of the following means:
  - (1) An interoperable electronic medical records system.

- (2) An electronic prescribing technology.
- (3) A pharmacy benefit management system.
- (4) A pharmacy record.
- b. An entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. If the entry is not made electronically, the pharmacist shall communicate the name and manufacturer of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means.
- c. Communication under this subsection shall not be required in either of the following circumstances:
- (1) There is no federal food and drug administration-approved interchangeable biological product for the product prescribed.
- (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

87 Acts, ch  $215,\, \$32;\, 2004$  Acts, ch  $1036,\, \$17;\, 2017$  Acts, ch  $5,\, \$3$  Referred to in \$514E7

## 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 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 Verification of automated dispensing, technician product verification, for dispensing. and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist and shall be determined in accordance with rules adopted by the board.

87 Acts, ch 215, \$33; 96 Acts, ch 1070, \$4; 2002 Acts, ch 1108, \$25; 2008 Acts, ch 1016, \$5; 2016 Acts, ch 1093, \$7; 2018 Acts, ch 1142, \$4

Notwithstanding section 147.107, subsection 2, or this section, board of pharmacy is authorized to approve a pilot or demonstration research project relating to authority of prescription verification and pharmacist ability to provide enhanced patient care; rules adoption and legislative reporting required; see 2011 Acts, ch 63, §36; 2012 Acts, ch 1113, §31; 2013 Acts, ch 138, §128

## 155A.33A Technician product verification programs.

- 1. A pharmacist in charge of a pharmacy located in this state may formally establish a technician product verification program to optimize the provision of pharmacist patient care services. The board may require a pharmacist in charge intending to implement a technician product verification program to submit a program plan for board consideration and approval. The plan shall demonstrate that onsite practice hours for a pharmacist will not be reduced but will be redistributed directly to patient care activities.
- 2. The board shall adopt rules for the development, implementation, and oversight of technician product verification programs. The rules shall address program policy and procedures, pharmacist and pharmacy technician training, program quality assurance and evaluation, recordkeeping, redistribution of pharmacist activities, and other matters necessary for the development, implementation, and oversight of the program.

2018 Acts, ch 1142, §5

#### 155A.34 Transfer of prescriptions.

Any prescription transfer shall be from a licensed pharmacy to another licensed pharmacy and be performed in accordance with rules adopted by the board.

87 Acts, ch 215, §34; 2008 Acts, ch 1016, §6; 2018 Acts, ch 1142, §6

#### 155A.35 Patient medication records.

A licensed pharmacy shall maintain patient medication records in accordance with rules adopted by the board.

87 Acts, ch 215, §35

## 155A.36 Medication delivery systems.

Drugs dispensed utilizing unit dose packaging shall comply with labeling and packaging requirements in accordance with rules adopted by the board.

87 Acts, ch 215, §36

# 155A.37 Code of professional responsibility for board employees.

- 1. The board shall adopt a code of professional responsibility to regulate the conduct of board employees responsible for inspections and surveys of pharmacies.
- 2. The code shall contain a procedure to be followed by personnel of the board in all of the following:
  - a. On entering a pharmacy.
  - b. During inspection of the pharmacy.
  - c. During the exit conference.
- 3. The code shall contain standards of conduct that personnel of the board are to follow in dealing with the staff and management of the pharmacy and the general public.
- 4. The board shall establish a procedure for receiving and investigating complaints of violations of this code. The board shall investigate all complaints of violations.
- 5. The board may adopt rules establishing sanctions for violations of this code of professional responsibility.

87 Acts, ch 215, §37; 2004 Acts, ch 1167, §10

#### 155A.38 Dispensing drug samples.

A person authorized pursuant to this chapter to dispense shall, when dispensing drug samples, do so without additional charge to the patient.

88 Acts, ch 1232, §3

# 155A.39 Program to monitor impaired pharmacists, pharmacist-interns, or pharmacy technicians — immunity and funding.

- 1. The board may establish a review committee and may implement a program to monitor impaired pharmacists, pharmacist-interns, and pharmacy technicians pursuant to section 272C.3, subsection 1, paragraph "k".
- 2. An employee or a member of the board, a review committee member, or any other person who furnishes information, data, reports, or records in good faith for the purpose of aiding an impaired pharmacist, pharmacist-intern, or pharmacy technician, shall be immune from civil liability. This immunity from civil liability shall be liberally construed to accomplish the purpose of this section and is in addition to other immunity provided by law.
- 3. An employee or member of the board or a review committee member is presumed to have acted in good faith. A person alleging a lack of good faith has the burden of proof on that issue.
- 4. The board may add a surcharge of not more than ten percent of the applicable fee to a pharmacist license fee, pharmacist license renewal fee, pharmacist-intern registration fee, pharmacy technician registration fee, or pharmacy technician registration renewal fee authorized under this chapter to fund a program to monitor impaired pharmacists, pharmacist-interns, or pharmacy technicians.
- 5. The board may accept, transfer, and expend funds made available by the federal or state government or by another public or private source to be used in a program authorized by this section.
- 6. Funds and surcharges collected under this section shall be deposited in an account and may be used by the board to administer a program authorized by this section, but shall not be used for costs incurred for a participant's initial evaluation, referral services, treatment, or rehabilitation subsequent to intervention.

7. The board may disclose that the license of a pharmacist, the registration of a pharmacist-intern, or the registration of a pharmacy technician who is the subject of an order of the board that is confidential pursuant to section 272C.6 is suspended, revoked, canceled, restricted, or retired; or that the pharmacist, pharmacist-intern, or pharmacy technician is in any manner otherwise limited in the practice of pharmacy; or other relevant information pertaining to the pharmacist, pharmacist-intern, or pharmacy technician which the board deems appropriate.

8. The board may adopt rules necessary for the implementation of this section. 97 Acts, ch 39, \$5; 2017 Acts, ch 93, \$3

### 155A.40 Criminal history record checks.

- 1. The board may request and obtain, notwithstanding section 692.2, subsection 5, criminal history data for any applicant for an initial or renewal license or registration issued pursuant to this chapter or chapter 147, any applicant for reinstatement of a license or registration issued pursuant to this chapter or chapter 147, or any licensee or registrant who is being monitored as a result of a board order or agreement resolving an administrative disciplinary action, for the purpose of evaluating the applicant's, licensee's, or registrant's eligibility for licensure, registration, or suitability for continued practice of the profession. Criminal history data may be requested for all owners, managers, and principal employees of a pharmacy or drug wholesaler licensed pursuant to this chapter. The board shall adopt rules pursuant to chapter 17A to implement this section. The board shall inform the applicant, licensee, or registrant of the criminal history requirement and obtain a signed waiver from the applicant, licensee, or registrant prior to submitting a criminal history data request.
- 2. A request for criminal history data shall be submitted to the department of public safety, division of criminal investigation, pursuant to section 692.2, subsection 1. The board may also require such applicants, licensees, and registrants to provide a full set of fingerprints, in a form and manner prescribed by the board. Such fingerprints may be submitted to the federal bureau of investigation through the state criminal history repository for a national criminal history check. The board may authorize alternate methods or sources for obtaining criminal history record information. The board may, in addition to any other fees, charge and collect such amounts as may be incurred by the board, the department of public safety, or the federal bureau of investigation in obtaining criminal history information. Amounts collected shall be considered repayment receipts as defined in section 8.2.
- 3. Criminal history information relating to an applicant, licensee, or registrant obtained by the board pursuant to this section is confidential. The board may, however, use such information in a license or registration denial proceeding. In a disciplinary proceeding, such information shall constitute investigative information under section 272C.6, subsection 4, and may be used only for purposes consistent with that section.
- 4. This section shall not apply to a manufacturer of a prescription drug or device that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

2005 Acts, ch 35, §31; 2005 Acts, ch 179, §188

#### 155A.41 Continuous quality improvement program.

- 1. Each licensed pharmacy shall implement or participate in a continuous quality improvement program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors and for improving patient use of medications and patient care services. Under the program, each pharmacy shall assess its practices and identify areas for quality improvement.
- 2. The board shall adopt rules for the administration of a continuous quality improvement program. The rules shall address all of the following:
  - a. Program requirements and procedures.
  - b. Program record and reporting requirements.
  - c. Any other provisions necessary for the administration of a program. 2005 Acts, ch 179, §189

#### 155A.42 Limited distributor license.

- 1. A person other than a wholesale distributor, licensed pharmacy, or practitioner, shall not engage in any of the following activities in this state without a limited distributor license:
- a. Distribution of a medical gas or device at wholesale or to a patient pursuant to a prescription drug order.
  - b. Wholesale distribution of a prescription animal drug.
- c. Wholesale distribution of a prescription drug, or brokering the distribution of a prescription drug at wholesale, by a manufacturer, a manufacturer's co-licensed partner, or a repackager.
- d. Intracompany distribution of a prescription drug, including pharmacy chain distribution centers.
- e. Distribution at wholesale of a combination product as defined by the United States food and drug administration, medical convenience kit, intravenous fluid or electrolyte, dialysis solution, radioactive drug, or irrigation or sterile water solution to be dispensed by prescription only.
- *f.* Distribution of a dialysis solution by the manufacturer or the manufacturer's agent to a patient pursuant to a prescription drug order, provided that a licensed pharmacy processes the prescription drug order.
- 2. The board shall adopt rules establishing the requirements for a limited distributor license, licensure fees, compliance standards, and any other relevant matters. A limited distributor shall not be required to have an onsite pharmacist.
- 3. The board may deny, suspend, or revoke a limited distributor's license, or otherwise discipline a limited distributor, for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States, or for a violation of this chapter, chapter 124, 124B, 126, or 205, or a rule of the board.

2007 Acts, ch 19, §6; 2017 Acts, ch 145, §22; 2018 Acts, ch 1141, §15

#### 155A.43 Pharmaceutical collection and disposal program — annual allocation.

Of the fees collected by the board pursuant to sections 124.301 and 147.80 and this chapter, and retained by the board pursuant to section 147.82, the board may annually allocate a sum deemed by the board to be adequate for administering the pharmaceutical collection and disposal program. The program shall provide for the management and disposal of unused, excess, and expired pharmaceuticals, including the management and disposal of controlled substances pursuant to state and federal regulations. The board may contract with one or more vendors for the provision of supplies and services to manage and maintain the program and to safely and appropriately dispose of pharmaceuticals collected through the program.

2011 Acts, ch 129, §88, 156; 2014 Acts, ch 1026, §143; 2015 Acts, ch 137, §74, 162, 163; 2017 Acts, ch 93, §4

#### 155A.44 Vaccine and immunization administration.

- 1. In accordance with rules adopted by the board, a licensed pharmacist may administer vaccines and immunizations pursuant to this section.
- 2. The board shall adopt rules requiring pharmacists to complete training pursuant to continuing education requirements and establish protocols for the review of prescriptions and administration of vaccines and immunizations. The rules shall allow a licensed pharmacist who has completed the required training to administer vaccines and immunizations in accordance with the rules of the board and shall include the United States centers for disease control and prevention's protocol for the administration of the vaccinations and immunizations.
- 3. Prior to the administration of a vaccination or immunization authorized by subsection 4, paragraph "b", subparagraphs (2) through (4), pursuant to the required 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 subsection 4, paragraph "b", subparagraphs (2) through (4), to a patient's primary health care provider, primary physician, and a statewide immunization registry or health information network.

4. A licensed pharmacist shall only administer the following vaccines and immunizations to the designated age categories:

- a. Vaccination and immunization of patients ages six years through seventeen years shall be limited to vaccines or immunizations for influenza and other emergency immunizations or vaccines in response to a public health emergency.
- b. Patients ages eighteen years and older may receive a vaccination or immunization administered by a licensed pharmacist for any of the following:
- (1) An immunization or vaccination described in paragraph "a", including all forms of the influenza vaccine.
- (2) An immunization or vaccination recommended by the United States centers for disease control and prevention advisory committee on immunization practices in its approved vaccination schedule for adults.
- (3) An immunization or vaccine recommended by the United States centers for disease control and prevention for international travel.
  - (4) A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application. 2013 Acts, ch 8, \$1

For future repeal of this section, effective July 1, 2021, see 2020 Acts, ch 1103, §46, 51

## 155A.45 Inspection reports — disclosure.

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.

2016 Acts, ch 1093, §8

# 155A.46 Statewide protocols.

- 1. a. A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and consistent with subsection 2, order and administer the following to patients ages eighteen years and older:
  - (1) Naloxone.
  - (2) Nicotine replacement tobacco cessation products.
- (3) An immunization or vaccination recommended by the United States centers for disease control and prevention advisory committee on immunization practices in its approved vaccination schedule for adults.
- (4) An immunization or vaccination recommended by the United States centers for disease control and prevention for international travel.
  - (5) A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application.
- (6) Other emergency immunizations or vaccinations in response to a public health emergency.
- b. A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and consistent with subsection 2, order and administer the following to patients ages six months and older:
  - (1) A vaccine or immunization for influenza.
  - (2) Other emergency immunizations or vaccines in response to a public health emergency.
- c. A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and consistent with subsection 2, order and administer the final two doses in a course of vaccinations for HPV to patients ages eleven years and older.
- d. Prior to the ordering and administration of a vaccination 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.
- 2. A pharmacist ordering or administering a prescription drug, product, test, or treatment pursuant to subsection 1 shall do all of the following:

- a. Maintain a record of all prescription drugs, products, tests, and treatments administered pursuant to this section.
- b. Notify the patient's primary health care provider of any prescription drugs, products, tests, or treatments administered to the patient, or enter such information in a patient record system also used by the primary health care provider, as permitted by the primary health care provider. If the patient does not have a primary health care provider, the pharmacist shall provide the patient with a written record of the prescription drugs, products, tests, or treatment provided to the patient and shall advise the patient to consult a physician.
- c. Complete continuing pharmacy education related to statewide protocols recognized and approved by the board.

2018 Acts, ch 1142, §7