PHARMACY, §155A.3

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 an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed 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" means one or more of the following:
- a. A substance recognized as a drug in the current official United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia, or other drug compendium or any supplement to any of them.
- b. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.
- c. A substance, other than food, intended to affect the structure or any function of the body of humans or other animals.
- d. A substance intended for use as a component of any substance specified in paragraph "a", "b", or "c".
 - e. A controlled substance.
- 15. "Drug product selection" means the act of selecting the source of supply of a drug product.
- 16. "Drug sample" means a drug that is distributed without consideration to a pharmacist or practitioner.
- 17. "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.
- 18. "Electronic signature" means a confidential personalized digital key, code, or number used for secure electronic transmissions which identifies and authenticates the signatory.
- 19. "Facsimile order" or "facsimile prescription" means an order or prescription which is transmitted by a device which sends an exact image to the receiver.

§155A.3, PHARMACY 2

20. "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.

- 21. "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.
- 22. "Internship" means a practical experience program approved by the board for persons training to become pharmacists.
- 23. "Label" means written, printed, or graphic matter on the immediate container of a drug or device.
- 24. "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.
- 25. "Limited drug and device distributor" means a person operating or maintaining, either within or outside this state, a location at which limited noncontrolled prescription drugs, prescription devices, and medical gases, are distributed to patients in this state pursuant to a prescription drug order; or a person operating or maintaining a location at which limited quantities of drugs, devices, or medical gases are distributed at wholesale in this state. A "limited drug and device distributor" does not include a pharmacy licensed pursuant to this chapter or a drug wholesaler providing prescription drugs to patients in this state pursuant to a drug manufacturer's prescription drug assistance program.
- 26. "Logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer or other owner of a drug, but does not take title to the drug or have general responsibility to direct its sale or other disposition.
- 27. "Managing pharmacy" means a licensed pharmacy that oversees the activities of a telepharmacy site.
 - 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.

3 PHARMACY, \$155A.3

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" means any of the following:
- a. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.
- b. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following statements:
 - (1) Caution: Federal law prohibits dispensing without a prescription.
- (2) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (3) Caution: Federal law restricts this device to sale by, or on the order of, a physician.
 - (4) Rx only.
- c. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only, or is restricted to use by a practitioner only.
- 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. "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.
- 43. "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.
- 44. "Telepharmacy" means the practice of pharmacy via telecommunications as provided by the board by rule.
- 45. "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.
- 46. "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.
- 47. "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.
- 48. "Wholesaler" means a person operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs or devices, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, distributed from, or offered for sale at wholesale in this state. "Wholesaler" does not include those wholesalers who sell only proprietary or over-the-counter medicines. "Wholesaler" also does not include

§155A.3, PHARMACY 4

a commercial carrier that temporarily stores prescription drugs or devices, medicinal chemicals, medicines, or poisons while in transit.

"Wholesale salesperson" or "manufacturer's representative" means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Wholesale salesperson" or "manufacturer's representative" does not include an individual who sells only proprietary medicines.

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 Referred to in §124B.1, §124B.6, §135M.2, §147.107, §321J.2, §423.3, §462A.14, §510B.1, §514L.1, §716A.3 NEW subsection 3 and former subsections 3 – 19 renumbered as 4 – 20

NEW subsection 21 and former subsections 20 - 35 renumbered as 22 - 37

Former subsection 36 amended and renumbered as 38

Former subsections 37 - 47 renumbered as 39 - 49