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. *"Limited distributor"* does not include a secondary distributor as defined in section 135.190.

25. *"Managing pharmacy"* means a licensed pharmacy that oversees the activities of a telepharmacy site.

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 support person"* means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

37. *"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.

38. *"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.

39. *"Practitioner"* means a physician, dentist, podiatric physician, prescribing psychologist, veterinarian, optometrist, pharmacist, 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.

40. *"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.

41. *"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.

42. *"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.

43. *"Product"* means the same as defined in 21 U.S.C. §360eee.

44. *"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.

45. *"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.

46. *"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.

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. *"Therapeutic substitution"* means the replacement of a prescribed drug, biological product, or device with an alternative molecule or device with assumed equivalent therapeutic effect. The alternative drug, biological product, or device may be within the same class or from another class with assumed therapeutic equivalence.

51. *"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.

52. *"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.

53. *"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.

54. *"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.

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.

55. *"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. *"Wholesale distributor"* does not include a secondary distributor as defined in section 135.190.

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; 2021 Acts, ch 68, §2, 3; 2023 Acts, ch 86, §23; 2024 Acts, ch 1056, §2, 3

Referred to in §124.308, 124B.1, 124B.6, 135M.2, 147.107, 155A.47, 321J.2, 423.3, 462A.14, 510B.1, 514F.7, 514F.9, 514L.1, 716A.3
Subsection 39 amended
NEW subsection 50 and former subsections 50 – 54 renumbered as 51 – 55