

§13702-A. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

1. Automated pharmacy systems. "Automated pharmacy systems" means mechanical systems that perform operations or activities, other than compounding, relative to the storage, packaging, labeling, dispensing or distribution of medications, and systems that collect, control and maintain all transactional information.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

1-A. Biological product. "Biological product" has the same meaning as in 42 United States Code, Section 262.

[PL 2019, c. 34, §1 (NEW).]

2. Board. "Board" means the Maine Board of Pharmacy.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

2-A. Collaborative drug therapy management. "Collaborative drug therapy management" means the initiating, administering, monitoring, modifying and discontinuing of a patient's drug therapy by a pharmacist as authorized by a practitioner in accordance with a collaborative practice agreement. "Collaborative drug therapy management" includes collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration; and, under the supervision of, or in direct consultation with, a practitioner, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation does not include a diagnostic component.

[PL 2021, c. 271, §1 (AMD).]

2-B. Collaborative practice agreement. "Collaborative practice agreement" means a written and signed agreement between one or more pharmacists with training and experience relevant to the scope of the collaborative practice and a practitioner that supervises or provides direct consultation to the pharmacist or pharmacists engaging in collaborative drug therapy management that:

A. Defines the collaborative practice, which must be within the scope of the supervising practitioner's practice, in which the pharmacist or pharmacists may engage; [PL 2013, c. 308, §1 (NEW).]

B. States the beginning and ending dates of the period of time during which the agreement is in effect; and [PL 2013, c. 308, §1 (NEW).]

C. Includes individually developed guidelines for the prescriptive practice of the participating pharmacist or pharmacists. [PL 2013, c. 308, §1 (NEW).]

[PL 2013, c. 308, §1 (NEW).]

3. Commissioner. "Commissioner" means the Commissioner of Professional and Financial Regulation.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

4. Compounding. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device by a pharmacist:

A. For the pharmacist's patient for dispensing as the result of a practitioner's prescription drug order; [PL 2021, c. 289, §2 (NEW).]

B. For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing; [PL 2021, c. 289, §2 (NEW).]

C. In anticipation of prescription drug orders to be received by the pharmacist based on routine, regularly observed prescribing patterns for the pharmacist's patient; or [PL 2021, c. 289, §2 (NEW).]

D. For nonpatient-specific drugs for distribution to licensed veterinarians for veterinarian office use for nonfood-producing animals, as that term is defined in board rule. [PL 2021, c. 289, §2 (NEW).]

[PL 2021, c. 289, §2 (AMD).]

5. Dangerous substance. "Dangerous substance" means a substance described in section 13731, subsection 2.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

6. Deliver or delivery. "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

7. Department. "Department" means the Department of Professional and Financial Regulation.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

8. Device. "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 prescribed by a practitioner and dispensed by a pharmacist.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

9. Dispense or dispensing. "Dispense" or "dispensing" means the preparation and delivery of a prescription drug in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug pursuant to a lawful order of a practitioner.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

10. Distribute. "Distribute" means the delivery of a drug other than by administering or dispensing.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

11. Drug. "Drug" means:

A. Articles recognized as drugs in the official United States Pharmacopeia and National Formulary, other drug compendiums or any supplement to any of them; [PL 2007, c. 402, Pt. DD, §2 (NEW).]

B. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; [PL 2007, c. 402, Pt. DD, §2 (NEW).]

C. Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and [PL 2007, c. 402, Pt. DD, §2 (NEW).]

D. Articles intended for use as a component of any articles specified in paragraphs A to C. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

12. Electronic transmission. "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

12-A. Eligible product developer. "Eligible product developer" means a person that seeks to develop an application for the approval of a drug under the Federal Food, Drug, and Cosmetic Act,

Section 505(b) or 505(j) or the licensing of a biological product under the federal Public Health Service Act, Section 351.

[PL 2017, c. 434, §1 (NEW).]

13. Free clinic. "Free clinic" means an incorporated nonprofit health facility that provides health care to people at no charge.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

14. Generic and therapeutically equivalent drug. "Generic" and "therapeutically equivalent drug" means any drug that has identical amounts of the same active ingredients in the same dosage form and in the same concentration that, when administered in the same amounts, will produce or can be expected to have the same therapeutic effect as the drug prescribed.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

14-A. Interchangeable biological product. "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has:

A. Licensed and determined meets the standards for interchangeability pursuant to 42 United States Code, Section 262(k)(4); or [PL 2019, c. 34, §2 (NEW).]

B. Determined is therapeutically equivalent as set forth in the most recent edition of or supplement to the federal Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" or a successor publication. [PL 2019, c. 34, §2 (NEW).]

[PL 2019, c. 34, §2 (NEW).]

15. Labeling. "Labeling" means the process of preparing and affixing a label to the outside of any drug container, exclusive of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label must include all information required by federal law or regulation and state law or rule.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

16. Mail order contact lens supplier. "Mail order contact lens supplier" means a person or entity, other than an optometrist or physician licensed in this State, that fills contact lens prescriptions by mail or carrier for a patient who resides in this State.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

17. Mail order prescription pharmacy. "Mail order prescription pharmacy" means an entity that dispenses prescription medications by mail or carrier from a facility not located in this State to a patient who resides in this State.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

18. Manufacture. "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a device or drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that manufacture does not include the preparation or compounding of a drug by an individual for personal use or the preparation, compounding, packaging or labeling of a drug:

A. By a pharmacist or practitioner incidental to administering or dispensing a drug in the course of professional practice; or [PL 2007, c. 402, Pt. DD, §2 (NEW).]

B. By a practitioner or by authorization under the practitioner's supervision for the purpose of or incidental to research, teaching or chemical analysis and not for sale. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

19. Manufacturer. "Manufacturer" means a person engaged in the manufacture of prescription drugs.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

20. Nonprescription drugs. "Nonprescription drugs" means nonnarcotic drugs that may be sold without a prescription and that are prepackaged for use by the consumer and labeled in accordance with the requirements of the laws and rules of this State and the Federal Government.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

20-A. Opioid medication. "Opioid medication" means a controlled substance containing an opioid included in schedule II of 21 United States Code, Section 812 or 21 Code of Federal Regulations, Part 1308.

[PL 2015, c. 488, §28 (NEW).]

21. Person. "Person" means an individual, corporation, partnership, association or any other legal entity.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

22. Pharmacist. "Pharmacist" means an individual provider of health care services licensed by this State to engage in the practice of pharmacy.

A. "Chain pharmacist" means an individual who is engaged in the practice of pharmacy within a chain; that is, where there is a corporate grouping of 4 or more pharmacies. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

B. "Hospital pharmacist" means an individual who is engaged in the practice of pharmacy in a hospital setting. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

C. "Independent pharmacist" means an individual who is engaged in the practice of pharmacy in an independent pharmacy; that is, where there are fewer than 4 pharmacies under the same ownership. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

D. "Qualified assistant pharmacist" means an individual licensed by this State as a qualified assistant apothecary, qualified assistant or assistant pharmacist, provided that the license is in full force and effect, except for the right to serve as a pharmacist in charge. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

[PL 2021, c. 146, §1 (AMD).]

23. Pharmacist in charge. "Pharmacist in charge" means a pharmacist who accepts responsibility for the operation of a licensed pharmacy in conformance with applicable laws.

[PL 2021, c. 289, §3 (AMD).]

24. Pharmacy. "Pharmacy" means:

A. Any pharmacy or drug outlet located in a retail store, mail order business, free clinic or rural health center with facilities located in this State that is engaged in dispensing, delivering or distributing prescription drugs; or [PL 2007, c. 402, Pt. DD, §2 (NEW).]

B. Any mail order prescription company, or wholesaler, with facilities located in this State or doing business in this State that is engaged in dispensing, delivering or distributing prescription drugs. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

24-A. Pharmacy intern. "Pharmacy intern" means a person who:

A. Is either enrolled in or a graduate of a school or college of pharmacy; and [PL 2011, c. 496, §1 (NEW).]

B. Is licensed with the board and is authorized to engage in the practice of pharmacy while under the direct supervision of a licensed pharmacist. [PL 2011, c. 496, §1 (NEW).]

[PL 2011, c. 496, §1 (NEW).]

25. Pharmacy technician. "Pharmacy technician" means a person employed by a pharmacy who works in a supportive role to, and under the direct supervision of, a licensed pharmacist.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

26. Physician. "Physician" means an allopathic physician or osteopathic physician.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

27. Poison. "Poison" means an agent that when ingested, inhaled or otherwise absorbed by a living organism is capable of producing a deleterious response seriously injuring function or producing death.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

28. Practice of pharmacy. "Practice of pharmacy" means the provision of health care services that include the interpretation and evaluation of prescription drug orders; the compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices; the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records for these drugs and devices; the administration of vaccines licensed by the United States Food and Drug Administration that are recommended by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practices, or successor organization, for administration to adults; the administration to adults by intramuscular and subcutaneous injection of drugs approved by the United States Food and Drug Administration; the performance of collaborative drug therapy management; the responsibility for advising, when necessary or regulated, of therapeutic values, content, hazards and use of drugs and devices; the ordering and dispensing of over-the-counter nicotine replacement products approved by the United States Food and Drug Administration; the prescribing, dispensing and administering of an HIV prevention drug, as defined in section 13786-E, subsection 1, paragraph B, pursuant to a standing order or collaborative practice agreement or to protocols developed by the board; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy.

[PL 2021, c. 146, §2 (AMD); PL 2021, c. 265, §5 (AMD); PL 2021, c. 271, §2 (AMD).]

29. Practitioner. "Practitioner" means an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

30. Prescription drug or legend drug. "Prescription drug" or "legend drug" means a drug that:

A. Under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(1) "Caution: Federal law prohibits dispensing without prescription."; or

(2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."; or [PL 2007, c. 402, Pt. DD, §2 (NEW).]

B. Is required by an applicable federal or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

31. Prescription drug order. "Prescription drug order" means a lawful written or oral order of a practitioner for a drug or device. Written orders may be issued on a prescription form or by electronic transmission.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

31-A. Proper name. "Proper name," as it relates to a biological product, means the nonproprietary name for a biological product designated by the federal Food and Drug Administration for use on each package of the product.

[PL 2019, c. 34, §3 (NEW).]

32. Rural health center. "Rural health center" means an incorporated nonprofit health facility that provides comprehensive primary health care to citizens in rural areas.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

33. Targeted methamphetamine precursor. "Targeted methamphetamine precursor" means any product containing any amount of ephedrine, pseudoephedrine or phenylpropanolamine or their salts, isomers or salts of isomers, either alone or in combination with other ingredients:

A. In dry or solid nonliquid form; or [PL 2007, c. 402, Pt. DD, §2 (NEW).]

B. In liquid, liquid-filled capsule or glycerin matrix form if designation as a targeted methamphetamine precursor has been completed by rule adopted pursuant to section 13795, subsection 5, paragraph A. [PL 2007, c. 402, Pt. DD, §2 (NEW).]

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

34. Wholesaler. "Wholesaler" means a person who buys prescription drugs for resale and distribution to persons other than consumers.

[PL 2007, c. 402, Pt. DD, §2 (NEW).]

SECTION HISTORY

PL 2007, c. 402, Pt. DD, §2 (NEW). PL 2009, c. 308, §1 (AMD). PL 2011, c. 496, §1 (AMD). PL 2011, c. 577, §1 (AMD). PL 2013, c. 308, §§1, 2 (AMD). PL 2015, c. 488, §28 (AMD). PL 2017, c. 185, §1 (AMD). PL 2017, c. 434, §1 (AMD). PL 2019, c. 34, §§1-3 (AMD). PL 2021, c. 146, §§1, 2 (AMD). PL 2021, c. 265, §5 (AMD). PL 2021, c. 271, §§1, 2 (AMD). PL 2021, c. 289, §§2, 3 (AMD).

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