CHAPTER 117

MAINE PHARMACY ACT

SUBCHAPTER 1

TITLE AND DEFINITIONS

§13701. Short title

This chapter shall be known and may be cited as the "Maine Pharmacy Act." [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13702. Definitions

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 716, §1 (AMD). PL 1997, c. 117, §9 (AMD). PL 1997, c. 245, §§3,4 (AMD). RR 1999, c. 1, §46 (COR). PL 1999, c. 42, §§1,2 (AMD). PL 1999, c. 130, §§1-5 (AMD). PL 2005, c. 430, §6 (AMD). PL 2005, c. 430, §10 (AFF). PL 2007, c. 402, Pt. DD, §1 (RP).

§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 repacking 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).

SUBCHAPTER 2

MAINE BOARD OF PHARMACY

§13711. Establishment

There is established, within the department, in accordance with Title 5, chapter 379, the Maine Board of Pharmacy. The board has all of the duties, powers and authority specifically granted by and necessary to the enforcement of this Act. [PL 1997, c. 245, §6 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1997, c. 245, §6 (AMD).

§13712. Membership

The board consists of 7 members, two of whom must be public members as defined in Title 5, section 12004-A and the remainder of whom must be licensed pharmacists who possess the qualifications specified in section 13713. At the time of the appointment, at least one of the licensed pharmacists must be a hospital pharmacist, at least one must be a chain pharmacist and at least one must be an independent pharmacist. [PL 2007, c. 402, Pt. DD, §3 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2007, c. 402, Pt. DD, §3 (AMD).

§13713. Qualifications

1. Public members. The public members of the board must be residents of this State who are at least 21 years of age and shall not be, nor ever have been, members of the profession of pharmacy, the spouse of a member of the profession of pharmacy, a person who has ever had any material financial interest in providing pharmacy services or a person who has engaged in any activity directly related to the practice of pharmacy.
[PL 1987, c. 710, §5 (NEW).]

2. Licensed pharmacists. The licensed pharmacist members of the board shall, at the time of their appointment:

A. Be residents of this State; [PL 1987, c. 710, §5 (NEW).]

B. Be licensed and in good standing to engage in the practice of pharmacy in this State; [PL 1987, c. 710, §5 (NEW).]

C. Be engaged in the practice of pharmacy in this State; and [PL 1987, c. 710, §5 (NEW).]

D. Have 5 years of experience in the practice of pharmacy in this State after licensure. [PL 1987, c. 710, §5 (NEW).]

[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13714. Appointment

The Governor shall appoint the members of the board. Prior to appointing any pharmacist as a member of the board, the Governor may solicit recommendations of candidates from the Maine Pharmacy Association and other pharmaceutical organizations as appropriate. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13715. Terms of office

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 600, §A268 (RP).

§13715-A. Terms of office

1. Length. Members of the board are appointed for terms of 3 years. Appointments of members must comply with Title 10, section 8009.
[PL 2007, c. 402, Pt. DD, §4 (AMD).]

2. Grounds for removal. The Governor may remove a member of the board for cause.
[PL 1993, c. 600, Pt. A, §269 (NEW).]

SECTION HISTORY

PL 1993, c. 600, §A269 (NEW). PL 2007, c. 402, Pt. DD, §4 (AMD).

§13716. Organization

1. Officers. The board shall elect from its members a president and other officers as it considers appropriate and necessary to conduct its business.
[PL 2007, c. 402, Pt. DD, §5 (AMD).]

2. Terms of office. Officers elected by the board serve terms of one year commencing with the day of their elections.
[PL 2007, c. 402, Pt. DD, §5 (AMD).]

3. Executive director.
[PL 1995, c. 397, §108 (RP).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1995, c. 397, §108 (AMD). PL 2007, c. 402, Pt. DD, §5 (AMD).

§13717. Compensation

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1995, c. 397, §109 (RP).

§13718. Meetings

1. Number. The board shall meet at least once a year to transact its business, which includes the election of officers and the reorganization of the board. The board shall meet at additional times as it may determine. Additional meetings may be called by the president or by 2/3 of the members of the board.
[PL 2007, c. 402, Pt. DD, §6 (AMD).]

2. Place.
[PL 2007, c. 402, Pt. DD, §6 (RP).]

3. Notice.
[PL 2007, c. 402, Pt. DD, §6 (RP).]

4. Quorum.
[PL 2013, c. 246, Pt. B, §24 (RP).]

5. Open meeting.

[PL 2007, c. 402, Pt. DD, §6 (RP).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2007, c. 402, Pt. DD, §6 (AMD). PL 2013, c. 246, Pt. B, §24 (AMD).

§13719. Employees

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1995, c. 397, §110 (RP).

§13720. Rules

The board shall make, adopt, amend and repeal such rules as may, from time to time, be determined necessary by the board for the proper administration and enforcement of this Act. These rules shall be promulgated in accordance with the Maine Administrative Procedure Act, Title 5, chapter 375. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13721. Licensure and discipline

1. Responsibility. The board's responsibility for the control and regulation of the practice of pharmacy in this State includes, but is not limited to, the following actions:

A. The licensing by examination or by endorsement of applicants who are qualified to engage in the practice of pharmacy under this Act; [PL 2021, c. 289, §4 (AMD).]

B. The renewal of licenses to engage in the practice of pharmacy; [PL 1987, c. 710, §5 (NEW).]

C. The determination and issuance of standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this State and the specification and enforcement of requirements for practical training, including internship; [PL 1987, c. 710, §5 (NEW).]

D. The inspection during business hours of all pharmacies, dispensaries, stores, hospital pharmacies, extended care facilities, boarding homes, nursing homes, substance use disorder treatment centers, penal institutions, family planning centers or other drug outlets in which drugs or medicines are manufactured, stored, distributed, compounded, dispensed or retailed in this State; [PL 2017, c. 407, Pt. A, §145 (AMD).]

E. The licensing of any pharmacy as set out in section 13751 and any manufacturer or wholesaler whose products are distributed in this State; [PL 2007, c. 402, Pt. DD, §7 (AMD).]

F. The enforcement of those provisions of this Act relating to the conduct or competence of pharmacists practicing in this State and the processing of complaints which could lead to the suspension, revocation or restriction of licenses to engage in the practice of pharmacy; [PL 1987, c. 710, §5 (NEW).]

G. The licensing of pharmacy interns and adoption of rules governing the training, qualification and employment of pharmacy interns and pharmacy students; and [PL 2011, c. 496, §2 (AMD).]

H. The licensing of pharmacy technicians, including the fee as set under section 13724, and adoption of rules governing the training, qualification and employment of pharmacy technicians. [PL 2007, c. 402, Pt. DD, §8 (AMD).]

[PL 2021, c. 289, §4 (AMD).]

2. Reciprocal inspections. The board may enter into reciprocal inspection agreements with any state in which a mail order prescription facility selling drugs to Maine citizens is located.
[PL 1997, c. 245, §8 (AMD).]

3. Pharmacist health program. The board may establish protocols for the operation of a professional review committee as defined in Title 24, section 2502, subsection 4-A. The protocols must include the committee's reporting information the board considers appropriate regarding reports received, contracts or investigations made and the disposition of each report, as long as the committee is not required to disclose any personally identifiable information. The protocols may not prohibit an impaired pharmacist or pharmacy technician from seeking alternative forms of treatment.

The board has the power to contract with other agencies, individuals, firms or associations for the conduct and operation of a pharmacist health program operated by a professional review committee as that term is defined in Title 24, section 2502, subsection 4-A.
[PL 2007, c. 288, §2 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1997, c. 245, §§7,8 (AMD). PL 2005, c. 262, §B1 (AMD). PL 2007, c. 288, §2 (AMD). PL 2007, c. 402, Pt. DD, §§7, 8 (AMD). PL 2011, c. 496, §2 (AMD). PL 2017, c. 407, Pt. A, §145 (AMD). PL 2021, c. 289, §4 (AMD).

§13722. Medications, drugs, devices and other materials

1. Responsibility. The board has the following responsibilities in regard to medications, drugs, devices and other materials used in this State in the diagnosis, mitigation and treatment or prevention of injury, illness and disease. The board shall:

A. Promulgate rules concerning the sale and dispensing of medications, drugs, devices and other materials, including the right to seize any such drugs, devices and other materials found to be detrimental to the public health and welfare by the board after appropriate hearing as required under the Maine Administrative Procedure Act, Title 5, chapter 375; [PL 1987, c. 710, §5 (NEW).]

B. Establish the specifications of minimum professional and technical equipment, environment, supplies and procedure for the compounding, dispensing or administering of medications, drugs, devices and other materials within the practice of pharmacy; [PL 2021, c. 146, §3 (AMD).]

B-1. Establish standards for the use, maintenance and supervision of automated pharmacy systems; [PL 2021, c. 289, §5 (AMD).]

B-2. Establish the terms and conditions for compounding drugs for veterinarian office use by rule, including, at a minimum:

(1) Requirements and specifications of minimum professional and technical equipment, environments, supplies and procedures and quality assurance requirements;

(2) Labeling requirements;

(3) Limits on the supply for administration to the veterinarian's patient and the supply for dispensing to the veterinarian's client;

(4) Record-keeping requirements; and

(5) Procedures for notifications regarding defective drug products and adverse events.

Compounding drugs for veterinarian office use is not permitted until rules are adopted by the board pursuant to this paragraph. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A; [PL 2021, c. 289, §6 (NEW).]

C. Assure that standards for purity and quality of medications, drugs, devices and other materials within the practice of pharmacy are met; [PL 1987, c. 710, §5 (NEW).]

D. Issue and renew licenses for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs; [PL 2007, c. 402, Pt. DD, §9 (AMD).]

E. Promulgate rules concerning the sale and the dispensing of any exempt narcotic preparation. An "exempt narcotic preparation" means any medicinal preparation that contains in 30 milliliters or, if a solid or semisolid preparation, in 30 grams:

(1) Not more than 130 milligrams of opium;

(2) Not more than 15 milligrams of morphine or any of its salts;

(3) Not more than 65 milligrams of codeine or any of its salts;

(4) Not more than 30 milligrams of dihydrocodeine or any of its salts; or

(5) Not more than one of the drugs named in subparagraphs (1) to (4).

A record shall be kept of the sale of exempt narcotic preparations. The record must contain the date of sale, signature and address of the purchaser, name of the preparation, purpose for which purchased and signature of the person making the sale; and [PL 1987, c. 710, §5 (NEW).]

F. After notice and hearing, designate as potent medicinal substances any compounds of barbituric acid, amphetamines or any other central nervous system stimulants or depressants, psychic energizers or any other drugs having a tendency to depress or stimulate which are likely to be injurious to health if improperly used. [PL 1987, c. 710, §5 (NEW).]

[PL 2021, c. 146, §3 (AMD); PL 2021, c. 289, §§5, 6 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1999, c. 130, §6 (AMD). PL 2007, c. 402, Pt. DD, §9 (AMD). PL 2021, c. 146, §3 (AMD). PL 2021, c. 289, §§5, 6 (AMD).

§13723. Other duties, powers and authority

The board has such other duties, powers and authority as may be necessary to enforce this Act and the board may adopt rules pursuant to this Act, which include, but are not limited to, the following. [PL 1987, c. 710, §5 (NEW).]

1. Professional associations. The board may join professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board.
[PL 1987, c. 710, §5 (NEW).]

2. Bond. In addition to any statutory requirements, the board may require such surety bonds as it considers necessary to guarantee the performance and discharge of the duties of any officer or employee receiving and disbursing funds.
[PL 2007, c. 402, Pt. DD, §10 (AMD).]

3. Seal.
[PL 2007, c. 402, Pt. DD, §10 (RP).]

4. Reports.
[PL 2007, c. 402, Pt. DD, §10 (RP).]

5. Fees.
[PL 2005, c. 262, Pt. B, §2 (RP).]

6. Grants. The board may receive and expend funds, in addition to its annual allocation, from parties other than the State, as long as:

A. The funds are awarded for the pursuit of a specific objective that the board is authorized to accomplish by this Act or that the board is qualified to accomplish by reason of its jurisdiction or professional expertise; [PL 2007, c. 402, Pt. DD, §10 (AMD).]

B. The funds are expended for the pursuit of the objective for which they are awarded; [PL 1987, c. 710, §5 (NEW).]

C. Activities connected with or occasioned by the expenditures of the funds do not interfere with or impair the performance of the board's duties and responsibilities and do not conflict with the exercise of the board's powers as specified by this Act; [PL 1987, c. 710, §5 (NEW).]

D. The funds are kept in a separate, special state account; and [PL 1987, c. 710, §5 (NEW).]

E. Periodic reports are made to the commissioner concerning the board's receipt and expenditure of the funds. [PL 1987, c. 710, §5 (NEW).]

[PL 2007, c. 402, Pt. DD, §10 (AMD).]

7. Investigatory powers. The board shall notify the Department of the Attorney General upon receipt of a complaint. Upon receipt of the notifications, the Attorney General shall notify the department within a timely period if the alleged violation requires criminal investigation. If a case does not require criminal investigation, the board or its authorized representatives may investigate and gather evidence concerning alleged violations of this Act or of the rules of the board. The board or an authorized representative pursuant to paragraph A may remove from any premises authorized for inspection pursuant to section 13721, subsection 1, paragraph D certain original records relating to scheduled drugs or controlled substances, including, but not limited to, prescription records, shipping and delivery records, patient profiles, inventories and other drug records for the purposes of analysis, duplication and furthering the investigation. A signed inventory receipt of any records being removed must be furnished to the premises by the board or an authorized representative. When a means of producing legible photocopies is readily available at the site of the records being removed, an authorized representative removing the records shall leave photocopies of the records as part of an inventory receipt in accordance with this subsection. Except when photocopies are left as part of an inventory receipt, the board or an authorized representative removing records from the premises shall, within 48 hours from the time of removal, provide to a representative of the premises photocopies of any removed records, together with a certificate identifying the agency in possession of the records, or return the original records. Inventory receipts and photocopies of any removed records provided by the board or an authorized representative are admissible as evidence if offered by any representative of the premises to prove compliance with any rule of the board or requirement of law.

A. Prescriptions, orders and records required by this chapter and stocks of prescription and legend drugs are open only to the board, the board's authorized representatives, federal and state law enforcement officers whose duty it is to enforce the laws of this State or of the United States relating to scheduled drugs or controlled substances or to enforce conditions of probation or other supervision imposed by a court relating to scheduled drugs or controlled substances and other law enforcement officers authorized by the board, the Attorney General or the district attorney for the purposes of inspecting, investigating and gathering evidence of violations of law or any rule of the board. A person having knowledge by virtue of the person's office of any such prescription, order or record may not divulge that knowledge, except before a licensing board or representative or in connection with a prosecution or proceeding in court. [PL 2009, c. 415, Pt. A, §19 (RPR).]

B. The Bureau of Health, the board, their officers, agents, inspectors and representatives, all peace officers within the State and all prosecuting 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 or legend drugs or their equivalent. [PL 1991, c. 274, §2 (AMD).]

C. [PL 1995, c. 621, §4 (RP).]

[PL 2009, c. 415, Pt. A, §19 (AMD).]

8. Embargo. The board may embargo certain drugs or devices as follows.

A. Notwithstanding anything in this Act to the contrary, if a duly authorized representative of the board finds or has probable cause to believe that any drug or device is adulterated or misbranded within the meaning of the United States Food and Drug Act, the board representative shall affix to the drug or device a tag or other appropriate marking giving notice that the article is or is suspected of being adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until provision for removal or disposal is given by the board, its representative or the court. No person may remove or dispose of the embargoed drug or device by sale or otherwise without the permission of the board or its representative or, after summary proceedings have been instituted, without permission from the court. [PL 2007, c. 402, Pt. DD, §10 (AMD).]

B. When a drug or device detained or embargoed under paragraph A has been declared by a representative of the board to be adulterated or misbranded, the board shall, as soon as practical, report the declaration to the Attorney General's office, along with sufficient information to permit the Attorney General to bring a petition for an injunction to the judge of the court in whose jurisdiction the article is detained or embargoed. If the judge determines that the drug or device so detained or embargoed is not adulterated or misbranded, the board shall direct the immediate removal of the tag or other marking. [PL 1987, c. 710, §5 (NEW).]

C. If the court finds the detained or embargoed drug or device is adulterated or misbranded, that drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of the board representative and all court costs and fees, storage and other proper expense shall be borne by the owner of the drug or device. When the adulteration or misbranding may be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after the costs, fees and expenses have been paid and a good and sufficient bond has been posted, may direct that the drug or device be delivered to the owner for labeling or processing under the supervision of a board representative. The expense of the supervision shall be paid by the owner. The bond shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid. [PL 1987, c. 710, §5 (NEW).]

[PL 2007, c. 402, Pt. DD, §10 (AMD).]

9. Budget.

[PL 1995, c. 397, §111 (RP).]

10. Procedure. Except as otherwise provided, the board shall exercise all of its duties, powers and authority in accordance with the Maine Administrative Procedure Act, Title 5, chapter 375.

[PL 1987, c. 710, §5 (NEW).]

11. Exemption. The board may exempt a free clinic from all fees, in whole or in part, set under this chapter.

[PL 2007, c. 402, Pt. DD, §10 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1991, c. 274, §2 (AMD). PL 1995, c. 251, §1 (AMD). PL 1995, c. 397, §111 (AMD). PL 1995, c. 499, §4 (AMD). PL 1995, c. 499, §5 (AFF). PL 1995, c. 621, §4 (AMD). PL 1997, c. 245, §§9,10 (AMD). PL 1999, c. 42, §3 (AMD). PL 2005, c. 262, §B2 (AMD). PL 2007, c. 344, §10 (AMD). PL 2007, c. 402, Pt. DD, §10 (AMD). PL 2009, c. 415, Pt. A, §19 (AMD).

§13724. Fees

The Director of the Office of Professional and Occupational Regulation may establish by rule fees for purposes authorized under this chapter in amounts that are reasonable and necessary for their respective purposes in accordance with this section. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. [PL 2019, c. 536, §3 (NEW).]

1. General fees. Except as provided in subsection 2, the fee for any one purpose may not exceed $325.
[PL 2019, c. 536, §3 (NEW).]

2. Manufacturer of an opioid medication fee. The fee for a manufacturer of an opioid medication is $55,000. This subsection does not apply to a manufacturer of an opioid medication if all of that manufacturer's opioid medications are approved by the United States Food and Drug Administration for use only in veterinary medicine.
[PL 2019, c. 536, §3 (NEW).]

SECTION HISTORY

PL 2005, c. 262, §B3 (NEW). PL 2007, c. 402, Pt. DD, §11 (AMD). PL 2011, c. 286, Pt. B, §5 (REV). PL 2019, c. 536, §3 (RPR).

§13725. Insulin Safety Net Program

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE UNTIL 1/01/27)

(WHOLE SECTION TEXT REPEALED 1/01/27)

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Eligible individual" means an individual who has been determined to qualify for assistance under the program pursuant to subsection 3 or 4. [PL 2021, c. 303, §1 (NEW).]

B. "Insulin" has the same meaning as in section 13786-D, subsection 1, paragraph A, except for an insulin product that has a wholesale acquisition cost of $8 or less per milliliter or applicable National Council for Prescription Drug Plan billing unit, for the entire assessment time period, adjusted annually based on the Consumer Price Index Annual Average, for All Urban Consumers, CPI-U: U.S. City Averages, All Items reported by the United States Department of Labor, Bureau of Labor Statistics. [PL 2021, c. 303, §1 (NEW).]

C. "Manufacturer" means a manufacturer engaged in the manufacturing of insulin that is self-administered on an outpatient basis, except for a manufacturer with an annual gross revenue of $2,000,000 or less from insulin sales in this State. [PL 2021, c. 303, §1 (NEW).]

D. "Urgent need of insulin" means having readily available for use less than a 7-day supply of insulin and in need of insulin in order to avoid the likelihood of suffering significant health consequences. [PL 2021, c. 303, §1 (NEW).]
[PL 2021, c. 303, §1 (NEW).]

2. Insulin Safety Net Program established. The board shall establish the Insulin Safety Net Program, referred to in this section as "the program," in accordance with the requirements of this section. Under the program, by March 1, 2022, each manufacturer shall establish procedures to make insulin available in accordance with this section and as required under subsections 3 and 4 to pharmacies for dispensing to eligible individuals who are in urgent need of insulin or who need access to an affordable insulin supply.
[PL 2021, c. 303, §1 (NEW).]

3. Urgent need safety net. A pharmacy shall dispense a 30-day supply of insulin, as permitted under section 13786-D, to an eligible individual in urgent need of insulin in accordance with this subsection.

A. To be eligible, an individual must demonstrate on an application form developed by the board that the individual:

(1) Is a resident of this State;

(2) Is not enrolled in MaineCare or any other health coverage or prescription drug coverage that limits the total amount of cost-sharing that the enrollee is required to pay for a 30-day supply of insulin, including copayments, deductibles or coinsurance, to $75 or less, regardless of the type or amount of insulin prescribed;

(3) Has not received an urgent-need supply of insulin through the program within the previous 12 months; and

(4) Has an urgent need of insulin. [PL 2021, c. 303, §1 (NEW).]

B. The board shall make the application form accessible through the board's publicly accessible website and make the form available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics and community health clinics. [PL 2021, c. 303, §1 (NEW).]

C. In addition to a completed, signed and dated application, an individual shall also present to a pharmacy a valid insulin prescription and identification indicating residency in the form of a valid Maine identification card, driver's license or permit. If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian shall provide the pharmacy with proof of residency. Upon receipt of the information required by this paragraph, the pharmacist shall dispense the prescribed insulin in an amount that will provide the individual a 30-day supply. If an individual does not have a valid prescription, a pharmacist may dispense an emergency refill of insulin pursuant to section 13786-D. [PL 2021, c. 303, §1 (NEW).]

D. The pharmacy shall notify the health care practitioner who issued the prescription order presented under paragraph C no later than 72 hours after the insulin is dispensed. [PL 2021, c. 303, §1 (NEW).]

E. The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment for insulin dispensed under paragraph C that is in accordance with the standards developed by a national council for prescription drug programs for electronic claims processing, unless the manufacturer agrees to send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed. If the pharmacy submits an electronic claim to the manufacturer or the manufacturer's vendor, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost. [PL 2021, c. 303, §1 (NEW).]

F. The pharmacy may collect an insulin copayment from the eligible individual to cover the pharmacy's costs of processing and dispensing in an amount not to exceed $35 for the 30-day supply of insulin dispensed under paragraph C. [PL 2021, c. 303, §1 (NEW).]

G. The pharmacy shall provide each eligible individual an information sheet provided by the board with contact information for the Health Insurance Consumer Assistance Program established in Title 24-A, chapter 56-A, subchapter 2-A, including the program's publicly accessible website, toll-free telephone number and e-mail address, so that the individual may access additional information and assistance related to ongoing insulin coverage options, including assistance in: applying for MaineCare; applying for a qualified health plan offered through the federally facilitated marketplace, subject to open and special enrollment periods; accessing information on providers

who participate in prescription drug discount programs, including providers who are authorized to participate in the federal program under section 340b of the federal Public Health Service Act, United States Code, Title 42, section 256b; and accessing insulin manufacturers' patient assistance programs and other assistance programs through nonprofit organizations. [PL 2021, c. 303, §1 (NEW).]

H. The pharmacy shall retain a copy of the application form submitted by the individual under paragraph A to the pharmacy for reporting and compliance purposes. [PL 2021, c. 303, §1 (NEW).]

[PL 2021, c. 303, §1 (NEW).]

4. Manufacturer's patient assistance. A manufacturer shall establish a patient assistance program to provide access to insulin to any eligible individual who meets the requirements of this subsection and who demonstrates a continued need for insulin. Each manufacturer's patient assistance program must meet the requirements of this subsection.

A. Each manufacturer shall provide the Health Insurance Consumer Assistance Program established in Title 24-A, chapter 56-A, subchapter 2-A information regarding the manufacturer's patient assistance program, including contact information for individuals to call for assistance in accessing the patient assistance program. [PL 2021, c. 303, §1 (NEW).]

B. To be eligible to participate in a manufacturer's patient assistance program, an individual must:

(1) Be a Maine resident with a valid identification card that indicates Maine residency in the form of a Maine identification card or driver's license or permit. If the individual is under the age of 18, the individual's parent or legal guardian shall provide proof of residency;

(2) Have a family income that is equal to or less than 400 percent of the federal poverty guidelines; and

(3) Not be enrolled in MaineCare or eligible to receive health care coverage through a federally funded program or to receive prescription drug benefits through the United States Department of Veterans Affairs or not be enrolled in prescription drug coverage through an individual or group health plan that limits the total amount of cost-sharing that an enrollee is required to pay for a 30-day supply of insulin, including copayments, deductibles or coinsurance, to $75 or less, regardless of the type or amount of insulin needed.

Notwithstanding the requirement in this paragraph, an individual who is enrolled in Medicare Part D is eligible for a manufacturer's patient assistance program if the individual has spent $1,000 on prescription drugs in the current calendar year and meets the eligibility requirements in subparagraphs (1) and (2). [PL 2021, c. 303, §1 (NEW).]

C. An individual who is interested in participating in a manufacturer's patient assistance program may apply directly to the manufacturer or through the individual's health care practitioner, if the practitioner participates in the manufacturer's patient assistance program. [PL 2021, c. 303, §1 (NEW).]

D. Upon receipt of an application for the manufacturer's patient assistance program, the manufacturer shall process the application and determine eligibility. The manufacturer shall notify the applicant of the determination within 10 business days of receipt of the application. If necessary, the manufacturer may request additional information from the applicant. If additional information is needed, the manufacturer shall notify the applicant within 5 business days of receipt of the application as to what information is being requested. Within 3 business days of receipt of the requested information, the manufacturer shall determine eligibility and notify the applicant of the determination. If the individual has been determined to be not eligible, the manufacturer shall include the reasons for denying eligibility in the notification. The individual may seek an appeal of the determination in accordance with this section. If the individual is determined to be eligible,

the manufacturer shall provide the individual with an eligibility statement or other indication that the individual has been determined eligible for the manufacturer's patient assistance program. An individual's eligibility is valid for 12 months and is renewable upon a redetermination of eligibility. [PL 2021, c. 303, §1 (NEW).]

E. If the eligible individual has prescription drug coverage through an individual or group health plan, the manufacturer may determine that the individual's insulin needs are better addressed by providing financial assistance for copayments and other cost-sharing requirements of the individual's individual or group health plan. The manufacturer shall establish a copayment assistance program to provide such financial assistance. The manufacturer shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy. Under the manufacturer's copayment assistance program, an eligible individual may not be required to pay more than a copayment of $35 for a 30-day supply of insulin. [PL 2021, c. 303, §1 (NEW).]

F. The eligible individual shall submit to a pharmacy the eligibility statement provided by the manufacturer under paragraph D. Upon receipt of an individual's eligibility status, the pharmacy shall dispense insulin in accordance with this paragraph.

(1) The pharmacy shall submit an order containing the name of the insulin product and the daily dosage amount as contained in a valid prescription to the product's manufacturer. The pharmacy shall include with the order to the manufacturer the following information: the pharmacy's name and shipping address; office telephone number, fax number, e-mail address and contact name; and any specific days or times when deliveries are not accepted by the pharmacy.

(2) Upon receipt of an order from a pharmacy and the information described in this paragraph, the manufacturer shall send to the pharmacy a 90-day supply of insulin as ordered, unless a lesser amount is requested in the order, at no charge to the individual or pharmacy. Except as authorized under paragraph E, the pharmacy shall provide the insulin to the individual at no charge to the individual. The pharmacy may not provide insulin received from the manufacturer to any individual other than the individual associated with the specific order.

(3) The pharmacy may not seek reimbursement for the insulin received from the manufacturer or from any 3rd-party payor. The pharmacy may collect a copayment from the individual to cover the pharmacy's costs for processing and dispensing in an amount not to exceed $50 for each 90-day supply if the insulin is sent to the pharmacy.

(4) The pharmacy may submit to a manufacturer a reorder for an individual if the individual's eligibility statement under paragraph D has not expired. Upon receipt of a reorder from a pharmacy, the manufacturer shall send to the pharmacy an additional 90-day supply of the product, unless a lesser amount is requested, at no charge to the individual or pharmacy if the individual's eligibility statement has not expired.

(5) Notwithstanding subparagraph (2), a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option. [PL 2021, c. 303, §1 (NEW).]

G. If an individual disagrees with a manufacturer's determination of eligibility under this subsection, the individual may contact the board to request a review of eligibility. The review of eligibility must be conducted by the board administrator, in consultation with a board member. The individual requesting the review shall submit to the board, with the request, all documents submitted by the individual to the manufacturer. The board shall provide the reviewer or reviewers with the documents submitted by the individual. The review of eligibility must be completed within 10 business days of receipt of all the necessary documents from the individual. The review decision is final. If the review determines that the individual is eligible for the manufacturer's patient

assistance program, the manufacturer shall provide the individual with an eligibility statement in accordance with this subsection. [PL 2021, c. 303, §1 (NEW).]

[PL 2021, c. 303, §1 (NEW).]

5. Additional 30-day urgent-need insulin supply pending eligibility for other coverage or assistance. If an individual has applied for MaineCare coverage but has not been determined eligible or has been determined eligible but MaineCare coverage has not become effective or if the individual has been determined ineligible for the manufacturer's patient assistance program by the manufacturer and the individual has requested a review pursuant to subsection 4, paragraph G but the reviewer has not rendered a decision, the individual is entitled to access insulin under the provisions of subsection 3 if the individual has an urgent need of insulin. To access insulin under this subsection, the individual must attest to the pharmacy that the individual meets the requirements of subsection 2.

[PL 2021, c. 303, §1 (NEW).]

6. Dissemination of information about program. In consultation with the Health Insurance Consumer Assistance Program, established in Title 24-A, chapter 56-A, subchapter 2-A, the board shall develop an information sheet to post on its publicly accessible website and provide a link to the information sheet on the website to be used by pharmacies, health care practitioners, hospital emergency departments, urgent care clinics and community health clinics. The information sheet must contain: a description of the urgent need insulin safety net, including how to apply for the benefits of the program; a description of each insulin manufacturer's patient assistance program, including contact information for accessing the assistance programs for each manufacturer; information on how to contact the Health Insurance Consumer Assistance Program, established in Title 24-A, chapter 56-A, subchapter 2-A; and information on how to contact the board if a manufacturer determines that an individual is not eligible for the manufacturer's patient assistance program.

[PL 2021, c. 303, §1 (NEW).]

7. Enforcement; penalty for noncompliance. A person who violates this chapter is subject to enforcement action by the board through any board action authorized in accordance with section 13731 or any civil penalty or criminal or civil action authorized in section 13731.

[PL 2021, c. 303, §1 (NEW).]

8. Confidential information. Any health information or records provided to the board under this section are confidential if the information or records identify or permit the identification of an individual who is seeking to access urgently needed insulin under subsection 3 or to participate in a manufacturer's patient assistance program under this section. A manufacturer shall maintain the confidentiality of any information received from any individual applying for the manufacturer's patient assistance program under this section and is prohibited from selling, sharing or disseminating data received under this section unless required to under this section or unless the individual has provided the manufacturer with a signed authorization.

[PL 2021, c. 303, §1 (NEW).]

9. Reports. Beginning February 15, 2023 and annually thereafter, each manufacturer shall report to the board on the number of Maine residents who accessed and received insulin on an urgent-need basis in the preceding calendar year; the number of Maine residents participating in the manufacturer's patient assistance program in the preceding calendar year, including the number of Maine residents who the manufacturer determined were ineligible for its patient assistance program; and the total value of the insulin, determined by the wholesale acquisition cost of the insulin, provided by the manufacturer in the preceding calendar year. Beginning April 15, 2023 and annually thereafter, the board shall submit a report of the aggregate information reported by manufacturers pursuant to this subsection to the joint standing committee of the Legislature having jurisdiction over health coverage, insurance and financial services matters.

[PL 2021, c. 303, §1 (NEW).]

10. Repeal. This section is repealed January 1, 2027.
[PL 2021, c. 303, §1 (NEW).]

SECTION HISTORY

PL 2021, c. 303, §1 (NEW).

SUBCHAPTER 3

LICENSING

§13731. Unlawful practice; penalties; injunctions

1. Applicability. It is unlawful for any person to engage in the practice of pharmacy unless licensed to practice under this Act, except that:

A. Physicians, dentists, veterinarians or other practitioners of the healing arts who are licensed under the laws of this State may dispense and administer prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law; [PL 2013, c. 373, §1 (NEW).]

B. A licensed retail pharmacy that is located in Canada, the United Kingdom of Great Britain and Northern Ireland, the Commonwealth of Australia or New Zealand that meets its country's statutory and regulatory requirements may export prescription drugs by mail or carrier to a resident of this State for that resident's personal use. A licensed retail pharmacy described in this paragraph is exempt from licensure under this Act; and [PL 2013, c. 373, §1 (NEW).]

C. An entity that contracts to provide or facilitate the exportation of prescription drugs from a licensed retail pharmacy described in paragraph B may provide or facilitate the provision of prescription drugs from that pharmacy by mail or carrier to a resident of this State for that resident's personal use. An entity that provides or facilitates the provision of prescription drugs pursuant to this paragraph is exempt from licensure under this Act. [PL 2013, c. 373, §1 (NEW).]
[PL 2013, c. 373, §1 (AMD).]

2. Authorization to deal with dangerous substances. Practitioners, drug jobbers, drug wholesalers, drug manufacturers, pharmacists and pharmacies licensed under this chapter and approved animal shelters as provided in Title 7, section 3913, are authorized to deal professionally with dangerous substances. A dangerous substance is:

A. Any substance listed under the Federal Uniform Controlled Substance Act, sections 1 through 5; or [PL 1987, c. 710, §5 (NEW).]

B. Anything deemed to be dangerous by the Federal Drug Administration, other federal agency, or the Attorney General of the United States. [PL 1987, c. 710, §5 (NEW).]
[PL 2007, c. 402, Pt. DD, §12 (AMD).]

3. Violation. Any person who violates this chapter commits a Class E crime and, notwithstanding Title 17-A, sections 1704 and 1705, may be punished by a fine of not more than $1,000. Each violation of each section of this chapter constitutes a separate offense.
[PL 2019, c. 113, Pt. C, §84 (AMD).]

4. Violation; suspension; penalty. For any violation of this chapter, in addition to other disciplinary action which may be taken by the board, the board may suspend the violator's license for up to 90 days or impose a civil penalty of up to $500, or both, for each violation of each section of this chapter. The jurisdiction to suspend a license for up to 90 days shall be concurrent with that of the District Court.

[PL 1987, c. 710, §5 (NEW); PL 1999, c. 547, Pt. B, §78 (AMD); PL 1999, c. 547, Pt. B, §80 (AFF).]

5. Action to enjoin. The State may bring an action to enjoin any licensee or person from violating this chapter, regardless of whether proceedings have been or may be instituted in the District Court or whether criminal proceedings have been or may be instituted.
[PL 1987, c. 710, §5 (NEW); PL 1999, c. 547, Pt. B, §78 (AMD); PL 1999, c. 547, Pt. B, §80 (AFF).]

6. Fees; fines; forfeitures.
[PL 1995, c. 397, §112 (RP).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1995, c. 397, §112 (AMD). PL 1999, c. 547, §B78 (AMD). PL 1999, c. 547, §B80 (AFF). PL 2007, c. 402, Pt. DD, §12 (AMD). PL 2013, c. 373, §1 (AMD). PL 2019, c. 113, Pt. C, §84 (AMD).

§13732. Qualifications for licensure by examination

1. Requirements. To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination must:

A. Have submitted a written application in the form prescribed by the board together with the required examination and license fee as set under section 13724; [PL 2005, c. 262, Pt. B, §4 (AMD).]

B. Have attained the age of 21 years; [PL 1987, c. 710, §5 (NEW).]

C. [PL 2021, c. 289, §7 (RP).]

D. Have graduated and received the first professional undergraduate degree from a pharmacy degree program accredited by the American Council on Pharmaceutical Education or have received a degree from an equivalent program, which has been approved by the board, from a school outside the United States; [PL 1987, c. 710, §5 (NEW).]

E. Have completed an internship or other program that has been approved by the board or demonstrated, to the board's satisfaction, experience in the practice of pharmacy that meets or exceeds the minimum internship requirement of the board; and [PL 2005, c. 262, Pt. B, §4 (AMD).]

F. Have successfully passed an examination approved by the board. [PL 2005, c. 262, Pt. B, §4 (AMD).]

G. [PL 2005, c. 262, Pt. B, §5 (RP).]
[PL 2021, c. 289, §7 (AMD).]

2. Examinations. Examinations shall be prepared and administered according to this subsection.

A. The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ and cooperate with any organization or consultant in the preparation and grading of an appropriate examination, but shall retain the sole discretion and responsibility of determining which applicants have successfully passed the examination. [PL 1987, c. 710, §5 (NEW).]

B. [PL 2007, c. 402, Pt. DD, §13 (RP).]
[PL 2007, c. 402, Pt. DD, §13 (AMD).]

3. Internship and other training programs. Internship and practical experience requirements shall be determined as follows.

A. All applicants for licensure by examination must obtain practical experience in the practice of pharmacy concurrent with or after college attendance under such terms and conditions as the board may determine. [PL 1987, c. 710, §5 (NEW).]

B. The board shall establish standards for internship or any other program necessary to qualify an applicant for the licensure examination and shall also determine the necessary qualifications of any preceptors used in any internship or other program. [PL 1987, c. 710, §5 (NEW).]

[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2005, c. 262, §§B4,5 (AMD). PL 2007, c. 402, Pt. DD, §13 (AMD). PL 2021, c. 289, §7 (AMD).

§13733. Qualifications for licensure by endorsement

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1995, c. 257, §1 (AMD). PL 1999, c. 130, §7 (AMD). PL 2005, c. 262, §§B6-8 (AMD). PL 2007, c. 402, Pt. DD, §14 (AMD). PL 2021, c. 289, §8 (RP).

§13733-A. Licensure by endorsement

In order to obtain a license as a pharmacist by endorsement, an applicant for licensure must meet the requirements of Title 10, section 8003-H and any applicable rules adopted pursuant to that section. [PL 2021, c. 289, §9 (NEW).]

SECTION HISTORY

PL 2021, c. 289, §9 (NEW).

§13734. Renewal of licenses

1. Renewal. A license expires on the date set by the commissioner pursuant to Title 10, section 8003, subsection 4 for the licensing period for which the license was issued. A renewal license is issued for each ensuing licensing period in the absence of any reason or condition that might warrant the refusal to grant a license, upon receipt by the board of the written request of the applicant and the fee for the license as set under section 13724 and upon the applicant's presenting evidence of compliance with the requirements of section 13735.

Licenses may be renewed up to 90 days after the date of expiration upon payment of a late fee as set under section 13724 in addition to the renewal fee as set under section 13724. Any person who submits an application for renewal more than 90 days after the license renewal date is subject to all requirements governing new applicants under this chapter, including a late fee, renewal fee and additional late fee as set under section 13724, except that the board may, giving due consideration to the protection of the public, waive examination if that renewal application is made within 2 years from the date of that expiration.

[PL 2007, c. 402, Pt. DD, §15 (AMD).]

2. Inactive renewal license. A licensed pharmacist not practicing pharmacy within this State shall pay, on or before the expiration date as determined by the commissioner, a renewal fee as set under section 13724, in return for which an inactive renewal license must be issued.

A licensed pharmacist holding an inactive renewal license who desires to practice pharmacy in this State is required to submit proof satisfactory to the board that, during the calendar year preceding application for active licensure, the pharmacist has participated in not less than 15 hours of approved courses of continuing professional pharmaceutical education as defined in section 13735. The board

may make exceptions to the continuing education requirement of this section in emergency or hardship cases.

If any person fails or neglects to procure the annual inactive renewal license, after the expiration of 30 days that person's original license expires. That person, in order to regain licensure, is required to pay one renewal fee as set under section 13724 in addition to the sum of all fees that person may be in arrears.
[PL 2007, c. 402, Pt. DD, §15 (AMD).]

3. Fees.
[PL 2005, c. 262, Pt. B, §9 (RP).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 600, §A270 (AMD). PL 2005, c. 262, §B9 (AMD). PL 2007, c. 402, Pt. DD, §15 (AMD).

§13735. Continuing pharmacy education

An annual renewal license may not be issued by the board until the applicant certifies to the board that, during the calendar year preceding an application for renewal, the applicant has participated in not less than 15 hours of approved courses of continuing professional pharmaceutical education as set out in this section. For a pharmacist authorized to administer drugs and immunizations, of the 15 hours to be completed, at least 2 hours must be in board-approved courses on drug administration as described in section 13702-A, subsection 28. A pharmacist who enters into a collaborative practice agreement must agree to complete, in each year of the agreement, 5 of the 15 hours required in this section in the areas of practice covered by the agreement. The continuing professional pharmaceutical educational courses consist of postgraduate studies, institutes, seminars, workshops, lectures, conferences, extension studies, correspondence courses or such other forms of continuing professional pharmaceutical education as may be approved by the board. [PL 2021, c. 84, §1 (AMD).]

These courses consist of subject matter pertinent to the following general areas of professional pharmaceutical education: the socioeconomic and legal aspects of health care; the properties and actions of drugs and dosage forms; and the ideology, characteristics and therapeutics of the disease state. The specific subject matter of the courses may include, but is not limited to, pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, drug administration as it relates to the area of permitted practice, pharmacy jurisprudence, public health and communicable diseases, pharmaceutical marketing, professional practice management, anatomy, histology and such other subject matter as represented in curricula of accredited colleges of pharmacy. The content of each course offered for credit under this continuing professional educational program must be approved in advance of the course by the board or its representative. The board may make exceptions to this section in emergency or hardship cases. [PL 2009, c. 308, §2 (AMD).]

Each application for approval of a continuing education program or course must be submitted according to the guidelines prescribed by rule by the board, together with a fee as set under section 13724. [PL 2007, c. 402, Pt. DD, §16 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1999, c. 130, §8 (AMD). PL 2005, c. 262, §B10 (AMD). PL 2007, c. 402, Pt. DD, §16 (AMD). PL 2009, c. 308, §2 (AMD). PL 2013, c. 308, §3 (AMD). PL 2021, c. 84, §1 (AMD).

SUBCHAPTER 4

DISCIPLINE

§13741. Informal conference

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 600, §A271 (AMD). PL 1999, c. 130, §9 (AMD). PL 2007, c. 402, Pt. DD, §17 (AMD). PL 2011, c. 286, Pt. K, §1 (RP).

§13742. Grounds for discipline

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 600, §A272 (AMD). PL 1999, c. 130, §10 (AMD). PL 2007, c. 402, Pt. DD, §18 (RP).

§13742-A. Denial or refusal to renew license; disciplinary sanctions; crimes; criminal prosecutions

1. Disciplinary action. In addition to the grounds enumerated in Title 10, section 8003, subsection 5-A, paragraph A, the board may deny a license, refuse to renew a license or impose the disciplinary sanctions authorized by Title 10, section 8003, subsection 5-A for:

A. Misuse of alcohol, drugs or other substances that has resulted or may result in the applicant or licensee performing duties in a manner that endangers the health or safety of patients; [PL 2013, c. 105, §9 (AMD).]

B. A professional diagnosis of a mental or physical condition that has resulted or may result in the applicant or licensee performing duties in a manner that endangers the health or safety of patients; [PL 2007, c. 402, Pt. DD, §19 (NEW).]

C. Engaging in unprofessional conduct by violating any standard of professional behavior, including but not limited to a breach of confidentiality of health care information pursuant to state law, that has been established in the practice for which the licensee is licensed; [PL 2017, c. 434, §2 (AMD).]

D. Engaging in false, misleading or deceptive advertising; [PL 2019, c. 165, §27 (AMD).]

E. Failing to comply with section 13800; [PL 2021, c. 303, §2 (AMD).]

F. A violation of section 13800-B; or [PL 2021, c. 303, §3 (AMD).]

G. A violation of section 13725. [PL 2021, c. 303, §4 (NEW).]

This subsection applies to all types of licenses issued by the board.
[PL 2021, c. 303, §§2-4 (AMD).]

2. Crime in course of business. If any licensed pharmacist is convicted in state or federal court of a crime that is committed during the course of duties performed as a licensed pharmacist or committed through the use of the pharmacy in which the pharmacist is employed, or that the pharmacist owns or operates, and that demonstrates unfitness to practice as a pharmacist, including, but not limited to, convictions for defrauding the Medicaid program and for illegally distributing prescription drugs, the pharmacist's license is subject to disciplinary action as set forth in subsection 1.
[PL 2007, c. 402, Pt. DD, §19 (NEW).]

3. Criminal prosecutions. Nothing in this chapter bars criminal prosecution for any violation of this chapter when that violation is a criminal offense under the laws of this State or of the United States.
[PL 2007, c. 402, Pt. DD, §19 (NEW).]

4. Injunction. Notwithstanding any other provision of law, the Attorney General may seek injunctive relief against a person who violates subsection 1, paragraph E. If the Attorney General

prevails in an action under this subsection, the court must order the person to reimburse the State for the Attorney General's costs of prosecuting the action, including reasonable attorney's fees.
[PL 2017, c. 434, §4 (NEW).]

SECTION HISTORY

PL 2007, c. 402, Pt. DD, §19 (NEW). PL 2013, c. 105, §9 (AMD). PL 2017, c. 434, §§2-4 (AMD). PL 2019, c. 165, §§27-29 (AMD). PL 2021, c. 303, §§2-4 (AMD).

§13743. Reinstatement

1. Penalties.

[PL 2007, c. 402, Pt. DD, §20 (RP).]

2. Reinstatement. Any person whose license to practice pharmacy in this State has been suspended, revoked or restricted pursuant to this chapter, whether voluntarily or by action of the board, may at reasonable intervals petition the board for reinstatement of the license. The petition must be made in writing in a form prescribed by the board. Upon investigation and hearing, the board may grant or deny the petition or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant those modifications.
[PL 1987, c. 710, §5 (NEW).]

3. Criminal prosecutions.
[PL 2007, c. 402, Pt. DD, §20 (RP).]

4. Judicial review.
[PL 2007, c. 402, Pt. DD, §20 (RP).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2007, c. 402, Pt. DD, §20 (AMD).

SUBCHAPTER 5

PHARMACY FACILITIES

§13751. Registration

1. Licensure. All pharmacies, manufacturers, wholesalers and mail order contact lens suppliers shall annually obtain a license from the board.
[PL 2007, c. 402, Pt. DD, §21 (AMD).]

2. Classifications. Pharmacies must be licensed in classifications set out in this subsection.

Each pharmacy must apply for a license in one of the following classifications:

A. Retail pharmacy; [PL 2007, c. 402, Pt. DD, §22 (AMD).]

B. Mail order prescription pharmacy; [PL 2007, c. 402, Pt. DD, §22 (AMD).]

C. Wholesale pharmacy; [PL 2007, c. 402, Pt. DD, §22 (AMD).]

D. Rural health center; [PL 2019, c. 454, §1 (AMD).]

E. Free clinic; or [PL 2019, c. 454, §1 (AMD).]

F. Vending machine outlet. [PL 2019, c. 454, §1 (NEW).]
[PL 2019, c. 454, §1 (AMD).]

3. Rules. The board shall establish by rule the criteria that each pharmacy must meet to qualify for licensure in each classification designated in subsection 2. The board may issue various types of

licenses with varying restrictions to the pharmacies referred to in subsection 2, paragraph A when the board determines it necessary by reason of the type of pharmacy requesting a license.
[PL 2007, c. 402, Pt. DD, §23 (AMD).]

3-A. Mail order contact lens suppliers. In order to meet the board's minimum licensure requirements, a mail order contact lens supplier must:

A. Apply for a license, if filling contact lens prescriptions by mail or carrier for a patient that resides in this State; [PL 2005, c. 262, Pt. B, §11 (AMD).]

B. Pay a license fee, as set under section 13724; [PL 2005, c. 262, Pt. B, §11 (AMD).]

C. Provide the name and address of the owner, partners or corporation and its officers; [PL 1997, c. 117, §11 (NEW).]

D. Fill only written contact lens prescriptions containing expiration dates that do not exceed 24 months from the date of issue; [PL 1997, c. 117, §11 (NEW).]

E. Maintain a record of every contact lens prescription filled for a period of 5 years; and [PL 1997, c. 117, §11 (NEW).]

F. Supply, upon request, all information needed by the board to ensure compliance with this subchapter. [PL 1997, c. 117, §11 (NEW).]

The board may adopt rules establishing additional licensure requirements and disciplinary actions for violation of this subchapter and board rules. Rules adopted pursuant to this subsection are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A.
[PL 2005, c. 262, Pt. B, §11 (AMD).]

4. Nonprescription drugs. It shall be lawful for a person to sell and distribute nonprescription drugs. Any person engaging in the sale and distribution of those items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule may be adopted by the board under this Act which requires the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise applies to or interferes with the sale and distribution of those medicines.
[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1997, c. 117, §§10,11 (AMD). PL 1999, c. 42, §§4,5 (AMD). PL 2005, c. 262, §B11 (AMD). PL 2007, c. 402, Pt. DD, §§21-23 (AMD). PL 2019, c. 454, §1 (AMD).

§13752. Application

1. Procedures. The board shall specify by rule the licensing procedures to be followed, including, but not limited to, specification of forms for use in applying for licensure and the times and places for filing an application.
[PL 2007, c. 402, Pt. DD, §24 (AMD).]

2. Required information. Applications for licenses must include the fee as set under section 13724 and the following information about the proposed pharmacy and pharmacist in charge:

A. Ownership of the pharmacy; [PL 2007, c. 402, Pt. DD, §24 (AMD).]

B. Location of the pharmacy; [PL 2007, c. 402, Pt. DD, §24 (AMD).]

C. Identity of the pharmacist licensed to practice in the State who will be the pharmacist in charge of the pharmacy, when one is required by this chapter, and such further information as the board may determine necessary. The board shall adopt rules identifying the duties and responsibilities of the pharmacist in charge, which must include, at a minimum, responsibility for ensuring the

pharmacy's compliance with all state and federal laws, rules and regulations pertaining to the practice of pharmacy, the distribution of drugs by the pharmacy and the licensure of pharmacy personnel. A pharmacist may be the pharmacist in charge for only one pharmacy, except as otherwise determined by the board by rule. The position of pharmacist in charge may not be held by a qualified assistant pharmacist; and [PL 2021, c. 289, §10 (AMD).]

D. Attestation by the pharmacist identified as the pharmacist in charge that the pharmacist has read and understands the requirements and duties of a pharmacist in charge set forth in board rules. [PL 2021, c. 289, §11 (AMD).]

[PL 2021, c. 289, §§10, 11 (AMD).]

3. Transferability. Licenses issued by the board pursuant to this chapter are not transferable or assignable.

[PL 2007, c. 402, Pt. DD, §24 (AMD).]

4. Professional responsibility. The board shall specify by rule minimum standards for the professional responsibility in the conduct of any pharmacy that has employees or personnel engaged in the practice of pharmacy. The board may require that the portion of the facility to which the license applies be operated only under the direct supervision of no less than one pharmacist licensed to practice in this State and not otherwise and to provide such other special requirements as necessary. A change in the pharmacist in charge who is responsible for the pharmacy must be reported to the board together with the fee as set under section 13724.

[PL 2007, c. 402, Pt. DD, §24 (AMD).]

5. Minimum inventory. The board shall ascertain that the applicant has a sufficient amount of prescription inventory on location to respond appropriately to prescription orders.

[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1999, c. 130, §11 (AMD). PL 2005, c. 262, §§B12-14 (AMD). PL 2007, c. 402, Pt. DD, §24 (AMD). PL 2021, c. 289, §§10, 11 (AMD).

§13752-A. Site inspection required

1. Opening facility. Pharmacies licensed pursuant to this subchapter may open and operate the facility only:

A. Upon the approval of the board or its representative; or [PL 2007, c. 402, Pt. DD, §25 (AMD).]

B. Upon the pharmacist in charge certifying to the board, on forms prescribed by the board, that the facility is secure, suitable for operation as a pharmacy and in compliance with applicable federal and state laws, rules and regulations governing the practice of pharmacy. [PL 2007, c. 402, Pt. DD, §25 (AMD).]

[PL 2007, c. 402, Pt. DD, §25 (AMD).]

2. Facility inspection. Licensed pharmacies that open and operate pursuant to subsection 1, paragraph B must be inspected by a member of the board or its representative within 30 days of opening. Facilities that are found to be insecure, not suitable for operation as a pharmacy or not in compliance with applicable federal and state laws, rules and regulations governing the practice of pharmacy are subject to a board-ordered emergency revocation of the license. The pharmacy may not operate after revocation. The emergency revocation is a final agency action and is not subject to judicial review, but a new application for licensure may be submitted pursuant to section 13752, and if approved, a site inspection must be performed pursuant to subsection 1, paragraph A.

[PL 2007, c. 402, Pt. DD, §25 (AMD).]

SECTION HISTORY

PL 1999, c. 130, §12 (NEW). PL 2007, c. 402, Pt. DD, §25 (AMD).

§13753. Notifications

1. Changes. All licensed pharmacies shall report to the board, by mail, fax or electronic communication as accepted by the board, the occurrence of any of the following changes:

A. Permanent closing, which requires 10 calendar days' prior notice to the public and to the board; [PL 2021, c. 289, §12 (AMD).]

B. Change of ownership, which requires 10 calendar days' prior notice to the board; [PL 2021, c. 289, §12 (AMD).]

C. Change of pharmacist, in charge which requires notice no later than 10 calendar days after the change; and [PL 2021, c. 289, §12 (AMD).]

D. Any other matters and occurrences as the board may require by rule. [PL 1987, c. 710, §5 (NEW).]

[PL 2021, c. 289, §12 (AMD).]

2. Other reportable events. Disasters, accidents and emergencies which 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 shall be immediately reported to the board.

[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2007, c. 402, Pt. DD, §26 (AMD). PL 2021, c. 289, §12 (AMD).

§13754. Violations and penalties

1. Unlicensed practice. No pharmacy licensed pursuant to section 13751 may be operated until a license has been issued to that facility by the board. Any person who violates this section is subject to the provisions of Title 10, section 8003-C.

[PL 2007, c. 402, Pt. DD, §27 (AMD).]

2. Reinstatement. Reinstatement of a license that has been suspended, revoked or restricted by the board may be granted in accordance with the procedures specified by section 13743, subsection 2.

[PL 2007, c. 402, Pt. DD, §27 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2007, c. 402, Pt. DD, §27 (AMD).

§13755. Vaccine clinics

A pharmacy may operate a vaccine administration clinic inside, outside or off the pharmacy's premises. [PL 2011, c. 577, §2 (NEW).]

SECTION HISTORY

PL 2011, c. 577, §2 (NEW).

§13756. Electronic prescribing of opioid medication

By July 1, 2017, a pharmacy must have the capability to process electronic prescriptions from prescribers for an opioid medication or request a waiver from the Commissioner of Health and Human Services stating the reasons for the waiver including but not limited to a lack of capability, the availability of broadband infrastructure and a plan for developing the ability to receive electronically prescribed opioid medication. The commissioner may grant a waiver for circumstances in which exceptions are appropriate, including technological failures. [PL 2015, c. 488, §29 (NEW).]

SECTION HISTORY

PL 2015, c. 488, §29 (NEW).

SUBCHAPTER 6

MANUFACTURERS AND WHOLESALERS

§13758. Licensure

1. Purpose; statement of intent. The purpose of this section is to require licensure of manufacturers and wholesalers within or outside the State. The intent of the Legislature is that the board may not adopt rules regarding companies without wholesale facilities or manufacturers' facilities located in this State that are more restrictive than federal law or regulation.
[PL 2007, c. 402, Pt. DD, §28 (AMD).]

2. Licensure, manufacturers and wholesalers. All manufacturers and wholesalers whose products are distributed in the State in any manner must be licensed by the board.
[PL 2007, c. 402, Pt. DD, §28 (AMD).]

3. Licensure, individuals. An individual who is employed by a manufacturer or wholesaler that is licensed under this subchapter need not obtain licensure under this subchapter.
[PL 2007, c. 402, Pt. DD, §28 (AMD).]

4. Form. License forms must state: Applicant's name; address; day phone; 24-hour phone; ownership status; manufacturer or wholesaler designation; Drug Enforcement Agency and Federal Drug Administration numbers; and date executed. License forms must be executed by an owner or officer of the entity, providing printed name and title.
[PL 2007, c. 402, Pt. DD, §28 (AMD).]

5. Fees. Each licensee shall pay a fee as set under section 13724.
[PL 2007, c. 402, Pt. DD, §28 (AMD).]

6. Violations. It is unlawful for manufacturers or wholesale companies to distribute prescription drugs in this State unless licensed under the provisions of this subchapter or subchapter 5.
[PL 2007, c. 402, Pt. DD, §28 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1987, c. 861, §18 (AMD). PL 1989, c. 502, §B75 (AMD). PL 1997, c. 245, §11 (AMD). PL 2005, c. 262, §B15 (AMD). PL 2007, c. 402, Pt. DD, §28 (AMD).

§13759. Gifts to practitioners prohibited

1. Prohibition. Except as provided in subsection 2, a manufacturer or wholesaler licensed under section 13758 or an agent of a manufacturer or wholesaler licensed under section 13758 may not offer or give the following to a practitioner:

A. A cash gift in any amount; or [PL 2017, c. 267, §1 (NEW).]

B. A gift for which reciprocity is expected or implied. [PL 2017, c. 267, §1 (NEW).]
[PL 2017, c. 267, §1 (NEW).]

2. Exceptions. A manufacturer or wholesaler licensed under section 13758 does not violate subsection 1 by engaging in the following activities:

A. Giving noncash items of minimal value that will directly benefit the practitioner's patients, including:

(1) Prescription drug samples for distribution to patients;

(2) Educational materials; and

(3) Modest meals and refreshments, as defined by the board by rule pursuant to section 13720, provided to a practitioner in connection with a meeting or presentation about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, as long as the meeting or presentation occurs in a venue and manner conducive to informational communication; [PL 2017, c. 267, §1 (NEW).]

B. Giving funding to academic institutions and residency and fellowship programs to support the participation of medical, nursing, physician assistant, veterinarian and pharmacy students, residents and fellows in professional meetings, including educational meetings, as long as the program identifies such funding recipients based on independent institutional criteria and the funds are distributed to recipients without specific attribution to sponsors; or [PL 2017, c. 267, §1 (NEW).]

C. Giving reasonable honoraria to a practitioner and making payment of the reasonable expenses, as defined by the board by rule pursuant to section 13720, of a practitioner at a professional or educational conference or meeting. [PL 2017, c. 267, §1 (NEW).]

Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2017, c. 267, §1 (NEW).]

SECTION HISTORY

PL 2017, c. 267, §1 (NEW).

SUBCHAPTER 7

SERVICES AT RURAL HEALTH CENTERS

§13761. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 1987, c. 710, §5 (NEW).]

1. Pharmacy provider. "Pharmacy provider" means a pharmacy licensed in this State participating with a rural health center under this subchapter.
[PL 1993, c. 716, §2 (AMD).]

2. Rural community health center.
[PL 1993, c. 716, §3 (RP).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 716, §§2,3 (AMD).

§13762. Center to be licensed

1. License required. A rural health center that desires to contract for pharmaceutical services with a pharmacy shall submit an application together with the required fee as set under section 13724. The board may adopt rules that are no more restrictive than those regulating private pharmacy practice in the State. A rural health center is eligible for licensure under this subchapter if:

A. It serves a rural area without a pharmacy; [PL 1993, c. 716, §4 (NEW).]

B. It is located in a community where available pharmacy services can not meet the documented need; or [PL 1993, c. 716, §4 (NEW).]

C. It requires a license in order to receive pharmaceutical discounts authorized by the federal Veterans' Health Care Act of 1992, Title VI. [PL 1993, c. 716, §4 (NEW).]
[PL 2005, c. 262, Pt. B, §16 (AMD).]

2. Renewal. A license expires on the date set by the commissioner pursuant to Title 10, section 8003, subsection 4 for the licensing period for which the license was issued. A renewal license is issued for each ensuing licensing period in the absence of any reason or condition that might warrant the refusal to grant a license and upon receipt by the board of the written request of the applicant and the required fee for the license as set under section 13724.

Licenses may be renewed up to 90 days after the date of expiration upon payment of a late fee in addition to a renewal fee as set under section 13724. Any person who submits an application for renewal more than 90 days after the license renewal date is subject to all requirements governing new applicants under this chapter, including a late fee, renewal fee and additional late fee as set under section 13724.
[PL 2007, c. 402, Pt. DD, §29 (AMD).]

3. Notice. Any rural health center wishing to be licensed under this subchapter shall notify the board of its intent to establish a contract with a pharmacy for pharmaceutical services and shall apply for a license, submit floor plans of the physical plant and pay a required fee as set under section 13724. The application must include the name, address and registration number of the provider of pharmaceutical services.
[PL 2005, c. 262, Pt. B, §18 (AMD).]

4. Board action. The board shall approve or disapprove of the application within 60 days of receipt and shall notify the applicant in writing of its decision and the reason for the decision.
[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 716, §4 (AMD). PL 2005, c. 262, §§B16-18 (AMD). PL 2007, c. 402, Pt. DD, §29 (AMD).

§13763. Scope of license

A licensee under this subchapter shall comply with section 13784; section 13785, subsections 1 to 7; and any applicable rules adopted by the board. No licensee may refill a prescription and all orders must be treated as new orders. In all other respects, notwithstanding any other provision of law, a licensee may provide pharmaceutical services under this subchapter subject to section 13764. A licensee may purchase drugs. [PL 1993, c. 716, §5 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 716, §5 (AMD).

§13764. Rules

The board shall adopt rules in conformity with the Maine Administrative Procedure Act, Title 5, chapter 375, to carry out the purposes of this subchapter. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

SUBCHAPTER 8

THIRD-PARTY PRESCRIPTION PROGRAM ACT

§13771. Short title

This subchapter shall be known and may be cited as the "Third-party Prescription Program Act."
[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13772. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 1987, c. 710, §5 (NEW).]

1. Third-party prescription program. "Third-party prescription program" means any system of providing for the reimbursement of pharmaceutical goods and services under a contractual arrangement or agreement between a provider of goods and services and another party who is not the consumer of those goods and services. These programs include, but are not limited to, insurance plans which provide coverage for prescription drugs or other pharmaceutical services.
[PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13773. Notice

A 3rd-party prescription program may not be instituted in this State until the program provider has filed written notice of the provisions of the program with the Superintendent of Insurance and the board and given written notice to all pharmacies that are located within the counties covered by the program at least 30 days prior to the commencement of the program. In the case of chain or branch pharmacies, the notice must be given to the main office or headquarters. These pharmacies have 30 days from the date of notice to enroll in the program. [PL 1997, c. 245, §12 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1989, c. 720, §1 (AMD). PL 1997, c. 245, §12 (AMD).

§13774. Denial of payment

No program administrator may deny to any pharmacy payment for services which may have resulted from the fraudulent or illegal use of an identification card by any person, unless the pharmacy has been notified that the card has been canceled or discontinued and that the program administrator has been unsuccessful in attempting to regain possession of the card. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13775. Reimbursement rates

A 3rd-party prescription program is prohibited from charging a pharmacy a registration fee or other fixed charge, either annually or otherwise, except in cases where a charge is necessary to specifically cover any equipment, forms or materials required by the program. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13776. Contract renewal and changes

Any changes in benefits or provisions in any contract may not be made unilaterally by either the program administrator or the pharmacy. Any change in a contract offered to one pharmacy shall be offered to all the state pharmacies participating in the program. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13777. Exceptions

This Act does not apply to any medical assistance or public health programs administered by the Department of Health and Human Services, including, but not limited to, the Medicaid program and the Low Cost Drug Program; to any employee benefit plan that is subject to the Employee Retirement Income Security Act of 1974, 29 United States Code, Section 1001, et seq.; and to any 3rd-party prescription programs administered in accordance with and subject to the limitations of the former Nonprofit Service Organizations Preferred Provider Arrangement Act of 1985, Title 24, chapter 19, subchapter II, or the Preferred Provider Arrangement Act, Title 24-A, chapter 32. [PL 1999, c. 790, Pt. A, §39 (AMD); PL 2003, c. 689, Pt. B, §6 (REV).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1989, c. 720, §2 (AMD). PL 1999, c. 790, §A39 (AMD). PL 2003, c. 689, §B6 (REV).

SUBCHAPTER 9

MISCELLANEOUS PROVISIONS

§13781. Generic and therapeutically equivalent substitution

A written prescription issued by a practitioner in this State may contain a box in the lower right-hand corner of the prescription form. The following words must appear to the left of this box: "Any drug that is the generic and therapeutic equivalent of the drug or any biological product that is an interchangeable biological product of the biological product specified above in this prescription must be dispensed, provided that no check mark ( ) has been handwritten in the box in the lower right-hand corner." [PL 2019, c. 34, §4 (AMD).]

Except with regard to a patient who is paying for a drug or biological product with the patient's own resources, any pharmacist receiving a prescription in which no handwritten check mark ( ) is found in the box provided shall substitute a generic and therapeutically equivalent drug for the drug or an interchangeable biological product for the biological product specified on the prescription if the substituted drug or interchangeable biological product is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States and the price of the substituted drug or interchangeable biological product does not exceed the price of the drug or biological product specified by the practitioner; except that, when the cost of a prescription is to be reimbursed under the MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a generic and therapeutically equivalent drug or an interchangeable biological product only when the Department of Health and Human Services has determined that the substitute drug or interchangeable biological product would be a more cost-effective alternative than the drug or biological product prescribed by the practitioner. Except for prescribed drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a patient who is paying for a drug or biological product with the patient's own resources, a pharmacist shall inquire about the patient's preference for either the brand-name drug or generic and therapeutically equivalent drug or for either the prescribed biological product or interchangeable biological product and dispense the drug or biological product that the patient prefers. [PL 2019, c. 34, §4 (AMD).]

Except with regard to a patient who is paying for a drug or biological product with the patient's own resources, if a written prescription issued by a practitioner in this State does not contain the box described in this section, a pharmacist shall substitute a generic and therapeutically equivalent drug for the drug or an interchangeable biological product for the biological product specified on the prescription if the substituted drug or interchangeable biological product is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States

and the price of the substituted drug or interchangeable biological product does not exceed the price of the drug or biological product specified by the practitioner, unless a practitioner has handwritten on the prescription form, along with the practitioner's signature, "dispense as written," "DAW," "brand," "brand necessary" or "brand medically necessary"; except that, when the cost of a prescription is to be reimbursed under the MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a generic and therapeutically equivalent drug or an interchangeable biological product only when the Department of Health and Human Services has determined that the substitute drug or interchangeable biological product would be a more cost-effective alternative than the drug or biological product prescribed by the practitioner. Except for prescribed drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a patient who is paying for a drug or biological product with the patient's own resources, a pharmacist shall inquire about the patient's preference for either the brand-name drug or generic and therapeutically equivalent drug or for either the prescribed biological product or interchangeable biological product and dispense the drug or biological product that the patient prefers. [PL 2019, c. 34, §4 (AMD).]

Any pharmacist who substitutes a generic and therapeutically equivalent drug or an interchangeable biological product under this section shall inform the person to whom the drug or interchangeable biological product is dispensed of the substitution. When any substitution is made under this section, the pharmacist shall cause all information as required by section 13794, the name of the generic and therapeutically equivalent drug and the name or abbreviation of the drug manufacturer or distributor of that substitute drug or, in the case of an interchangeable biological product, the proper name and the name of the manufacturer of the interchangeable biological product, to appear on the container label of the drug or interchangeable biological product dispensed. [PL 2019, c. 34, §4 (AMD).]

This section does not apply to prescriptions ordered by practitioners for patients in hospitals when those prescriptions are filled by a hospital pharmacy or in any institution where a formulary system is established. [PL 1987, c. 710, §5 (NEW).]

Within 5 business days after a pharmacist dispenses a biological product, the dispensing pharmacist or the pharmacist's designee shall enter in an electronic records system that is electronically accessible to the practitioner who prescribed the biological product the specific biological product dispensed, including the name of the biological product and the manufacturer. For purposes of this paragraph, "electronic records system" means an interoperable electronic medical records system, an electronic prescribing technology, a pharmacist benefit management system or an electronic pharmacy record. Entry into an electronic records system as described in this paragraph is presumed to provide notice to the practitioner. If a pharmacist cannot make an entry in an electronic records system, the pharmacist shall notify the practitioner of the specific biological product dispensed by facsimile, telephone, electronic transmission or other similar means. Notice to a practitioner under this paragraph is not required if the federal Food and Drug Administration has not approved an interchangeable biological product for the product prescribed or a refill prescription is not changed from the biological product dispensed on the prior filling of the prescription. [PL 2019, c. 34, §4 (NEW).]

The board shall maintain a link on the board's publicly accessible website to the current list of all biological products determined by the federal Food and Drug Administration to be an interchangeable biological product. [PL 2019, c. 34, §4 (NEW).]

For the purposes of this section, "drug" does not include biological products. [PL 2019, c. 34, §4 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1997, c. 245, §§13,14 (AMD). PL 2003, c. 384, §1 (AMD). PL 2003, c. 689, §B6 (REV). PL 2007, c. 85, §§1, 2 (AMD). PL 2019, c. 34, §4 (AMD).

§13782. Advertising

It is lawful for any pharmacy, pharmacist or other licensee of the board to advertise to the public the current retail price charged for any drugs, medicines or appliances as defined in the United States Code, Title 21, Section 3211 (g) (1) which bears the legend "Caution: Federal law prohibits dispensing without prescription." The advertising may be according to either the brand name or the generic name of the drug. No media advertising of any drugs included in the United States Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236, is permitted. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13782-A. Price disclosure

1. Price disclosure required. A pharmacist or pharmacy technician employed by a pharmacy shall disclose upon the request of any person making an inquiry in person or by telephone the price of any brand or generic drug sold by that pharmacy.
[PL 2007, c. 402, Pt. DD, §30 (AMD).]

2. Information required for price disclosure. In order to have sufficient information to disclose a prescription price, a pharmacist or pharmacy technician may ask the person making the inquiry for the following information:

A. The brand or generic name of the medication; [PL 1997, c. 245, §15 (NEW).]

B. The dose or strength of the medication, if applicable; or [PL 1997, c. 245, §15 (NEW).]

C. The quantity of the medication. [PL 1997, c. 245, §15 (NEW).]
[PL 1997, c. 245, §15 (NEW).]

3. Information not provided. If the inquiring person can not provide some or all of the information in subsection 2 and this information is necessary for the requested price to be determined, then the pharmacist or pharmacy technician may contact the prescribing practitioner in order to obtain the necessary information prior to disclosing the prescription price.
[PL 1997, c. 245, §15 (NEW).]

SECTION HISTORY

PL 1997, c. 245, §15 (NEW). PL 2007, c. 402, Pt. DD, §30 (AMD).

§13783. Posting prices

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1997, c. 245, §16 (RP).

§13784. Patient information regulation

1. Explanation by pharmacist. With each new prescription dispensed, the pharmacist, in addition to labeling the prescription in accordance with the requirements of the State, must orally explain to the patient or the patient's agent the directions for use and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation shall be by telephone or in writing. This section does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications or to those prescriptions for patients who are to be discharged from a hospital or institution.
[PL 1987, c. 710, §5 (NEW).]

2. Maintenance of current reference material. To ensure that proper information is available to each pharmacist, each pharmacy or pharmacist shall maintain current reference material on drug interactions.

[PL 1987, c. 710, §5 (NEW).]

3. Retail price. With each prescription dispensed, the pharmacist shall disclose to the patient in writing the usual and customary price of the prescription and the cost of any payment toward the price required of the patient.
[RR 2003, c. 2, §120 (AFF); PL 2003, c. 375, §1 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). RR 2003, c. 2, §120 (AFF). PL 2003, c. 375, §1 (AMD). PL 2003, c. 375, §2 (AFF).

§13785. Patient profile record system regulation

A patient profile record system shall be maintained in all pharmacies for persons for whom prescriptions are dispensed. The patient profile record system shall be devised to enable the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile record or document may be maintained for all members of a family living at the same address and possessing the same family name. The following information shall be recorded: [PL 1987, c. 710, §5 (NEW).]

1. Name. The family name and the first name of the person for whom the medication is intended;
[PL 1987, c. 710, §5 (NEW).]

2. Address. The address to correspond to the name in subsection 1;
[PL 1987, c. 710, §5 (NEW).]

3. Age group. An indication of the patient's age group, that is, infant, child or adult;
[PL 1987, c. 710, §5 (NEW).]

4. Original date of dispensing. The original date the medication is dispensed pursuant to the receipt of a practitioner's prescription;
[PL 1987, c. 710, §5 (NEW).]

5. Prescription identification. The number or designation identifying the prescription;
[PL 1987, c. 710, §5 (NEW).]

6. Prescriber's name. The name of the person prescribing the drug or device;
[PL 1987, c. 710, §5 (NEW).]

7. Drug information. The name, strength and quantity of the drug; and
[PL 1987, c. 710, §5 (NEW).]

8. Initials of pharmacist; date of refill. The initials of the dispensing pharmacist and the date of dispensing the medication as a renewal or refill, if those initials and that date are not recorded on the back of the original prescription.
[PL 1987, c. 710, §5 (NEW).]

The pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any chronic conditions which may relate to drug utilization as communicated to the pharmacy by the patient. [PL 1987, c. 710, §5 (NEW).]

Upon receipt of a prescription, a pharmacist shall examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potentially harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem which may include consultation with the practitioner. [PL 1987, c. 710, §5 (NEW).]

A patient profile record must be maintained for a period of not less than the amount of time required under federal Medicare laws, beginning from the date of the last entry in the profile record. As used in

this section, "Medicare" means the Health Insurance for the Aged Act, Title XVIII of the Social Security Amendments of 1965, as amended. [PL 1999, c. 130, §13 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1999, c. 130, §13 (AMD).

§13786. Identification of persons prescribing medicines on hospital prescription blanks

Any practitioner who writes a prescription upon a prescription blank of a hospital or clinic shall sign that practitioner's name and cause that name to be printed, stamped or typed on the blank. [PL 1987, c. 710, §5 (NEW).]

This section applies to any registered nurse who writes a prescription while working under the control or supervision of a physician. The name of the physician under whom the nurse works must be printed, stamped or typed on the blank. [PL 2019, c. 627, Pt. B, §19 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2019, c. 627, Pt. B, §19 (AMD).

§13786-A. Security requirements; rules

1. Rules. The Department of Public Safety, after consultation with the Board of Osteopathic Licensure, the Board of Licensure in Medicine and the Board of Pharmacy, shall adopt rules that establish security requirements for all written prescriptions for schedule II drugs issued by health care providers. For purposes of this section, "schedule II drug" has the same meaning as in the federal Controlled Substances Act of 1970, 21 United States Code, Section 812. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A and must be brought back for review by the joint standing committee of the Legislature having jurisdiction over criminal justice matters during the 2nd Regular Session of the 120th Legislature. The rules must include a procedure to obtain a waiver for prescription blanks that provide substantially equivalent protection against forgery. The rules must deal with the following subjects:

A. Measures designed to prevent unauthorized copying of a completed or blank prescription form; [PL 2001, c. 419, §23 (NEW).]

B. Measures designed to prevent the erasure or modification of information written on the prescription by the prescribing health care provider; and [PL 2001, c. 419, §23 (NEW).]

C. Measures to prevent the use of counterfeit prescription forms. [PL 2001, c. 419, §23 (NEW).] [PL 2001, c. 419, §23 (NEW).]

2. Out-of-state prescription security requirements. Notwithstanding any law or rule to the contrary, a prescription for a schedule II drug written by an out-of-state practitioner on a prescription blank that does not comply with the requirements for a security prescription blank, as defined in the Department of Public Safety rule pursuant to subsection 1, may be filled by a pharmacist only if:

A. The pharmacist receives and makes a record of oral confirmation of the validity of the prescription from the out-of-state practitioner or the practitioner's agent and the pharmacist makes a reasonable effort to determine that the oral confirmation came from the practitioner or the practitioner's agent, which may include a telephone call to the practitioner's telephone number listed in a telephone directory or other directory or other good faith efforts to confirm the identity of the person giving the oral confirmation; and [PL 2003, c. 326, §1 (NEW).]

B. The pharmacist demands, inspects and records a valid photographic identification from any person presenting a prescription or receiving a filled prescription unless:

(1) The person is the patient for whom the prescription is written;

(2) The person's identity is personally known to the pharmacist; and

(3) The pharmacist confirms by reviewing the pharmacy records that the pharmacist has previously demanded, inspected and recorded a valid photographic identification from the person. [PL 2003, c. 326, §1 (NEW).]

[PL 2003, c. 326, §1 (NEW).]

3. Valid photographic identification. For the purposes of subsection 2, a valid photographic identification is limited to the following:

A. A valid Maine motor vehicle operator's license; [PL 2003, c. 326, §1 (NEW).]

B. A valid Maine identification card issued under Title 29-A, section 1410; [PL 2003, c. 326, §1 (NEW).]

C. A valid United States passport; or [PL 2003, c. 326, §1 (NEW).]

D. A valid passport or motor vehicle operator's license of another state, territory or possession of the United States or a foreign country only if it:

(1) Contains a photograph of the person presenting the prescription;

(2) Is encased in tamper-resistant plastic or is otherwise tamper-resistant; and

(3) Identifies the date of birth of the person presenting the prescription. [PL 2003, c. 326, §1 (NEW).]

[PL 2003, c. 326, §1 (NEW).]

4. Partial filling of out-of-state prescriptions. The partial filling of a prescription for a schedule II drug written by an out-of-state practitioner on a prescription blank that does not comply with the requirements for a security prescription blank, as defined in the Department of Public Safety rule pursuant to subsection 1, is permissible if the pharmacist is unable after reasonable effort to obtain the oral confirmation described in subsection 2 in the case of the practitioner's office being closed during nights, weekends or holidays. The partial filling is limited to a 72-hour supply of the controlled substance. The remaining portion of the prescription may be filled within the 72-hour period upon obtaining the oral confirmation. No further quantity may be filled beyond the 72 hours without a new prescription.

[PL 2003, c. 326, §1 (NEW).]

SECTION HISTORY

PL 2001, c. 419, §23 (NEW). PL 2003, c. 326, §1 (AMD).

§13786-B. Partial dispensing of prescription for opioid medication

1. Partial dispensing authorized. Notwithstanding any law or rule to the contrary, a pharmacist may partially dispense a prescription for an opioid medication in a lesser quantity than the recommended full quantity indicated on the prescription if requested by the patient for whom the prescription is written. The remaining quantity of the prescription in excess of the recommended full quantity is void and may not be dispensed without a new prescription.

[PL 2015, c. 488, §30 (NEW).]

2. Notice to practitioner. If a pharmacist partially dispenses a prescription for an opioid medication as permitted under this section, the pharmacist or the pharmacist's designee shall, within a reasonable time following the partial dispensing but not more than 7 days, notify the practitioner of the quantity of the opioid medication actually dispensed. The notice may be conveyed by a notation on the patient's electronic health record or by electronic transmission, by facsimile or by telephone to the practitioner.

[PL 2015, c. 488, §30 (NEW).]

SECTION HISTORY

PL 2015, c. 488, §30 (NEW).

§13786-C. Dispensing of prescription of opioid medication; immunity

A pharmacist who dispenses opioid medication in good faith is immune from any civil liability that might otherwise result from dispensing medication in excess of the limit established in section 2210, subsection 1, paragraphs A and B; section 2600-C, subsection 1, paragraphs A and B; section 3300-F, subsection 1, paragraphs A and B; section 3657, subsection 1, paragraphs A and B; or section 18308, subsection 1, paragraphs A and B, if the medication was dispensed in accordance with a prescription issued by a practitioner. In a proceeding regarding immunity from liability, there is a rebuttable presumption of good faith. [PL 2015, c. 488, §31 (NEW).]

SECTION HISTORY

PL 2015, c. 488, §31 (NEW).

§13786-D. Prescribing and dispensing insulin

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Insulin" includes various types of insulin analogs and insulin-like medications, regardless of activation period or whether the solution is mixed before or after dispensation. [PL 2019, c. 666, Pt. B, §1 (NEW).]

B. "Insulin-related devices and supplies" means needles, syringes, cartridge systems, prefilled pen systems, glucose meters and test strips. "Insulin-related devices and supplies" does not include insulin pump devices. [PL 2019, c. 666, Pt. B, §1 (NEW).]

[PL 2019, c. 666, Pt. B, §1 (NEW).]

2. Authorization. As authorized by the board in accordance with rules adopted under subsection 3, a pharmacist may dispense emergency refills of insulin and associated insulin-related devices and supplies by prescription drug order or standing order or pursuant to a collaborative practice agreement authorizing insulin to be dispensed. The insulin dispensed under this subsection must be in a quantity that is at least a 30-day supply unless the intended recipient requests a lesser quantity upon consultation with the pharmacist. The intended recipient shall provide evidence of a previous prescription from a practitioner and attest that a refill of that previous prescription may not be readily or easily obtained under the circumstances. Upon receiving evidence of a previous prescription from a practitioner, the pharmacist shall immediately notify that practitioner that an emergency refill of insulin was dispensed and instruct the recipient to seek follow-up care from the practitioner as soon as possible.
[PL 2021, c. 20, §1 (AMD).]

3. Rules; protocols. The board by rule shall establish standards for authorizing pharmacists to dispense insulin in accordance with subsection 2, including protocols for notifying practitioners when emergency refills of insulin are dispensed. Rules adopted under this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2021, c. 20, §2 (AMD).]

SECTION HISTORY

PL 2019, c. 666, Pt. B, §1 (NEW). PL 2021, c. 20, §§1, 2 (AMD).

§13786-E. Prescribing, dispensing and administering HIV prevention drugs

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "CDC guidelines" means guidelines related to nonoccupational exposure to potential HIV infection, or any subsequent guidelines, published by the federal Department of Health and Human Services, Centers for Disease Control and Prevention. [PL 2021, c. 265, §6 (NEW).]

B. "HIV prevention drug" means a preexposure prophylaxis drug, post-exposure prophylaxis drug or other drug approved for the prevention of HIV infection by the federal Food and Drug Administration. [PL 2021, c. 265, §6 (NEW).]

C. "Post-exposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines following potential exposure to HIV infection. [PL 2021, c. 265, §6 (NEW).]

D. "Preexposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines to prevent HIV infection. [PL 2021, c. 265, §6 (NEW).]

[PL 2021, c. 265, §6 (NEW).]

2. Authorization. Notwithstanding any provision of law to the contrary and as authorized by the board in accordance with rules adopted under subsection 3, a pharmacist may prescribe, dispense and administer HIV prevention drugs pursuant to a standing order or collaborative practice agreement or to protocols developed by the board for when there is no prescription drug order, standing order or collaborative practice agreement in accordance with the requirements in this subsection and may also order laboratory testing for HIV infection as necessary.

A. Before furnishing an HIV prevention drug to a patient, a pharmacist shall complete a training program approved by the board on the use of protocols developed by the board for prescribing, dispensing and administering an HIV prevention drug, on the requirements for any laboratory testing for HIV infection and on guidelines for prescription adherence and best practices to counsel patients prescribed an HIV prevention drug. [PL 2021, c. 265, §6 (NEW).]

B. A pharmacist shall dispense or administer a preexposure prophylaxis drug in at least a 30-day supply, and up to a 60-day supply, as long as all of the following conditions are met:

(1) The patient tests negative for HIV infection, as documented by a negative HIV test result obtained within the previous 7 days. If the patient does not provide evidence of a negative HIV test result in accordance with this subparagraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of primary care providers and clinics within a reasonable travel distance of the patient's residence;

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reporting checklist of acute HIV infection signs and symptoms;

(3) The patient does not report taking any contraindicated medications;

(4) The pharmacist provides counseling to the patient, consistent with CDC guidelines, on the ongoing use of a preexposure prophylaxis drug. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for a preexposure prophylaxis drug and that a pharmacist may not dispense or administer more than a 60-day supply of a preexposure prophylaxis drug to a single patient once every 2 years without a prescription;

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the patient profile record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis drugs dispensed or administered to each patient;

(6) The pharmacist does not dispense or administer more than a 60-day supply of a preexposure prophylaxis drug to a single patient once every 2 years, unless otherwise directed by a practitioner; and

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this paragraph. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care providers to contact regarding follow-up care. [PL 2021, c. 265, §6 (NEW).]

C. A pharmacist shall dispense or administer a complete course of a post-exposure prophylaxis drug as long as all of the following conditions are met:

(1) The pharmacist screens the patient and determines that the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for a post-exposure prophylaxis drug under CDC guidelines;

(2) The pharmacist provides HIV testing to the patient or determines that the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for a post-exposure prophylaxis drug under this subsection, the pharmacist may dispense or administer a post-exposure prophylaxis drug;

(3) The pharmacist provides counseling to the patient, consistent with CDC guidelines, on the use of a post-exposure prophylaxis drug. The pharmacist shall also inform the patient of the availability of a preexposure prophylaxis drug for persons who are at substantial risk of acquiring HIV; and

(4) The pharmacist notifies the patient's primary care provider of the dispensing or administering of the post-exposure prophylaxis drug. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care providers to contact regarding follow-up care. [PL 2021, c. 265, §6 (NEW).]

[PL 2021, c. 265, §6 (NEW).]

3. Rules; protocols. The board by rule shall establish standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs in accordance with subsection 2, including adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement. Rules adopted under this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2021, c. 265, §6 (NEW).]

SECTION HISTORY

PL 2021, c. 265, §6 (NEW).

§13786-F. Dispensing of emergency supplies of chronic maintenance drug

1. Definition. For the purposes of this section, "chronic maintenance drug" means a medication prescribed to treat a chronic, long-term condition and that is taken on a regular, recurring basis.
[PL 2021, c. 566, §2 (NEW).]

2. Emergency supply. A pharmacist may dispense an emergency supply of a chronic maintenance drug without a current, valid prescription from a practitioner, subject to the following requirements:

A. The pharmacy at which the pharmacist is practicing has a record of a prescription for the chronic maintenance drug in the name of the patient who is requesting the emergency supply, including the amount of the chronic maintenance drug dispensed as provided in the most recent prescription or the standard unit of dispensing for the chronic maintenance drug, and the record of that prescription

for the chronic maintenance drug does not include a notation from a practitioner that no emergency supply is permitted; [PL 2021, c. 566, §2 (NEW).]

B. The pharmacist attempts but is unable to obtain authorization to refill the prescription described in paragraph A from the practitioner who issued the prescription or another practitioner responsible for the patient's care; [PL 2021, c. 566, §2 (NEW).]

C. In the pharmacist's professional judgment, the chronic maintenance drug is essential to sustain the life of the patient or to continue therapy for a chronic condition of the patient and failure to dispense the chronic maintenance drug could reasonably produce undesirable health consequences or cause physical or mental discomfort; [PL 2021, c. 566, §2 (NEW).]

D. Except as provided in this subsection, the amount of the chronic maintenance drug dispensed does not exceed a 30-day supply as provided in the prescription or, if the standard unit of dispensing for the chronic maintenance drug exceeds a 30-day supply, the amount of the chronic maintenance drug dispensed does not exceed the smallest standard unit of dispensing; [PL 2021, c. 566, §2 (NEW).]

E. With respect to a chronic maintenance drug that is a controlled substance included in Schedule III or IV of 21 United States Code, Section 812 or 21 Code of Federal Regulations, Section 1308, the amount of the chronic maintenance drug dispensed does not exceed a 7-day supply; [PL 2021, c. 566, §2 (NEW).]

F. The chronic maintenance drug is not a controlled substance included in Schedule I or II of 21 United States Code, Section 812 or 21 Code of Federal Regulations, Section 1308; and [PL 2021, c. 566, §2 (NEW).]

G. The pharmacist has not dispensed the chronic maintenance drug in an emergency supply under this subsection to the same patient more than twice in the preceding 12-month period. [PL 2021, c. 566, §2 (NEW).]

The pharmacist shall exercise professional judgment in determining the amount of the chronic maintenance drug to be dispensed, up to the maximum amount specified in this subsection. The pharmacist shall notify the practitioner who issued the prescription or another practitioner responsible for the patient's care no later than 72 hours after the chronic maintenance drug is dispensed. The pharmacist shall fulfill all documentation and other requirements established by the board when dispensing an emergency supply of a chronic maintenance drug.
[PL 2021, c. 566, §2 (NEW).]

3. Rules. The board may adopt rules for determining what constitutes a chronic maintenance drug and what reporting procedures are necessary in dispensing an emergency supply of a chronic maintenance drug. Rules adopted by the board pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2021, c. 566, §2 (NEW).]

SECTION HISTORY

PL 2021, c. 566, §2 (NEW).

§13787. Hypodermic syringes; prescriptions

(REPEALED)

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 394, §1 (RP).

§13787-A. Sale of hypodermic apparatus

1. Authorized seller. A hypodermic apparatus, as defined in Title 17-A, section 1101, subsection 2, may be sold only by a manufacturer or dealer of embalming supplies, manufacturer or dealer of medical or dental supplies, wholesale druggist, manufacturing pharmacist, pharmacist, veterinarian, agricultural supply store or manufacturer of surgical instruments.
[PL 1993, c. 394, §2 (NEW).]

2. Purchaser. Any person who is 18 years of age or older may purchase a hypodermic apparatus from a seller described in subsection 1.
[PL 1993, c. 394, §2 (NEW).]

3. Criminal immunity.

[PL 2021, c. 434, §12 (RP).]

4. Immunity limited. This section does not limit prosecution for violation of any law prohibiting or regulating the use, possession, dispensing, distribution or promotion of controlled substances or scheduled drugs.
[PL 2021, c. 434, §13 (AMD).]

5. Medicaid not affected. This section does not diminish, expand or otherwise affect Medicaid reimbursement for hypodermic apparatuses.
[PL 1993, c. 394, §2 (NEW).]

SECTION HISTORY

PL 1993, c. 394, §2 (NEW). PL 2003, c. 688, §A39 (AMD). PL 2021, c. 434, §§12, 13 (AMD).

§13788. Sale of poisonous drugs

Each licensed pharmacist who sells a poison shall affix to the package sold a label plainly marked with the name and address of the store and the word "POISON" and the name of the poison sold, and shall enter at the time of sale in a permanently bound book to be kept for that purpose the name and address of the purchaser, the date of sale, the name of the poison and the quantity sold and the person making the sale shall sign the entry. This section shall not apply to sales on prescription of practitioners, sales at wholesale to pharmacists or sales to hospitals, colleges or public institutions. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13789. Possession of drug samples

No person may purchase manufacturers' drug samples from any person for purposes of resale. If those samples are given gratuitously to a licensed pharmacist, qualified assistant pharmacist or medical practitioner, any such sample may be given to any person, as long as the sample is kept in containers suitably labeled to conform to the Federal Food and Drug Act and the state food and drug laws and this gift is subject to the laws relating to the sale of drugs. [PL 2007, c. 402, Pt. DD, §31 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2007, c. 402, Pt. DD, §31 (AMD).

§13790. Using drugs not in prescription

If a pharmacist knowingly uses any drugs or ingredients in preparing or compounding a written or oral prescription of any practitioner different from those named in the prescription, that use shall constitute a civil violation for which a forfeiture of not more than $1,000 nor less than $50 may be adjudged. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13791. Return of drugs

A drug or pharmaceutical preparation that has been dispensed on prescription may be returned to pharmacy stock after being in possession and under the control of another person and may be dispensed again if the drug is packaged in an unbroken, sealed container or if, in the case of a hospital, a licensed pharmacist determines that the drug has not been impaired. [PL 1993, c. 231, §1 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1993, c. 231, §1 (AMD).

§13792. Sale by certain methods prohibited

1. Methods of sale prohibited. A person may not sell, distribute, vend or otherwise dispose of any drug, medicine or pharmaceutical or medical preparation by means of any public exhibition, entertainment, performance, carnival or by vending machines, except as described in subsection 2. [PL 2019, c. 454, §2 (NEW).]

2. Sale of nonprescription drugs by vending machines. The Maine Board of Pharmacy shall adopt rules to allow a pharmacy licensed as a vending machine outlet in accordance with section 13751 to sell or distribute nonprescription drugs by vending machines. The rules must include, but are not limited to, the following:

A. A requirement that only nonprescription drugs may be dispensed by a vending machine; [PL 2019, c. 454, §2 (NEW).]

B. A requirement that nonprescription drugs dispensed by a vending machine must be stored in accordance with manufacturer recommendations, including those that require a stable temperature; [PL 2019, c. 454, §2 (NEW).]

C. A requirement that nonprescription drugs dispensed by a vending machine must be sold only in the manufacturer's clearly labeled, original, unbroken, tamper-proof and expiration-dated packaging; [PL 2019, c. 454, §2 (NEW).]

D. A requirement that nonprescription drugs dispensed by a vending machine may not be older than the manufacturer's expiration date; [PL 2019, c. 454, §2 (NEW).]

E. [PL 2023, c. 160, §1 (RP).]

F. A requirement that a vending machine through which nonprescription drugs are dispensed must have an obvious and legible statement on the machine that identifies the owner of the machine, a toll-free telephone number at which the consumer may contact the owner of the machine, a statement advising the consumer to check the expiration date of the product before using the product and the telephone number of the board; [PL 2019, c. 454, §2 (NEW).]

G. Identification of any nonprescription drugs that may not be dispensed by a vending machine; and [PL 2019, c. 454, §2 (NEW).]

H. Identification of locations at which a vending machine dispensing nonprescription drugs may not be located, including the following:

(1) Private schools as defined in Title 20-A, section 1, subsection 22;

(2) Public preschool programs as defined in Title 20-A, section 1, subsection 23-A;

(3) Public schools as defined in Title 20-A, section 1, subsection 24; and

(4) Child care facilities as defined in Title 22, section 8301-A, subsection 1-A, paragraph B. [PL 2019, c. 454, §2 (NEW).]

[PL 2023, c. 160, §1 (AMD).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 2019, c. 454, §2 (RPR). PL 2023, c. 160, §1 (AMD).

§13793. Adulterating and selling drugs

Whoever fraudulently adulterates, for the purpose of sale, any drug or medicine or sells any fraudulently adulterated drug or medicine, knowing the same to be adulterated, shall be punished by a fine of not more than $1,000 or by imprisonment for not more than 11 months. These adulterated drugs and medicines shall be forfeited and destroyed under the direction of the court. [PL 1987, c. 710, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW).

§13794. Labeling of prescriptions

Every drug dispensed pursuant to prescription, whether for a legend drug or not, must carry on the label the following information: the prescription number; the date of filling; the patient's name; directions for use; the name and strength of the drug and the amount dispensed, including either the brand name of the drug or, if a generic and therapeutically equivalent drug or interchangeable biological product is dispensed the label must be in accordance with section 13781; the beyond use date of the drug; the name of the practitioner prescribing the drug; and the name, address and telephone number of the pharmacy where the prescription was compounded and dispensed. For purposes of this section, "beyond use date" means a date beyond which the contents of the prescription are not recommended to be used. [PL 2019, c. 34, §5 (AMD).]

A drug dispensed in accordance with the provisions of Title 22, chapter 251, subchapter 3, article 5 does not require the name of the patient's sexual partner on the label. [PL 2009, c. 533, §5 (NEW).]

SECTION HISTORY

PL 1987, c. 710, §5 (NEW). PL 1999, c. 130, §14 (AMD). PL 2009, c. 533, §5 (AMD). PL 2019, c. 34, §5 (AMD).

§13795. Photographic proof of identification; discretion to sell or dispense; immunity

1. Photographic proof of identification. As a precondition to filling any prescription, dispensing any drug or selling any targeted methamphetamine precursor, a pharmacist or person acting at the direction of a pharmacist may demand, inspect and record proof of identification, including valid photographic identification, from any patient presenting a prescription or any person acting on behalf of the patient or person purchasing a targeted methamphetamine precursor. Valid photographic identification includes but is not limited to the following:

A. A valid Maine motor vehicle operator's license; [PL 1995, c. 175, §1 (NEW).]

B. A valid Maine identification card issued under Title 29-A, section 1410; [PL 1997, c. 437, §46 (AMD).]

C. A valid United States passport; [PL 1995, c. 175, §1 (NEW).]

D. A valid passport, motor vehicle operator's license of another state, territory, possession or foreign country or official identification card issued by the United States Government only if it:

(1) Contains a photograph of the person presenting the identification;

(2) Is encased in tamper-resistant plastic or otherwise possesses indicia of tamper-resistance; and

(3) Identifies the person's date of birth; or [PL 2005, c. 430, §7 (AMD); PL 2005, c. 430, §10 (AFF).]

E. Other valid, tamper-resistant, photographic identification as provided in rules adopted by the board pursuant to section 13722, subsection 1, paragraph A and in accordance with Title 5, chapter 375. [PL 1997, c. 245, §17 (AMD).]

[PL 2005, c. 430, §7 (AMD); PL 2005, c. 430, §10 (AFF).]

2. Refusal to fill prescription, dispense drug or sell targeted methamphetamine precursor; law enforcement reporting. A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription, dispense any drug or sell any targeted methamphetamine precursor if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription or any person acting on behalf of the patient, or the intention of the customer to use the drug or targeted methamphetamine precursor according to the instructions for use. A pharmacist or person acting at the direction of a pharmacist may make a report to a law enforcement agency when that person has reasonable cause to suspect that a prescription is not legitimate or appropriate, that a person has presented photographic identification that is not valid or that a customer has the intention to use a drug or targeted methamphetamine precursor in a manner inconsistent with the instructions for use.

[PL 2005, c. 430, §7 (AMD); PL 2005, c. 430, §10 (AFF).]

3. Immunity; presumption of good faith. A pharmacist or person acting at the direction of a pharmacist who in good faith and pursuant to subsection 2 refuses to fill any prescription, dispense any drug or sell any targeted methamphetamine precursor or who makes a report to a law enforcement agency is immune from any civil liability that might otherwise result from that action, including, but not limited to, any civil liability that might otherwise arise under state or local laws or rules regarding confidentiality of information. In a proceeding regarding immunity from liability, there is a rebuttable presumption of good faith.

[PL 2005, c. 430, §7 (NEW); PL 2005, c. 430, §10 (AFF).]

4. Record keeping. With regard to purchases of targeted methamphetamine precursors, a pharmacy may keep a log of information about the purchaser, which may include name, date of birth, address and amount of targeted methamphetamine precursors purchased.

[PL 2005, c. 430, §7 (NEW); PL 2005, c. 430, §10 (AFF).]

5. Rulemaking. The Commissioner of Health and Human Services may adopt rules to implement this subsection. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

A. If the Director of the Maine Drug Enforcement Agency within the Department of Public Safety finds that the ease of availability of liquid, liquid-filled capsule or glycerin matrix forms of products containing ephedrine, pseudoephedrine or phenylpropanolamine or their salts, isomers or salts of isomers, either alone or in combination with other ingredients, referred to in this paragraph as "products," is a threat to the public health, safety and welfare, then the Director of the Maine Drug Enforcement Agency shall notify the Commissioner of Health and Human Services. The Commissioner of Health and Human Services shall consult with the joint standing committee of the Legislature having jurisdiction over health and human services matters, providing the reasons for undertaking rulemaking, and may, after consultation, adopt rules designating the products as targeted methamphetamine precursors pursuant to section 13702-A, subsection 33, paragraph B. [PL 2011, c. 657, Pt. AA, §84 (AMD).]

B. If the Director of the Maine Drug Enforcement Agency finds that sales of targeted methamphetamine precursors that are made without verifying the identity of the purchaser pose a threat to public health, safety and welfare, then the Director of the Maine Drug Enforcement Agency shall notify the Commissioner of Health and Human Services. The Commissioner of Health and Human Services shall consult with the joint standing committee of the Legislature

having jurisdiction over health and human services matters, providing the reasons for undertaking rulemaking, and may, after consultation, adopt rules requiring a person making a sale of a targeted methamphetamine precursor pursuant to section 13796 to demand from the purchaser and to inspect and record prior to the sale proof of identification, including valid photographic identification, and to keep a log of sales. [PL 2011, c. 657, Pt. AA, §84 (AMD).]

[PL 2011, c. 657, Pt. AA, §84 (AMD).]

SECTION HISTORY

PL 1995, c. 175, §1 (NEW). PL 1997, c. 245, §17 (AMD). PL 1997, c. 437, §46 (AMD). PL 2005, c. 430, §7 (AMD). PL 2005, c. 430, §10 (AFF). PL 2007, c. 695, Pt. B, §18 (AMD). PL 2011, c. 657, Pt. AA, §84 (AMD).

§13796. Retail sale of targeted methamphetamine precursors

1. Definitions.

[PL 2011, c. 584, §1 (RP).]

1-A. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Electronic logging system" means a system that:

(1) Blocks the illegal sale of over-the-counter cold and allergy medications containing a targeted methamphetamine precursor;

(2) Is available free of charge to the State and its taxpayers, retailers and law enforcement;

(3) Operates in real time and communicates across state lines in real time with similar systems; and

(4) Complies with the requirements of the national Criminal Justice Information Exchange or its successor program and the National Information Exchange Model or its successor program. [PL 2011, c. 584, §2 (NEW).]

B. "Override function" means a function in an electronic logging system that may be used to override a stop-sale alert and allows the completion of a sale. [PL 2011, c. 584, §2 (NEW).]

C. "Package" means an item packaged and marked for retail sale that is not designed to be broken down or subdivided for the purpose of retail sale. [PL 2011, c. 584, §2 (NEW).]

D. "Retailer" or "retail store" means a person or business entity engaged in this State in the business of selling products to the general public on a retail basis, including pharmacies. [PL 2011, c. 584, §2 (NEW).]

E. "Sale" or "sold" includes barter, exchange, transfer and gift. [PL 2011, c. 584, §2 (NEW).]

F. "Stop-sale alert" means a notification that alerts the retailer that completion of the sale would result in the seller's or purchaser's violating the targeted methamphetamine precursor quantity limits. [PL 2011, c. 584, §2 (NEW).]

[PL 2011, c. 584, §2 (NEW).]

2. Restrictions on packaging.

[PL 2013, c. 223, §1 (RP).]

3. Restrictions on the sale of targeted methamphetamine precursors. The following restrictions on location in the retail store, manner of sale and amount of sale apply to sales of targeted methamphetamine precursors. The limits under this subsection on the amount of targeted methamphetamine precursors that may be sold apply to the total amount of base ephedrine,

phenylpropanolamine and pseudoephedrine contained in packages and not the overall weight of the packages.

A. A retailer may not sell to the same person a targeted methamphetamine precursor that causes the sales to that person of targeted methamphetamine precursors within a 24-hour period to exceed 3.6 grams. [PL 2011, c. 584, §3 (AMD).]

A-1. A person may not purchase more than 3.6 grams of a targeted methamphetamine precursor within a 24-hour period. [PL 2011, c. 584, §3 (NEW).]

A-2. A retailer may not sell to the same person a targeted methamphetamine precursor that causes the sale to that person of targeted methamphetamine precursors within a 30-day period to exceed 9 grams. [PL 2011, c. 584, §3 (NEW).]

A-3. A person may not purchase more than 9 grams of a targeted methamphetamine precursor within a 30-day period. [PL 2011, c. 584, §3 (NEW).]

B. Except with regard to single-dose packages of not more than 60 milligrams that are kept within 30 feet and in direct line of sight of a staffed cash register or store counter, a retailer shall keep targeted methamphetamine precursors in a location that is locked or otherwise not accessible by customers. [PL 2011, c. 584, §3 (AMD).]

C. Except with regard to single-dose packages of not more than 60 milligrams that are kept within 30 feet and in direct line of sight of a staffed cash register or store counter, the sale of targeted methamphetamine precursors must be completed by:

(1) A licensed pharmacist or licensed pharmacy technician; or

(2) An employee of the retailer who accepts payment for the targeted methamphetamine precursor as long as:

(a) The employee works under the direct supervision of a pharmacist in the pharmacy area of the retail store; and

(b) A licensed pharmacist or licensed pharmacy technician has given individual, express approval for the purchase. [PL 2007, c. 402, Pt. DD, §33 (AMD).]

D. Except with regard to single-dose packages of not more than 60 milligrams that are kept within 30 feet and in direct line of sight of a staffed cash register or store counter, a retailer shall require a person purchasing a targeted methamphetamine precursor to present a valid government-issued photograph identification document at the point of sale. A retailer shall record the:

(1) Name and address of the purchaser;

(2) Name of the targeted methamphetamine precursor purchased including the number of grams the product contains;

(3) Date and time of purchase; and

(4) Form of identification presented, issuing government entity and corresponding identification number. [PL 2011, c. 584, §3 (NEW).]

E. Except with regard to single-dose packages of not more than 60 milligrams that are kept within 30 feet and in direct line of sight of a staffed cash register or store counter, a retailer shall maintain a written or electronic logbook and require a person purchasing a targeted methamphetamine precursor to sign the logbook. A purchaser must sign the logbook acknowledging that the purchaser understands the applicable sales limit and that providing false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 United States Code, Section 1001. [PL 2011, c. 584, §3 (NEW).]

[PL 2011, c. 584, §3 (AMD).]

4. Exceptions. The provisions of this section do not apply to a targeted methamphetamine precursor that is obtained by prescription or by sale or transfer in the regular course of lawful business to a veterinarian, physician, pharmacist, retail distributor, wholesaler, manufacturer, warehouse operator or common carrier or an agent of that person or entity.
[PL 2005, c. 430, §8 (NEW); PL 2005, c. 430, §10 (AFF).]

5. Electronic logging. Beginning January 1, 2013, a retailer who has access to the Internet shall, before completing a sale under this section, electronically submit the information obtained pursuant to subsection 3, paragraph D to an electronic logging system. If the electronic logging system generates a stop-sale alert, the retailer may not complete the sale. If the retailer has concern for personal safety or the safety of others if a sale is not completed, the retailer may use the system's override function to complete the sale and must maintain a log of the sale. If the retailer experiences mechanical or electronic failure of the electronic logging system and is unable to comply with the electronic logging requirement, the retailer shall maintain a written log or an alternative electronic record-keeping mechanism until such time as the retailer is able to comply with the electronic logging requirement.
[PL 2011, c. 584, §4 (NEW).]

6. Immunity; presumption of good faith. A retailer is immune from liability for any claims, costs, expenses, injuries, liabilities, losses or damages of any kind resulting from the retailer's use of the electronic logging system in accordance with this section unless the injury or loss is the result of willful, reckless or intentional misconduct by the retailer. In a civil proceeding in which the retailer's use of an electronic logging system pursuant to this section is an issue, there is a rebuttable presumption of good faith on the part of the retailer.
[PL 2011, c. 584, §4 (NEW).]

7. Political subdivision ordinances. A political subdivision, as defined in Title 30-A, section 2252, may not adopt an ordinance regulating the sale or purchase of a targeted methamphetamine precursor, and any ordinance that violates this subsection is void and has no force or effect.
[PL 2011, c. 584, §4 (NEW).]

SECTION HISTORY

PL 2005, c. 430, §8 (NEW). PL 2005, c. 430, §10 (AFF). PL 2007, c. 402, Pt. DD, §§32, 33 (AMD). PL 2011, c. 584, §§1-4 (AMD). PL 2013, c. 223, §1 (AMD).

§13797. Prescription drug price information

A pharmacist or person acting at the direction of a pharmacist who is asked for consumer price information regarding prescription drugs shall provide to the consumer, on the telephone or in person, depending on the circumstances, the current usual and customary price for cash customers and, if reasonably obtainable by the pharmacist or person acting at the direction of the pharmacist, the price applicable to the consumer. A pharmacy shall post a notice to consumers informing them that they may obtain current usual and customary price information from the pharmacist. [PL 2005, c. 610, §1 (NEW).]

SECTION HISTORY

PL 2005, c. 610, §1 (NEW).

§13798. Expedited partner therapy

An individual licensed under this chapter may not be disciplined for dispensing drugs pursuant to a lawful prescription in accordance with the provisions of Title 22, chapter 251, subchapter 3, article 5.
[PL 2009, c. 533, §6 (NEW).]

SECTION HISTORY

PL 2009, c. 533, §6 (NEW).

§13799. Consumer choice preserved

Nothing in this chapter may be construed to prohibit: [PL 2013, c. 373, §2 (NEW).]

1. Ordering or receiving prescription drugs. An individual who is a resident of the State from ordering or receiving prescription drugs for that individual's personal use from outside the United States by mail or carrier from a licensed retail pharmacy described in section 13731, subsection 1, paragraph B or an entity described in section 13731, subsection 1, paragraph C; or
[PL 2013, c. 373, §2 (NEW).]

2. Dispensing or providing prescription drugs. A licensed retail pharmacy described in section 13731, subsection 1, paragraph B or an entity described in section 13731, subsection 1, paragraph C from dispensing, providing or facilitating the provision of prescription drugs from outside the United States by mail or carrier to a resident of the State for that resident's personal use.
[PL 2013, c. 373, §2 (NEW).]

SECTION HISTORY

PL 2013, c. 373, §2 (NEW).

§13800. Access to distributed drugs

A manufacturer or wholesaler licensed under section 13758 shall make a drug distributed in this State available for sale in this State to an eligible product developer for purposes of conducting testing required to support an application for 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, §5 (NEW).]

The manufacturer or wholesaler licensed under section 13758 shall make the drug available for sale at a price no greater than the wholesale acquisition cost and without any restriction that would block or delay the eligible product developer's application in a manner inconsistent with Section 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code, Section 355-1(f)(8) (2016). [PL 2017, c. 434, §5 (NEW).]

An eligible product developer that receives a drug at a price no greater than the wholesale acquisition cost for that drug pursuant to this section shall charge consumers in this State the same price or less for the drug manufactured by that eligible product developer. [PL 2017, c. 434, §5 (NEW).]

As used in this section, "wholesale acquisition cost" means the manufacturer's list price for a brand-name drug or a generic drug per person per year or course of treatment when sold to wholesalers or direct purchasers in the United States, not including discounts or rebates, for the most recent month for which information is available. [PL 2017, c. 434, §5 (NEW).]

SECTION HISTORY

PL 2017, c. 434, §5 (NEW).

§13800-A. Liability for product of another; exemption

A manufacturer or wholesaler licensed under section 13758 is not liable for injuries alleged to have been caused by the failure to include adequate safety warnings on a product's label or by a defect in the product's design if: [PL 2017, c. 434, §5 (NEW).]

1. Access to distributed drugs. The manufacturer or wholesaler has made the product distributed in this State available to an eligible product developer in accordance with section 13800; and
[PL 2017, c. 434, §5 (NEW).]

2. Manufactured or sold by another. The product was not manufactured or sold by that manufacturer or wholesaler.
[PL 2017, c. 434, §5 (NEW).]

SECTION HISTORY

PL 2017, c. 434, §5 (NEW).

§13800-B. Prohibition on providing conversion therapy to minors

An individual licensed under this chapter may not advertise, offer or administer conversion therapy to a minor. [PL 2019, c. 165, §30 (NEW).]

SECTION HISTORY

PL 2019, c. 165, §30 (NEW).

§13800-C. Opioid medication product registration fee

This section governs opioid medication product registration fees. As used in this section, "unit of an opioid medication" means the lowest identifiable quantity of the opioid medication that is dispensed. [PL 2019, c. 536, §4 (NEW).]

1. Registration fee. Except as provided in subsection 2, a manufacturer that sells, delivers or distributes an opioid medication in this State shall pay an annual registration fee of $250,000 to the board on December 31st of each year.
[PL 2019, c. 536, §4 (NEW).]

2. Exception. A manufacturer that does not sell, deliver or distribute 2,000,000 or more units of an opioid medication within this State in the year in which a registration fee is due is not required to pay the registration fee. To qualify for the exception under this subsection, a manufacturer must demonstrate to the board, by January 31st of the year following the year in which the registration fee is due, in a manner determined by the board, that the manufacturer did not sell, deliver or distribute 2,000,000 or more units of an opioid medication within this State in the year in which the manufacturer seeks to claim the exception. The board may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2019, c. 536, §4 (NEW).]

3. Calculation of units of an opioid medication sold, delivered or distributed. When calculating the number of units of an opioid medication sold, delivered or distributed by a manufacturer under subsection 2, units of an opioid medication may be excluded when prescribed for the purpose of medication-assisted treatment of substance use disorder. The board periodically shall provide to the Department of Health and Human Services a list of medications exempted under this subsection.
[PL 2019, c. 536, §4 (NEW).]

4. Registration fee review and report.

[PL 2019, c. 536, §4 (NEW); MRSA T. 32 §13800-C, sub-§4 (RP).]

SECTION HISTORY

PL 2019, c. 536, §4 (NEW).

§13800-D. Insulin product registration fee

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE UNTIL 1/01/27)

(WHOLE SECTION TEXT REPEALED 1/01/27)

This section governs insulin product registration fees. As used in this section, "unit of insulin" means the lowest identifiable quantity of insulin that is dispensed. [PL 2021, c. 303, §5 (NEW).]

1. Registration fee. Except as provided in subsection 2, a manufacturer that produces insulin that is sold, delivered or distributed in this State shall pay an annual registration fee of $75,000 to the board

on December 31st of each year in addition to any license renewal fee required to be paid by the manufacturer under this chapter.
[PL 2021, c. 303, §5 (NEW).]

2. Exception. A manufacturer that is a nonprofit organization or whose aggregate total of insulin sold, delivered or distributed in this State does not exceed 500,000 units of insulin in the year in which a registration fee under subsection 1 is due is not required to pay the registration fee. To qualify for the exception under this subsection, a manufacturer must demonstrate to the board, by January 31st of the year following the year in which the registration fee is due, in a manner determined by the board, that the aggregate total of insulin produced by the manufacturer that was sold, delivered or distributed within this State in the year in which the manufacturer seeks to claim the exception did not exceed 500,000 units. The board may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
[PL 2023, c. 610, §4 (AMD).]

This section is repealed January 1, 2027. [PL 2021, c. 303, §5 (NEW).]

SECTION HISTORY

PL 2021, c. 303, §5 (NEW). PL 2023, c. 610, §4 (AMD).

SUBCHAPTER 10

NONDISCRIMINATION IN PHARMACEUTICALS PRICING

(REPEALED)

§13801. Definitions

(REPEALED)

SECTION HISTORY

PL 1993, c. 716, §6 (NEW). PL 1999, c. 574, §1 (RP).

§13802. Price discrimination prohibited

(REPEALED)

SECTION HISTORY

PL 1993, c. 716, §6 (NEW). PL 1999, c. 574, §1 (RP).

§13803. Purchases by State

(REPEALED)

SECTION HISTORY

PL 1993, c. 716, §6 (NEW). PL 1999, c. 574, §1 (RP).

§13804. Exceptions

(REPEALED)

SECTION HISTORY

PL 1993, c. 716, §6 (NEW). PL 1995, c. 548, §1 (AMD). PL 1999, c. 574, §1 (RP).

§13805. Enforcement

(REPEALED)

SECTION HISTORY

PL 1993, c. 716, §6 (NEW). PL 1999, c. 574, §1 (RP).

SUBCHAPTER 11

NONCONTROLLED PRESCRIPTION DRUG DISPENSING AND ADMINISTRATION

§13810. Drug administration by nurses under certain conditions

A professional nurse or an advanced practice registered nurse who is an employee of a home health care provider, as defined in Title 22, section 2142, subsection 3, or a hospice program or hospice provider, as defined in Title 22, section 8621, subsection 10, may: [PL 1997, c. 109, §1 (NEW).]

1. Possession. Possess, in the course of employment, such noncontrolled prescription drugs as are approved by the board. In adopting the rules the board shall consult with the Board of Licensure in Medicine, the Board of Osteopathic Licensure, the State Board of Nursing, the Maine Hospice Council, the Department of Health and Human Services and the Home Care Alliance of Maine. Rules adopted pursuant to this subsection are routine technical rules as defined by Title 5, chapter 375, subchapter II-A; and
[PL 1997, c. 109, §1 (NEW); PL 2003, c. 689, Pt. B, §6 (REV).]

2. Administration. Administer, in the course of employment, such drugs as are approved under subsection 1 according to written protocols approved annually by the employer's professional advisory committee, which must include a physician licensed under chapter 36 or chapter 48.
[PL 1997, c. 109, §1 (NEW).]

SECTION HISTORY

PL 1997, c. 109, §1 (NEW). PL 2003, c. 689, §B6 (REV).

§13811. Drug administration by certified midwives under certain conditions

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE UNTIL CONTINGENCY: See PL 2015, c. 502, §16)

A midwife who can verify to a licensed pharmacist by certification card that the midwife has met the certification standards of an international certification agency whose mission is to establish and administer certification for the credential of certified professional midwife or other certifying body recognized by the board may: [PL 2007, c. 669, §1 (NEW).]

1. Possession. Possess, in the course of the practice of midwifery, only the noncontrolled prescription drugs and substances set out in this subsection:

A. Oxygen; [PL 2007, c. 669, §1 (NEW).]

B. Oxytocin, excluding the oxytocic drug methergine, for the sole purpose of postpartum control of maternal hemorrhage; [PL 2007, c. 669, §1 (NEW).]

C. Vitamin K; [PL 2007, c. 669, §1 (NEW).]

D. Eye prophylaxis; and [PL 2007, c. 669, §1 (NEW).]

E. Local anesthetics or numbing agents for repair of lacerations; and [PL 2007, c. 669, §1 (NEW).]
[PL 2007, c. 669, §1 (NEW).]

2. Administration. Administer, in the course of the practice of midwifery, those drugs that are listed in subsection 1. When administering oxytocin, a certified midwife may not administer more than

20 units of oxytocin to a single patient. Oxytocin may be administered only for postpartum purposes in order to treat hemorrhaging and specifically may not be used to induce labor. When a certified midwife administers oxytocin in accordance with this subsection, the certified midwife shall report that use to the maternal and child health division of the Department of Health and Human Services, the Maine Center for Disease Control and Prevention within 7 days of the use of oxytocin.
[PL 2007, c. 669, §1 (NEW).]

SECTION HISTORY

PL 2007, c. 669, §1 (NEW). PL 2015, c. 502, §12 (RP). PL 2015, c. 502, §16 (AFF).

§13811. Drug administration by certified midwives under certain conditions

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT REPEALED ON CONTINGENCY: See PL 2015, c. 502, §16)

(REPEALED)

SECTION HISTORY

PL 2007, c. 669, §1 (NEW). PL 2015, c. 502, §12 (RP). PL 2015, c. 502, §16 (AFF).

§13812. Dispensing of medication by pharmacist

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT EFFECTIVE UNTIL CONTINGENCY: See PL 2015, c. 502, §16)

1. Dispensing of medication. A pharmacist, who in good faith relies upon a certification card presented by a midwife identifying that the midwife has met the certification standards described under section 13811, may sell and dispense to the midwife the noncontrolled prescription drugs and substances identified in section 13811.
[PL 2007, c. 669, §2 (NEW).]

2. Good faith. A pharmacist, or person acting at the direction of a pharmacist, who:

A. In good faith sells and dispenses noncontrolled prescription drugs and substances to a midwife pursuant to this section is not liable for any adverse reactions caused by any method of use by the midwife; and [PL 2007, c. 669, §2 (NEW).]

B. Makes a report relating to the dispensing of noncontrolled prescription drugs and substances to a midwife pursuant to section 13811 to an enforcement agency is immune from any civil liability that may result from that action, including, but not limited to, any civil liability that might otherwise arise under state or local laws or rules regarding confidentiality of information. [PL 2007, c. 669, §2 (NEW).]

In a proceeding in which a pharmacist, or person acting at the direction of a pharmacist, invokes the immunity provided pursuant to this section, there is a rebuttable presumption of good faith.
[PL 2007, c. 669, §2 (NEW).]

SECTION HISTORY

PL 2007, c. 669, §2 (NEW). PL 2015, c. 502, §13 (RP). PL 2015, c. 502, §16 (AFF).

§13812. Dispensing of medication by pharmacist

(CONTAINS TEXT WITH VARYING EFFECTIVE DATES)

(WHOLE SECTION TEXT REPEALED ON CONTINGENCY: See PL 2015, c. 502, §16)

(REPEALED)

SECTION HISTORY

PL 2007, c. 669, §2 (NEW). PL 2015, c. 502, §13 (RP). PL 2015, c. 502, §16 (AFF).

SUBCHAPTER 11-A

PRESCRIBING AND DISPENSING OF NALOXONE HYDROCHLORIDE AND OTHER OPIOID OVERDOSE-REVERSING MEDICATIONS

§13815. Authorization

1. Rules for dispensing naloxone hydrochloride.
[PL 2017, c. 364, §6 (RP).]

2. Rules for prescribing and dispensing naloxone hydrochloride or another opioid overdose-reversing medication. The board by rule shall establish standards for authorizing pharmacists to prescribe and dispense naloxone hydrochloride or another opioid overdose-reversing medication in accordance with Title 22, section 2353, subsection 2, paragraphs A-1 and C-1. The rules must establish adequate training requirements and protocols for prescribing and dispensing naloxone hydrochloride or another opioid overdose-reversing medication when there is no prescription drug order, standing order or collaborative practice agreement authorizing naloxone hydrochloride or another opioid overdose-reversing medication to be dispensed to the intended recipient. Rules adopted under this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. A pharmacist authorized by the board pursuant to this subsection to prescribe and dispense naloxone hydrochloride or another opioid overdose-reversing medication may prescribe and dispense naloxone hydrochloride or another opioid overdose-reversing medication in accordance with Title 22, section 2353, subsection 2, paragraphs A-1 and C-1. An opioid overdose-reversing medication referenced in this subsection must be approved by the federal Food and Drug Administration.

[PL 2023, c. 161, §8 (AMD).]

SECTION HISTORY

PL 2015, c. 508, §5 (NEW). PL 2017, c. 249, §2 (RPR). PL 2017, c. 364, §§6, 7 (AMD). PL 2023, c. 161, §8 (AMD).

SUBCHAPTER 12

COLLABORATIVE PRACTICE FOR EMERGENCY CONTRACEPTION

§13821. Short title

This subchapter is known and may be cited as "the Collaborative Practice for Emergency Contraception Act." [PL 2003, c. 524, §1 (NEW).]

SECTION HISTORY

PL 2003, c. 524, §1 (NEW).

§13822. Collaborative practice authorized

Notwithstanding any other provision of law, a licensed pharmacist who has completed the training required in section 13823 may initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within the prescriber's scope of practice. [PL 2003, c. 524, §1 (NEW).]

SECTION HISTORY

PL 2003, c. 524, §1 (NEW).

§13823. Training required

Prior to performing any procedure authorized under this chapter, a pharmacist must have completed a training program on emergency contraception, delivered by an entity authorized by a national council on pharmaceutical education, or another training program approved by the board. The training program must include, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services and documentation. [PL 2003, c. 524, §1 (NEW).]

SECTION HISTORY

PL 2003, c. 524, §1 (NEW).

§13824. Provision of standardized fact sheet required

For each emergency contraception drug therapy initiated pursuant to this subchapter, the pharmacist shall provide the recipient of the emergency contraceptive drugs with a standardized fact sheet developed by the board that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical follow-up and referral information, information on sexual assault and referral information and other appropriate information. [PL 2003, c. 524, §1 (NEW).]

SECTION HISTORY

PL 2003, c. 524, §1 (NEW).

§13825. Confidentiality

Nothing in this subchapter affects the provisions of law relating to maintaining the confidentiality of medical records. [PL 2003, c. 524, §1 (NEW).]

SECTION HISTORY

PL 2003, c. 524, §1 (NEW).

SUBCHAPTER 12-A

PRESCRIBING, DISPENSING AND ADMINISTERING CONTRACEPTIVES

§13826. Authorization to prescribe, dispense and administer contraceptives

1. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Injectable hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that is administered by injection. [PL 2023, c. 115, §1 (NEW).]

B. "Self-administered hormonal contraceptive" means a drug composed of a single hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may self-administer. "Self-administered hormonal contraceptive" includes an oral hormonal contraceptive, a hormonal vaginal ring and a hormonal contraceptive patch. [PL 2023, c. 115, §1 (NEW).]

[PL 2023, c. 115, §1 (NEW).]

2. Authorization. A pharmacist may prescribe, dispense or administer a self-administered hormonal contraceptive or injectable hormonal contraceptive in accordance with the requirements set forth in subsection 3.

[PL 2023, c. 115, §1 (NEW).]

3. Requirements. In order to prescribe, dispense or administer contraceptives under this section, a pharmacist shall:

A. Successfully complete a training program approved by the board related to prescribing, dispensing and administering contraceptives that reflects evidence-based medical eligibility guidelines for contraceptive use and best practices to counsel patients; [PL 2023, c. 115, §1 (NEW).]

B. Obtain a certificate of authorization issued by the board pursuant to subsection 4; [PL 2023, c. 115, §1 (NEW).]

C. Obtain a completed self-screening risk assessment from a patient prior to counseling the patient and issuing a prescription to the patient for a self-administered hormonal contraceptive or injectable hormonal contraceptive. The self-screening risk assessment and counseling provided by a pharmacist must be based on evidence-based medical eligibility guidelines for contraceptive use and best practices to counsel patients; [PL 2023, c. 115, §1 (NEW).]

D. Refer the patient to the patient's practitioner upon dispensing a self-administered hormonal contraceptive or administering an injectable hormonal contraceptive or, if the patient does not have a practitioner responsible for the patient's regular care, advise the patient to consult a practitioner; [PL 2023, c. 115, §1 (NEW).]

E. Provide the patient with a written record of the prescribed self-administered hormonal contraceptive or injectable hormonal contraceptive; and [PL 2023, c. 115, §1 (NEW).]

F. Dispense the self-administered hormonal contraceptive or administer the injectable hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription. [PL 2023, c. 115, §1 (NEW).]

[PL 2023, c. 115, §1 (NEW).]

4. Certificate of authorization. A pharmacist shall apply in the form prescribed by the board and submit a certificate fee as set forth in section 13724 for a certificate of authorization to prescribe, dispense and administer contraceptives pursuant to this section. The certificate of authorization expires and is subject to conditions in the same manner as in section 13734. The board shall issue a certificate of authorization to a pharmacist who holds a valid unrestricted license in this State and who submits evidence acceptable to the board that the pharmacist has completed the training described in subsection 3, paragraph A.

[PL 2023, c. 115, §1 (NEW).]

5. Rulemaking. The board shall adopt rules to implement the requirements of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

[PL 2023, c. 115, §1 (NEW).]

SECTION HISTORY

PL 2023, c. 115, §1 (NEW).

SUBCHAPTER 13

ADMINISTRATION OF DRUGS AND VACCINES

§13831. Authority

1. Administration of influenza vaccines. A pharmacist licensed in this State who meets the qualifications and requirements of section 13832 and rules adopted by the board may administer

topically or by injection or by inhalation all forms of influenza vaccines, including intranasal influenza vaccines, to a person 3 years of age or older without a prescription.
[PL 2023, c. 170, §1 (AMD).]

2. Administration of other vaccines. A pharmacist licensed in this State who meets the qualifications and requirements of section 13832 and rules adopted by the board, in addition to influenza vaccines under subsection 1, may administer 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 a person 18 years of age or older. A pharmacist may administer 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 a person 3 years of age or older and under 18 years of age according to a valid prescription from a prescriber licensed under chapter 31, 36 or 48. A pharmacist may administer vaccines licensed by the United States Food and Drug Administration that are outside the guidelines recommended by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practices, or successor organization, for administration to a person 18 years of age or older according to a valid prescription if the prescription specifically states that the vaccine is medically necessary.
[RR 2023, c. 2, Pt. A, §49 (COR).]

2-A. Administration of COVID-19 vaccines. A pharmacist licensed in this State who meets the qualifications and requirements of section 13832 and rules adopted by the board may administer and order COVID-19 vaccines licensed or authorized under an emergency use authorization 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, to a person 3 years of age or older. For the purposes of this subsection, "COVID-19" has the same meaning as in Title 24-A, section 4320-P, subsection 1, paragraph A.
[PL 2021, c. 28, Pt. B, §2 (NEW).]

3. Emergency administration of certain drugs. A pharmacist may administer epinephrine or diphenhydramine, or both, to a person in an emergency situation resulting from an adverse reaction to a vaccine administered by the pharmacist.
[PL 2011, c. 577, §3 (AMD).]

4. Vaccine clinics. A pharmacist or pharmacy licensed under this chapter may operate a vaccine administration clinic inside, outside or off the pharmacy's premises if the pharmacist or pharmacy obtains approval from the board for the plan of operation of such clinics pursuant to rules adopted under section 13835, subsection 1.
[PL 2011, c. 577, §4 (NEW).]

5. Administration of injectable drugs. A pharmacist who meets the qualifications and requirements of section 13832 and rules adopted by the board may administer to adults by intramuscular and subcutaneous injection drugs approved by the United States Food and Drug Administration under the following conditions:

A. Upon the order of a practitioner to dispense and administer the drug, as long as the practitioner is notified after administration is complete in accordance with section 13833, subsection 3; or [PL 2021, c. 271, §3 (NEW).]

B. While engaged in collaborative drug therapy management pursuant to a collaborative practice agreement in accordance with the requirements of subchapter 14. [PL 2021, c. 271, §3 (NEW).]
[PL 2021, c. 271, §3 (NEW).]

6. Administration of vaccines by pharmacy technician. A pharmacy technician may administer vaccines in accordance with the requirements of this section if the pharmacy technician:

A. Holds a valid unrestricted pharmacy technician license in this State; [PL 2023, c. 245, §1 (NEW).]

B. Consistent with rules adopted by the board, works under the direct supervision of a pharmacist who meets the requirements of section 13832; [PL 2023, c. 245, §1 (NEW).]

C. Possesses a current certificate of administration issued by the board. The pharmacy technician must submit an application in the form prescribed by the board together with the requirements set forth under this section and certificate fee as set forth under section 13724. The certificate of administration expires and is subject to the conditions in the same manner as in section 13734; and [PL 2023, c. 245, §1 (NEW).]

D. Submits evidence acceptable to the board that the pharmacy technician has completed a certification program approved by the board consisting of at least 6 hours of vaccine-related training that includes, at a minimum, training on the safe and effective administration of vaccines, hands-on injection technique, clinical evaluation of indications and contraindications of vaccines and the recognition and treatment of emergency reactions to vaccines and cardiovascular life support training as described in section 13832, subsection 5. [PL 2023, c. 245, §1 (NEW).]

[PL 2023, c. 245, §1 (NEW).]

REVISOR'S NOTE: (Subsection 6 as enacted by PL 2023, c. 170, §3 is REALLOCATED TO TITLE 32, SECTION 13831, SUBSECTION 7)

7. (REALLOCATED FROM T. 32, §13831, sub-§6) Notification of vaccines administration. A pharmacist licensed in this State who meets the qualifications and requirements of section 13832 and rules adopted by the board shall provide a written immunization record to the person, or the person's representative, receiving a vaccine administered under this section. Within 72 hours of administering a vaccine, a pharmacist shall notify the person's primary care provider, if any, of administration of the vaccine. Beginning August 1, 2023, a pharmacist shall report the administration of the vaccine to the appropriate state immunization information reporting system within 72 hours of administering the vaccine.

[PL 2023, c. 170, §3 (NEW); RR 2023, c. 1, Pt. A, §28 (RAL).]

SECTION HISTORY

PL 2009, c. 308, §3 (NEW). PL 2011, c. 577, §§3, 4 (AMD). PL 2013, c. 6, §1 (AMD). PL 2015, c. 211, §1 (AMD). PL 2021, c. 28, Pt. B, §2 (AMD). PL 2021, c. 271, §3 (AMD). PL 2023, c. 170, §§1-3 (AMD). PL 2023, c. 245, §1 (AMD). RR 2023, c. 1, Pt. A, §28 (COR). RR 2023, c. 2, Pt. A, §49 (COR).

§13832. Qualifications; requirements

In order to administer a drug or vaccine under this subchapter, a pharmacist must: [PL 2011, c. 577, §5 (AMD).]

1. Certificate; application and fee. Possess a current certificate of administration issued by the board pursuant to this subchapter. The pharmacist must submit an application in the form prescribed by the board together with the requirements set forth under this subchapter and certificate fee as set forth under section 13724. The certificate of administration expires and is subject to the conditions in the same manner as stated in section 13734;

[PL 2009, c. 308, §3 (NEW).]

2. License. Hold a valid unrestricted pharmacist license in this State;

[PL 2009, c. 308, §3 (NEW).]

3. Training. Submit evidence acceptable to the board that the pharmacist:

A. Has completed a 20-hour course of study in the areas of drug administration authorized under this subchapter and as described in subsection 4 within the 3 years immediately preceding application for a certificate of administration; [PL 2023, c. 245, §2 (AMD).]

B. Has graduated with a Doctor of Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education or successor organization within the 3 years immediately preceding application for a certificate of administration that includes completion of training in the areas of drug administration authorized under this subchapter satisfactory to the board, including instruction in the areas identified in subsection 4 received as part of the pharmacist's pharmacy degree program; or [PL 2023, c. 245, §2 (AMD).]

C. Has a valid certificate of administration issued by any jurisdiction of the United States or its territories within the 3 years immediately preceding application for a certificate of administration that authorizes the pharmacist to administer drugs comparable to those authorized under this chapter and that is based on the pharmacist's completion of training or course work as described in subsection 4, or its equivalent as determined by the board, and has continuous administration practice since the pharmacist received such training or since completion of a retraining program as required in this subchapter, as long as such retraining incorporates the areas identified in subsection 4; [PL 2023, c. 245, §2 (AMD).]

[PL 2023, c. 245, §2 (AMD).]

4. Didactic; practical course. Satisfactorily complete a didactic and practical course approved by the board that includes the current guidelines and recommendations of the federal Department of Health and Human Services, Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body, and that includes, but is not limited to, disease epidemiology, indications for use of vaccines, vaccine characteristics, injection techniques, adverse reactions to vaccines, emergency response to adverse events, immunization screening, informed consent, record keeping, registries, including the immunization information system established under Title 22, section 1064, registry training and reporting mechanisms, including reporting adverse events, life support training, biohazard waste disposal and sterile techniques and related topics; and

[PL 2009, c. 308, §3 (NEW).]

5. Life support training. Submit evidence of completing cardiovascular life support training accepted by the American Heart Association, the American Red Cross or other similar training organization.

[PL 2009, c. 308, §3 (NEW).]

SECTION HISTORY

PL 2009, c. 308, §3 (NEW). PL 2011, c. 577, §5 (AMD). PL 2023, c. 245, §2 (AMD).

§13833. Treatment protocol

A pharmacist shall administer drugs and vaccines in compliance with a treatment protocol established by a practitioner authorized under the laws of this State to order administration of those drugs and vaccines approved by the board. A copy of the original treatment protocol and any subsequent revisions to the treatment protocol must be kept on the premises of the pharmacy and be available to the board or the board's representative upon request. At a minimum the treatment protocol must include: [PL 2021, c. 289, §13 (AMD).]

1. Standards. Standards for observation of the person receiving the drug or vaccine to determine whether the person has an adverse reaction, as adopted in rules by the board;

[PL 2011, c. 577, §6 (AMD).]

2. Procedures. Procedures to be followed by the pharmacist when administering epinephrine or diphenhydramine, or both, to a person who has an adverse reaction to a vaccine administered by the pharmacist; and
[PL 2011, c. 577, §6 (AMD).]

3. Notification. Notification to the authorized practitioner who issued the prescription, standing order or protocol under section 13831, subsection 2 of the administration by the pharmacist of the drug or vaccine, or both, within 3 business days.
[PL 2011, c. 577, §6 (AMD).]

SECTION HISTORY

PL 2009, c. 308, §3 (NEW). PL 2011, c. 577, §6 (AMD). PL 2021, c. 289, §13 (AMD).

§13834. Prohibited acts

1. Delegate authority. A pharmacist may not delegate the pharmacist's authority to administer drugs or vaccines; except that a pharmacist licensed under this chapter who has obtained a certificate of administration pursuant to section 13832 may delegate the authority to administer vaccines to a pharmacy technician who is under that pharmacist's direct supervision and has met the requirements of section 13831, subsection 6 or may delegate the authority to administer drugs and vaccines to a pharmacy intern who is under that pharmacist's direct supervision and who has obtained drug administration training pursuant to section 13832, subsection 3. A pharmacy intern may administer drugs and vaccines only to a person 18 years of age or older.
[PL 2023, c. 245, §3 (AMD).]

2. Administer drugs or vaccines. A pharmacist may not engage in the administration of drugs or vaccines unless the pharmacist meets the qualifications and requirements of section 13832 and the pharmacist has obtained a board-issued certificate of administration. A pharmacy technician may not engage in the administration of vaccines unless the pharmacy technician meets the qualifications and requirements of section 13831, subsection 6 and the pharmacy technician has obtained a board-issued certificate of administration.
[PL 2023, c. 245, §3 (AMD).]

SECTION HISTORY

PL 2009, c. 308, §3 (NEW). PL 2011, c. 577, §7 (AMD). PL 2013, c. 98, §1 (AMD). PL 2023, c. 245, §3 (AMD).

§13835. Rules

The board, after consultation with the Maine Center for Disease Control and Prevention and the Board of Licensure in Medicine, shall adopt rules to implement this subchapter. The rules must include, at a minimum: [PL 2009, c. 308, §3 (NEW).]

1. Criteria. Criteria for the operation of a vaccine administration clinic inside, outside or off the premises of a retail pharmacy, rural health clinic or free clinic licensed under section 13751. The rules must require the plan of operation for any vaccine administration clinics to be operated by a pharmacist or pharmacy. Criteria for the administration of drugs by intramuscular or subcutaneous injection inside, outside or off the premises of a retail pharmacy, rural health clinic or free clinic licensed under section 13751 and must require one-time board approval of the plan for the administration of drugs by intramuscular or subcutaneous injection by a pharmacist or pharmacy and may not require board approval for each administration;
[PL 2021, c. 271, §4 (AMD); PL 2021, c. 289, §14 (AMD).]

2. Record keeping. Record keeping and documentation procedures and reporting requirements, giving preference to electronic means when available; and
[PL 2009, c. 308, §3 (NEW).]

3. Recipient assessment. Recipient assessment, consent and rights.
[PL 2009, c. 308, §3 (NEW).]

Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. [PL 2009, c. 308, §3 (NEW).]

SECTION HISTORY

PL 2009, c. 308, §3 (NEW). PL 2011, c. 577, §8 (AMD). PL 2021, c. 271, §4 (AMD). PL 2021, c. 289, §14 (AMD).

SUBCHAPTER 14

COLLABORATIVE DRUG THERAPY MANAGEMENT

§13841. Authority

1. Engage in collaborative drug therapy management. A pharmacist licensed in this State who meets the qualifications and requirements of section 13842 and rules adopted by the board may engage in collaborative drug therapy management pursuant to a collaborative practice agreement with a practitioner.
[PL 2013, c. 308, §4 (NEW).]

2. Scope of authority. A pharmacist engaging in collaborative drug therapy management pursuant to subsection 1 is entitled to adequate access to a patient's history, disease status, drug therapy and laboratory and procedure results and may:

A. Collect and review a patient's history; [PL 2013, c. 308, §4 (NEW).]

B. Obtain and check vital signs; [PL 2013, c. 308, §4 (NEW).]

C. Order and evaluate the results of laboratory tests directly related to drug therapy under the supervision of, or in direct consultation with, a practitioner and in accordance with approved protocols applicable to the practice setting and when the evaluation does not include a diagnostic component; and [PL 2013, c. 308, §4 (NEW).]

D. Initiate, administer, monitor, modify and discontinue drug therapy for a particular patient pursuant to the collaborative practice agreement with a practitioner who is treating the patient, as long as the action is reported to the practitioner in a timely manner as determined by rules adopted pursuant to section 13846. [PL 2021, c. 271, §5 (AMD).]
[PL 2021, c. 271, §5 (AMD).]

SECTION HISTORY

PL 2013, c. 308, §4 (NEW). PL 2021, c. 271, §5 (AMD).

§13842. Qualifications

In order to enter into a collaborative practice agreement with a practitioner under this subchapter, a pharmacist must: [PL 2013, c. 308, §4 (NEW).]

1. License. Hold a valid unrestricted pharmacist license in this State;
[PL 2013, c. 308, §4 (NEW).]

2. Training. Submit evidence acceptable to the board that the pharmacist:

A. Possesses certification from the Board of Pharmacy Specialties or successor organization or has completed an accredited residency program. If the residency program is not in the area of practice covered by the agreement, the pharmacist must complete a continuing education certificate program

of at least 15 hours of continuing education in each clinical area of practice covered by the agreement; [PL 2013, c. 308, §4 (NEW).]

B. Has graduated with a Doctor of Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education, has 2 years of professional experience and has completed a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement; or [PL 2013, c. 308, §4 (NEW).]

C. Has graduated with a Bachelor of Science in Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education, has 3 years of professional experience and has completed a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement. [PL 2013, c. 308, §4 (NEW).]

[PL 2013, c. 308, §4 (NEW).]

SECTION HISTORY

PL 2013, c. 308, §4 (NEW).

§13843. Collaborative practice agreement

A pharmacist may engage in collaborative drug therapy management pursuant to a collaborative practice agreement in accordance with this section. [PL 2013, c. 308, §4 (NEW).]

1. Submit to board. The pharmacist shall submit a copy of the collaborative practice agreement to the board and the licensing board that licenses the practitioner prior to the commencement of the collaborative practice.
[PL 2013, c. 308, §4 (NEW).]

2. Review and revision. The signatories to a collaborative practice agreement shall establish a procedure for reviewing and, if necessary, revising the procedures and protocols of the collaborative practice agreement.
[PL 2013, c. 308, §4 (NEW).]

3. Health information privacy. Services provided pursuant to a collaborative practice agreement must be performed in compliance with the federal Health Insurance Portability and Accountability Act of 1996, 42 United States Code, Section 1320d et seq. and its regulations, 45 Code of Federal Regulations, Parts 160-164.
[PL 2013, c. 308, §4 (NEW).]

4. Amendments to agreement. Amendments to a collaborative practice agreement must be documented, signed and dated.
[PL 2013, c. 308, §4 (NEW).]

5. Assessment; risk management. A collaborative practice agreement must include a plan for measuring and assessing patient outcomes and must include proof that liability insurance is maintained by all parties to the agreement.
[PL 2013, c. 308, §4 (NEW).]

6. Contents of agreement. A practitioner and a pharmacist desiring to engage in collaborative practice in accordance with this subchapter shall execute a collaborative practice agreement that must contain, but is not limited to:

A. A provision that states that activity in the initial 3 months of a collaborative practice agreement is limited to monitoring drug therapy. After the initial 3 months, the practitioner and pharmacist shall meet to review the collaborative practice agreement and determine the scope of the agreement, which may after the initial 3 months include a pharmacist's initiating, administering, monitoring, modifying and discontinuing a patient's drug therapy and reporting these actions to the practitioner

in a timely manner in accordance with rules adopted pursuant to section 13846; [PL 2021, c. 271, §6 (AMD).]

B. Identification and signatures of the parties to the collaborative practice agreement, the dates the agreement is signed and the beginning and ending dates of the period of time during which the agreement is in effect; [PL 2013, c. 308, §4 (NEW).]

C. A provision that allows either party to cancel the collaborative practice agreement by written notification; [PL 2013, c. 308, §4 (NEW).]

D. Specification of the site and setting at which the collaborative practice will occur; [PL 2013, c. 308, §4 (NEW).]

E. Specification of the qualifications of the participants in the collaborative practice agreement; [PL 2013, c. 308, §4 (NEW).]

F. A detailed description of the types of diseases, drugs or drug categories involved and collaborative drug therapy management allowed in each patient's case; and [PL 2013, c. 308, §4 (NEW).]

G. A procedure for the referral of each patient to the practitioner. [PL 2013, c. 308, §4 (NEW).] [PL 2021, c. 271, §6 (AMD).]

SECTION HISTORY

PL 2013, c. 308, §4 (NEW). PL 2021, c. 271, §6 (AMD).

§13844. Conditions or diseases managed; scope of practice

1. Generally accepted standards of care. A pharmacist may engage in collaborative drug therapy management pursuant to a collaborative practice agreement only for conditions or diseases with generally accepted standards of care.
[PL 2013, c. 308, §4 (NEW).]

2. Prohibition. A pharmacist who is engaged in collaborative drug therapy management pursuant to a collaborative practice agreement may not, as part of the collaborative practice, participate in research or clinical or investigational trials.
[PL 2013, c. 308, §4 (NEW).]

3. Limitation. A collaborative practice agreement may include only the conditions or diseases to be managed that meet the qualifications and scope of practice for each party to the agreement.
[PL 2013, c. 308, §4 (NEW).]

SECTION HISTORY

PL 2013, c. 308, §4 (NEW).

§13845. Practice protocols

A pharmacist may engage in collaborative drug therapy management in compliance with a treatment protocol established by the practitioner with whom the pharmacist has a collaborative practice agreement. A copy of the treatment protocol must be submitted to the board. At a minimum, the treatment protocol must include a statement by the practitioner that describes the activities in which the pharmacist is authorized to engage and a provision that allows the practitioner, when appropriate, to override a collaborative practice decision made by the pharmacist. [PL 2013, c. 308, §4 (NEW).]

SECTION HISTORY

PL 2013, c. 308, §4 (NEW).

§13846. Rules

The board and the Board of Licensure in Medicine, after consultation with the Department of Health and Human Services, shall adopt rules to implement this subchapter. The rules must include rules establishing record-keeping and documentation procedures and reporting requirements and must allow for electronic filing when possible. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. [PL 2013, c. 308, §4 (NEW).]

SECTION HISTORY

PL 2013, c. 308, §4 (NEW).

§13847. Exemptions

Nothing in this subchapter may be construed to limit the scope of practice of a pharmacist pursuant to this chapter or to apply to collaborative practice agreements entered into between a pharmacist and a hospital solely for the treatment of inpatients at the hospital. [PL 2013, c. 308, §4 (NEW).]

SECTION HISTORY

PL 2013, c. 308, §4 (NEW).

SUBCHAPTER 15

TELEHEALTH SERVICES

§13848. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings. [PL 2021, c. 291, Pt. B, §19 (NEW).]

1. Asynchronous encounter. "Asynchronous encounter" means an interaction between a patient and a person licensed under this chapter through a system that has the ability to store digital information, including, but not limited to, still images, video files, audio files, text files and other relevant data, and to transmit such information without requiring the simultaneous presence of the patient and the person licensed under this chapter.
[PL 2021, c. 291, Pt. B, §19 (NEW).]

2. Store and forward transfer. "Store and forward transfer" means the transmission of a patient's records through a secure electronic system to a person licensed under this chapter.
[PL 2021, c. 291, Pt. B, §19 (NEW).]

3. Synchronous encounter. "Synchronous encounter" means a real-time interaction conducted with an interactive audio or video connection between a patient and a person licensed under this chapter or between a person licensed under this chapter and another health care provider.
[PL 2021, c. 291, Pt. B, §19 (NEW).]

4. Telehealth services. "Telehealth services" means health care services delivered through the use of information technology and includes synchronous encounters, asynchronous encounters, store and forward transfers and telemonitoring.
[PL 2021, c. 291, Pt. B, §19 (NEW).]

5. Telemonitoring. "Telemonitoring" means the use of information technology to remotely monitor a patient's health status via electronic means, allowing the person licensed under this chapter to track the patient's health data over time. Telemonitoring may be synchronous or asynchronous.
[PL 2021, c. 291, Pt. B, §19 (NEW).]

SECTION HISTORY

PL 2021, c. 291, Pt. B, §19 (NEW).

§13849. Telehealth services permitted

A person licensed under this chapter may provide telehealth services as long as the licensee acts within the scope of practice of the licensee's license, in accordance with any requirements and restrictions imposed by this subchapter and in accordance with standards of practice. [PL 2021, c. 291, Pt. B, §19 (NEW).]

SECTION HISTORY

PL 2021, c. 291, Pt. B, §19 (NEW).

§13849-A. Confidentiality

When providing telehealth services, a person licensed under this chapter shall comply with all state and federal confidentiality and privacy laws. [PL 2021, c. 291, Pt. B, §19 (NEW).]

SECTION HISTORY

PL 2021, c. 291, Pt. B, §19 (NEW).

§13849-B. Professional responsibility

All laws and rules governing professional responsibility, unprofessional conduct and generally accepted standards of practice that apply to a person licensed under this chapter also apply to that licensee while providing telehealth services. [PL 2021, c. 291, Pt. B, §19 (NEW).]

SECTION HISTORY

PL 2021, c. 291, Pt. B, §19 (NEW).

§13849-C. Rulemaking

The board shall adopt rules governing telehealth services by persons licensed under this chapter. These rules must establish standards of practice and appropriate restrictions for the various types and forms of telehealth services. Rules adopted pursuant to this section are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A. [PL 2021, c. 291, Pt. B, §19 (NEW).]

SECTION HISTORY

PL 2021, c. 291, Pt. B, §19 (NEW).