

Article 4A.

North Carolina Pharmacy Practice Act.

Part 1. North Carolina Pharmacy Practice Act.

§ 90-85.2. Legislative findings.

The General Assembly of North Carolina finds that mandatory licensure of all who engage in the practice of pharmacy is necessary to insure minimum standards of competency and to protect the public from those who might otherwise present a danger to the public health, safety and welfare. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.3. Definitions.

(a) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means.

(b) "Board" means the North Carolina Board of Pharmacy.

(b1) "Certified pharmacy technician" means a pharmacy technician who (i) has passed a nationally recognized pharmacy technician certification board examination, or its equivalent, that has been approved by the Board and (ii) obtains and maintains certification from a nationally recognized pharmacy technician certification board that has been approved by the Board.

(b2) "Clinical pharmacist practitioner" means a licensed pharmacist who meets the guidelines and criteria for such title established by the joint subcommittee of the North Carolina Medical Board and the North Carolina Board of Pharmacy and is authorized to enter into drug therapy management agreements with physicians in accordance with the provisions of G.S. 90-18.4.

(c) "Compounding" means taking two or more ingredients and combining them into a dosage form of a drug, exclusive of compounding by a drug manufacturer, distributor, or packer.

(d) "Deliver" means the actual, constructive or attempted transfer of a drug, a device, or medical equipment from one person to another.

(e) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article including any component part or accessory, whose label or labeling bears the statement "Caution: federal law requires dispensing by or on the order of a physician." The term does not include:

(1) Devices used in the normal course of treating patients by health care facilities and agencies licensed under Chapter 131E or Article 2 of Chapter 122C of the General Statutes;

(2) Devices used or provided in the treatment of patients by medical doctors, dentists, physical therapists, occupational therapists, speech pathologists, optometrists, chiropractors, podiatrists, and nurses licensed under Chapter 90 of the General Statutes, provided they do not dispense devices used to administer or dispense drugs.

(f) "Dispense" means preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing". Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing".

(g) "Drug" means:

(1) Any article recognized as a drug in the United States Pharmacopeia, or in any other drug compendium or any supplement thereto, or an article recognized as a drug by the United States Food and Drug Administration;

- (2) Any article, other than food or devices, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;
- (3) Any article, other than food or devices, intended to affect the structure or any function of the body of man or other animals; and
- (4) Any article intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection.

(h) "Emancipated minor" means any person under the age of 18 who is or has been married or who is or has been a parent; or whose parents or guardians have surrendered their rights to the minor's services and earnings as well as their right to custody and control of the minor's person; or who has been emancipated by an appropriate court order.

(i) "Health care provider" means any licensed health care professional; any agent or employee of any health care institution, health care insurer, health care professional school; or a member of any allied health profession.

(i1) "Immunizing pharmacist" means a licensed pharmacist who meets all of the following qualifications:

- (1) Holds a current provider level cardiopulmonary resuscitation certification issued by the American Heart Association or the American Red Cross, or an equivalent certification.
- (2) Has successfully completed a certificate program in vaccine administration accredited by the Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education, or a similar health authority or professional body approved by the Board.
- (3) Maintains documentation of three hours of continuing education every two years, designed to maintain competency in the disease states, drugs, and vaccine administration.
- (4) Has successfully completed training approved by the Division of Public Health's Immunization Branch for participation in the North Carolina Immunization Registry.
- (5) Has notified the North Carolina Board of Pharmacy and the North Carolina Medical Board of immunizing pharmacist status.
- (6) Administers vaccines, long-acting injectable medications, or immunizations in accordance with G.S. 90-18.15B.

(j) "Label" means a display of written, printed or graphic matter upon the immediate or outside container of any drug.

(k) "Labeling" means preparing and affixing a label to any drug container, exclusive of labeling by a manufacturer, packer or distributor of a nonprescription drug or a commercially packaged prescription drug or device.

(l) "License" means a license to practice pharmacy including a renewal license issued by the Board.

(l1) "Medical equipment" means any of the following items that are intended for use by the consumer in the consumer's place of residence:

- (1) A device.
- (2) Ambulation assistance equipment.
- (3) Mobility equipment.
- (4) Rehabilitation seating.
- (5) Oxygen and respiratory care equipment.

- (6) Rehabilitation environmental control equipment.
- (7) Diagnostic equipment.
- (8) A bed prescribed by a physician to treat or alleviate a medical condition.

The term "medical equipment" does not include (i) medical equipment used or dispensed in the normal course of treating patients by or on behalf of home care agencies, hospitals, and nursing facilities licensed under Chapter 131E of the General Statutes or hospitals or agencies licensed under Article 2 of Chapter 122C of the General Statutes; (ii) medical equipment used or dispensed by professionals licensed under Chapters 90 or 93D of the General Statutes, provided the professional is practicing within the scope of that professional's practice act; (iii) upper and lower extremity prosthetics and related orthotics; or (iv) canes, crutches, walkers, and bathtub grab bars.

- (l2) "Mobile pharmacy" means a pharmacy that meets all of the following conditions:
 - (1) Is either self-propelled or moveable by another vehicle that is self-propelled.
 - (2) Is operated by a nonprofit corporation.
 - (3) Dispenses prescription drugs at no charge or at a reduced charge to persons whose family income is less than two hundred percent (200%) of the federal poverty level and who do not receive reimbursement for the cost of the dispensed prescription drugs from Medicare, Medicaid, a private insurance company, or a governmental unit.

- (m) "Permit" means a permit to operate a pharmacy, deliver medical equipment, or dispense devices, including a renewal license issued by the Board.

- (n) "Person" means an individual, corporation, partnership, association, unit of government, or other legal entity.

- (o) "Person in loco parentis" means the person who has assumed parental responsibilities for a child.

- (p) "Pharmacist" means a person licensed under this Article to practice pharmacy.

- (q) "Pharmacy" means any place where prescription drugs are dispensed or compounded.

- (q1) "Pharmacy personnel" means pharmacists and pharmacy technicians.

- (q2) "Pharmacy technician" means a person who may, under the supervision of a pharmacist, perform technical functions to assist the pharmacist in preparing and dispensing prescription medications.

- (r) "Practice of pharmacy" is as specified in G.S. 90-85.3A.

- (s) "Prescription drug" means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement:

"Caution: Federal law prohibits dispensing without prescription."

- (t) "Prescription order" means a written or verbal order for a prescription drug, prescription device, or pharmaceutical service from a person authorized by law to prescribe such drug, device, or service. A prescription order includes an order entered in a chart or other medical record of a patient.

- (u) "Unit dose medication system" means a system in which each dose of medication is individually packaged in a properly sealed and properly labeled container. (1981 (Reg. Sess., 1982), c. 1188, s. 1; 1983, c. 196, ss. 1-3; 1991, c. 578, s. 1; 1993 (Reg. Sess., 1994), c. 692, s. 2; 1995, c. 94, s. 24; 1999-246, s. 1; 1999-290, ss. 4, 5; 2001-375, s. 1; 2002-159, s. 37; 2013-246, ss. 1, 2; 2013-379, s. 1; 2021-3, s. 2.9(b).)

§ 90-85.3A. Practice of pharmacy.

(a) A pharmacist is responsible for interpreting and evaluating drug orders, including prescription orders; compounding, dispensing, and labeling prescription drugs and devices; properly and safely storing drugs and devices; maintaining proper records; and controlling pharmacy goods and services.

(b) A pharmacist may advise and educate patients and health care providers concerning therapeutic values, content, uses, and significant problems of drugs and devices; assess, record, and report adverse drug and device reactions; take and record patient histories relating to drug and device therapy; monitor, record, and report drug therapy and device usage; perform drug utilization reviews; and participate in drug and drug source selection and device and device source selection as provided in G.S. 90-85.27 through G.S. 90-85.31.

(c) An immunizing pharmacist is authorized and permitted to administer drugs as provided in G.S. 90-85.15B, and in accordance with rules adopted by each of the Board of Pharmacy, the Board of Nursing, and the North Carolina Medical Board. These rules shall be designed to ensure the safety and health of the patients for whom such drugs are administered.

(d) An approved clinical pharmacist practitioner may collaborate with physicians in determining the appropriate health care for a patient subject to the provisions of G.S. 90-18.4. (2013-246, s. 3.)

§ 90-85.4. North Carolina Pharmaceutical Association.

The North Carolina Pharmaceutical Association, and the persons composing it, shall continue to be a body politic and corporate under the name and style of the North Carolina Pharmaceutical Association, and by that name have the right to sue and be sued, to plead and be impleaded, to purchase and hold real estate and grant the same, to have and to use a common seal, and to do any other things and perform any other acts as appertain to bodies corporate and politic not inconsistent with the Constitution and laws of the State. (1881, c. 355, s. 1; Code, s. 3135; Rev., s. 4471; C.S., s. 6650; 1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.5. Objective of Pharmaceutical Association.

The objective of the Association is to unite the pharmacists of this State for mutual aid, encouragement, and improvement; to encourage scientific research, develop pharmaceutical talent and to elevate the standard of professional thought. (1881, c. 355, s. 2; Code, s. 3136; Rev., s. 4472; C.S., s. 6651; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1991, c. 125, s. 1.)

§ 90-85.6. Board of Pharmacy; creation; membership; qualification of members.

(a) **Creation.** – The responsibility for enforcing the provisions of this Article and the laws pertaining to the distribution and use of drugs is vested in the Board. The Board shall adopt reasonable rules for the performance of its duties. The Board shall have all of the duties, powers and authorities specifically granted by and necessary for the enforcement of this Article, as well as any other duties, powers and authorities that may be granted from time to time by other appropriate statutes. The Board may establish a program for the purpose of aiding in the recovery and rehabilitation of pharmacists who have become addicted to controlled substances or alcohol, and the Board may use money collected as fees to fund such a program.

(b) **Membership.** – The Board shall consist of six members, one of whom shall be a representative of the public, and the remainder of whom shall be pharmacists.

(c) **Qualifications.** – The public member of the Board shall not be a health care provider or the spouse of a health care provider. He shall not be enrolled in a program to prepare him to be a

health care provider. The public member of the Board shall be a resident of this State at the time of his appointment and while serving as a Board member. The pharmacist members of the Board shall be residents of this State at the time of their appointment and while serving as Board members. (1905, c. 108, ss. 5-7, 9; Rev., ss. 4473, 4475; 1907, c. 113, s. 1; C.S., ss. 6652, 6654; 1945, c. 572, s. 1; 1981, c. 717, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1997-177, s. 1.)

§ 90-85.7. Board of Pharmacy; selection; vacancies; commission; term; per diem; removal.

(a) The Board of Pharmacy shall consist of six persons. Five of the members shall be licensed as pharmacists within this State and shall be elected and commissioned by the Governor as hereinafter provided. Pharmacist members shall be chosen in an election held as hereinafter provided in which every person licensed to practice pharmacy in North Carolina and residing in North Carolina shall be entitled to vote. Each pharmacist member of said Board shall be elected for a term of five years and until his successor shall be elected and shall qualify. Members chosen by election under this section shall be elected upon the expiration of the respective terms of the members of the present Board of Pharmacy. No pharmacist shall be nominated for membership on said Board, or shall be elected to membership on said Board, unless, at the time of such nomination, and at the time of such election, he is licensed to practice pharmacy in North Carolina. In case of death, resignation or removal from the State of any pharmacist member of said Board, the pharmacist members of the Board shall elect in his place a pharmacist who meets the criteria set forth in this section to fill the unexpired term.

One member of the Board shall be a person who is not a pharmacist and who represents the interest of the public at large. The Governor shall appoint this member.

All Board members serving on June 30, 1989, shall be eligible to complete their respective terms. No member appointed or elected to a term on or after July 1, 1989, shall serve more than two complete consecutive five-year terms. The Governor may remove any member appointed by him for good cause shown and may appoint persons to fill unexpired terms of members appointed by him.

It shall be the duty of a member of the Board of Pharmacy, within 10 days after receipt of notification of his appointment and commission, to appear before the clerk of the superior court of the county in which he resides and take and subscribe an oath to properly and faithfully discharge the duties of his office according to law.

(b) All nominations and elections of pharmacist members of the Board shall be conducted by the Board of Pharmacy, which is hereby constituted a Board of Pharmacy Elections. Every pharmacist with a current North Carolina license residing in this State shall be eligible to vote in all elections. The list of pharmacists shall constitute the registration list for elections. The Board of Pharmacy Elections is authorized to make rules and regulations relative to the conduct of these elections, provided such rules and regulations are not in conflict with the provisions of this section and provided that notice shall be given to all pharmacists residing in North Carolina. All such rules and regulations shall be adopted subject to the procedures of Chapter 150B of the General Statutes of North Carolina. From any decision of the Board of Pharmacy Elections relative to the conduct of such elections, appeal may be taken to the courts in the manner otherwise provided by Chapter 150B of the General Statutes.

(c) All rules, regulations, and bylaws of the North Carolina Board of Pharmacy so far as they are not inconsistent with the provisions of this Article, shall continue in effect.

(d) Notwithstanding G.S. 93B-5, Board members shall receive as compensation for their services per diem not to exceed one hundred dollars (\$100.00) for each day during which they are

engaged in the official business of the Board. (1905, c. 108, ss. 5-7; Rev., s. 4473; C.S., s. 6652; 1981, c. 717, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1983, c. 196, s. 4; 1989, c. 118; 1989 (Reg. Sess., 1990), c. 825.)

§ 90-85.8. Organization.

The Board shall elect from its members a president, vice-president, and other officers as it deems necessary. The officers shall serve one-year terms and until their successors have been elected and qualified. (1905, c. 108, s. 8; Rev., s. 4474; C.S., s. 6653; 1923, c. 82; 1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.9. Meetings.

The Board shall meet at least twice annually for the purpose of administering examinations and conducting other business. Four Board members constitute a quorum. The Board shall keep a record of its proceedings, a register of all licensed persons, and a register of all persons to whom permits have been issued. The Board shall report, in writing, annually to the Governor and the presiding officer of each house of the General Assembly. (1905, c. 108, s. 8; Rev., s. 4474; C.S., s. 6653; 1923, c. 82; 1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.10. Employees; Executive Director.

The Board shall employ as Executive Director a pharmacist to serve as a full-time employee of the Board. The Executive Director shall serve as secretary and treasurer of the Board and shall perform administrative functions as authorized by the Board. The Board shall have the authority to employ other personnel as it may deem necessary to carry out the requirements of this Article. (1905, c. 108, s. 9; Rev., s. 4475; 1907, c. 113, s. 1; C.S., s. 6654; 1945, c. 572, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.11. Compensation of employees.

The Board shall determine the compensation of its employees. Employees shall be reimbursed for all necessary expenses incurred in the performance of their official duties. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.11A. Acquisition of real property; equipment; liability insurance.

(a) The Board shall have the power to acquire, hold, rent, encumber, alienate, and otherwise deal with real property in the same manner as a private person or corporation, subject only to approval of the Governor and the Council of State. Collateral pledged by the Board for an encumbrance is limited to the assets, income, and revenues of the Board.

(b) The Board may purchase, rent, or lease equipment and supplies and purchase liability insurance or other insurance to cover the activities of the Board, its operations, or its employees. (2001-407, s. 1.)

§ 90-85.12. Executive Director to make investigations and prosecute.

(a) Upon receiving information concerning a violation of this Article that is a threat to the public safety, health, or welfare, the Executive Director shall promptly conduct an investigation, and if he finds evidence of the violation, he may file a complaint and prosecute the offender in a Board hearing. If the Executive Director receives information concerning a violation of this Article that does not pose a threat to the public safety, health, or welfare, the Executive Director may

conduct an investigation, and if he finds evidence of the violation, he may file a complaint and prosecute the offender in a Board hearing.

(b) In all prosecutions of unlicensed persons for the violation of any of the provisions of this Article, a certificate signed under oath by the Executive Director shall be competent and admissible evidence in any court of this State that the person is not licensed, as required by law. (1905, c. 108, s. 11; Rev., s. 4477; C.S., s. 6656; 1923, c. 74, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 2005-402, s. 1.2.)

§ 90-85.13. Approval of schools and colleges of pharmacy.

The Board shall approve schools and colleges of pharmacy upon a finding that students successfully completing the course of study offered by the school or college can reasonably be expected to practice pharmacy safely and properly. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.14. Practical experience program.

The Board shall issue regulations governing a practical experience program. These regulations shall assure that the person successfully completing the program will have gained practical experience that will enable him to safely and properly practice pharmacy. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.15. Application, qualifications, and criminal record check for licensure as a pharmacist; prerequisites.

(a) Each applicant for licensure under this Article as a pharmacist shall file an application with the Executive Director on the form furnished by the Board, verified under oath, setting forth all of the following:

- (1) The applicant's name.
- (2) The applicant's age.
- (3) The place at which and the time that the applicant has spent in the study of pharmacy.
- (4) The applicant's experience in compounding and dispensing prescriptions under the supervision of a pharmacist.

(b) The Board shall license an applicant to practice pharmacy if, in addition to completing an application as specified in subsections (a) of this section, the applicant meets all of the following qualifications:

- (1) Holds an undergraduate degree from a school of pharmacy approved by the Board.
- (2) Has had up to one year of experience, approved by the Board, under the supervision of a pharmacist.
- (3) Has passed the required examination offered by the Board.
- (4) Has appeared at a time and place designated by the Board and submitted to an examination as to the applicant's qualifications for being licensed. The applicant must demonstrate to the Board the physical and mental competency to practice pharmacy.

(c) The Board shall require each applicant to provide the Board with a criminal record report. All applicants shall obtain criminal record reports from one or more reporting services designated by the Board to provide criminal record reports. The Board shall keep all information obtained pursuant to this subsection privileged, in accordance with applicable State law and federal

guidelines, and the information shall be confidential and shall not be a public record under Chapter 132 of the General Statutes. Applicants are required to pay the designated reporting service for the cost of these reports. (1905, c. 108, s. 13; Rev., ss. 4479, 4480; 1915, c. 165; C.S., s. 6658; 1921, c. 52; 1933, c. 206, ss. 1, 2; 1935, c. 181; 1937, c. 94; 1971, c. 481; 1981, c. 717, s. 4; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1983, c. 196, s. 5; 2002-147, s. 8; 2014-100, s. 17.1(o); 2017-144, s. 1.)

§ 90-85.15A. Pharmacy technicians.

(a) Registration, Generally. – A registration program for pharmacy technicians is established for the purposes of identifying those persons who are employed or are eligible for employment as pharmacy technicians. The Board must maintain a registry of pharmacy technicians that contains the name of each pharmacy technician, the name and location of a pharmacy in which the pharmacy technician works, the pharmacist-manager who employs the pharmacy technician, and the dates of that employment.

(a1) Registration of Noncertified Pharmacy Technicians. – The Board must register a pharmacy technician who pays the fee required under G.S. 90-85.24, is employed by a pharmacy holding a valid permit under this Article, and completes a required training program provided by the supervising pharmacist-manager as specified in subsection (b) of this section. A pharmacy technician must register with the Board within 30 days after the date the pharmacy technician completes a training program provided by the supervising pharmacist-manager. The registration must be renewed annually by paying a registration fee.

(a2) Registration of Certified Pharmacy Technicians. – The Board must register a certified pharmacy technician who pays the fee required under G.S. 90-85.24 and provides proof of current certification. The registration must be renewed annually by paying a registration fee and providing proof of current certification.

(b) Responsibilities of Pharmacist-Manager to Noncertified Pharmacy Technicians. – A pharmacist-manager may hire a person who has a high school diploma or equivalent or is currently enrolled in a program that awards a high school diploma or equivalent to work as a pharmacy technician. Pursuant to G.S. 90-85.21, a pharmacist-manager must notify the Board within 21 days of the date the pharmacy technician began employment. The pharmacist-manager must provide a training program for a pharmacy technician that includes pharmacy terminology, pharmacy calculations, dispensing systems and labeling requirements, pharmacy laws and regulations, record keeping and documentation, and the proper handling and storage of medications. The requirements of a training program may differ depending upon the type of employment. The training program must be provided and completed within 180 days of the date the pharmacy technician began employment.

(b1) Responsibilities of Pharmacist-Manager to Certified Pharmacy Technicians. – A pharmacist-manager may hire a certified pharmacy technician who has registered with the Board pursuant to subsection (a2) of this section. Pursuant to G.S. 90-85.21, a certified pharmacy technician shall notify the Board within 10 days of beginning employment as a pharmacy technician. The supervising pharmacist-manager and certified pharmacy technician shall be deemed to have satisfied the pharmacy technician training program requirements of subsection (b) of this section.

(c) Supervision. – A pharmacist may not supervise more than two pharmacy technicians unless the pharmacist-manager receives written approval from the Board. The Board may not allow a pharmacist to supervise more than two pharmacy technicians unless the additional pharmacy technicians are certified pharmacy technicians. The Board must respond to a request

from a pharmacist-manager to allow a pharmacist to supervise more than two pharmacy technicians within 60 days of the date it received the request. The Board must respond to the request in one of three ways:

- (1) Approval of the request.
- (2) Approval of the request as amended by the Board.
- (3) Disapproval of the request. A disapproval of a request must include a reasonable explanation of why the request was not approved.

(d) Disciplinary Action. – The Board may, in accordance with Chapter 150B of the General Statutes and rules adopted by the Board, issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew the registration of a pharmacy technician if the pharmacy technician has done one or more of the following:

- (1) Made false representations or withheld material information in connection with registering as a pharmacy technician.
- (2) Been found guilty of or plead guilty or nolo contendere to a felony involving the use or distribution of drugs.
- (3) Indulged in the use of drugs to an extent that it renders the pharmacy technician unfit to assist a pharmacist in preparing and dispensing prescription medications.
- (4) Developed a physical or mental disability that renders the pharmacy technician unfit to assist a pharmacist in preparing and dispensing prescription medications.
- (4a) Been negligent in assisting a pharmacist in preparing and dispensing prescription medications.
- (5) Failed to comply with the laws governing pharmacy technicians, including any provision of this Article or rules adopted by the Board governing pharmacy technicians.

(e) Exemption. – This section does not apply to pharmacy students who are enrolled in a school of pharmacy approved by the Board under G.S. 90-85.13.

(f) Rule-Making Authority. – The Board may adopt rules necessary to implement this section. (2001-375, s. 2; 2013-379, s. 2.)

§ 90-85.15B. Immunizing pharmacists.

(a) Except as provided in subsections (a1), (b1), and (c) of this section, an immunizing pharmacist may only administer vaccinations or immunizations to persons at least 18 years of age pursuant to a specific prescription order.

(a1) An immunizing pharmacist may administer to persons at least 18 years of age the vaccines or immunizations recommended by the Advisory Committee on Immunization Practices if the vaccinations or immunizations are administered under written protocols as defined in 21 NCAC 46 .2507(b)(12) and 21 NCAC 32U .0101(b)(12) and in accordance with the supervising physician's responsibilities as defined in 21 NCAC 46 .2507(e) and 21 NCAC 32 .0101(e), and the physician is licensed in and has a practice physically located in North Carolina. When supervised by an immunizing pharmacist, pharmacy interns and pharmacy technicians meeting the requirements of subsection (f) of this section may administer the vaccinations or immunizations recommended by the Advisory Committee on Immunization Practices to persons at least 18 years of age in accordance with this subsection.

(b) Repealed by Session Laws 2023-15, s. 3(a), effective May 19, 2023.

(b1) When a person chooses, or a parent or legal guardian provides written consent for a person under 18 years of age in accordance with subsection (g) of this section, an immunizing pharmacist may administer (i) an influenza vaccine, (ii) a COVID-19 vaccine recommended by the Advisory Committee on Immunization Practices (iii) a COVID-19 vaccine authorized under an emergency use authorization by the United States Food and Drug Administration and recommended by the Advisory Committee on Immunization Practices, or (iv) a combination of COVID-19 and influenza vaccines recommended by the Advisory Committee on Immunization Practices to persons at least 7 years of age pursuant to 21 NCAC 46 .2507 and 21 NCAC 32U .0101. When supervised by an immunizing pharmacist, pharmacy interns and pharmacy technicians meeting the requirements of subsection (f) of this section, may administer (i) an influenza vaccine, (ii) a COVID-19 vaccine recommended by the Advisory Committee on Immunization Practices, (iii) a COVID-19 vaccine authorized under an emergency use authorization by the United States Food and Drug Administration, or (iv) a combination of COVID-19 and influenza vaccines recommended by the Advisory Committee on Immunization Practices to persons at least 7 years of age in accordance with this subsection.

(c) An immunizing pharmacist may administer any other vaccinations approved by the United States Food and Drug Administration in accordance with the protocols established by the Advisory Committee on Immunization Practices to persons at least six years of age pursuant to a specific prescription order initiated by a prescriber following a physical examination of the patient by the prescriber.

(c1) An immunizing pharmacist may administer a long-acting injectable medication, including testosterone injections and vitamin B12, to persons at least 18 years of age pursuant to a specific prescription order initiated by a prescriber following an examination of the patient which conforms to the standards of acceptable and prevailing medical practice by the prescriber. An immunizing pharmacist who administers a long-acting injectable medication pursuant to this section shall do all of the following:

- (1) Maintain a record of any administration of a long-acting injectable performed by the immunizing pharmacist to the patient in a patient profile or record.
- (2) Within 72 hours after the administration of the long-acting injectable performed by the immunizing pharmacist to the patient, notify the prescriber regarding which medication and dosage was administered to the patient. If the long-acting injectable is in the class of psychotropic medications, the immunizing pharmacist shall notify the prescriber within 48 hours of administering the medication.
- (3) Within 72 hours of receipt of a specific prescription, notify the prescriber of the long-acting injectable medication if the medication was not administered to the patient. If the prescription is in the class of psychotropic medications, the immunizing pharmacist shall notify the prescriber if the medication was not administered within 48 hours of receipt of the prescription.

(c2) An immunizing pharmacist may dispense, deliver, or administer the following medications:

- (1) Nicotine replacement therapy that is approved by the United States Food and Drug Administration.
- (2) Self-administered oral or transdermal contraceptives after the patient completes an assessment consistent with the Centers for Disease Control and Prevention's United States Medical Eligibility Criteria (US MEC) for Contraceptive Use;

however, an immunizing pharmacist shall not dispense, deliver, or administer ulipristal acetate for emergency contraception without a prescription from a prescriber licensed under this Chapter.

- (3) Prenatal vitamins.
- (4) Post-exposure prophylaxis medications for the prevention of human immunodeficiency virus pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.
- (5) Glucagon for the treatment of severe hypoglycemia.

(c3) An immunizing pharmacist may administer to a patient any prescribed, self-administered injectable medication.

(d) An immunizing pharmacist who administers a vaccine or immunization to any patient pursuant to this section shall do all of the following:

- (1) Maintain a record of any vaccine or immunization administered to the patient in a patient profile.
- (2) Within 72 hours after administration of the vaccine or immunization, notify any primary care provider identified by the patient. If the patient does not identify a primary care provider, the immunizing pharmacist shall direct the patient to information describing the benefits to a patient of having a primary care physician, prepared by any of the following: North Carolina Medical Board, North Carolina Academy of Family Physicians, North Carolina Medical Society, or Community Care of North Carolina.
- (3) Except for influenza vaccines administered under G.S. 90-85.15B(c), access the North Carolina Immunization Registry prior to administering the vaccine or immunization and record any vaccine or immunization administered to the patient in the registry within 72 hours after the administration. In the event the registry is not operable, an immunizing pharmacist shall report as soon as reasonably possible.

(d1) An immunizing pharmacist who dispenses, delivers, or administers a medication listed in subsection (c2) of this section to a patient shall do all of the following:

- (1) Maintain a record of medication administered to the patient in a patient profile.
- (2) Within 72 hours after administration of the medication, notify any primary care provider identified by the patient. If the patient does not identify a primary care provider, the immunizing pharmacist shall direct the patient to information describing the benefits to a patient of having a primary care provider, including information about federally qualified health centers, free clinics, and local health departments, prepared by any of the following: North Carolina Medical Board, North Carolina Academy of Family Physicians, North Carolina Medical Society, or Community Care of North Carolina.
- (3) Furnish patient records to the patient upon the patient's request.
- (4) Furnish patient records to the primary care provider identified by the patient upon the primary care provider's request.
- (5) If the immunizing pharmacist has administered or dispensed a hormonal contraceptive to the patient, the immunizing pharmacist shall counsel the patient about preventative care, including well-woman visits, sexually transmitted infection testing information, and Pap smear testing.

(e) An immunizing pharmacist that dispenses, delivers, or administers the medications listed in subsection (c2) of this section shall do all of the following:

- (1) Comply with rules adopted by the North Carolina Medical Board and the North Carolina Board of Pharmacy governing the approval of the individual immunizing pharmacist to dispense, deliver, or administer the medications with limitations that the Boards determine to be in the best interest of patient health and safety.
- (2) Have current approval from both Boards.
- (3) Provide the name, business address, business phone, and business fax number of the pharmacy on any communication with a prescriber.
- (4) Provide the name of the immunizing pharmacist who dispenses, delivers, or administers the medication on any communication with the provider.

(f) Prior to administering a vaccine or immunization pursuant to subsection (a1) or (b1) of this section, a pharmacy technician or pharmacy intern shall meet the following requirements:

- (1) Complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.
- (2) The pharmacy technician or pharmacy intern shall have a current certificate in basic cardiopulmonary resuscitation.
- (3) The pharmacy technician shall annually complete a minimum of two hours of ACPE approved, immunization-related continuing pharmacy education.

(g) Prior to the administration of a vaccine or immunization administered to a person under 18 years of age pursuant to this section, an immunizing pharmacist shall obtain written parental consent from the parent or legal guardian of the patient. An immunizing pharmacist, a pharmacy technician, or pharmacy intern shall, if the person is under 18 years of age, inform the patient or legal guardian accompanying the person of the importance of a well-child visit with a pediatrician, family physician, or other licensed primary-care provider. (2013-246, s. 4; 2014-115, s. 40; 2019-21, s. 1; 2021-3, s. 2.9(a); 2021-110, ss. 1-3, 8; 2023-15, s. 3(a); 2023-65, s. 9.3(a).)

§ 90-85.16. Examination.

The license examination shall be given by the Board at least twice each year. The Board shall determine the subject matter of each examination and the place, time and date for administering the examination. The Board shall also determine which persons have passed the examination. The examination shall be designed to determine which applicants can reasonably be expected to safely and properly practice pharmacy. (1905, c. 108, s. 13; Rev., ss. 4479, 4480; 1915, c. 165; C.S., s. 6658; 1921, c. 52; 1933, c. 206, ss. 1, 2; 1935, c. 181; 1937, c. 94; 1971, c. 481; 1981, c. 717, s. 4; 1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.17. License renewal.

In accordance with Board regulations, each license to practice pharmacy shall expire on December 31 and shall be renewed annually by filing with the Board on or after December 1 an application for license renewal furnished by the Board, accompanied by the required fee. It shall be unlawful to practice pharmacy more than 60 days after the expiration date without renewing the license. All licensees shall give the Board notice of a change of mailing address or a change of place of employment within 30 days after the change. The Board may require licensees to obtain up

to 30 hours of continuing education every two years from Board-approved providers as a condition of license renewal, with a minimum of 10 hours required per year. (1905, c. 108, ss. 18, 19, 27; Rev., ss. 3653, 4484; 1911, c. 48; C.S., s. 6662; 1921, c. 68, s. 2; 1947, c. 781; 1953, c. 1051; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 2005-402, s. 4.)

§ 90-85.18. Approval of continuing education programs.

The Board shall approve providers of continuing education programs upon finding that the provider is competent to and does offer an educational experience designed to enable those who successfully complete the program to more safely and properly practice pharmacy. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.19. Reinstatement.

Whenever a pharmacist who has not renewed his license for five or more years seeks to renew or reinstate his license, he must appear before the Board and submit evidence that he can safely and properly practice pharmacy. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.20. Licensure without examination.

(a) The Board may issue a license to practice pharmacy, without examination, to any person who is licensed as a pharmacist in another jurisdiction if the applicant shall present satisfactory evidence of possessing the same qualifications as are required of licensees in this State, that he was licensed by examination in such other jurisdiction, and that the standard of competence required by such other jurisdiction is substantially equivalent to that of this State at that time. The Board must be satisfied that a candidate for licensure has a satisfactory understanding of the laws governing the practice of pharmacy and distribution of drugs in this State.

(b) Repealed by Session Laws 1991, c. 125, s. 2. (1905, c. 108, s. 16; Rev., s. 4482; C.S., s. 6660; 1945, c. 572, s. 2; 1971, c. 468; 1977, c. 598; 1981, c. 717, ss. 6, 7; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1983, c. 196, ss. 6, 7; 1991, c. 125, s. 2.)

§ 90-85.21. Pharmacy permit.

(a) In accordance with Board regulations, each pharmacy in North Carolina shall annually register with the Board on a form provided by the Board. The application shall identify the pharmacist-manager of the pharmacy and all pharmacy personnel employed in the pharmacy. All pharmacist-managers shall notify the Board of any change in pharmacy personnel within 30 days of the change. In addition to identifying the pharmacist-manager, a pharmacy may identify a pharmacy permittee's designated agent that the Board shall notify of any investigation of the pharmacy or a pharmacist employed by the pharmacy. The notice shall include the specific reason for the investigation and be given prior to the initiation of any disciplinary proceedings.

(a1) A mobile pharmacy shall register annually with the Board in the manner prescribed in subsection (a) of this section, and the registration shall be renewed annually. A mobile pharmacy shall be considered a single pharmacy and shall not be required to pay a separate registration fee for each location but shall pay the annual registration fee prescribed in G.S. 90-85.24. A mobile pharmacy shall provide the Board with the address of every location from which prescription drugs will be dispensed by the mobile pharmacy.

(b) Each physician who dispenses prescription drugs, for a fee or other charge, shall annually register with the Board on the form provided by the Board, and with the licensing board having jurisdiction over the physician. Such dispensing shall comply in all respects with the

relevant laws and regulations that apply to pharmacists governing the distribution of drugs, including packaging, labeling, and record keeping. Authority and responsibility for disciplining physicians who fail to comply with the provisions of this subsection are vested in the licensing board having jurisdiction over the physician. The form provided by the Board under this subsection shall be as follows:

Application For Registration
With The Pharmacy Board
As A Dispensing Physician

1. Name and Address of Dispensing Physician

2. Affix Dispensing Label Here

3. Physician's North Carolina License Number _____

4. Are you currently practicing in a professional association registered with the North Carolina Medical Board?

_____ Yes _____ No. If yes, enter the name and registration number of the professional corporation:

5. I certify that the information is correct and complete.

Signature

Date

(1927, c. 28, s. 1; 1953, c. 183, s. 2; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1987, c. 687; 1995, c. 94, s. 25; 1999-246, s. 2; 2001-375, s. 3; 2005-427, s. 1.)

§ 90-85.21A. Applicability to out-of-state operations.

(a) Any pharmacy operating outside the State which ships, mails, or delivers in any manner a dispensed legend drug into this State shall annually register with the Board on a form provided by the Board. In order to satisfy the registration requirements of this subsection, a pharmacy shall certify that the pharmacy employs a pharmacist who is responsible for dispensing, shipping, mailing, or delivering dispensed legend drugs into this State or in a state approved by the Board and has met requirements for licensure equivalent to the requirements for licensure in this State. In order for the pharmacy's certification of the pharmacists to be valid, a pharmacist shall agree in writing, on a form approved by the Board, to be subject to the jurisdiction of the Board, the provisions of this Article, and the rules adopted by the Board. If the Board revokes this certification, the pharmacy shall no longer have authority to dispense, ship, mail, or deliver in any manner a dispensed legend drug into this State.

(b) Any pharmacy subject to this section shall at all times maintain a valid unexpired license, permit, or registration necessary to conduct such pharmacy in compliance with the laws of the state in which such pharmacy is located. No pharmacy operating outside the State may ship, mail, or deliver in any manner a dispensed legend drug into this State unless such drug is lawfully dispensed by a licensed pharmacist in the state where the pharmacy is located.

(c) The Board shall be entitled to charge and collect not more than five hundred dollars (\$500.00) for original registration of a pharmacy under this section, and for renewal thereof, not more than two hundred dollars (\$200.00), and for reinstatement thereof, not more than two hundred dollars (\$200.00).

(d) The Board may deny a nonresident pharmacy registration upon a determination that the pharmacy has a record of being formally disciplined in its home state for violations that relate to the compounding or dispensing of legend drugs and presents a threat to the public health and safety.

(e) Except as otherwise provided in this subsection, the Board may adopt rules to protect the public health and safety that are necessary to implement this section. Notwithstanding G.S. 90-85.6, the Board shall not adopt rules pertaining to the shipment, mailing, or other manner of delivery of dispensed legend drugs by pharmacies required to register under this section that are more restrictive than federal statutes or regulations governing the delivery of prescription medications by mail or common carrier. A pharmacy required to register under this section shall comply with rules adopted pursuant to this section.

(f) The Board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of this section. (1993, c. 455, s. 1; 1998-212, s. 12.3B(b); 2004-199, s. 25; 2005-402, s. 3.)

§ 90-85.21B. Unlawful practice of pharmacy.

It shall be unlawful for any person, firm, or corporation not licensed or registered under the provisions of this Article to:

- (1) Use in a trade name, sign, letter, or advertisement any term, including "drug", "pharmacy", "prescription drugs", "prescription", "Rx", or "apothecary", that would imply that the person, firm, or corporation is licensed or registered to practice pharmacy in this State.
- (2) Hold himself or herself out to others as a person, firm, or corporation licensed or registered to practice pharmacy in this State. (2003-284, s. 10.8D.)

§ 90-85.21C. Pharmacy permit exemption for dispensing and delivery of home renal products.

Each location or facility within or outside this State from which dialysate or drugs necessary to perform home renal dialysis are dispensed and delivered to a patient in this State is exempt from the pharmacy permit requirements established by G.S. 90-85.21 and G.S. 90-8.21A, provided that all the following criteria are met:

- (1) The dialysate or drugs have been approved or cleared by United States Food and Drug Administration.
- (2) The dialysate or drugs are lawfully held by a manufacturer or an agent of the manufacturer that is properly licensed by the North Carolina Department of Agriculture and Consumer Services as a manufacturer, or as a wholesaler, or as both, as required by G.S. 106-145.3.
- (3) The dialysate or drugs are held, delivered, and dispensed in their original, sealed packaging from the manufacturing facility.
- (4) The dialysate or drugs are delivered only by the manufacturer, or an agent of the manufacturer, and only upon receipt of a physician's order.
- (5) The manufacturer or an agent of the manufacturer delivers the dialysate or drugs directly to either of the following:

- a. A patient with chronic kidney failure or a designee of the patient, for self-administration of the dialysis therapy.
- b. A health care provider, or health care facility licensed under Chapter 122C, 131D, or 131E of the General Statutes, for administration or delivery of the dialysis therapy to a patient with chronic kidney failure. (2015-28, s. 1.)

§ 90-85.21D. Dialysis facilities as designated agents to receive home medications for patients with renal failure.

Pharmacies may ship medications for home use by patients with renal failure to renal dialysis facilities for delivery to (i) patients who receive dialysis treatments in a Medicare certified dialysis facility or (ii) patients who self-dialyze at home, provided that all of the following criteria are met:

- (1) The patient authorizes, in writing, the dialysis facility staff to act as the patient's designated agent for the purpose of receiving mailed medical packages at the dialysis facility.
- (2) The pharmacy, whether in-state or out-of-state, is licensed as a pharmacy in North Carolina.
- (3) The medications for home use are dispensed by the licensed pharmacist pursuant to a valid prescription order.
- (4) The delivered medication packages are held in a secure location in an area not accessible to the public and delivered by the dialysis facility staff, unopened, to the patient.
- (5) Medication packages are individually labeled with the patient name.
- (6) The medications exclude controlled substances, as defined under G.S. 90-87. (2015-28, s. 1.)

§ 90-85.22. Device and medical equipment permits; exemptions.

(a) Devices. – Each place, whether located in this State or out-of-state, where devices are dispensed or delivered to the user in this State shall register annually with the Board on a form provided by the Board and obtain a device permit. A business that has a current pharmacy permit does not have to register and obtain a device permit. Records of devices dispensed in pharmacies or other places shall be kept in accordance with rules adopted by the Board.

(b) Medical Equipment. – Each place, whether located in this State or out-of-state, that delivers medical equipment to the user of the equipment in this State shall register annually with the Board on a form provided by the Board and obtain a medical equipment permit. A business that has a current pharmacy permit or a current device permit does not have to register and obtain a medical equipment permit. Medical equipment shall be delivered only in accordance with requirements established by rules adopted by the Board.

(c) This section shall not apply to any of the following:

- (1) A pharmaceutical manufacturer registered with the Food and Drug Administration.
- (2) A wholly owned subsidiary of a pharmaceutical manufacturer registered with the Food and Drug Administration.
- (3) The dispensing and delivery of home renal products in accordance with the criteria specified in G.S. 90-85.21C. (1981 (Reg. Sess., 1982), c. 1188, s. 1; 1993 (Reg. Sess., 1994), c. 692, s. 1; 2001-339, s. 1; 2015-28, s. 2.)

§ 90-85.23. License and permit to be displayed.

Every pharmacist-manager's license, every permit, and every current renewal shall be conspicuously posted in the place of business owned by or employing the person to whom it is issued. The licenses and every last renewal of all other pharmacists employed in the pharmacy must be readily available for inspection by agents of the Board. Failure to display any license or permit and the most recent renewal shall be a violation of this Article and each day that the license or permit or renewal is not displayed shall be a separate and distinct offense. (1905, c. 108, ss. 18, 26; Rev., ss. 3651, 4485; C.S., s. 6663; 1921, c. 68, s. 3; 1953, c. 1051; 1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.24. Fees collectible by Board.

(a) The Board of Pharmacy shall be entitled to charge and collect not more than the following fees:

- (1) For the examination of an applicant for license as a pharmacist, two hundred dollars (\$200.00), plus the cost of the test material;
- (2) For renewing the license as a pharmacist, one hundred thirty-five dollars (\$135.00);
- (3) For reinstatement of a license as a pharmacist, one hundred thirty-five dollars (\$135.00);
- (4) For annual registration of a pharmacy technician, thirty dollars (\$30.00);
- (5) For reinstatement of a registration of a pharmacy technician, thirty dollars (\$30.00);
- (6) For licenses without examination as provided in G.S. 90-85.20, original, six hundred dollars (\$600.00);
- (7) For original registration of a pharmacy, five hundred dollars (\$500.00), and renewal thereof, two hundred dollars (\$200.00);
- (8) For reinstatement of the registration of a pharmacy, two hundred dollars (\$200.00);
- (9) For annual registration as a dispensing physician under G.S. 90-85.21(b), seventy-five dollars (\$75.00);
- (10) For reinstatement of registration as a dispensing physician, seventy-five dollars (\$75.00);
- (11) For annual registration as a dispensing physician assistant under G.S. 90-18.1, seventy-five dollars (\$75.00);
- (12) For reinstatement of registration as a dispensing physician assistant, seventy-five dollars (\$75.00);
- (13) For annual registration as a dispensing nurse practitioner under G.S. 90-18.2, seventy-five dollars (\$75.00);
- (14) For reinstatement of registration as a dispensing nurse practitioner, seventy-five dollars (\$75.00);
- (15) For registration of any change in pharmacist personnel as required under G.S. 90-85.21(a), thirty-five dollars (\$35.00);
- (16) For a duplicate of any license, permit, or registration issued by the Board, twenty-five dollars (\$25.00);

- (17) For original registration to dispense devices, deliver medical equipment, or both, five hundred dollars (\$500.00);
- (18) For renewal of registration to dispense devices, deliver medical equipment, or both, two hundred dollars (\$200.00);
- (19) For reinstatement of a registration to dispense devices, deliver medical equipment, or both, two hundred dollars (\$200.00);
- (20) For annual registration as a dispensing optometrist under G.S. 90-127.4, seventy-five dollars (\$75.00);
- (21) For reinstatement of registration as a dispensing optometrist under G.S. 90-127.4, seventy-five dollars (\$75.00).

(b) All fees under this section shall be paid before any applicant may be admitted to examination or the applicant's name may be placed upon the register of pharmacists or before any license or permit, or any renewal or reinstatement thereof, may be issued by the Board. (1905, c. 108, s. 12; Rev., s. 4478; C.S., s. 6657; 1921, c. 57, s. 3; 1945, c. 572, s. 3; 1953, c. 183, s. 1; 1965, c. 676, s. 1; 1973, c. 1183; 1981, c. 72; c. 717, s. 3; 1981 (Reg. Sess., 1982), c. 1188, s. 2; 1983, c. 196, s. 8; 1987, c. 260; 1987 (Reg. Sess., 1988), c. 1039, s. 4; 1993 (Reg. Sess., 1994), c. 692, s. 3; 1997-231, s. 1; 2001-375, s. 4; 2005-402, s. 2; 2023-129, s. 5.3(b).)

§ 90-85.25. Disasters and emergencies.

(a) In the event of an occurrence which the Governor of the State of North Carolina has declared a state of emergency, or in the event of an occurrence for which a county or municipality has enacted an ordinance to deal with states of emergency under G.S. 166A-19.31, or to protect the public health, safety, or welfare of its citizens under G.S. 160A-174(a) or G.S. 153A-121(a), as applicable, the Board may waive the requirements of this Article in order to permit the provision of drugs, devices, and professional services to the public.

(b) The pharmacist in charge of a pharmacy shall report within 10 days to the Board any disaster, accident, theft, or emergency which may affect the strength, purity, or labeling of drugs and devices in the pharmacy. (1981 Reg. Sess., 1982), c. 1188, s. 1; 1998-212, s. 12.3B(a); 2012-12, s. 2(gg).)

§ 90-85.26. Prescription orders preserved.

(a) Every pharmacist-manager of a pharmacy shall maintain for at least three years the original of every prescription order and refill compounded or dispensed at the pharmacy except for prescription orders recorded in a patient's medical record. An automated data processing system may be used for the storage and retrieval of refill information for prescriptions pursuant to the regulations of the Board. A pharmacist-manager may comply with this section by capturing and maintaining an electronic image of a prescription order or refill. An electronic image of a prescription order or refill shall constitute the original prescription order, and a hard copy of the prescription order or refill is not required to be maintained. If a pharmacist-manager elects to maintain prescription orders by capturing electronic images of prescription orders or refills, the pharmacy's computer system must be capable of maintaining, printing, and providing in an electronic or paper format, upon a request by the Board, all of the information required by this Chapter or rules adopted pursuant to this Chapter within 48 hours of such a request.

(b) Every pharmacy permittee's designated agent shall maintain documentation of alleged medication errors and incidents described in G.S. 90-85.47(e)(1) for which the pharmacy permittee

has knowledge. (1905, c. 108, s. 21; Rev., s. 4490; C.S., s. 6666; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 2005-427, s. 2; 2007-248, s. 1.)

§ 90-85.26A. Clinical pharmacist practitioners subcommittee.

The North Carolina Board of Pharmacy shall appoint and maintain a subcommittee of the Board consisting of four licensed pharmacists to work jointly with the subcommittee of the North Carolina Medical Board to develop rules to govern the provision of drug therapy management by clinical pharmacist practitioners and to determine reasonable fees to accompany an application for approval or renewal of such approval as provided in G.S. 90-6. The rules developed by this subcommittee shall govern the performance of acts by clinical pharmacist practitioners and shall become effective when they have been adopted by both Boards. (1999-290, s. 6.)

§ 90-85.26B. Registration of dispensing optometrists.

Each dispensing optometrist who dispenses prescription drugs, for a fee or other charge, shall annually register with the Board on the form provided by the Board and with the licensing board having jurisdiction over the dispensing optometrist. Such dispensing shall comply in all respects with the relevant laws and regulations that apply to pharmacists governing the distribution of drugs, including packaging, labeling, and record keeping. Authority and responsibility for disciplining dispensing optometrists who fail to comply with the provisions of this section are vested in the Board and the licensing board having jurisdiction over the dispensing optometrist. The Board may discipline a dispensing optometrist's registration. The licensing board having jurisdiction over the dispensing optometrist may discipline the optometrist's license to practice optometry. (2023-129, s. 5.3(a).)

§ 90-85.27. Definitions.

As used in G.S. 90-85.28 through G.S. 90-85.31:

- (1) Biological product. – As defined in section 351(i) of the Public Health Service Act, 42 U.S.C. § 262(i).
- (1a) Equivalent drug product. – A drug product which has the same established name, active ingredient, strength, quantity, and dosage form, and which is therapeutically equivalent to the drug product identified in the prescription.
- (2) Established name. – As defined in section 502(e)(3) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352(e)(3).
- (3) Good manufacturing practice. – As defined in Part 211 of Chapter 1 of Title 21 of the Code of Federal Regulations.
- (3a) Interchangeable biological product. – A biological product determined by the United States Food and Drug Administration to meet the standards for interchangeability set forth in 42 U.S.C. § 262(k)(4).
- (4) Manufacturer. – The actual manufacturer of the finished dosage form of the drug.
- (4a) Narrow therapeutic index drugs. – Those pharmaceuticals having a narrowly defined range between risk and benefit. Such drugs have less than a twofold difference in the minimum toxic concentration and minimum effective concentration in the blood or are those drug product formulations that exhibit limited or erratic absorption, formulation-dependent bioavailability, and wide inpatient pharmacokinetic variability that requires blood-level monitoring.

Drugs identified as having narrow therapeutic indices shall be designated by the North Carolina Secretary of Health and Human Services upon the advice of the State Health Director, North Carolina Board of Pharmacy, and North Carolina Medical Board, as narrow therapeutic index drugs and shall be subject to the provisions of G.S. 90-85.28(b1). The North Carolina Board of Pharmacy shall submit the list of narrow therapeutic index drugs to the Codifier of Rules, in a timely fashion for publication in January of each year in the North Carolina Register.

- (5) Prescriber. – Anyone authorized to prescribe drugs pursuant to the laws of this State. (1979, c. 1017, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 3; 1983, c. 196, s. 9; 1997-76, s. 1; 1997-443, s. 11A.118(b); 2015-27, s. 1; 2022-74, s. 9K.4(a).)

§ 90-85.28. Selection by pharmacists permissible; prescriber may permit or prohibit selection; price limit on selected drugs; communication of dispensed biological products under specified circumstances.

(a) A pharmacist dispensing a prescription for a drug product prescribed by its brand name may select any equivalent drug or interchangeable biological product which meets all of the following standards:

- (1) The manufacturer's name and the distributor's name, if different from the manufacturer's name, shall appear on the label of the stock package.
- (2) It shall be manufactured in accordance with current good manufacturing practices.
- (3) All oral solid dosage forms shall have a logo, or other identification mark, or the product name to identify the manufacturer or distributor.
- (4) The manufacturer shall have adequate provisions for drug recall.
- (5) The manufacturer shall have adequate provisions for return of outdated drugs, through the distributor or otherwise.

(b) The pharmacist shall not select an equivalent drug or interchangeable biological product if the prescriber instructs otherwise by one of the following methods:

- (1) A prescription form shall be preprinted or stamped with two signature lines at the bottom of the form which read:

"

Product Selection Permitted	Dispense as Written"
On this form, the prescriber shall communicate instructions to the pharmacist by signing the appropriate line.	
(2) In the event the preprinted or stamped prescription form specified in subdivision (1) of subsection (b) of this section is not readily available, the prescriber may handwrite "Dispense as Written" or words or abbreviations of the same meaning on a prescription form.	
(3) When ordering a prescription orally, the prescriber shall specify either that the prescribed drug product be dispensed as written or that product selection is permitted. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period prescribed by law.	

(b1) A prescription for a narrow therapeutic index drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's

product, and the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product. For purposes of this subsection, the term "refilled" shall include a new prescription written at the expiration of a prescription which continues the patient's therapy on a narrow therapeutic index drug.

(b2) Within five business days following the dispensing of a biological product requiring a prescription, the pharmacist or a designee shall communicate to the prescriber the product name and manufacturer of the specific biological product dispensed to the patient. This required communication shall be conveyed by making an entry into any of the following that is electronically accessible to the prescriber:

- (1) An interoperable electronic medical records system.
- (2) Electronic prescribing technology.
- (3) A pharmacy benefit management system.
- (4) The North Carolina Health Information Exchange Network.
- (5) A pharmacy record.

Entry into one of the electronic records systems listed in this subsection by the pharmacist or a designee is presumed to provide the required communication and notice to the prescriber. Otherwise, the pharmacist or a designee shall provide the required communication to the prescriber by facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required under any of the following circumstances:

- (1) There is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed.
- (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(b3) The Board of Pharmacy shall maintain a link on its Internet Web site to the current list of biological products determined by the United States Food and Drug Administration to be interchangeable with a specific biological product.

(b4) Expired.

(c) The pharmacist shall not select an equivalent drug or interchangeable biological product unless its price to the purchaser is less than the price of the prescribed drug product. (1979, c. 1017, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 3; 1997-76, s. 2; 2015-27, s. 2; 2022-74, s. 9K.4(b).)

§ 90-85.29. Prescription label.

The prescription label of every drug product dispensed shall contain the brand name of any drug product dispensed, or in the absence of a brand name, the established name. The prescription drug label of every drug product dispensed shall:

- (1) Contain the discard date when dispensed in a container other than the manufacturer's original container. The discard date shall be the earlier of one year from the date dispensed or the manufacturer's expiration date, whichever is earlier, and
- (2) Not obscure the expiration date and storage statement when the product is dispensed in the manufacturer's original container.

As used in this section, "expiration date" means the expiration date printed on the original manufacturer's container, and "discard date" means the date after which the drug product dispensed in a container other than the original manufacturer's container shall not be used. Nothing in this section shall impose liability on the dispensing pharmacist or the prescriber for damages related to

or caused by a drug product that loses its effectiveness prior to the expiration or disposal date displayed by the pharmacist or prescriber. (1979, c. 1017, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 3; 1993, c. 529, s. 7.5.)

§ 90-85.30. Prescription record.

The pharmacy file copy of every prescription shall include the brand or trade name, if any, or the established name and the manufacturer of the drug product dispensed. (1979, c. 1017, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 3.)

§ 90-85.31. Prescriber and pharmacist liability not extended.

The selection of an equivalent drug or interchangeable biological product pursuant to this Article shall impose no greater liability upon the pharmacist for selecting the dispensed drug or biological product or upon the prescriber of the same than would be incurred by either for dispensing the drug or biological product specified in the prescription. (1979, c. 1017, s. 1; 1981 (Reg. Sess., 1982), c. 1188, s. 3; 2015-27, s. 3.)

§ 90-85.32. Rules pertaining to filling, refilling, transfer, and mail or common-carrier delivery of prescription orders.

(a) Except as otherwise provided in this section, the Board may adopt rules governing the filling, refilling and transfer of prescription orders not inconsistent with other provisions of law regarding the distribution of drugs and devices. The rules shall assure the safe and secure distribution of drugs and devices. Prescriptions marked PRN shall not be refilled more than one year after the date issued by the prescriber unless otherwise specified.

(b) Notwithstanding G.S. 90-85.6, the Board shall not adopt rules pertaining to the shipment, mailing, or other manner of delivery of dispensed legend drugs that are more restrictive than federal statutes or regulations governing the delivery of prescription medications by mail or common carrier. (1981 (Reg. Sess., 1982), c. 1188, s. 1; 1998-212, s. 12.3B(c).)

§ 90-85.33. Unit dose medication systems.

The Board may adopt regulations governing pharmacists providing unit dose medication systems. The regulations shall ensure the safe and proper distribution of drugs in the patient's best health interests. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.34. Unique pharmacy practice.

Consistent with the provisions of this Article, the Board may regulate unique pharmacy practices including, but not limited to, nuclear pharmacy and clinical pharmacy, to ensure the best interests of patient health and safety. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.34A. Public health pharmacy practice.

(a) A registered nurse in a local health department clinic may dispense prescription drugs and devices, other than controlled substances as defined in G.S. 90-87, under the following conditions:

- (1) The registered nurse has training acceptable to the Board in the labeling and packaging of prescription drugs and devices;
- (2) Dispensing by the registered nurse shall occur only at a local health department clinic;

- (3) Only prescription drugs and devices contained in a formulary recommended by the Department of Health and Human Services and approved by the Board shall be dispensed;
- (4) The local health department clinic shall obtain a pharmacy permit in accordance with G.S. 90-85.21;
- (5) Written procedures for the storage, packaging, labeling and delivery of prescription drugs and devices shall be approved by the Board; and
- (6) The pharmacist-manager, or another pharmacist at his direction, shall review dispensing records at least weekly, provide consultation where appropriate, and be responsible to the Board for all dispensing activity at the local health department clinic.

(b) This section is applicable only to prescriptions issued on behalf of persons receiving local health department clinic services and issued by an individual authorized by law to prescribe drugs and devices.

(c) This section does not affect the practice of nurse practitioners pursuant to G.S. 90-18.2 or of physician assistants pursuant to G.S. 90-18.1. (1985, c. 359; 1989 (Reg. Sess., 1990), c. 1004, s. 2; 1997-443, s. 11A.22.)

§ 90-85.35. Availability of patient records.

Pharmacists employed in health care facilities shall have access to patient records maintained by those facilities when necessary for the pharmacist to provide pharmaceutical services. The pharmacist shall make appropriate entries in patient records. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.36. Availability of pharmacy records.

(a) Except as provided in subsections (b) and (c) below, written or electronic prescription orders on file in a pharmacy or other place where prescriptions are dispensed are not public records and any person having custody of or access to the prescription orders may divulge the contents or provide a copy only to the following persons:

- (1) An adult patient for whom the prescription was issued or a person who is legally appointed guardian of that person;
- (2) An emancipated minor patient for whom the prescription order was issued or a person who is the legally appointed guardian of that patient;
- (3) An unemancipated minor patient for whom the prescription order was issued when the minor's consent is sufficient to authorize treatment of the condition for which the prescription was issued;
- (4) A parent or person in loco parentis of an unemancipated minor patient for whom the prescription order was issued when the minor's consent is not sufficient to authorize treatment for the condition for which the prescription is issued;
- (5) The licensed practitioner who issued the prescription;
- (6) The licensed practitioner who is treating the patient for whom the prescription was issued;
- (7) A pharmacist who is providing pharmacy services to the patient for whom the prescription was issued;
- (8) Anyone who presents a written authorization for the release of pharmacy information signed by the patient or his legal representative;

- (9) Any person authorized by subpoena, court order or statute;
- (10) Any firm, association, partnership, business trust, corporation or company charged by law or by contract with the responsibility of providing for or paying for medical care for the patient for whom the prescription order was issued;
- (11) A member or designated employee of the Board;
- (12) The executor, administrator or spouse of a deceased patient for whom the prescription order was issued;
- (13) Researchers and surveyors who have approval from the Board. The Board shall issue this approval when it determines that there are adequate safeguards to protect the confidentiality of the information contained in the prescription orders and that the researchers or surveyors will not publicly disclose any information that identifies any person;
- (14) The person owning the pharmacy or his authorized agent; or
- (15) A HIPAA covered entity, or business associate described in 45 C.F.R. § 160.103, or a health care provider who is not a covered entity, for purposes of treatment, payment, or health care operations to the extent that disclosure is permitted or required by applicable State or federal law.

(b) A pharmacist may disclose any information to any person only when he reasonably determines that the disclosure is necessary to protect the life or health of any person.

(c) Records required to be kept by G.S. 90-93(d) (Schedule V) are not public records and shall be disclosed at the pharmacist's discretion. (1905, c. 108, s. 21; Rev., s. 4490; C.S., s. 6666; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1991, c. 125, s. 3; 2011-314, s. 1.)

§ 90-85.37. Embargo.

Notwithstanding any other provisions of law, whenever an authorized representative of the Board has reasonable cause to believe that any drug or device presents a danger to the public health, he shall affix to the drug or device a notice that the article is suspected of being dangerous to the public health and warning all persons not to remove or dispose of the article. Whenever an authorized representative of the Board has reasonable cause to believe that any drug or device presents a danger to the public health and that there are reasonable grounds to believe that it might be disposed of pending a judicial resolution of the matter, he shall seize the article and take it to a safe and secure place. When an article has been embargoed under this section, the Board shall, as soon as practical, file a petition in Orange County District Court for a condemnation order for such article. If the judge determines after hearing, that the article is not dangerous to the public health, the Board shall direct the immediate removal of the tag or other marking, and where appropriate, shall direct that the article be returned to its owner. If the judge finds the article is dangerous to the public health, he shall order its destruction at the owner's expense and under the Board's supervision. If the judge determines that the article is dangerous to the public health, he shall order the owner of the article to pay all court costs, reasonable attorney's fees, storage fees, and all other costs incident to the proceeding. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.38. Disciplinary authority.

(a) The Board may, in accordance with Chapter 150B of the General Statutes, issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew a license to practice pharmacy, or require licensees to successfully complete remedial education if the licensee has done any of the following:

- (1) Made false representations or withheld material information in connection with securing a license or permit.
- (2) Been found guilty of or plead guilty or nolo contendere to any felony in connection with the practice of pharmacy or the distribution of drugs.
- (3) Indulged in the use of drugs to an extent that renders the pharmacist unfit to practice pharmacy.
- (4) Made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person.
- (5) Developed a physical or mental disability that renders the pharmacist unfit to practice pharmacy with reasonable skill, competence and safety to the public.
- (6) Failed to comply with the laws governing the practice of pharmacy and the distribution of drugs.
- (7) Failed to comply with any provision of this Article or rules adopted by the Board.
- (8) Engaged in, or aided and abetted an individual to engage in, the practice of pharmacy without a license.
- (9) Been negligent in the practice of pharmacy.
- (10) Engaged in unprofessional conduct, including the departure from or failure to comply with the requirements of G.S. 90-85.15B(c1) and (d1), when dispensing, delivering, or administering medication for patients.

(b) The Board, in accordance with Chapter 150B of the General Statutes, may suspend, revoke, or refuse to grant or renew any permit for the same conduct as stated in subsection (a). The administration of required lethal substances or any assistance whatsoever rendered with an execution under Article 19 of Chapter 15 of the General Statutes does not constitute the practice of pharmacy under this Article, and any assistance rendered with an execution under Article 19 of Chapter 15 of the General Statutes shall not be the cause for disciplinary action under this Article.

(c) Any license or permit obtained through false representation or withholding of material information shall be void and of no effect. (1905, c. 108, ss. 17, 25; Rev., s. 4483; C.S., s. 6661; 1967, c. 807; 1973, c. 138; 1981, c. 412, s. 4; c. 717, s. 8; c. 747, s. 66; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1987, c. 827, s. 1; 2001-375, s. 5; 2013-154, s. 1(c); 2021-110, s. 7.)

§ 90-85.39. Injunctive authority.

The Board may apply to any court for an injunction to prevent violations of this Article or of any rules enacted pursuant to it. The court is empowered to grant the injunctions regardless of whether criminal prosecution or other action has been or may be instituted as a result of the violation. (1981 (Reg. Sess., 1982), c. 1188, s. 1.)

§ 90-85.40. Violations.

(a) It shall be unlawful for any owner or manager of a pharmacy or other place to allow or cause anyone other than a pharmacist to dispense or compound any prescription drug unless that person is a pharmacy technician or a pharmacy student who is enrolled in a school of pharmacy approved by the Board and is working under the supervision of a pharmacist.

(b) Every person lawfully authorized to compound or dispense prescription drugs shall comply with all the laws and regulations governing the labeling and packaging of such drugs by pharmacists.

(c) It shall be unlawful for any person not licensed as a pharmacist to compound or dispense any prescription drug, unless that person is a pharmacy technician or a pharmacy student who is enrolled in a school of pharmacy approved by the Board and is working under the supervision of a pharmacist.

(d) It shall be unlawful for any person to manage any place of business where devices are dispensed or sold at retail without a permit as required by this Article.

(d1) It is unlawful for a person to own or manage a place of business from which medical equipment is delivered without a permit as required by this Article.

(e) It shall be unlawful for any person without legal authorization to dispose of an article that has been embargoed under this Article.

(f) It shall be unlawful to violate any provision of this Article or of any rules or regulations enacted pursuant to it.

(g) This Article shall not be construed to prohibit any person from performing an act that person is authorized to perform pursuant to North Carolina law. Health care providers who are authorized to prescribe drugs without supervision are authorized to dispense drugs without supervision.

(h) A violation of this Article shall be a Class 1 misdemeanor. (1905, c. 108, ss. 4, 23, 24; Rev., ss. 3649, 3650, 4487; C.S., ss. 6667, 6668, 6669; 1921, c. 68, ss. 6, 7; Ex. Sess. 1924, c. 116; 1953, c. 1051; 1957, c. 617; 1959, c. 1222; 1981 (Reg. Sess., 1982), c. 1188, s. 1; 1993, c. 539, s. 621; 1994, Ex. Sess., c. 24, s. 14(c); 1993 (Reg. Sess., 1994), c. 692, s. 4; 2001-375, ss. 6, 7.)

§ 90-85.41. Board agreements with special peer review organizations for impaired pharmacy personnel.

(a) The North Carolina Board of Pharmacy may, under rules adopted by the Board in compliance with Chapter 150B of the General Statutes, enter into agreements with special impaired pharmacy personnel peer review organizations. Peer review activities to be covered by such agreements shall include investigation, review and evaluation of records, reports, complaints, litigation, and other information about the practices and practice patterns of pharmacy personnel licensed or registered by the Board, as such matters may relate to impaired pharmacy personnel. Special impaired pharmacy personnel peer review organizations may include a statewide supervisory committee and various regional and local components or subgroups.

(b) Agreements authorized under this section shall include provisions for the impaired pharmacy personnel peer review organizations to receive relevant information from the Board and other sources, conduct any investigation, review, and evaluation in an expeditious manner, provide assurance of confidentiality of nonpublic information and of the peer review process, make reports of investigations and evaluations to the Board, and to do other related activities for operating and promoting a coordinated and effective peer review process. The agreements shall include provisions assuring basic due process for pharmacy personnel that become involved.

(c) The impaired pharmacy personnel peer review organizations that enter into agreements with the Board shall establish and maintain a program for impaired pharmacy personnel licensed or registered by the Board for the purpose of identifying, reviewing, and evaluating the ability of those pharmacists to function as pharmacists, and pharmacy technicians to function as pharmacy technicians, and to provide programs for treatment and rehabilitation. The Board may provide funds for the administration of these impaired pharmacy personnel peer review programs. The Board shall adopt rules to apply to the operation of impaired pharmacy personnel peer review programs, with provisions for: (i) definitions of impairment; (ii) guidelines for program elements;

(iii) procedures for receipt and use of information of suspected impairment; (iv) procedures for intervention and referral; (v) arrangements for monitoring treatment, rehabilitation, posttreatment support, and performance; (vi) reports of individual cases to the Board; (vii) periodic reporting of statistical information; and (viii) assurance of confidentiality of nonpublic information and of the peer review process.

(d) Upon investigation and review of a pharmacist licensed by the Board, or a pharmacy technician registered with the Board, or upon receipt of a complaint or other information, an impaired pharmacy personnel peer review organization that enters into a peer review agreement with the Board shall report immediately to the Board detailed information about any pharmacist licensed or pharmacy technician registered by the Board, if:

- (1) The pharmacist or pharmacy technician constitutes an imminent danger to the public or himself or herself.
- (2) The pharmacist or pharmacy technician refuses to cooperate with the program, refuses to submit to treatment, or is still impaired after treatment and exhibits professional incompetence.
- (3) It reasonably appears that there are other grounds for disciplinary action.

(e) Any confidential patient information and other nonpublic information acquired, created, or used in good faith by an impaired pharmacy personnel peer review organization pursuant to this section shall remain confidential and shall not be subject to discovery or subpoena in a civil case. No person participating in good faith in an impaired pharmacy personnel peer review program developed under this section shall be required in a civil case to disclose any information (including opinions, recommendations, or evaluations) acquired or developed solely in the course of participating in the program.

(f) Impaired pharmacy personnel peer review activities conducted in good faith pursuant to any program developed under this section shall not be grounds for civil action under the laws of this State, and the activities are deemed to be State directed and sanctioned and shall constitute "State action" for the purposes of application of antitrust laws. (1999-81, s. 1; 2001-375, s. 8.)

§ 90-85.42. Reserved for future codification purposes.

§ 90-85.43. Reserved for future codification purposes.

Part 2. Drug, Supplies, and Medical Device Repository Program.

§ 90-85.44. Drug, Supplies, and Medical Device Repository Program established.

(a) Definitions. – As used in this section unless the context clearly requires otherwise, the following definitions apply:

- (1) Board. – As defined in G.S. 90-85.3.
- (2) Dispense. – As defined in G.S. 90-85.3.
- (3) Drug. – As defined in G.S. 90-85.3.
- (4) Eligible donor. – The following are eligible donors under the Program:
 - a. A patient or the patient's family member.
 - b. A manufacturer, wholesaler, or supplier of drugs, supplies, or medical devices.
 - c. A pharmacy, free clinic, hospital, or a hospice care program.
- (5) Eligible patient. – An uninsured or underinsured patient who meets the eligibility criteria established by the Board, free clinic, or pharmacy.

- (6) Free clinic. – A private, nonprofit, community-based organization that provides health care services at little or no charge to low-income, uninsured, and underinsured persons through the use of volunteer health care professionals.
- (7) Medical device. – A device as defined in G.S. 90-85.3(e).
- (8) Pharmacist. – As defined in G.S. 90-85.3.
- (9) Pharmacy. – As defined in G.S. 90-85.3.
- (10) Practitioner. – A physician or other provider of health services licensed or otherwise permitted to distribute, dispense, or administer drugs, supplies, or medical devices.
- (11) Program. – The Drug, Supplies, and Medical Device Repository Program established under this act.
- (12) Supplies. – Supplies associated with or necessary for the administration of a drug.

(b) Program Purpose. – The Board shall establish and administer the Program. The purpose of the Program is to allow an eligible donor to donate unused drugs, supplies, and medical devices to uninsured and underinsured patients in this State. The unused drugs, supplies, and medical devices shall be donated to a free clinic or pharmacy that elects to participate in the Program. A free clinic that receives a donated unused drug, supplies, or medical device under the Program may distribute the drug, supplies, or medical device to another free clinic or pharmacy for use under the Program.

(c) Requirements of Participating Pharmacists or Free Clinics. – A pharmacist may accept and dispense drugs, supplies, and medical devices donated to the Program to eligible patients if all of the following requirements are met:

- (1) The drug, supplies, or medical device is in the original, unopened, sealed, and tamper-evident packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened.
- (2) The pharmacist has determined that the drug, supplies, or medical device is safe for redistribution.
- (3) The drug has not reached its expiration date.
- (4) The drug, supplies, or medical device is not adulterated or misbranded, as determined by a pharmacist.
- (5) The drug, supplies, or medical device is prescribed by a practitioner for use by an eligible patient and is dispensed by a pharmacist.

(d) Fee. – A participating pharmacist or free clinic shall not resell a drug, supplies, or a medical device donated to the Program. A pharmacist or free clinic may charge an eligible patient a handling fee to receive a donated drug, supplies, or medical device, which shall not exceed the amount specified in rules adopted by the Board.

(e) Program Participation Voluntary. – Nothing in this section requires a free clinic or pharmacy to participate in the Program.

(f) Eligible Patient. – The Board shall establish eligibility criteria for individuals to receive donated drugs, supplies, or medical devices. Board eligibility criteria shall provide that individuals meeting free clinic or pharmacy eligibility criteria are eligible patients. Dispensing shall be prioritized to patients who are uninsured or underinsured. Dispensing to other patients shall be permitted if an uninsured or underinsured patient is not available.

(g) Rules. – The Board shall adopt rules necessary for the implementation of the Program. Rules adopted by the Board shall provide for the following:

- (1) Requirements for free clinics and pharmacies to accept and dispense donated drugs, supplies, and medical devices pursuant to the Program, including eligibility criteria, confidentiality of donors, and standards and procedures for a free clinic or pharmacy to accept and safely store and dispense donated drugs, supplies, and medical devices.
 - (2) The amount of the maximum handling fee that a free clinic or pharmacy may charge for distributing or dispensing donated drugs, supplies, or medical devices.
 - (3) A list of drugs, supplies, and medical devices, arranged either by category or by individual drug, supply, or medical device, that the Program will accept for dispensing.
- (h) Immunity. – The following limited immunities apply under the Program:
- (1) Unless a pharmaceutical manufacturer exercises bad faith, the manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a drug or medical device manufactured by the manufacturer that is donated by any person under the Program, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or medical device.
 - (2) The following individuals or entities are immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the drug, supplies, or medical device is dispensed under the Program, and no disciplinary action may be taken against a pharmacist or practitioner as long as the drug, supplies, or medical device is donated in accordance with the requirements of this section:
 - a. A pharmacy or free clinic participating in the Program.
 - b. A pharmacist dispensing a drug, supplies, or medical device pursuant to the Program.
 - c. A practitioner administering a drug, supplies, or medical devices pursuant to the Program.
 - d. An eligible donor who has donated a drug, supplies, or a medical device pursuant to the Program. (2009-423, s. 2; 2019-54, s. 1.)