

NORTH CAROLINA GENERAL ASSEMBLY
1981 SESSION

CHAPTER 1188
HOUSE BILL 1050

AN ACT TO REGULATE THE PRACTICE OF PHARMACY.

The General Assembly of North Carolina enacts:

Section 1. Part 1 of Article 4 of Chapter 90 of the General Statutes is rewritten to read:

"ARTICLE 4.

"North Carolina Pharmacy Practice Act.

"§ 90-53. **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.

"§ 90-54. **Definitions.** — (1) 'Administer' means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means.

- (2) 'Board' means the North Carolina Board of Pharmacy.
- (3) '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.
- (4) 'Deliver' means the actual, constructive or attempted transfer of a drug or device from one person to another.
- (5) 'Device' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article including any component part or accessory, that is required by law to be dispensed only pursuant to a prescription order.
- (6) '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'.
- (7) 'Drug' means:
 - a. 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;
 - b. 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;
 - c. any article, other than food or devices, intended to affect the structure or any function of the body of man or other animals; and,
 - d. any article intended for use as a component of any articles specified in clause a., b. or c. of this subsection.
- (8) '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.
- (9) '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.
- (10) 'Label' means a display of written, printed or graphic matter upon the immediate or outside container of any drug.
- (11) '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.
- (12) 'License' means a license to practice pharmacy including a renewal license issued by the board.
- (13) 'Permit' means a permit to operate a pharmacy or dispense devices, including a renewal license issued by the board.
- (14) 'Person' means an individual, corporation, partnership, association, unit of government, or other legal entity.
- (15) 'Person in loco parentis' means the person who has assumed parental responsibilities for a child.
- (16) 'Pharmacist' means a person licensed under this Article to practice pharmacy.
- (17) 'Pharmacy' means any place where prescription drugs are dispensed or compounded.
- (18) 'Practice of pharmacy' means the responsibility 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. 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. 90-59. A licensed pharmacist who has received special training may be authorized and permitted to administer drugs pursuant to a specific prescription order in accordance with rules and regulations adopted by each of the Boards of Pharmacy, the Board of Nursing, and the Board of Medical Examiners of the State of North Carolina. Such rules and regulations shall be designed to ensure the safety and health of the patients for whom such drugs are administered.
- (19) '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'.
- (20) '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.
- (21) 'Unit dose medication system' means a system in which each dose of medication is individually packaged in a properly sealed and properly labeled container.

"§ 90-55. 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.

"§ 90-55.1. 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.

"§ 90-56. Board of Pharmacy; creation; membership; qualificatio 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.

(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.

"§ 90-56.1. Board of Pharmacy; selection; vacancies; commission; term; 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 three 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, 1981, shall be eligible to complete their respective terms. No member appointed or elected to a term on or after July 1, 1981, shall serve more than two complete consecutive three-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 150A 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 150A 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.

"§ 90-56.2. 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.

"§ 90-56.3. 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.

"§ 90-56.4. 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.

"§ 90-56.5. Compensation. — 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.

"§ 90-56.6. Executive Director to make investigations and prosecute. — (a) Upon receiving information concerning a violation of this Article, 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.

(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.

"§ 90-56.7. 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.

"§ 90-56.8. 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.

"§ 90-56.9. Application and examination for licensure as a pharmacist; prerequisites. —

(a) Any person who desires to be licensed as a pharmacist shall file an application with the Executive Director on the form furnished by the board, verified under oath, setting forth the applicant's name, age, the place at which and the time that he has spent in the study of pharmacy, and his experience in compounding and dispensing prescriptions under the supervision of a pharmacist. The applicant shall also appear at a time and place designated by the board and submit to an examination as to his qualifications for being licensed. The

applicant must demonstrate to the board his physical and mental competency to practice pharmacy.

(b) On or after July 1, 1982, all applicants shall have received an undergraduate degree from a school of pharmacy approved by the board. Applicants shall be required to have had up to one year of experience, approved by the board, under the supervision of a pharmacist and shall pass the required examination offered by the board. Upon completing these requirements and upon paying the required fee, the applicant shall be licensed.

"§ 90-56.10. 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.

"§ 90-56.11. 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 10 hours of continuing education from board-approved providers as a condition of license renewal.

"§ 90-56.12. 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.

"§ 90-56.13. 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.

"§ 90-56.14. 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) An applicant who has taken and failed to pass an examination for licensure in North Carolina after July 1, 1977, shall not be granted reciprocal licensure in this State until having completed at least five years of the practice of pharmacy in another state.

"§ 90-56.15. Pharmacy permit. — 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 pharmacist personnel employed in the pharmacy. All pharmacist-managers shall notify the board of any change in pharmacist personnel within 30 days of such change.

"§ 90-56.16. Devices; registration. — Each place where devices are dispensed shall register annually with the board on a form provided by the board; provided this section shall not apply to places with current pharmacy permits.

Records of devices dispensed in pharmacies or other places shall be kept in accordance with regulations promulgated by the Board of Pharmacy.

"§ 90-56.17. License / 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.

"§ 90-57. Disaster reports. — 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.

"§ 90-58. Prescription orders preserved. — 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.

"§ 90-60. Filling/refilling regulations. — The board may promulgate rules governing the filling, refilling and transfer of prescription orders not inconsistent with other provisions of law regarding the distribution of drugs and devices. Such regulations 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.

"§ 90-61. 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.

"§ 90-62. 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.

"§ 90-63. 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.

"§ 90-64. Availability of pharmacy records. — (a) Except as provided in subsections (b) and (c) below, written prescription orders on file in a pharmacy 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; or
 - (14) The person owning the pharmacy or his authorized agent.
- (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.

"§ 90-65. 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 a 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.

"§ 90-66. Disciplinary authority. — (a) The board may, in accordance with Chapter 150A 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:

- (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 him 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) a physical or mental disability that renders him 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 the rules and regulations of the board;
- (8) engaged in, or aided and abetted an individual to engage in, the practice of pharmacy without a license; or
- (9) was negligent in the practice of pharmacy.

(b) The board, in accordance with Chapter 150A of the General Statutes, may suspend, revoke, or refuse to grant or renew any permit for the same conduct as stated in subsection (a).

(c) Any license or permit obtained through false representation or withholding of material information shall be void and of no effect.

"§ 90-67. 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.

"§ 90-68. 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 except as an aide to and under 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, except as an aide to and 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.

(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 misdemeanor punishable in the discretion of the court."

Sec. 2. G.S. 90-60, as amended by Chapter 72 of the 1981 Session Laws, is recodified as G.S. 90-56.18.

Sec. 3. G.S. 90-76.1 through G.S. 90-76.5 are recodified as G.S. 90-59 through G.S. 90-59.4, respectively.

Sec. 4. G.S. 90-76.6 is repealed.

Sec. 5. Part 2 of Article 4 of Chapter 90 of the General Statutes is repealed.

Sec. 6. This act shall become effective July 1, 1982.

In the General Assembly read three times and ratified, this the 17th day of June, 1982.